

**UNITED STATES
 SECURITIES AND EXCHANGE COMMISSION**
 Washington, D.C. 20549

**FORM F-1
 REGISTRATION STATEMENT**
 UNDER
 THE SECURITIES ACT OF 1933

BioNTech SE

(Exact Name of Registrant as Specified in Its Charter)

Not Applicable
 (Translation of Registrant's name into English)

Federal Republic of Germany
 (State or Other Jurisdiction of
 Incorporation or Organization)

2836
 (Primary Standard Industrial
 Classification Code Number)

NOT APPLICABLE
 (I.R.S. Employer
 Identification Number)

Prof. Ugur Sahin, M.D.
 An der Goldgrube 12
 D-55131 Mainz
 Germany

Tel: +49 6131-9084-0
 (Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

BioNTech USA Holding, LLC
 228 E 45th Street, Suite 9e
 New York, NY 10017
 (347) 694-5321

(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent For Service)

Copies to:

Paul Claydon
 Eric W. Blanchard
 Kristian Wiggert
 Matthew T. Gehl
 Covington & Burling LLP
 265 Strand
 London WC2R 1BH
 United Kingdom
 +44 20 7067 2000

Jochen Dieselhorst
 Peter Versteegen
 Freshfields Bruckhaus Deringer LLP
 Hohe Bleichen 7
 20354 Hamburg
 Germany
 +49 40 36 90 60

Deanna Kirkpatrick
 Yasin Keshvargar
 Davis Polk & Wardwell LLP
 450 Lexington Avenue
 New York, New York
 10017
 (212) 450-4000

Stephan Hutter
 Skadden, Arps, Slate,
 Meagher & Flom LLP
 TaunusTurm
 Taunustor 1
 60310 Frankfurt am Main
 Germany
 +49 69 74 22 00

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933.

Emerging growth company

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 7(a)(2)(B) of the Securities Act.

† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

CALCULATION OF REGISTRATION FEE

Title Of Each Class Of Securities To Be Registered(1)	Proposed Maximum Aggregate Offering Price(2)(3)	Amount Of Registration Fee(4)
Ordinary shares, no par value per share	\$	\$
(1) All ordinary shares will be represented by American Depositary Shares, or ADSs, with each ADS representing ordinary shares. ADSs issuable upon deposit of the ordinary shares registered hereby will be registered pursuant to a separate Registration Statement on Form F-6.		
(2) Estimated solely for the purpose of calculating the amount of the registration fee pursuant to Rule 457(o) of the Securities Act of 1933, as amended.		
(3) Includes additional ordinary shares represented by ADSs that may be sold upon exercise of an option to purchase additional ordinary shares to be granted to the underwriters.		
(4) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.		

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to such Section 8(a), may determine.

The information contained in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective.

PRELIMINARY PROSPECTUS

SUBJECT TO COMPLETION, DATED AUGUST 5, 2019

American Depositary Shares



Representing Ordinary Shares

We are offering _____ American Depositary Shares, or ADSs, with each ADS representing _____ ordinary shares. This is our initial public offering and no public market currently exists for our ordinary shares or the ADSs. We have applied to list the ADSs on the Nasdaq Global Select Market under the symbol "BNTX."

Investing in the ADSs involves a high degree of risk. See "[Risk Factors](#)" beginning on page 13 of this prospectus.

We are an "emerging growth company" and a "foreign private issuer" as defined under the U.S. federal securities laws and, as such, will be eligible for reduced public company disclosure requirements. See "Prospectus Summary—Implications of Being an Emerging Growth Company and a Foreign Private Issuer" for additional information.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	PER ADS	TOTAL
Public offering price	\$	\$
Underwriting discounts and commissions(1)	\$	\$
Proceeds to BioNTech SE before expenses	\$	\$

(1) We have agreed to reimburse the underwriters for certain expenses incurred in this offering. See "Underwriting" for details.

We have granted the underwriters an option for a period of 30 days from the date of this prospectus to purchase an additional _____ ADSs. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable by us will be \$ _____, and the total proceeds to us, before expenses, will be \$ _____.

Delivery of the ADSs is expected to be made on or about _____, 2019.

J.P. Morgan

BofA Merrill Lynch

UBS Investment Bank

SVB Leerink

Canaccord Genuity

Bryan, Garnier & Co.

Berenberg

Wolfe Capital Markets and Advisory

Kempen

Mirae

Prospectus dated _____, 2019

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We have not, and the underwriters have not, authorized anyone to provide you with information that is different from that contained in this prospectus, any amendment or supplement to this prospectus, or any free writing prospectus we may authorize to be delivered or made available to you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are offering to sell ADSs and seeking offers to purchase ADSs only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date on the cover page of this prospectus, regardless of the time of delivery of this prospectus or the sale of any ADSs. Our business, financial condition, results of operations and prospects may have changed since the date on the cover page of this prospectus.

For investors outside the United States: Neither we nor the underwriters have taken any action that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of our ADSs and the distribution of this prospectus outside of the United States.

ABOUT THIS PROSPECTUS

Unless otherwise indicated or the context otherwise requires, all references in this prospectus to the terms “BioNTech,” the “Company,” “we,” “us” and “our” refer to BioNTech SE and our wholly owned subsidiaries.

PRESENTATION OF FINANCIAL INFORMATION

This prospectus includes our audited consolidated financial statements as of and for the years ended December 31, 2018 and 2017, which have been prepared in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB, which differ in certain significant respects from U.S. generally accepted accounting principles, or U.S. GAAP.

Our financial information is presented in Euros. For the convenience of the reader, we have translated some of our financial information into U.S. dollars. Unless otherwise indicated, these translations were made at the rate of €1.00 to \$, the noon buying rate of the Federal Reserve Bank of New York on , 2019. Such U.S. dollar amounts are not necessarily indicative of the amounts of U.S. dollars that could actually have been purchased upon exchange of Euros at the dates indicated. All references in this prospectus to “\$” mean U.S. dollars and all references to “€” mean Euros.

We have made rounding adjustments to some of the figures contained in this prospectus. Accordingly, numerical figures shown as totals in some tables may not be exact arithmetic aggregations of the figures that preceded them.

TRADEMARKS, SERVICE MARKS AND TRADE NAMES

The BioNTech SE logo, FixVac®, RiboMab®, RiboCytokine®, MammaTyper® and other trademarks or service marks of BioNTech appearing in this prospectus are the property of the Company. Solely for convenience, some of the trademarks, service marks, logos and trade names referred to in this prospectus are presented without the ® and ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensors to these trademarks, service marks and trade names. This prospectus contains additional trademarks, service marks and trade names of others. All trademarks, service marks and trade names appearing in this prospectus are, to our knowledge, the property of their respective owners. We do not intend our use or display of other companies’ trademarks, service marks, copyrights or trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

MARKET AND INDUSTRY DATA

This prospectus contains industry, market and competitive position data that are based on industry publications and studies conducted by third parties as well as our own internal estimates and research. These industry publications and third-party studies generally state that the information they contain has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe that each of these publications and third-party studies is reliable, we have not independently verified the market and industry data obtained from these third-party sources. Forecasts and other forward-looking information obtained from these sources are subject to the same qualifications and uncertainties as the other forward-looking statements contained in this prospectus. These forecasts and forward-looking information are subject to uncertainty and risk due to a variety of factors, including those described in “Risk Factors.” These and other factors could cause results to differ materially from those expressed in our forecasts or estimates or those of independent third parties. While we believe our internal research is reliable and the definitions of our market and industry are appropriate, neither such research nor these definitions have been verified by any independent source.

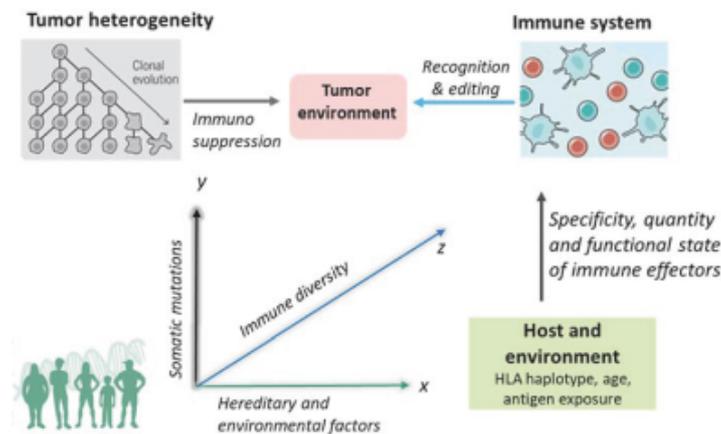
PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before deciding to invest in our ADSs, you should read this entire prospectus carefully, including the sections titled “Risk Factors,” “Business” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and related notes included elsewhere in this prospectus.

Overview

BioNTech was founded in 2008 on the understanding that every cancer patient’s tumor is unique and that in order to effectively address this challenge, we must create individualized treatments for each patient. To realize this vision, we combine decades of groundbreaking research in immunology, cutting-edge therapeutic platforms and a suite of patient profiling and bioinformatic tools to develop individualized immunotherapies for cancer as well as other diseases. We leverage powerful new therapeutic mechanisms and exploit a diverse array of biological targets to harness the power of each patient’s immune system to address the unique molecular signature of each patient’s underlying disease. We believe we are uniquely positioned to develop and commercialize the next generation of immunotherapies with the potential to significantly improve clinical outcomes for patients and usher in a new era of individualized medicine.

The interconnected dimensions of cancer heterogeneity on which we focus are illustrated below. The interaction between cancer and the immune system is shaped by various host, tumor and environmental factors. The complex interplay of these sources of interpatient heterogeneity both affects the course of disease and determines the most appropriate choice of treatment.



Leveraging our expertise in these factors, we and our collaborators have advanced a development pipeline of over 20 product candidates, of which seven have entered into eight ongoing clinical trials. While we believe our approach is broadly applicable across a number of therapeutic areas, our most advanced programs are focused on oncology, where we have treated over 250 patients across 17 tumor types to date. In our Phase 1 trials, we have observed single-agent antigen-specific immune responses in over 90% of advanced melanoma patients treated with BNT111, our wholly owned lead off-the-shelf immunotherapy product candidate from our FixVac platform. In addition, we have observed single-agent antigen-specific immune responses in patients treated with BNT121, the precursor to RO7198457 (BNT122), our lead individualized neoantigen specific immunotherapy product candidate from our iNeST platform, which we are co-developing with Genentech, Inc., or Genentech. For

both product candidates, we have also observed durable reduction in tumor volume in both the monotherapy and checkpoint-combination settings.

Our potentially first-in-class product candidates are the result of our pioneering development of numerous immunotherapeutic platforms across four drug classes:

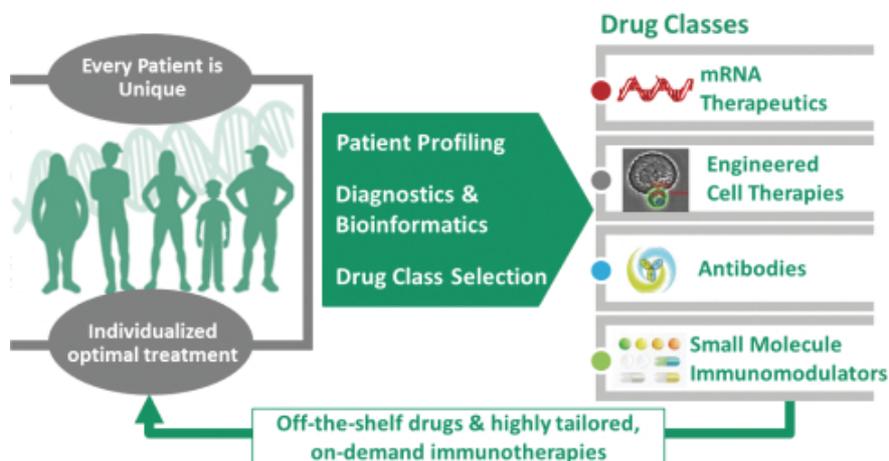
- **mRNA Therapeutics.** We have developed multiple proprietary formats and formulations of messenger ribonucleic acid, or mRNA, to deliver genetic information to cells, where it is used to express proteins for therapeutic effect.
- **Engineered Cell Therapies.** We are developing a range of cell therapies, including CAR-T cells, in which the patient's T cells are modified to target cancer-specific antigens.
- **Antibodies.** We are developing next-generation antibodies, including bispecifics, that are designed to target immune checkpoints and novel cancer antigens.
- **Small Molecule Immunomodulators.** We use small molecules to augment the activity of other drug classes by inducing specific and discrete patterns of immunomodulation.

Our Approach

We are focused on delivering on the promise of individualized immunotherapy for cancer patients. We believe that we can accomplish this by applying the following principles:

- Harnessing the full potential of the immune system by exploiting multiple drug classes and addressing multiple complementary immune pathways.
- Broadening the universe of patients benefiting from cancer immunotherapy.
- Improving the success rate of treatment by developing and engineering highly potent, precise and target-specific drug candidates either as off-the-shelf or individualized immunotherapies.
- Focusing on curative approaches by addressing interindividual variability and cancer heterogeneity.

Our patient-centric model utilizes patient profiling, diagnostics and bioinformatics to select from our suite of drug classes to provide individualized optimal treatment as illustrated below.



Our Pipeline

We are advancing a deep and broad portfolio of product candidates derived from our four drug classes.

Oncology								
Drug Class	Platform	Product Candidate	Indication (Targets)	Preclinical	Phase 1	Phase 2	Phase 3	Rights/ Collaborator
mRNA	FixVac (fixed combination of shared cancer antigens)	BNT111	Advanced Melanoma (Adjuvant & Metastatic)					Global
		BNT112	Prostate Cancer					Global
		BNT113	HPV+ Head and Neck Cancer ¹					Global
		BNT114	Triple Negative Breast Cancer					Global
		BNT115, BNT116	Other Cancers, including Ovarian Cancer					Global
	iNeST (patient-specific cancer antigen therapy)	RO7198457 (BNT122)	1L Melanoma with CPI ² Multiple Solid Tumors					Genentech (Global 50:50 profit/loss share)
	Intratumoral Immunotherapy	SAR441000 (BNT131)	Solid Tumors (<i>IL-12sc</i> , <i>IL-15sushi</i> , <i>GM-CSF</i> , <i>IFNα</i>)					Sanofi (Global profit/loss share)
	RiboMabs (mRNA-encoded antibodies)	BNT141	Multiple Solid Tumors					Global
	RiboCytokines (mRNA-encoded cytokines)	BNT142	Multiple Solid Tumors (<i>CD3+CLDN6</i>)					Global
		BNT151	Multiple Solid Tumors (Optimized <i>IL-2</i>)					Global
BNT152		Multiple Solid Tumors (<i>IL-7</i>)					Global	
Engineered Cell Therapies	CAR-T Cells	BNT153	Multiple Solid Tumors (<i>IL-2</i>)					Global
		BNT211	Multiple Solid Tumors (<i>CLDN6</i>)					Global
	TCRs	BNT212	Pancreatic, Other Cancers (<i>CLDN18.2</i>)					Global
		To be selected	Solid Tumors					Eli Lilly (Exclusive license option)
		To be selected	All Tumors					Global
Antibodies	Next-Gen CP ³ Immuno-modulators	GEN1046 (BNT311)	Multiple Solid Tumors (<i>PD-L1x4-1BB</i>)					Genmab (Global 50:50 profit/loss share)
	BNT312	Multiple Solid Tumors (<i>CD40x4-1BB</i>)						
SM Immuno-modulators	Targeted Cancer Antibodies	MVT-5873 (BNT321)	Pancreatic Cancer (<i>sLe^a</i>)					Global
	Toll-Like Receptor Binding	BNT411	Solid Tumors (<i>TLR7</i>)					Global
Other								
Drug Class	Platform	Product Candidate	Indication (Targets)	Preclinical	Phase 1	Phase 2	Phase 3	Rights/ Collaborator
mRNA	Infectious Disease Immunotherapies	BNT161	Influenza					Pfizer
			Up to 10 Indications					Penn ⁴
	Rare Disease PRT ⁵	To be selected	5 Rare Disease Indications					Genevant (Global 50:50 profit/loss share)

1 BNT113 is currently being studied in an investigator-initiated Phase 1 trial

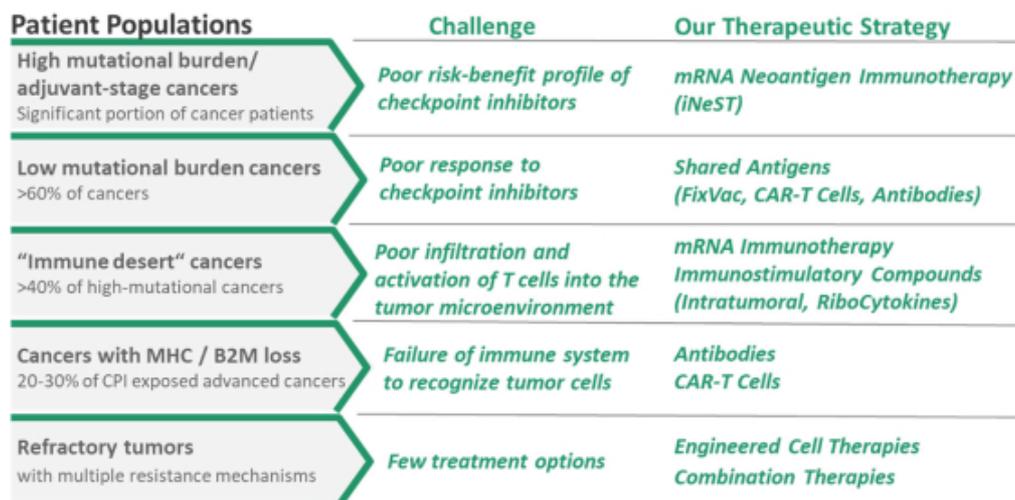
2 Checkpoint Inhibitor

3 Checkpoint

4 We are eligible to receive worldwide licenses

5 Protein Replacement Therapy

We believe the breadth of our technology is greater than the sum of its parts as it positions us to combine modes of action in a coordinated way to treat cancer in a more efficacious manner than current existing therapies. We further believe that our patient-centric approach and our broad, potentially synergistic portfolio of drug platforms place us at the forefront of the paradigm shift toward individualized immunotherapies and allow us to potentially address a larger share of cancer patients, as illustrated below:



We have established relationships with seven pharmaceutical collaborators, which comprise Genentech, Sanofi S.A., or Sanofi, Genmab A/S, or Genmab, Genevant Sciences, or Genevant, Eli Lilly and Company, or Eli Lilly, Bayer AG, or Bayer, and Pfizer Inc., or Pfizer, in order to advance our science and development capabilities and provide non-dilutive capital. In addition, we have established research collaborations with the University of Pennsylvania and Translational Oncology at the University Medical Center of the Johannes Gutenberg University Mainz (Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH), or TRON. We either wholly own or retain significant rights to all of our clinical stage programs, either in the form of a global share of profit and co-commercialization rights with our collaborators in certain markets or significant royalties and milestones.

Our ability to develop, control and optimize the manufacturing of our product candidates is a core strategic pillar and competitive advantage, especially for our individualized and mRNA product candidates. We operate three Good Manufacturing Practice, or GMP, certified manufacturing facilities in Germany, where we manufacture mRNA therapeutics and engineered cell therapies for our own pipeline and for external customers. We operate a fourth manufacturing facility in Germany where we manufacture custom peptides to support our extensive immunomonitoring activities, which are critical to our development programs. Additionally, we have collaborated with Siemens AG to develop efficient, semi-automated processes to produce our individualized mRNA immunotherapies on demand.

Our team is comprised of first-movers and entrepreneurs in the fields of immunology and oncology, with experience in pioneering cutting-edge technologies for new, forward-looking therapeutic applications in order to capture new opportunities. Our scientific founders each have over 25 years of experience characterizing the molecular signatures of cancer and discovering potent high-precision immunotherapies. They are translating this combined knowledge into the development of highly individualized treatments to target patients’ specific cancers and other diseases. Our co-founders, Chief Executive Officer Prof. Ugur Sahin, M.D., and Supervisory Board

member Prof. Christoph Huber, M.D., along with our Chief Medical Officer Özlem Türeci, M.D., have been published widely in the field of immunology and oncology and are recognized as thought leaders in their disciplines.

We were founded in 2008, and to date we have raised \$1.3 billion of capital in private placements of our shares and from our collaborators. Our investors currently include the Strüngmann Family Office, which is our majority shareholder, MIG Fonds, Salvia GmbH, Fidelity Management & Research Company, Redmile Group, Janus Henderson Investors and the Invus Group, LLC.

Our Strengths

Our key strengths include:

- We are a next-generation immunotherapy powerhouse pioneering individualized immunotherapies to address the shortcomings of existing treatments for cancer and other indications with significant unmet need.
- We are developing product candidates addressing highly specific immuno-oncology targets, employing a technology-agnostic approach.
- We have tested our lead mRNA product candidates in over 250 patients and have already demonstrated signs of single-agent clinical activity in our two lead programs.
- We have developed a very broad and advanced mRNA therapeutic portfolio for the treatment of cancer.
- We have a deep, diversified pipeline and expect data updates for up to five oncology programs by the end of 2020.
- We have formed multiple collaborations with leading pharmaceutical companies and have retained significant development, commercial and financial rights across our portfolio.
- We have created a vertically integrated business with comprehensive in-house manufacturing capabilities.
- Our scientific DNA, which is the foundation of the BioNTech approach, has attracted a talented team from nearly 50 countries around the world.

Our Strategy

To deliver our vision of truly individualized immunotherapies, we plan to:

- Rapidly advance our potential first-in-class product candidates derived from our FixVac and iNeST platforms toward market approvals in oncology, either on our own or with our collaborators.
- Progress additional product candidates through clinical development, leveraging our multiple drug classes and the synergies between them in order to expand our oncology pipeline.
- Maximize the potential and leverage the broad applicability of our mRNA drug class in additional therapeutic areas beyond cancer, including through selective collaborations.
- Strengthen our position as a leader in the highly automated, on-demand manufacture of individualized therapies with the goal of delivering our therapies globally.
- Establish a commercial organization to bring our portfolio of cancer immunotherapies to patients.
- Expand our current technology suite by continuing to develop existing and new drug classes and platforms, and selectively in-licensing technologies that are complementary to our existing pipeline.
- Maintain our culture of scientific excellence to continue to drive future innovation.

Risks Associated with Our Business

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are discussed more fully in the section of this prospectus titled “Risk Factors” immediately following this prospectus summary. These risks include, but are not limited to, the following:

- We are a clinical-stage biopharmaceutical company with no pharmaceutical products approved for commercial sale.
- We have incurred significant losses since our inception and we anticipate that we will continue to incur significant losses for the foreseeable future.
- We will require substantial additional financing to achieve our goals.
- We will need to develop and expand our company, and we may encounter difficulties in managing this development and expansion, which could disrupt our operations.
- Pharmaceutical product development is inherently uncertain, and there is no guarantee that any of our product candidates will receive marketing approval.
- No mRNA immunotherapy has been approved, and none may ever be approved, in this new potential category of therapeutics. mRNA drug development has substantial clinical development and regulatory risks due to the novel and unprecedented nature of this new category of therapeutics.
- Some of our product candidates are classified as gene therapies by the U.S. Food and Drug Administration and the European Medicines Agency. Even though our mRNA product candidates are designed to have a different mechanism of action from gene therapies, the association of our product candidates with gene therapies could result in increased regulatory burdens, impair the reputation of our product candidates, or negatively impact our platform or our business.
- Our product candidates may not work as intended, may cause undesirable side effects or may have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following marketing approval, if any.
- We may be unable to obtain regulatory approval for our product candidates under applicable international regulatory requirements.
- We face significant competition in an environment of rapid technological and scientific change, and our failure to effectively compete would prevent us from achieving significant market penetration.
- Even if we receive regulatory approval for our product candidates, the products may not gain market acceptance and we and our collaborators may not be able to effectively commercialize them.
- If we are not successful in developing and commercializing our product candidates, our ability to expand our business and achieve our strategic objectives will be impaired.
- We are dependent on our collaborators for advancing the development and commercialization of certain of our product candidates. These collaborations may not be successful, which could significantly limit the likelihood of receiving the potential economic benefits of such collaborations and adversely affect our ability to develop and commercialize our product candidates.
- We have entered into several arrangements with a related party for the performance of nonclinical research programs, and these arrangements present potential conflicts of interest.
- We rely on third parties in the conduct of significant aspects of our preclinical studies and clinical trials and intend to rely on third parties in the conduct of future clinical trials. If these third parties do not successfully carry out their contractual duties, fail to comply with applicable regulatory requirements or fail to meet expected deadlines, we may be unable to obtain regulatory approval for our product candidates.

- We may encounter difficulties in manufacturing, product release, shelf life, testing, storage, supply chain management or shipping.
- Certain of our product candidates are uniquely manufactured for each patient and we may encounter difficulties in production, particularly with respect to scaling our manufacturing capabilities.
- If our efforts to obtain, maintain, protect, defend and/or enforce the intellectual property related to our product candidates and technologies are not adequate, we may not be able to compete effectively in our market.
- We may be involved in lawsuits to protect or enforce our intellectual property or the intellectual property of our licensors, or to defend against third-party claims that we infringe, misappropriate or otherwise violate such third party's intellectual property.

Corporate Information

We were incorporated on June 2, 2008 as Petersberg 91, V V AG, a German stock corporation (*Aktiengesellschaft*). We changed our name to BioNTech AG on December 11, 2008. On March 8, 2019, we converted to a European stock corporation (*Societas Europaea*, or SE) under the laws of Germany and the European Union called BioNTech SE.

Our principal executive offices are located at An der Goldgrube 12, D-55131 Mainz, Germany. Our telephone number is +49 6131-9084-0. Our website address is <http://www.biontech.de>. The information contained on, or that can be accessed through, our website is not incorporated by reference into this prospectus. We have included our website address as an inactive textual reference only.

Implications of Being an Emerging Growth Company and a Foreign Private Issuer

Emerging Growth Company

As a company with less than \$1.07 billion in revenue during our last fiscal year, we are an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As such, we may take advantage of certain exemptions from various reporting requirements that are applicable to other publicly traded entities that are not emerging growth companies. These exemptions include:

- the ability to include only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations disclosure;
- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002, as amended;
- to the extent that we no longer qualify as a foreign private issuer, (i) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (ii) exemptions from the requirement to hold a non-binding advisory vote on executive compensation, including golden parachute compensation; and
- an exemption from compliance with the requirement that the Public Company Accounting Oversight Board has adopted regarding a supplement to the auditor's report providing additional information about the audit and the financial statements.

As a result, the information contained in this prospectus may be different from the information you receive from other public companies in which you hold shares.

Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards applicable to public companies. This provision allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. This transition period is only applicable under U.S. GAAP. As a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required or permitted by the IASB.

We may take advantage of these provisions for up to five years or until such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company upon the earliest to occur of: (i) the last day of the first fiscal year in which our annual gross revenues exceed \$1.07 billion, (ii) the date on which we have issued more than \$1 billion in non-convertible debt securities during the previous three years and (iii) the last business day of our most recently completed second fiscal quarter as of which the market value of our common equity held by non-affiliates exceeds \$700 million.

Foreign Private Issuer

Upon the completion of this offering, we will report under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as a non-U.S. company with foreign private issuer status. Even after we no longer qualify as an emerging growth company, as long as we continue to qualify as a foreign private issuer under the Exchange Act, we will be exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including:

- the rules under the Exchange Act requiring domestic filers to issue financial statements prepared under U.S. GAAP;
- the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act;
- the sections of the Exchange Act requiring insiders to file public reports of their share ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and
- the rules under the Exchange Act requiring the filing with the Securities and Exchange Commission, or the SEC, of quarterly reports on Form 10-Q containing unaudited financial statements and other specified information, and current reports on Form 8-K upon the occurrence of specified significant events.

Notwithstanding these exemptions, we will file with the SEC, within four months after the end of each fiscal year, or such applicable time as required by the SEC, an annual report on Form 20-F containing financial statements audited by an independent registered public accounting firm.

We may take advantage of these exemptions until such time as we are no longer a foreign private issuer. We would cease to be a foreign private issuer at such time as more than 50% of our outstanding voting securities are held by U.S. residents and any of the following three circumstances applies: (i) the majority of our executive officers or directors are U.S. citizens or residents, (ii) more than 50% of our assets are located in the United States or (iii) our business is administered principally in the United States.

Both foreign private issuers and emerging growth companies also are exempt from certain more stringent executive compensation disclosure rules. Thus, even if we no longer qualify as an emerging growth company, but remain a foreign private issuer, we will continue to be exempt from the more stringent compensation disclosures required of companies that are neither an emerging growth company nor a foreign private issuer.

THE OFFERING

ADSs offered by us	ADSs, each representing	ordinary shares
ADSs to be outstanding immediately following this offering	ADSs	
Ordinary shares to be outstanding immediately after the offering	ordinary shares	
Option to purchase additional ADSs	We have granted to the underwriters an option, exercisable for a period of 30 days after the date of this prospectus, to purchase an aggregate of up to an additional ADSs.	
American Depositary Shares	<p>The underwriters will deliver our ordinary shares in the form of American Depositary Shares, or ADSs. Each ADS, which may be evidenced by an American Depositary Receipt, or ADR, represents of our ordinary shares, no par value per share.</p> <p>As an ADS holder, you will not be treated as one of our shareholders and you will not have shareholder rights. The depositary, The Bank of New York Mellon, will be the holder of the ordinary shares underlying the ADSs. You will have the rights of an ADS holder or beneficial owner (as applicable) as provided in the deposit agreement among us, the depositary and holders and beneficial owners of ADSs from time to time. To better understand the terms of the ADSs, see “Description of American Depositary Shares.” We also encourage you to read the deposit agreement, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part.</p>	
Depositary	The Bank of New York Mellon	
Use of proceeds	<p>We estimate that the net proceeds to us from this offering will be approximately \$ million (or approximately \$ million if the underwriters exercise in full their option to purchase an additional ADSs), based on an assumed initial public offering price of \$ per ADS, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering as follows:</p> <ul style="list-style-type: none">• approximately \$ million to complete our ongoing and currently planned clinical trials for our FixVac product candidates BNT111, BNT113 and BNT114, as well as to fund our portion of the research and development expenses for each of the following: RO7198457 (BNT122), which is being developed in collaboration with Genentech, SAR441000 (BNT131), which is being developed in collaboration with Sanofi, and GEN1046 (BNT311), which is being developed in collaboration with Genmab;	

- approximately \$ to advance additional product candidates through Phase 1 clinical trials, including for our CAR T, RiboMabs and RiboCytokines platforms in oncology, and for our infectious disease and rare disease programs;
- approximately \$ to advance additional preclinical product candidates, develop additional product candidates leveraging our current therapeutic platforms and fund the further development of our core technologies; and
- approximately \$ million to fund the further expansion of our manufacturing and laboratory capacity and the continued development of our infrastructure.

We expect to use the remainder of any net proceeds from this offering, as well as our existing cash and cash equivalents, for general corporate purposes. We may also use a portion of the net proceeds to in-license or acquire or invest in complementary technologies, products, businesses or assets, either alone or together with a collaborator. However, we have no current plans, commitments or obligations to do so.

See “Use of Proceeds” for a more complete description of the intended use of proceeds from this offering.

Risk factors

See “Risk Factors” beginning on page 13 and the other information contained in this prospectus for a discussion of factors you should consider before deciding to invest in the ADSs.

Proposed Nasdaq Global Select Market symbol

We have applied to list the ADSs on the Nasdaq Global Select Market under the symbol “BNTX.”

Unless otherwise indicated, the number of our ordinary shares to be outstanding after this offering is based on 10,738,632 ordinary shares outstanding as of December 31, 2018.

The number of ordinary shares to be outstanding after this offering excludes:

- 658,109 ordinary shares issuable upon the exercise of options outstanding as of December 31, 2018; and
- ordinary shares available for future issuance under our Employee Stock Ownership Plan.

Unless otherwise indicated, all information contained in this prospectus:

- assumes no exercise of the outstanding options described above;
- assumes an initial public offering price of \$ per ADS, which is the midpoint of the price range set forth on the cover page of this prospectus; and
- assumes no exercise of the option granted to the underwriters to purchase up to additional ADSs in this offering.

SUMMARY CONSOLIDATED FINANCIAL DATA

The following tables set forth a summary of our historical consolidated financial data as of and for the years ended December 31, 2018 and 2017. We derived this summary from our audited consolidated financial statements included elsewhere in this prospectus. We present our consolidated financial statements in Euros and in accordance with IFRS as issued by the IASB.

The summary consolidated financial data below should be read together with our consolidated financial statements and related notes included elsewhere in this prospectus, as well as the sections of this prospectus titled “Selected Consolidated Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

	For the Years Ended	
	December 31,	
	2018	2017
(in thousands except per share data)		
Consolidated statements of operations:		
Revenues from contracts with customers	€ 127,575	€ 61,598
Cost of sales	(13,690)	(9,318)
Gross profit	113,885	52,280
Research and development expenses	(143,040)	(85,496)
Sales and marketing expenses	(3,041)	(6,603)
General and administrative expenses	(26,334)	(23,520)
Other operating income	5,396	2,349
Other operating expenses	(720)	(288)
Operating loss	(53,854)	(61,277)
Finance income	8,046	2,133
Finance expense	(48)	(26,007)
Interest expense related to lease liability	(1,721)	(676)
Share of loss of equity method investees	(84)	(78)
Loss before tax	(47,662)	(85,905)
Income taxes	(600)	(45)
Loss for the year	€ (48,262)	€(85,950)
Loss attributable to equity holders of the parent	€ (48,019)	€(85,653)
Loss attributable to non-controlling interests	(243)	(297)
Basic and diluted loss per share	€ (4.53)	€ (9.28)

The following table presents our summary consolidated statement of financial position as of December 31, 2018 (i) on an actual basis and (ii) on an as adjusted basis to give effect to the sale of ADSs representing ordinary shares by us in the offering at the assumed initial public offering price of \$ per ADS, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

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	As of December 31, 2018	
	Actual	As adjusted(1)
(in thousands)		
Consolidated statements of financial position:		
Cash and cash equivalents	€ 411,495	
Total assets	652,986	
Share capital	10,739	
Total liabilities	385,986	
Accumulated losses	(245,771)	
Total equity	267,000	

(1) Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ per ADS, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) each of cash and cash equivalents, total assets and total equity by \$ million, assuming the number of ADSs offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of ADSs we are offering. An increase (decrease) of in the number of ADSs offered by us would increase (decrease) each of cash and cash equivalents, total assets, share capital and total equity by approximately \$ million, assuming no change in the assumed initial public offering price and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

RISK FACTORS

Risks Related to our Financial Condition and Capital Requirements

We are a clinical-stage biopharmaceutical company with no pharmaceutical products approved for commercial sale. We have incurred significant losses since our inception and we anticipate that we will continue to incur significant losses for the foreseeable future, which makes it difficult to assess our future viability.

We have incurred net losses in each year since our inception in 2008, including net losses of €48.3 million and €86.0 million for the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018, we had an accumulated deficit of €245.8 million.

We have devoted most of our financial resources to research and development, including our clinical and preclinical development activities and the development of our platforms. To date, we have financed our operations primarily through the sale of equity securities and proceeds from collaborations and, to a lesser extent, through revenue from manufacturing operations and grants from governmental and private organizations. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through equity or debt financings, sales of assets, collaborations or grants. We have not commenced or completed pivotal clinical trials for our programs and it will be several years, if ever, before we or our collaborators have a product candidate ready for commercialization. Even if we obtain regulatory approval to market a product candidate, our future revenues will depend upon the size of any markets in which our product candidates have received approval, and our ability to achieve sufficient market acceptance, reimbursement from third-party payors, and adequate market share in those markets. We may never achieve profitability.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we and our collaborators:

- continue or expand our research or development of our programs in preclinical development;
- continue or expand the scope of our clinical trials for our product candidates;
- initiate additional preclinical, clinical, or other trials for our product candidates, including under our collaboration agreements;
- continue to invest in our immunotherapy platforms to conduct research to identify novel technologies;
- change or add to internal manufacturing capacity or capability;
- change or add additional suppliers;
- add additional infrastructure to our quality control, quality assurance, legal, compliance and other groups to support our operations as we progress our product candidates toward commercialization;
- attract and retain skilled personnel;
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts, including expansion of sites in Germany and new sites in the United States;
- seek marketing approvals and reimbursement for our product candidates;
- establish a sales, marketing, and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- seek to identify and validate additional product candidates;
- acquire or in-license other product candidates and technologies;
- make milestone or other payments under any in-license agreements;

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- maintain, protect, defend, enforce and expand our intellectual property portfolio; and
- experience any delays or encounter issues with any of the above.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict. If our operating results fall below expectations, the price of the ADSs could decline.

Our financial condition and operating results have varied in the past and will continue to fluctuate from one financial period to the next due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include the following, as well as other factors described elsewhere in this prospectus:

- delays or failures in advancement of existing or future product candidates into the clinic or in clinical trials;
- our ability to develop, manufacture and commercialize our programs;
- our ability to manage our growth;
- the outcomes of research programs, clinical trials, or other product development or approval processes conducted by us and our collaborators;
- the ability of our collaborators to develop and successfully commercialize products developed from our suite of therapeutic classes;
- our relationships, and any associated exclusivity terms, with collaborators;
- our contractual or other obligations to provide resources to fund our product candidates, and to provide resources to our collaborators or to the collaborations themselves;
- our operation in a net loss position for the foreseeable future;
- risks associated with the international aspects of our business outside Germany, including the conduct of clinical trials in multiple locations and potential commercialization in such locations;
- our ability to consistently manufacture our product candidates;
- our ability to accurately report our financial results in a timely manner;
- our dependence on, and the need to attract and retain, key management and other personnel;
- our ability to obtain, protect, maintain, defend and enforce our intellectual property rights;
- our ability to prevent the theft or infringement, misappropriation or other violation of our intellectual property, trade secrets, know-how or technologies;
- potential advantages that our competitors and potential competitors may have in securing funding, obtaining the rights to critical intellectual property or developing competing technologies or products;
- our ability to obtain additional capital that may be necessary to expand our business;
- our collaborators' ability to obtain additional capital that may be necessary to develop and commercialize products under our collaboration agreements;
- business interruptions such as power outages, strikes, acts of terrorism or natural disasters; and
- our ability to use our net operating loss carryforwards to offset future taxable income.

Due to the various factors mentioned above, and others, the results of any of our periods should not be relied upon as indications of our future operating performance.

The net losses we incur may fluctuate significantly from one reporting period to the next, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance.

In any particular period, our operating results could be below the expectations of securities analysts or investors, which could cause the price of the ADSs to decline. While as a general matter we intend to periodically report on the status of our product candidate pipeline, including articulating anticipated next steps in the form of development plans or potential data readouts, we may not always be able to provide forward-looking guidance on the timing of those next steps. In addition, we do not control the timing of disclosures of any milestones related to any of our programs that are managed by our collaborators. Any disclosure by a collaborator of data that are perceived as negative, whether or not such data are related to other data that we or others release, may have a material adverse impact on the price of the ADSs or overall valuation. The price of the ADSs may decline as a result of unexpected clinical trial results in one or more of our programs, including adverse safety events reported for any of our programs.

We have only generated limited revenue and may never be profitable.

Our ability to generate revenue and achieve profitability depends on our ability, alone or with collaborators, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, our product candidates. Although we generate limited revenue from sales of products by our external services business unit, we do not anticipate generating revenues from pharmaceutical product sales in the near term. Our ability to generate future revenues from pharmaceutical product sales depends heavily on our success in:

- completing research and preclinical and clinical development of our product candidates;
- seeking and obtaining U.S. and non-U.S. marketing approvals for product candidates for which we complete clinical trials;
- furthering the development of our own manufacturing capabilities and manufacturing relationships with third parties in order to provide adequate (in amount and quality) products and services to support clinical development and the market demand for our product candidates, if approved;
- obtaining market acceptance of our product candidates as a treatment option;
- launching and commercializing product candidates for which we obtain marketing approval and reimbursement, either through collaborations or, if launched independently, by establishing a sales force, marketing and distribution infrastructure;
- addressing any competing technological and market developments;
- implementing additional internal systems and infrastructure;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- maintaining, defending, protecting, enforcing and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

If one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond our expectations if we are required by the U.S. Food and Drug Administration, or the FDA, the European Medicines Agency, or the EMA, or other regulatory agencies to perform clinical and other trials or make changes to our manufacturing or quality systems in addition to those that we currently anticipate. Even if we are able to generate revenues from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

The amount of and our ability to use net operating losses and research and development credits to offset future taxable income may be subject to certain limitations and uncertainty.

In Germany, we have unused tax loss carryforwards for corporate taxes, though we have not recognized deferred tax assets related to such loss carryforwards for IFRS reporting purposes. In general, net operating loss,

or NOL, carryforwards in Germany do not expire. They are, however, subject to review and possible adjustment by the German tax authorities. Furthermore, under current German tax laws, certain substantial changes in the Company's ownership and business may further limit the amount of NOL carryforwards that can be used annually to offset future taxable income. In addition, we may in the future have U.S. federal and state NOL carryforwards due to our subsidiary in the United States.

We may not be able to utilize a material portion of our NOLs or credits in either Germany or the United States. In addition, the rules regarding the timing of revenue and expense recognition for tax purposes in connection with various transactions are complex and uncertain in many respects, and our recognition could be subject to challenge by taxing authorities. In the event any such challenge is sustained, our NOLs could be materially reduced or we could be determined to be a material cash taxpayer for one or more years. Furthermore, our ability to use our NOLs or credits is conditioned upon our attaining profitability and generating taxable income. As described above, we have incurred significant net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future. We do not know whether or when we will generate the taxable income necessary to utilize our NOL or credit carryforwards.

We will require substantial additional financing to achieve our goals, and a failure to obtain this capital on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations.

As of December 31, 2018, we had €411.5 million in cash and cash equivalents. We estimate that the net proceeds from this offering will be approximately \$, based on the assumed initial public offering price of \$ per ADS, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We expect that the net proceeds from this offering and our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements through at least the next months. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, government or other third-party funding, sales of assets, marketing and distribution arrangements, other collaborations and licensing arrangements, or a combination of these approaches. In any event, we will require additional capital to obtain regulatory approval for, and to commercialize, our product candidates. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations. Our spending will vary based on new and ongoing development and corporate activities. Due to high uncertainty of the length of time and activities associated with discovery and development of our product candidates, we are unable to estimate the actual funds we will require for development, marketing and commercialization activities.

Our future funding requirements, both near and long term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs, and results of preclinical or nonclinical studies and clinical trials for our product candidates;
- the results of research and our other platform activities;
- the clinical development plans we establish for our product candidates;
- the terms of any agreements with our current or future collaborators;
- the number and characteristics of product candidates that we develop or may in-license;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, the EMA and other comparable regulatory authorities;
- the cost of filing, prosecuting, obtaining, maintaining, protecting, defending and enforcing our patent claims and other intellectual property rights, including actions for patent and other intellectual property

infringement, misappropriation and other violations brought by third parties against us regarding our product candidates or actions by us challenging the patent or intellectual property rights of others;

- the effect of competing technological and market developments, including other products that may compete with one or more of our product candidates;
- the cost and timing of completion and further expansion of clinical and commercial scale manufacturing activities sufficient to support all of our current and future programs; and
- the cost of establishing sales, marketing, and distribution capabilities for any product candidates for which we may receive marketing approval and reimbursement in regions where we choose to commercialize our products on our own.

To date, we have financed our operations primarily through the sale of equity securities and revenue from collaborations and we cannot be certain that additional funding will be available on favorable terms, or at all. Until we can generate sufficient product sales or royalty revenue to finance our operations, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, sales of assets, licensing arrangements, and other marketing or distribution arrangements. Any fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts, at the right time, on favorable terms, or at all. Negative clinical trial data or setbacks, or perceived setbacks, in our programs or with respect to our technology could impair our ability to raise additional financing on favorable terms, or at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our shareholders, and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that may adversely affect our shareholders' rights.

Further, to the extent that we raise additional capital through the sale of ADSs, ordinary shares or securities convertible or exchangeable into ordinary shares, your ownership interest will be diluted. We have entered into two secured credit facilities with an aggregate drawing capacity of €20 million. If we raise additional capital through debt financing, we would be subject to fixed payment obligations and may be subject to security interests in our assets and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital through marketing and distribution arrangements, sales of assets or other collaborations, or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs. We also could be required to seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or intellectual property that we otherwise would seek to develop or commercialize ourselves. If we are unable to raise additional capital in sufficient amounts, at the right time, on favorable terms, or at all, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our products or product candidates, or one or more of our other research and development initiatives. Any of the above events could significantly harm our business, prospects, financial condition and results of operations, cause the price of the ADSs to decline, and negatively impact our ability to fund operations.

We will need to develop and expand our company, and we may encounter difficulties in managing this development and expansion, which could disrupt our operations.

As of July 31, 2019, we had more than 1,000 full-time employees and, in connection with the growth and advancement of our pipeline and becoming a public company, we expect to increase the number of employees and the scope of our operations. To manage our anticipated development and expansion, we must continue to implement and improve our managerial, operational, legal, compliance and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Also, our management may need to

divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these development activities.

As a growing biotechnology company, we are actively pursuing drug classes, platforms and product candidates in many therapeutic areas and across a wide range of diseases. Successfully developing products for and fully understanding the regulatory and manufacturing pathways to all of these therapeutic areas and disease states requires a significant depth of talent, resources and corporate processes in order to allow simultaneous execution across multiple areas. Due to our limited resources, we may not be able to effectively manage this simultaneous execution and the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, give rise to operational mistakes, legal or regulatory compliance failures, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The physical expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of our product candidates. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to compete effectively and commercialize our product candidates, if approved, will depend in part on our ability to effectively manage the future development and expansion of our company.

Our insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter and insurance coverage is becoming increasingly expensive. We do not know if we will be able to maintain existing insurance with adequate levels of coverage, and any liability insurance coverage we acquire in the future may not be sufficient to reimburse us for any expenses or losses we may suffer. If we obtain marketing approval for any product candidates that we or our collaborators may develop, we intend to acquire insurance coverage to include the sale of commercial products, but we may be unable to obtain such insurance on commercially reasonable terms or in adequate amounts. We currently maintain in insurance coverage for losses relating to an interruption of our development, manufacturing or commercialization efforts caused by contamination, and the coverage or coverage limits of our insurance policies may not be adequate. If our losses exceed our insurance coverage, our financial condition would be adversely affected. In the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources. Clinical trials or regulatory approvals for any of our product candidates could be suspended, which could adversely affect our results of operations and business, including by preventing or limiting the development and commercialization of any product candidates that we or our collaborators may develop. We also expect that operating as a public company will make it more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our Supervisory Board, our board committees or our Management Board.

Risks Related to our Business

Our business is dependent on the successful development, regulatory approval and commercialization of product candidates based on our technology platforms. If we and our collaborators are unable to obtain approval for and effectively commercialize our product candidates for the treatment of patients in their intended indications, our business would be significantly harmed.

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain, and we may not be able to obtain approvals for the commercialization of any product candidates we may develop. Any immunotherapy we may develop and the activities associated with its development and commercialization, including design, testing, manufacture, recordkeeping, labeling,

storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and by comparable global health authorities. To obtain the requisite regulatory approvals to commercialize any of our product candidates, we and our collaborators must demonstrate through extensive preclinical studies and clinical trials that our products are safe and effective, including in the target populations. Successful completion of clinical trials is a prerequisite to submitting a biologics license application, or BLA, or a new drug application, or NDA, to the FDA, a Marketing Authorization Application, or MAA, to the EMA, and similar marketing applications to comparable global regulatory authorities, for each product candidate and, consequently, the ultimate approval and commercial marketing of any product candidates.

Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any biopharmaceutical product candidates from regulatory authorities in any jurisdiction, and it is possible that none of our product candidates, or any product candidates we may seek to develop in the future, will ever obtain regulatory approval. We have limited experience in filing and supporting the applications necessary to gain marketing approvals and may need to rely on third-party contract research organizations, or CROs, regulatory consultants or collaborators to assist us in this process. To our knowledge, there is no current precedent for an mRNA-based immunotherapy such as the type we are developing being approved for sale by the FDA, European Commission or any other regulatory agency elsewhere in the world. Although we expect to submit BLAs for our mRNA-based product candidates in the United States, and in the European Union, mRNA therapies have been classified as gene therapy medicinal products, other jurisdictions may consider our mRNA-based product candidates to be new drugs, not biologics or gene therapy medicinal products, and require different marketing applications. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Any product candidates we develop may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals in the United States, the European Union and elsewhere, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application. The FDA, EMA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that the data are insufficient for approval and require additional preclinical, clinical or other trials. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. Additional delays or non-approval if an FDA panel of experts, referred to as an Advisory Committee, or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical trials, and the review process.

Regulatory agencies also may approve an immunotherapy for fewer or more limited indications than requested or may grant approval subject to the performance of post-marketing studies. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates.

The FDA, EMA and other regulatory agencies review the Quality or Chemistry, Manufacturing and Controls, or CMC, section of regulatory filings. Any aspects found unsatisfactory by regulatory agencies may

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result in delays in clinical trials and commercialization. In addition, the regulatory agencies typically conduct pre-approval inspections at the time of a BLA, MAA or comparable filing. Any findings by regulatory agencies and failure to comply with requirements may lead to delay in approval and failure to commercialize the potential mRNA product candidate.

If we experience delays in obtaining, or if we fail to obtain, approval of any product candidates we may develop, the commercial prospects for those product candidates will be harmed, and our ability to generate revenues will be materially impaired. Additionally, even if we are successful in obtaining marketing approval for product candidates, because our preclinical studies and clinical trials have not been designed with specific commercialization considerations, the commercial prospects for those product candidates could be harmed, and our ability to generate revenues could be materially impaired.

No mRNA immunotherapy has been approved, and none may ever be approved, in this new potential category of therapeutics. mRNA drug development has substantial clinical development and regulatory risks due to the novel and unprecedented nature of this new category of therapeutics.

As a potential new category of therapeutics, to our knowledge, no mRNA immunotherapies have been approved to date by the FDA, EMA or other regulatory agency. Successful discovery and development of mRNA-based (and other) immunotherapies by either us or our collaborators is highly uncertain and depends on numerous factors, many of which are beyond our or their control. To date, there has never been a Phase 3 trial for an mRNA-based product or a commercialized mRNA-based product. Our product candidates that appear promising in the early phases of development may fail to advance, experience delays in the clinic or clinical holds, or fail to reach the market for many reasons, including:

- discovery efforts aimed at identifying potential immunotherapies may not be successful;
- nonclinical or preclinical study results may show product candidates to be less effective than desired or have harmful or problematic side effects;
- clinical trial results may show the product candidates to be less effective than expected, including a failure to meet one or more endpoints or have unacceptable side effects or toxicities;
- manufacturing failures or insufficient supply of GMP materials for clinical trials, or higher than expected cost could delay or set back clinical trials, or make our product candidates commercially unattractive;
- our improvements in the manufacturing processes may not be sufficient to satisfy the clinical or commercial demand of our product candidates or regulatory requirements for clinical trials;
- changes that we make to optimize our manufacturing, testing or formulating of GMP materials could impact the safety, tolerability and efficacy of our product candidates;
- pricing or reimbursement issues or other factors could delay clinical trials or make any immunotherapy uneconomical or noncompetitive with other therapies;
- the failure to timely advance our programs or receive the necessary regulatory approvals, or a delay in receiving such approvals, due to, among other reasons, slow or failure to complete enrollment in clinical trials, withdrawal by trial participants from trials, failure to achieve trial endpoints, additional time requirements for data analysis, data integrity issues, BLA, MAA or the equivalent application, discussions with the FDA or the EMA, a regulatory request for additional nonclinical or clinical data, or safety formulation or manufacturing issues may lead to our inability to obtain sufficient funding; and
- the proprietary rights, products and technologies of our competitors may prevent our immunotherapies from being commercialized.

Currently, mRNA is considered a gene therapy product by the FDA. Unlike certain gene therapies that irreversibly alter cell DNA and may cause certain side effects, mRNA-based medicines are designed not to

irreversibly change cell DNA. Side effects observed in other gene therapies, however, could negatively impact the perception of immunotherapies despite the differences in mechanism. In addition, because no mRNA-based product has been approved, the regulatory pathway in the United States and may other jurisdictions for approval is uncertain. The pathway for an individualized therapy, such as our iNeST mRNA-based immunotherapy where each patient receives a different combination of mRNAs, remains particularly unsettled. The number and design of the clinical and preclinical studies required for the approval of these types of medicines have not been established, may be different from those required for gene therapy products or therapies that are not individualized or may require safety testing like gene therapy products. Moreover, the length of time necessary to complete clinical trials and submit an application for marketing approval by a regulatory authority varies significantly from one pharmaceutical product to the next and may be difficult to predict.

Our product candidates may not work as intended, may cause undesirable side effects or may have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

As with most biological products, use of our product candidates could be associated with side effects or adverse events which can vary in severity from minor reactions to death and in frequency from infrequent to prevalent. The potential for adverse events is especially acute in the oncology setting, where patients may have advanced disease, have compromised immune and other systems and be receiving numerous other therapies. Undesirable side effects or unacceptable toxicities caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, the EMA or comparable regulatory authorities. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects.

If unacceptable side effects arise in the development of our product candidates, we, the FDA, competent authorities of European Union member states, ethics committees, the institutional review boards, or IRBs, at the institutions in which our studies are conducted, or the Data Safety Monitoring Board, or DSMB, could suspend or terminate our clinical trials. The FDA or comparable regulatory authorities could also order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete any of our clinical trials or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

Monitoring the safety of patients receiving our product candidates is challenging, which could adversely affect our ability to obtain regulatory approval and commercialize our product candidates.

In our ongoing and planned clinical trials, we have contracted with and are expected to continue to contract with academic medical centers and hospitals experienced in the assessment and management of toxicities arising during clinical trials. Nonetheless, these centers and hospitals may have difficulty observing patients and treating toxicities, which may be more challenging due to personnel changes, inexperience, shift changes, house staff coverage or related issues. This could lead to more severe or prolonged toxicities or even patient deaths, which could result in us or the FDA, EMA or other comparable regulatory authority delaying, suspending or terminating one or more of our clinical trials, and which could jeopardize regulatory approval. We also expect the centers using our product candidates, if approved, on a commercial basis could have similar difficulty in managing adverse events. Medicines used at centers to help manage adverse side effects of our product candidates may not adequately control the side effects and may have a detrimental impact on the efficacy of the treatment. Use of these medicines may increase with new physicians and centers administering our product candidates.

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In addition, even if we successfully advance one of our product candidates into and through clinical trials, such trials will likely only include a limited number of subjects and limited duration of exposure to our product candidates. As a result, we cannot be assured that adverse effects of our product candidates will not be uncovered when a significantly larger number of patients are exposed to the product candidate. Further, any clinical trials may not be sufficient to determine the effect and safety consequences of taking our product candidates over a multi-year period.

If any of our product candidates receives marketing approval and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product;
- we may be required to recall a product or change the way such product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- we may be required to implement a Risk Evaluation and Mitigation Strategy, or REMS, or create a Medication Guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of the foregoing events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and result in the loss of significant revenues to us, which would materially and adversely affect our results of operations and business. In addition, if one or more of our product candidates or our immunotherapy approach generally prove to be unsafe, our technology platforms and pipeline could be affected, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

Preclinical development is uncertain. Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all and would have an adverse effect on our business.

Much of our pipeline is in preclinical development and these programs could be delayed or not advance into the clinic. Before we can initiate clinical trials for product candidates, we must complete extensive preclinical studies, including IND-enabling Good Laboratory Practice toxicology testing, that support our planned Investigational New Drug applications, or INDs, in the United States or similar applications in other jurisdictions. We must also complete extensive work on CMC activities (including collecting yield, purity and stability data) to be included in the IND filing. CMC activities for a new category of medicines such as mRNA therapies require extensive manufacturing processes and analytical development, which are uncertain and lengthy. For instance, batch failures have occurred as we scale up our manufacturing and may occur in the future. In addition, we have in the past and may in the future have difficulty identifying appropriate buffers and storage conditions to enable sufficient shelf life of batches of our preclinical or clinical product candidates. If we are required to produce new batches of our product candidates due to insufficient shelf life, it may delay the commencement or completion of preclinical or clinical trials of such product candidates. For example, we cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA or other regulatory authorities will accept the results of our preclinical testing or our proposed clinical programs or if the outcome of our preclinical testing, studies and CMC activities will ultimately support the

further development of our programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin.

Clinical development involves a lengthy and expensive process with an uncertain outcome, and delays can occur for a variety of reasons outside of our control. Clinical trials of our product candidates may be delayed, and certain programs may never advance in the clinic or may be more costly to conduct than we anticipate, any of which can affect our ability to fund our company and would have a material adverse impact on our business.

Clinical testing is expensive and complex and can take many years to complete. Its outcome is inherently uncertain. We may not be able to initiate, may experience delays in, or may have to discontinue clinical trials for our product candidates. We and our collaborators also may experience numerous unforeseen events during, or as a result of, any clinical trials that we or our collaborators conduct that could delay or prevent us or our collaborators from successfully developing our product candidates, including:

- the FDA, other regulators, IRBs or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site for any number of reasons, including concerns regarding safety and aspects of the clinical trial design;
- we may experience delays in reaching, or fail to reach, agreement on favorable terms with prospective trial sites and prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- we have optimized in the past and may in the future optimize our manufacturing processes, including through changes to the scale and site of manufacturing, which may lead to additional studies (including bridging and bioequivalence studies) or potentially significant changes in our clinical trial designs, requiring additional cost and time, and, as a consequence, lead to a delay in plans for progressing one or more product candidates;
- the outcome of our preclinical studies and our early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results;
- we may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful;
- in an effort to optimize product features, we have made in the past and may continue to make changes to our product candidates after we commence clinical trials of a medicine which may require us to repeat earlier stages of clinical testing or delay later-stage testing of the medicine;
- clinical trials of any product candidates may fail to show safety or efficacy, or may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional nonclinical studies or clinical trials, or we may decide to abandon product development programs;
- differences in trial design between early-stage clinical trials and later-stage clinical trials may make it difficult to extrapolate the results of earlier clinical trials to later clinical trials;
- preclinical and clinical data are often susceptible to varying interpretations and analyses, and many product candidates believed to have performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval;
- our product candidates may have undesirable side effects or other unexpected characteristics. One or more of such effects or events could cause regulators to impose a clinical hold on the applicable trial, or cause us or our investigators, IRBs or ethics committees to suspend or terminate the trial of that product candidate or any other of our product candidates for which a clinical trial may be ongoing;

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- the number of trial participants required for clinical trials of any product candidates may be larger than we anticipate, identification of trial participants for such trials may be limited, enrollment in these clinical trials may be slower than we anticipate due to perceived adverse effects, limited patient populations, competitive trials or other reasons, or participants may withdraw from clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or withdraw from the trial, which may require that we add new clinical trial sites;
- regulators may elect to impose a clinical hold, or we, our investigators, IRBs or ethics committees may elect to suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to an unacceptable benefit-risk ratio;
- the cost of preclinical or nonclinical testing and studies and clinical trials of any product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials may be insufficient or inadequate;
- safety or efficacy concerns regarding our product candidates may result from any concerns arising from nonclinical or clinical testing of other therapies targeting a similar disease state or other therapies, such as gene therapy, that are perceived as similar to ours; and
- the FDA or other regulatory authorities may require us to submit additional data, such as long-term toxicology studies, or impose other requirements before permitting us to initiate a clinical trial.

We could also encounter delays if a clinical trial is suspended or terminated by us, the FDA or other regulatory authorities, ethics committees, or the IRBs of the institutions in which such trials are being conducted, or if such trial is recommended for suspension or termination by the DSMB for such trial. We may in the future be delayed in gaining clearance from the FDA or other regulators to initiate clinical trials through, among other things, the imposition of a clinical hold in order to address comments from such regulators on our clinical trial design or other elements of our clinical trials. A suspension or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols; inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold; unforeseen safety issues or adverse side effects; failure to demonstrate a benefit, or adequate benefit-risk ratio, from using a product candidate; failure to establish or achieve clinically meaningful trial endpoints; changes in governmental regulations or administrative actions; or lack of adequate funding to continue the clinical trial. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. We could also experience delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. We must also complete extensive work on CMC activities that require extensive manufacturing processes and analytical development, which are uncertain and lengthy.

We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. For example, the FDA and regulatory authorities in other jurisdictions have limited experience with commercial development of several of our technologies. The FDA may require an Advisory Committee to deliberate on the adequacy of the safety and efficacy data to support licensure. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain licensure of the product candidates based on the completed clinical trials, as the FDA often adheres to the Advisory Committee's recommendations. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and approval may not be certain.

Moreover, the FDA and other regulatory authorities have indicated that prior to commencing later stage clinical trials for our mRNA-based product candidates we will need to scale up and further refine assays to measure and predict the potency of a given dose of these product candidates. Any delay in the scaling and refining of assays that are acceptable to the FDA or other regulatory authorities could delay the start of future clinical trials. Further, the FDA or other regulatory authorities may disagree with our clinical trial design and our interpretation of data for our clinical trials or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials.

Significant preclinical or nonclinical testing and studies or clinical trial delays for our product candidates also could allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. Any delays in the development of our product candidates may harm our business, financial condition and prospects significantly.

If we or our collaborators encounter difficulties enrolling participants in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We depend on enrollment of participants in our clinical trials for our product candidates. In the past, our collaborators have found, and we or our collaborators may in the future find, it difficult to enroll trial participants in our clinical studies, which could delay or prevent clinical studies of our product candidates. Identifying and qualifying trial participants to participate in clinical studies of our product candidates is critical to our success. The timing of our clinical studies depends on the speed at which we can recruit trial participants to participate in testing our product candidates. Delays in enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates. If trial participants are unwilling to participate in our studies because of negative publicity from adverse events in our trials or other trials of similar products, or those related to specific a therapeutic area, or for other reasons, including competitive clinical studies for similar patient populations, the timeline for recruiting trial participants, conducting studies, and obtaining regulatory approval of potential products may be delayed. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our product, or termination of the clinical studies altogether.

We may not be able to identify, recruit and enroll a sufficient number of trial participants, or those with required or desired characteristics to achieve diversity in a study, to complete our clinical trials in a timely manner. Patient and subject enrollment is affected by factors including:

- severity of the disease under investigation;
- complexity and design of the study protocol;
- size of the patient population;
- eligibility criteria for the study in question;
- proximity and availability of clinical study sites for prospective trial participants;
- availability of competing therapies and clinical trials, including between our own clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- ability to monitor trial participants adequately during and after treatment;
- ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and trial participants' perceptions of the potential advantages and side effects of the product candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating;

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- our ability to obtain and maintain participant informed consent; and
- the risk that trial participants enrolled in clinical trials will not complete a clinical trial.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of trial participants available to us because some trial participants who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by a third party. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of trial participants who are available for our clinical trials at such clinical trial sites. Moreover, because in some cases our product candidates represent a departure from more traditional methods for disease treatment and prevention, potential trial participants and their doctors may be inclined to use conventional therapies or other new therapies rather than enroll trial participants in any future clinical trial involving individualized product candidates. Additionally, if new product candidates, such as gene editing therapies, show encouraging results, potential trial participants and their doctors may be inclined to enroll trial participants in clinical trials using those product candidates. If such new product candidates show discouraging results or other adverse safety indications, potential trial participants and their doctors may be less inclined to enroll trial participants in our clinical trials.

In particular, certain conditions for which we plan to evaluate our current product candidates are rare diseases with limited patient pools from which to draw for clinical trials. The eligibility criteria of our clinical trials will further limit the pool of available trial participants. Additionally, the process of finding and diagnosing patients may prove costly.

A variety of risks associated with conducting research and clinical trials abroad and marketing our product candidates internationally could materially adversely affect our business.

Clinical trials of our product candidates are currently being conducted in numerous countries, including Germany, Austria, Belgium, Czechia, France, Italy, the Netherlands, Poland, Spain, Sweden, the United Kingdom, Israel, Australia, Canada and the United States, and we plan to commercialize our product candidates, if approved, globally. Accordingly, we expect that we will be subject to additional risks related to operating in multiple countries, including:

- differing regulatory requirements in such countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- increased difficulties in managing the logistics and transportation of storing and shipping product candidates produced in Germany and shipping the product candidate to the patient abroad;
- import and export requirements and restrictions;
- economic weakness, including inflation, or political instability in particular economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- taxes, including withholding of payroll taxes;
- currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing operations outside of Germany;
- workforce uncertainty in countries where labor unrest is more common;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems, and price controls;

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- potential liability under the U.S. Foreign Corrupt Practices Act of 1977 or comparable regulations in other jurisdictions;
- challenges enforcing our contractual and intellectual property rights, especially in those countries that do not respect and protect intellectual property rights to the same extent as do Germany and the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism.

These and other risks associated with our international operations and our collaborations with our collaborators may materially adversely affect our ability to attain or maintain profitable operations.

Interim top-line and preliminary data from studies or trials that we announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim top-line or preliminary data from preclinical studies or clinical trials. Interim data are subject to the risk that one or more of the outcomes may materially change as more data become available. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully evaluate all data. As a result, the top-line results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Preliminary or top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Additionally, interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed significant by you or others with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the top-line data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, product candidates may be harmed, which could significantly harm our business prospects.

Results of earlier studies and trials of our product candidates may not be predictive of future trial results.

Success in preclinical studies and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in clinical trials, even after positive results in earlier preclinical studies or clinical trials. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. Notwithstanding any potential promising results in earlier studies and trials, we cannot be certain that we will not face similar setbacks. Even if our clinical trials are completed, the results may not be sufficient to obtain

regulatory approval for our product candidates. In addition, the results of our preclinical studies may not be predictive of the results of outcomes in human clinical trials. For example, our tumor-specific cancer immunotherapy candidates and any future product candidates may demonstrate different chemical, biological and pharmacological properties in patients than they do in laboratory studies or may interact with human biological systems in unforeseen or harmful ways. Product candidates in later stages of clinical trials may fail to show the desired pharmacological properties or safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Even if we are able to initiate and complete clinical trials, the results may not be sufficient to obtain regulatory approval for our product candidates.

Our planned clinical trials or those of our collaborators may reveal significant adverse events not seen in our preclinical or nonclinical studies and may result in a safety profile that could delay or terminate clinical trials, or delay or prevent regulatory approval or market acceptance of any of our product candidates.

There is typically an extremely high rate of attrition for product candidates across categories of medicines proceeding through clinical trials. These product candidates may fail to show the desired safety and efficacy profile in later stages of clinical trials despite having progressed through nonclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in later-stage clinical trials due to lack of efficacy or unacceptable safety profiles, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as products and there can be no assurance that any of our current or future clinical trials will ultimately be successful or support further clinical development of any of our product candidates.

Some of our product candidates are being developed or are intended to be co-administered with other developmental therapies or approved medicines. For example, RO198457 (BNT122) is being developed to be co-administered with checkpoint inhibitors. Such combinations may have additional side effects which may be difficult to predict in future clinical trials.

If significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting trial participants to any of our clinical trials, trial participants may withdraw from trials, or we may be required to abandon the trials or our development efforts of one or more product candidates altogether. We, the FDA or other applicable regulatory authorities, ethics committees or an IRB may impose a clinical hold on, or suspend or terminate, clinical trials of a product candidate at any time for various reasons, including a belief that participants in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the drug from obtaining or maintaining marketing approval, an unfavorable benefit-risk ratio may inhibit market acceptance of the approved product due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition and prospects.

We may not be able to develop or obtain approval for companion diagnostics required for commercialization of some of our product candidates.

Administration of some of our product candidates may require the use of immuno-assays and bioinformatic tools in which patients are screened for optimal target antigens of our product candidates. If safe and effective use of a biologic product depends on an *in vitro* diagnostic, then the FDA generally requires approval or clearance of the diagnostic, known as a companion diagnostic, concurrently with approval of the therapeutic product. To date, the FDA has generally required *in vitro* companion diagnostics intended to select the patients who will respond to cancer treatment to obtain a pre-market approval, or PMA, for that diagnostic, which can take up to several years, simultaneously with approval of the biologic product. Similarly, in the European Union, an *in vitro* companion diagnostic may be placed on the market only if it conforms to certain “essential requirements” and bears the *Conformité Européene* Mark, or CE Mark, and the conformity assessment process to obtain the CE Mark can be lengthy.

For our individualized immunotherapy candidates, the FDA and similar regulatory authorities outside of the United States may require the development and regulatory approval of a companion diagnostic assay as a condition to approval. The FDA may require PMA supplemental approvals for use of that same companion diagnostic as a condition of approval of additional individualized therapeutic candidates. We do not have experience or capabilities in developing or commercializing companion diagnostics and plan to rely in large part on third parties to perform these functions. Companion diagnostic assays are subject to regulation by the FDA and other comparable regulatory authorities in other jurisdictions as medical devices and require separate regulatory approval prior to the use of such diagnostic assays with our individualized therapeutic candidates. If we, or any third parties that we engage to assist us, are unable to successfully develop companion diagnostic assays for use with our individualized therapeutic candidates, or are unable to obtain regulatory approval or experience delays in either development or obtaining regulatory approval, we may be unable to identify patients with the specific profile targeted by our product candidates for enrollment in our clinical trials. Accordingly, further investment may be required to further develop or obtain the required regulatory approval for the relevant companion diagnostic assay, which would delay or substantially impact our ability to conduct further clinical trials or obtain regulatory approval.

Because we are developing some of our product candidates for the treatment of diseases in which there is little clinical experience and, in some cases, using new endpoints or methodologies, the FDA, EMA or other regulatory authorities may not consider the endpoints of our clinical trials to provide clinically meaningful results.

There may not be pharmacologic therapies approved to treat the underlying causes of many diseases that we may address in the future. For instance, we and our collaborators are applying our technology to develop therapeutics in indications such as certain rare diseases, including some for which no or few clinical trials have been attempted. As a result, any future design and conduct of clinical trials of product candidates for the treatment of certain rare diseases may take longer, be more costly, or be less effective as part of the novelty of development in these diseases. Even if we decide to conduct clinical trials and the FDA does find our success criteria to be sufficiently validated and clinically meaningful, we may not achieve the pre-specified endpoint to a degree of statistical significance in any pivotal or other clinical trials we or our collaborators may conduct for our programs. Further, even if we do achieve the pre-specified criteria, our trials may produce results that are unpredictable or inconsistent with the results of the more traditional efficacy endpoints in the trial. The FDA also could give overriding weight to other efficacy endpoints over a primary endpoint, even if we achieve statistically significant results on that endpoint, if we do not do so on our secondary efficacy endpoints. The FDA also weighs the benefits of a product against its risks and the FDA may view the efficacy results in the context of safety as not being supportive of licensure. Other regulatory authorities in Europe and other countries may make similar findings with respect to these endpoints.

The FDA, EMA or other comparable regulatory authorities may disagree with our regulatory plan and we may fail to obtain regulatory approval of our product candidates.

If the results of our clinical trials are sufficiently compelling, we or our collaborators intend to discuss with the FDA submission of a BLA for our product candidates. However, we do not have any agreement or guidance from the FDA that our regulatory development plans will be sufficient for submission of a BLA for any of our product candidates. The FDA, EMA or other regulatory agencies may grant accelerated approval for our product candidates and, as a condition for accelerated approval, the FDA, EMA or other regulatory agencies may require a sponsor of a drug or biologic receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the drug or biologic may be subject to withdrawal procedures by the FDA, EMA or other regulatory agencies that are more accelerated than those available for regular approvals. In addition, the standard of care may change with the approval of new products in the same indications that we are studying. This may result in the FDA, EMA or other regulatory agencies requesting additional studies to show that our product candidate is superior to the new products.

Our clinical trial results may also not support approval. In addition, our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA, the EMA or comparable regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA, the EMA or comparable regulatory authorities that our product candidates are safe and effective for any of their proposed indications;
- the results of clinical trials may not meet the level of statistical significance required by the FDA, the EMA or comparable regulatory authorities for approval, including due to the heterogeneity of patient populations;
- we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;
- the FDA, the EMA or comparable regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA, the EMA or comparable regulatory authorities to support the submission of a BLA or other comparable submissions or to obtain regulatory approval in the United States or elsewhere;
- the FDA, the EMA or comparable regulatory authorities will inspect our manufacturing facilities and may not approve our facilities; and
- the approval policies or regulations of the FDA, the EMA or comparable regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

We may not be able to file INDs with the FDA, clinical trial applications with the competent authorities of European Union member states or similar applications with other comparable regulatory authorities to commence additional clinical trials on the timelines we expect, and even if we are able to, one or more of these regulatory authorities may not permit us to proceed.

The timing of filing on our product candidates is dependent on further preclinical, clinical and manufacturing success. We cannot be sure that submission of an IND or IND amendment with the FDA, a clinical trial application with the competent authorities of European Union member states or similar application with other comparable regulatory authorities will result in the FDA, the competent authorities of European Union member states or any comparable regulatory authority allowing testing and clinical trials to begin, or that, once begun, issues will not arise that result in the suspension or termination of such clinical trials. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND, clinical trial application or similar applications, we cannot guarantee that such regulatory authorities will not change their requirements in the future.

We may seek orphan drug designation for some or all of our product candidates across various indications, but we may be unable to obtain such designations or to maintain the benefits associated with orphan drug designation, including market exclusivity, which may cause our revenue, if any, to be reduced.

Our strategy includes filing for orphan drug designation where available for our product candidates. Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biologic intended to treat a rare disease or condition, which is defined as one occurring in a patient population of fewer than 200,000 in the United States, or a patient population of 200,000 or greater in the United States where there is no reasonable expectation that the cost of developing the drug or biologic will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives, such as opportunities for grant funding toward clinical trial costs, tax advantages, and user-fee waivers. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation,

the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a full new drug application or a BLA, to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the original manufacturer is unable to assure sufficient product quantity. Similar rules apply in the European Union with respect to drugs or biologics designated as orphan medicinal products.

In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties may receive and be approved for the same condition, and only the first applicant to receive approval will receive the benefits of marketing exclusivity. Even after an orphan-designated product is approved, the FDA can subsequently approve a later drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior if it is shown to be safer, more effective, or makes a major contribution to patient care. Similar considerations apply in the European Union with respect to drugs or biologics designated as orphan medicinal products. Orphan drug designation neither shortens the development time or regulatory review time of a drug, nor gives the drug any advantage in the regulatory review or approval process. In addition, while we may seek orphan drug designation for our product candidates, we may never receive such designations.

We may seek breakthrough therapy or fast-track designation for one or more of our product candidates, but we may not receive such designations. Even if we do, it may not lead to a faster development or regulatory review or approval process, and it may not increase the likelihood that such product candidates will receive marketing approval.

We may seek a breakthrough therapy designation in the United States for one or more of our product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for priority review if supported by clinical data at the time of the submission of the BLA.

Designation as a breakthrough therapy is at the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a drug may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and it would not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidate no longer meets the conditions for qualification or it may decide that the time period for FDA review or approval will not be shortened.

We may also seek Fast Track Designation in the United States for some of our product candidates. If a therapy is intended for the treatment of a serious or life-threatening condition and the therapy demonstrates the potential to address significant unmet medical needs for this condition, the drug sponsor may apply for Fast Track Designation. The FDA has broad discretion whether or not to grant this designation, and even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track Designation

if it believes that the designation is no longer supported by data from our clinical development program. Fast Track Designation alone does not guarantee qualification for the FDA's priority review procedures.

We expect some of the product candidates we develop will be regulated as biologics in the United States and therefore they may be subject to competition from biosimilars approved through an abbreviated regulatory pathway.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or the ACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or the BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first approved. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of the other company's product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for a 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

Some of our product candidates are classified as gene therapies by the FDA and the EMA, and the FDA has indicated that our product candidates will be reviewed within its Center for Biologics Evaluation and Research, or CBER. Even though our mRNA product candidates are designed to have a different mechanism of action from gene therapies, the association of our product candidates with gene therapies could result in increased regulatory burdens, impair the reputation of our product candidates, or negatively impact our platform or our business.

There have been few approvals of gene therapy products in the United States and other jurisdictions, and there have been well-reported significant adverse events associated with their testing and use. Gene therapy products have the effect of introducing new DNA and potentially irreversibly changing the DNA in a cell. In contrast, mRNA is highly unlikely to localize to the nucleus, integrate into cell DNA, or otherwise make any permanent changes to cell DNA. Consequently, we expect that our product candidates will have a different potential side effect profile from gene therapies because they lack risks associated with altering cell DNA irreversibly. Further, we may avail ourselves of ways of mitigating side effects in developing our product candidates to address safety concerns that are not available to all gene therapies, such as lowering the dose of our product candidates during repeat dosing or stopping treatment to potentially ameliorate undesirable side effects.

Regulatory requirements governing gene and cell therapy products have evolved and may continue to change in the future, and the implications for mRNA-based therapies is unknown. For example, the FDA has established the Office of Tissues and Advanced Therapies within CBER to consolidate the review of gene therapy and related products, and convenes the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. In the European Union, mRNA has been characterized as a Gene Therapy Medicinal

Product. In certain countries, mRNA therapies have not yet been classified or any such classification is not known to us. Specifically, in Japan, the Pharmaceuticals and Medical Devices Agency has not taken a position on the regulatory classification. Notwithstanding the differences between our mRNA product candidates and gene therapies, the classification of some of our mRNA product candidates as gene therapies in the United States, the European Union and potentially other countries could adversely impact our ability to develop our product candidates, and could negatively impact our platform and our business. For instance, a clinical hold on gene therapy products across the field due to risks associated with altering cell DNA irreversibly may apply to our mRNA product candidates irrespective of the mechanistic differences between gene therapies and mRNA.

Adverse events reported with respect to gene therapies or genome editing therapies could adversely impact one or more of our programs. Although our mRNA product candidates are designed not to make any permanent changes to cell DNA, regulatory agencies or others could believe that adverse effects of gene therapy products caused by introducing new DNA and irreversibly changing the DNA in a cell could also be a risk for our mRNA investigational therapies, and as a result may delay one or more of our trials or impose additional testing for long-term side effects. Any new requirements and guidelines promulgated by regulatory review agencies may have a negative effect on our business by lengthening the regulatory review process, requiring us to perform additional or larger studies, or increasing our development costs, any of which could lead to changes in regulatory positions and interpretations, delay or prevent advancement or approval and commercialization of our product candidates or lead to significant post-approval studies, limitations or restrictions. As we advance our product candidates, we will be required to consult with these regulatory agencies and advisory committees and comply with applicable requirements and guidelines. If we fail to do so, we may be required to delay or discontinue development of some or all of our product candidates.

The regulatory landscape that will govern our product candidates is uncertain. Regulations relating to more established gene therapy and cell therapy products are still developing, and changes in regulatory requirements could result in delays or discontinuation of development of our product candidates or unexpected costs in obtaining regulatory approval.

The regulatory requirements that we will be subject to are not entirely clear. Even with respect to more established products that fit into the categories of gene therapies or cell therapies, the regulatory landscape is still developing. For example, regulatory requirements governing gene therapy products and cell therapy products have changed frequently and may continue to change in the future. Moreover, there is substantial, and sometimes uncoordinated, overlap in those responsible for regulation of existing gene therapy products and cell therapy products. Although the FDA decides whether individual gene therapy protocols may proceed, the review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical study, even if the FDA has reviewed the study and approved its initiation. Conversely, the FDA can place an IND application on clinical hold even if such other entities have provided a favorable review. Furthermore, gene therapy clinical trials are also subject to review and oversight by an institutional biosafety committee, or IBC, a local institutional committee that reviews and oversees basic and clinical research conducted at the institution participating in the clinical trial. In addition, adverse developments in clinical trials of gene therapy products conducted by others may cause the FDA or other regulatory bodies to change the requirements for approval of any of our product candidates.

Complex regulatory environments exist in other jurisdictions in which we might consider seeking regulatory approvals for our product candidates, further complicating the regulatory landscape. For example, in the European Union a special committee called the Committee for Advanced Therapies, or CAT, was established within the EMA in accordance with Regulation (EC) No 1394/2007 on advanced-therapy medicinal products, or ATMPs, to assess the quality, safety and efficacy of ATMPs, and to follow scientific developments in the field. ATMPs include gene therapy products as well as somatic cell therapy products and tissue engineered products.

These various regulatory review committees and advisory groups and new or revised guidelines that they promulgate from time to time may lengthen the regulatory review process, require us to perform additional

studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. As the regulatory landscape for our CAR-T cell immunotherapy product candidates is new, we may face even more cumbersome and complex regulations than those emerging for gene therapy products and cell therapy products. Furthermore, even if our product candidates obtain required regulatory approvals, such approvals may later be withdrawn as a result of changes in regulations or the interpretation of regulations by applicable regulatory agencies.

Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product sales revenue to maintain our business.

We may be unable to obtain regulatory approval for our product candidates under applicable international regulatory requirements. The denial or delay of such approval would delay commercialization of our product candidates and adversely impact our potential to generate revenue, our business and our results of operations.

Approval by the FDA in the United States, if obtained, does not ensure approval by regulatory authorities in other countries or jurisdictions. In order to eventually market any of our product candidates in any other jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a jurisdiction-by-jurisdiction basis regarding safety and efficacy. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods.

Seeking regulatory approval in other jurisdictions could result in difficulties and costs for us and require additional preclinical studies or clinical trials which could be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. The European Union and other jurisdictions' regulatory approval processes involve all of the risks associated with FDA approval. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our products will be unrealized.

A third-party investigational drug used in combination with our product candidates may be unable to obtain regulatory approval, which may delay commercialization of our product candidates.

We are developing several of our product candidates to be used in combination with our and third-party drugs. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA, the EMA or similar regulatory authorities in other jurisdictions could revoke approval of the therapy used in combination with our product or that safety, efficacy, manufacturing or supply issues could arise with any of those existing therapies. If the therapies we use in combination with our product candidates are replaced as the standard of care for the indications we choose for any of our product candidates, the FDA, the EMA or similar regulatory authorities in other jurisdictions may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our own products, if approved, being removed from the market or being less successful commercially. We also plan to evaluate current and future product candidates in combination with one or more therapies that have not yet been approved for marketing by the FDA, the EMA or similar regulatory authorities in other jurisdictions. We will not be able to market any product candidate we develop in combination with an unapproved therapy if that unapproved therapy does not ultimately obtain marketing approval. In addition, unapproved therapies face the same risks described with respect to our product candidates currently in development and clinical trials, including the potential for serious adverse effects, delay in their clinical trials and lack of FDA, EMA or similar regulatory authority approval.

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If the FDA, the EMA or similar regulatory authorities in other jurisdictions do not approve these other drugs or revoke their approval of, or if safety, efficacy, manufacturing or supply issues arise with, the drugs we choose to evaluate in combination with any product candidate we develop, we may be unable to obtain approval of or market any product candidate we develop.

Even if we receive regulatory approval of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. We may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Even if we obtain regulatory approval in a jurisdiction, the applicable regulatory authority may still impose significant restrictions on the indicated uses or marketing of our product, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. For example, the holder of an approved BLA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. The holder of an approved BLA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws.

If we fail to comply with applicable regulatory requirements following approval of any of our product candidates, a regulatory agency may:

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval or revoke a license;
- suspend any ongoing clinical studies;
- refuse to approve a pending BLA or supplements to a BLA submitted by us;
- seize product; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize any approved products and generate revenues.

If any of our product candidates cause undesirable side effects, it could delay or prevent their regulatory approval, limit the commercial potential, or result in significant negative consequences following any potential marketing approval. Product candidates we may develop may be associated with an adverse immune response or other serious adverse events, undesirable side effects or unexpected characteristics. In addition to serious adverse events or side effects caused by any of our product candidates, the administration process or related procedures also can cause undesirable side effects. If any such events occur, the clinical trials of any of our product candidates could be suspended or terminated.

If in the future we are unable to demonstrate that such adverse events were caused by factors other than our product candidate, the FDA, the EMA or other regulatory authorities could order us to cease further development of, or deny approval of, any of our product candidates for any or all targeted indications. Even if we are able to demonstrate that all future serious adverse events are not product-related, such occurrences could affect patient recruitment or the ability of enrolled trial participants to complete the trial. Moreover, if we elect, or are required, to delay, suspend or terminate any clinical trial of any of our product candidates, the commercial prospects of such product candidates may be harmed and our ability to generate product sale revenues from any of these

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product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to identify and develop product candidates, and may harm our business, financial condition, result of operations and prospects significantly.

Additionally, if we successfully obtain regulatory approval for a product candidate, the FDA or other regulatory authority could require us to adopt a REMS or a risk management plan, or RMP, to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a medication guide outlining the risks of the product for distribution to patients, a communication plan to health care practitioners, extensive patient monitoring, or distribution systems and processes that are highly controlled, restrictive, and more costly than what is typical for the industry. Furthermore, if we or others later identify undesirable side effects caused by any product that we develop, several potentially significant negative consequences could result, including:

- regulatory authorities may suspend or withdraw approvals or revoke licenses of such product;
- regulatory authorities may require additional warnings on the label;
- we may be required to change the way a product is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients and their children; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of any products we may identify and develop and could have a material adverse impact on our business, financial condition, results of operations and prospects.

If we are successful in gaining approval for any of our product candidates we will continue to face significant regulatory oversight of the manufacturing and distribution of our products. Product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with GMP and adherence to commitments made in the BLA. If we or a regulatory agency discovers previously unknown problems with a product such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If we are not successful in discovering, developing and commercializing additional product candidates beyond our current portfolio, our ability to expand our business and achieve our strategic objectives would be impaired.

Although a substantial amount of our efforts will focus on the clinical trials and potential approval of our existing product candidates, a key element of our strategy is to discover, develop and potentially commercialize additional products beyond our current portfolio to treat various conditions and in a variety of therapeutic areas. We intend to do so by investing in our own drug and target discovery efforts, exploring potential collaborations for the development of new products, and in-licensing technologies. Identifying new product candidates requires substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Even if we identify product candidates that initially show promise, we may fail to successfully develop and commercialize such products for many reasons, including the following:

- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete;
- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;

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- a product candidate may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- an approved product may not be accepted as safe and effective by trial participants, the medical community or third-party payors.

If we are unsuccessful in identifying and developing additional products, our potential for growth may be impaired.

Risks Related to the Manufacturing of our Product Candidates and Future Pipeline

Our mRNA product candidates are based on novel technologies and any product candidates we develop may be complex and difficult to manufacture. We may encounter difficulties in manufacturing, product release, shelf life, testing, storage, supply chain management or shipping. If we or any of the third-party manufacturers we work with encounter such difficulties, our ability to supply materials for clinical trials or any approved product could be delayed or stopped.

The manufacturing processes for our product candidates are novel and complex. There are no immunotherapies commercialized to date or manufactured at such scale. Due to the novel nature of this technology and limited experience at larger scale production, we may encounter difficulties in manufacturing, product release, shelf life, testing, storage and supply chain management, or shipping. These difficulties could be due to any number of reasons including, but not limited to, complexities of producing batches at larger scale, equipment failure, choice and quality of raw materials and excipients, analytical testing technology, and product instability. In an effort to optimize product features, we have in the past and may in the future make changes to our product candidates in their manufacturing and stability formulation and conditions. This has in the past resulted in and may in the future result in our having to resupply batches for preclinical or clinical activities when there is insufficient product stability during storage and insufficient supply. Insufficient stability or shelf life of our product candidates could materially delay our or our collaborators' ability to continue the clinical trial for that product candidate or require us to begin a new clinical trial with a newly formulated drug product, due to the need to manufacture additional preclinical or clinical supply.

Our rate of innovation is high, which has resulted in and will continue to cause a high degree of technology change that can negatively impact product comparability during and after clinical development. Furthermore, technology changes may drive the need for changes in, modification to, or the sourcing of new manufacturing infrastructure or may adversely affect third-party relationships.

The process to generate mRNA product candidates is complex and, if not developed and manufactured under well-controlled conditions, can adversely impact pharmacological activity. Furthermore, we have not manufactured immunotherapies at commercial scale. We may encounter difficulties in scaling up our manufacturing process, thereby potentially impacting clinical and commercial supply. Additionally, for individualized therapies, we may encounter issues with our ability to timely and efficiently manufacture product given the on-demand requirements of such therapies, thereby potentially impacting clinical and commercial supply.

As we continue developing new manufacturing processes for our drug substance and drug product, the changes we implement to manufacturing process may in turn impact specification and stability of the drug product. Changes in our manufacturing processes may lead to failure of lots and this could lead to a substantial delay in our clinical trial. Our mRNA product candidates may prove to have a stability profile that leads to a lower than desired shelf life of the final approved immunotherapy. This poses risk in supply requirements, wasted stock and higher cost of goods.

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We are dependent on a number of equipment providers who are also implementing novel technology. Further, we have developed our own custom manufacturing equipment for certain of our product candidates. If such equipment malfunctions or we encounter unexpected performance issues, we could encounter delays or interruptions to clinical and commercial supply.

Due to the number of different programs, we may have cross contamination of products inside of our factories, CROs, suppliers, or in the clinic that affect the integrity of our products. Additionally, for some programs the manufacturing scale is extremely small compared to the standard volumes of supply, such that we run the risk of contaminating the process each time we reopen a container to use remaining supplies.

As we scale the manufacturing output for particular programs, we plan to continuously improve yield, purity, and the pharmaceutical properties of our product candidates from IND-enabling studies through commercial launch, including shelf life stability, and solubility properties of drug product and drug substance. Due to continuous improvement in manufacturing processes, we may switch processes for a particular program during development. However, after the change in process, more time is required for pharmaceutical property testing, such as six- or 12-month stability testing. That may require resupplying clinical material, or making additional GMP batches to keep up with clinical trial demand before such pharmaceutical property testing is completed.

We are utilizing a number of raw materials and excipients that are either new to the pharmaceutical industry or are being employed in a novel manner. Some of these raw materials and excipients have not been scaled to a level to support commercial supply and could experience unexpected manufacturing or testing failures, or supply shortages. Such issues with raw materials and excipients could cause delays or interruptions to clinical and commercial supply of our product candidates. Further, now and in the future one or more of our programs may have a single source of supply for raw materials and excipients.

We have established a number of analytical assays, and may have to establish several more, to assess the quality of our mRNA product candidates. We may identify gaps in our analytical testing strategy that might prevent release of product or could require product withdrawal or recall. For example, we may discover new impurities that have an impact on product safety, efficacy or stability. This may lead to an inability to release mRNA product candidates until the manufacturing or testing process is rectified.

Our product and product intermediates are extremely temperature sensitive, and we may learn that any or all of our products are less stable than desired. We may also find that transportation conditions negatively impact product quality. This may require changes to the formulation or manufacturing process for one or more of our product candidates and result in delays or interruptions to clinical or commercial supply. In addition, the cost associated with such transportation services and the limited pool of vendors may also add additional risks of supply disruptions.

Certain of our product candidates are uniquely manufactured for each patient and we may encounter difficulties in production, particularly with respect to scaling our manufacturing capabilities. If we or any of the third-party manufacturers with whom we contract encounter these types of difficulties, our ability to provide our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

We custom design and manufacture certain product candidates that are unique and tailored specifically for each patient. Manufacturing unique lots of these product candidates is susceptible to product loss or failure due to issues with:

- logistics associated with the collection of a patient's tumor, blood or other tissue sample;
- shipping such samples to a facility for genetic sequencing;
- next-generation sequencing of the tumor mRNA;

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- biopsy of a sufficient quantity of cancerous tissue to allow for proper sequencing and identification of tumor-specific mutations;
- identification of appropriate tumor-specific mutations;
- the use of a software program, including proprietary and open source components, which is hosted in the cloud and a part of our product candidate, to assist with the design of the patient-specific mRNA, which software must be maintained and secured;
- effective design of the patient-specific mRNA that encodes for the required neoantigens;
- batch-specific manufacturing failures or issues that arise due to the uniqueness of each patient-specific batch that may not have been foreseen;
- quality control testing failures;
- unexpected failures of batches placed on stability;
- shortages or quality control issues with single-use assemblies, consumables or critical parts sourced from third-party vendors that must be changed out for each patient-specific batch;
- significant costs associated with individualized manufacturing that may adversely affect our ability to continue development;
- successful and timely manufacture and release of the patient-specific batch;
- shipment issues encountered during transport of the batch to the patient site of care;
- the ability to define a consistent safety profile at a given dose when each participant receives a unique treatment; and
- our reliance on single-source suppliers.

We also continue to evolve our own custom manufacturing equipment. This equipment may not function as designed, which may lead to deviations in the drug product being produced. This can lead to increased batch failure and the inability to supply patients enrolled in the clinical trial. If our clinical development plans are expanded, due to the custom nature of the equipment and single-use assemblies, we may not be able to supply this expanded need reliably without significant investments. In addition, there will be considerable time to scale up our facilities or build new facilities before we can begin to meet any commercial demand if one or more of our product candidates are approved. This expansion or addition of new facilities could also lead to product comparability issues, which can further delay introduction of new capacity.

As certain of our product candidates are manufactured for each individual patient, we will be required to maintain a chain of identity with respect to each patient's tissue sample, sequence data derived from such tissue sample, results of analysis of such patient's genomic analysis, and the custom manufactured product for each patient. Maintaining such a chain of identity is difficult and complex, and failure to do so could result in product mix-up, adverse patient outcomes, loss of product, or regulatory action, including withdrawal of any approved products from the market. Further, as our product candidates are developed through early-stage clinical studies to later-stage clinical trials towards approval and commercialization, we expect that multiple aspects of the complicated collection, analysis, manufacture and delivery processes will be modified in an effort to optimize processes and results. These changes may not achieve the intended objectives, and any of these changes could cause our product candidates to perform differently than we expect, potentially affecting the results of clinical trials.

Our inability to manufacture sufficient quantities of our product candidates, or our failure to comply with applicable regulatory requirements, would materially and adversely affect our business.

Manufacturing is a vital component of our individualized immunotherapy approach, and we have invested significantly in our manufacturing facilities. All internal manufacturing is performed under GMP guidelines. We

do not rely on any external CMOs for the manufacture of our product candidates and at this time, we have limited redundancy among our facilities. Due to the individualized nature of our product candidates, we do not maintain product reserves. If any of our manufacturing facilities experiences difficulties, including related to manufacturing, product release, shelf life, testing, storage and supply chain management or shipping, our clinical development programs may be delayed or suspended until we can resume operations. We may also be required to incur significant expenditures to resolve such difficulties.

Our facilities are subject to various regulatory requirements and may be subject to the inspection of the FDA or other regulatory authorities. If we cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA or comparable regulatory authorities in other jurisdictions, we may not be able to rely on our manufacturing facilities for the manufacture of our product candidates. If the FDA, EMA or another comparable regulatory authority finds our facilities inadequate for the manufacture of our product candidates or if such facilities are subject to enforcement action in the future or are otherwise inadequate, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates.

Additionally, we may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If we were to encounter any of these difficulties, our ability to provide our product candidate to patients in clinical trials, or to provide product for the treatment of patients once approved, would be jeopardized.

We are subject to regulatory and operational risks associated with the physical and digital infrastructure at both our internal manufacturing facilities and at those of our external service providers.

While the design of our facilities is based on current standards for biotechnology facilities, it has not been reviewed or pre-approved by any regulatory agency, nor have our facilities been inspected by any regulatory agency such as the FDA. We have designed our facilities to incorporate a significant level of automation of equipment with integration of several digital systems to improve efficiency of operations. We have attempted to achieve a high level of digitization for clinical manufacturing facilities relative to industry standards. While this is meant to improve operational efficiency, this may pose additional risk of process equipment malfunction and even overall manufacturing system failure or shutdown due to internal or external factors including, but not limited to, design issues, system compatibility or potential cybersecurity breaches. This may lead to delay in supply or shutdown of our facilities. Any disruption in our manufacturing capabilities could cause delays in our production capacity for our drug substances or drug products, impose additional costs, or may require us to identify, qualify and establish an alternative manufacturing site, the occurrence of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

As we expand our development and commercial capacity, we may establish additional manufacturing capabilities and expand to other locations or geographies, which may lead to regulatory delays or prove costly. If we fail to select the correct location, complete the construction in an efficient manner, recruit the required personnel, and generally manage our growth effectively, the development and production of our product candidates could be delayed or curtailed. Additional investments may be needed if changes in our manufacturing process lead to required changes in our infrastructure.

Certain of our product candidates rely on the availability of specialty raw materials, which may not be available to us on acceptable terms or at all.

Our product candidates require many specialty raw materials, some of which are manufactured by small companies with limited resources and experience to support a commercial product, and the suppliers may not be able to deliver raw materials to our specifications. In addition, those suppliers normally support blood-based hospital businesses and generally do not have the capacity to support commercial products manufactured under GMP by biopharmaceutical firms. These suppliers may be ill-equipped to support our needs, especially in

non-routine circumstances like an FDA inspection or medical crisis, such as widespread contamination. We also do not have contracts with many of these suppliers, and we may not be able to contract with them on acceptable terms or at all. Accordingly, we have experienced and we may in the future experience delays in receiving key raw materials to support clinical or commercial manufacturing.

In addition, some raw materials are currently available from a single supplier, or a small number of suppliers. We cannot be sure that these suppliers will remain in business or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these materials for our intended purpose. In addition, the lead time needed to establish a relationship with a new supplier can be lengthy, and we may experience delays in meeting demand in the event we must switch to a new supplier. The time and effort to qualify a new supplier could result in additional costs, diversion of resources or reduced manufacturing yields, any of which would negatively impact our operating results. Further, we may be unable to enter into agreements with a new supplier on commercially reasonable terms, which could have a material adverse impact on our business.

Our product candidates are inherently sensitive to shipping and storage conditions and could be subject to risk of loss or damage.

Our product candidates are sensitive to temperature, storage and handling conditions. Loss in product candidates could occur if the product or product intermediates are not stored or handled properly. Shelf life for our product candidates may vary by product and is not fully quantified and is expected to be variable, and it is possible that our product candidates could be lost due to expiration prior to use. This has in the past led and could in the future lead to additional manufacturing costs and delays in our ability to supply required quantities for clinical trials or otherwise.

We are subject to significant regulatory oversight with respect to manufacturing our product candidates. Our manufacturing facilities or the manufacturing facilities of our third-party manufacturers or suppliers may not meet regulatory requirements. Failure to meet GMP requirements set forth in regulations promulgated by the FDA, the EMA and other comparable regulatory authorities could result in significant delays in and costs of our products.

The manufacturing of immunotherapies for clinical trials or commercial sale is subject to extensive regulation. GMP requirements govern manufacturing processes and procedures, including record-keeping, and the implementation and operation of quality systems to control and assure the quality of products and materials used in clinical trials. Poor control of the GMP production processes can lead to product quality failures that can impact our ability to supply product, resulting in cost overruns and delays to clinical timelines, which could be extensive. Such production process issues include but are not limited to:

- critical deviations in the manufacturing process;
- facility and equipment failures;
- contamination of the product due to an ineffective quality control strategy;
- facility contamination as assessed by the facility and utility environmental monitoring program;
- ineffective process, equipment or analytical change management, resulting in failed lot release criteria;
- raw material failures due to ineffective supplier qualification or regulatory compliance issues at critical suppliers;
- ineffective product stability;
- failed lot release or facility and utility quality control testing;
- ineffective corrective actions or preventative actions taken to correct or avoid critical deviations due to our developing understanding of the manufacturing process as we scale; and
- failed or defective components or consumables.

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We must supply all necessary documentation in support of a BLA or other marketing authorization application on a timely basis and must adhere to the FDA's, the EMA's and other countries' GMP requirements which are enforced, in the case of the FDA, in part through its facilities inspection program.

Regulatory authorities typically require representative manufacturing site inspections to assess adequate compliance with GMPs and manufacturing controls as described in the filing. If either we or one of our third-party manufacturing sites fails to provide sufficient quality assurance or control, approval to commercialize our product candidates may not be granted. Inspections by regulatory authorities may occur at any time during the development or commercialization phase of products. The inspections may be product-specific or facility-specific for broader GMP inspections or as a follow up to market or development issues that the regulatory agency may identify. Deficient inspection outcomes may influence the ability of our third-party manufacturers or suppliers to fulfill their supply obligations, impacting or delaying supply or delaying programs.

The manufacturing process for any products that we may develop is subject to the FDA's, the EMA's and other regulatory authorities' approval processes, and we may need to contract with manufacturers who we believe can meet applicable regulatory authority requirements on an ongoing basis. If we or our third-party manufacturers are unable to reliably produce product candidates to specifications acceptable to the FDA, the EMA or other regulatory authorities, we or our collaborators may not obtain or maintain the approvals we or they need to commercialize such products. Even if we or our collaborators obtain regulatory approval for any of our immunotherapies, there is no assurance that either we or our CMOs will be able to manufacture our product candidates to specifications acceptable to the FDA, EMA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates, impair commercialization efforts or increase our cost of goods. The occurrence of any of the foregoing could have an adverse effect on our business, financial condition, results of operations and growth prospects.

In addition, we may not have direct control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Furthermore, all of our contract manufacturers are engaged with other companies to supply or manufacture materials or products for such companies, which exposes our contract manufacturers to regulatory risks for the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may generally affect the regulatory status of our CMOs' facilities. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect supplies of our products and product candidates (including those of our collaborators) and our overall business operations. Our potential future dependence upon others for the manufacture of our product candidates and raw materials may adversely affect our future profit margins and our ability to commercialize any products that receive regulatory approval on a timely and competitive basis.

The FDA, EMA and other regulatory authorities may require us to submit product samples of any lot of any approved product together with the protocols showing the results of applicable tests at any time. Under some circumstances, the FDA or other regulatory authorities may require that we do not distribute a lot or lots until the relevant agency authorizes such release. Deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Our third-party CMOs have, in the past, experienced lot failures and some may have experienced product recalls. Lot failures or product recalls with respect to product produced by either our own facilities or those of our third-party manufacturers could cause us and our collaborators to delay clinical trials or product launches, which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects.

We also may encounter problems hiring and retaining the experienced scientific, quality-control and manufacturing personnel needed to operate our manufacturing processes and operations, which could result in delays in production or difficulties in maintaining compliance with applicable regulatory requirements. While we will train and qualify all personnel around the appropriate handling of our products and materials, we may not be able to control for or ultimately detect intentional sabotage or negligence by any employee or contractor.

Risks Related to the Commercialization of our Pipeline

The successful commercialization of our product candidates will depend in part on the extent to which governmental authorities, private health insurers and other third-party payors provide coverage and adequate reimbursement levels and implement pricing policies favorable for our product candidates. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments such as the medicines that we hope to develop and sell. In addition, because our several of our product candidates represent new approaches to the treatment of cancer, we cannot accurately estimate how these products would be priced, whether reimbursement could be obtained, or any potential revenue. Sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit, and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment in any of our products.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products, including genetic medicines. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS, as CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payors tend to follow CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for novel products such as ours. Reimbursement agencies in Europe may be more conservative than CMS. For example, a number of cancer drugs have been approved for reimbursement in the United States but have not been approved for reimbursement in certain European countries.

Outside the United States, certain countries, including a number of member states of the European Union, set prices and reimbursement for pharmaceutical products, with limited participation from the marketing authorization holders. We cannot be sure that such prices and reimbursement will be acceptable to us or our collaborators. If the regulatory authorities in these jurisdictions set prices or reimbursement levels that are not commercially attractive for us or our collaborators, our revenues from sales by us or our collaborators, and the potential profitability of our drug products, in those countries would be negatively affected. An increasing number of countries are taking initiatives to attempt to reduce large budget deficits by focusing cost-cutting efforts on pharmaceuticals for their state-run health care systems. These international price control efforts have impacted all regions of the world, but have been most drastic in the European Union. Additionally, some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then may experience delays in the reimbursement approval of our product or be subject to price regulations that would delay our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenues we are able to generate from the sale of the product in that particular country.

Moreover, increasing efforts by governmental and third-party payors, in the United States and abroad, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. For example, the U.S. government recently released a “Blueprint,” which is a plan to reduce the cost of drugs. The Blueprint contains certain measures that the HHS is already working to implement. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect to experience pricing pressures in connection with the sale of any of our product candidates, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products in the marketplace.

We face significant competition in an environment of rapid technological and scientific change, and our failure to effectively compete would prevent us from achieving significant market penetration. Most of our competitors have significantly greater resources than we do and we may not be able to compete successfully.

The pharmaceutical market is intensely competitive and rapidly changing. Many large pharmaceutical and biotechnology companies, academic institutions, governmental agencies, and other public and private research organizations are pursuing the development of novel drugs for the same diseases that we are targeting or expect to target. Many of our competitors have:

- greater financial, technical and human resources than we have at every stage of the discovery, development, manufacture and commercialization of products;
- more extensive experience in preclinical testing, conducting clinical trials, obtaining regulatory approvals, and in manufacturing, marketing and selling drug products;
- product candidates that are based on previously tested or accepted technologies;
- products that have been approved or are in late stages of development; and
- collaborative arrangements in our target markets with leading companies and research institutions.

We will face intense competition from drugs that have already been approved and accepted by the medical community for the treatment of the conditions for which we may develop drugs. We also expect to face competition from new drugs that enter the market. There are a number of drugs currently under development, which may become commercially available in the future, for the treatment of conditions for which we are trying, or may in the future try, to develop drugs. These drugs may be more effective, safer, less expensive, or marketed and sold more effectively, than any products we develop.

We anticipate competing with the largest pharmaceutical companies in the world, many of which are all currently conducting research in the fields of infectious diseases, immuno-oncology, rare genetic diseases and cancer immunotherapies. Some of these companies have greater financial and human resources than we currently have. In addition to these large pharmaceutical companies, we may directly compete with fully-integrated biopharmaceutical companies and other immunotherapy-focused oncology companies, as well as a number of companies focused on immunotherapies or shared tumor antigen and neoantigen therapeutics, some of which have entered into collaboration and funding agreements with larger pharmaceutical or biotechnology companies.

If we successfully develop product candidates, and obtain approval for them, we will face competition based on many different factors, including:

- the safety and effectiveness of our products relative to alternative therapies, if any;

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- the ease with which our products can be administered and the extent to which patients accept relatively new routes of administration;
- the timing and scope of regulatory approvals for these products;
- the availability and cost of manufacturing, marketing and sales capabilities;
- the price of any approved immunotherapy;
- reimbursement coverage; and
- intellectual property position.

Our competitors may develop or commercialize products with significant advantages over any products we develop based on any of the factors listed above or on other factors. In addition, our competitors may develop collaborations with or receive funding from larger pharmaceutical or biotechnology companies, providing them with an advantage over us. Our competitors may therefore be more successful in commercializing their products than we are, which could adversely affect our competitive position and business. Competitive products may make any products we develop obsolete or noncompetitive before we can recover the expenses of developing and commercializing our products, if approved.

The market opportunities for certain of our product candidates may be limited due to the rarity of the disease, or limited to those patients who are ineligible for or have failed prior treatments, and may be small. As the target patient populations for some of our programs are small, we must be able to successfully identify trial participants and achieve a significant market share to maintain profitability and growth.

The FDA often approves new therapies initially only for use by patients with relapsed or refractory advanced cancer. We expect to initially seek approval of certain of our product candidates in this context. Subsequently, for those products that prove to be sufficiently beneficial, if any, we would expect to seek approval in earlier lines of treatment and potentially as a first-line therapy but there is no guarantee that our product candidates, even if approved, would be approved for earlier lines of therapy, and, prior to any such approvals, we may have to conduct additional clinical trials. We are also developing product candidates for the treatment of rare diseases.

Our projections of the number of people who have or will have the diseases we may be targeting may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of trial participants may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. Even if we obtain significant market share for our products, if approved, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications.

We currently have no marketing and sales organization and as a company, we have no experience in marketing pharmaceutical products. If we are unable to establish marketing and sales capabilities on our own or through third parties, we may not be able to market and sell our product candidates effectively in the United States and other jurisdictions, if approved, or generate product sales revenue.

Given our stage of development, we have no sales, distribution or marketing capabilities, and we have not designed our preclinical studies and clinical trials with specific commercialization or marketing considerations in mind. To successfully commercialize any products that may result from our development programs, we will need to develop sales and marketing capabilities in the United States, Europe and other regions, either on our own or with others. We may enter into collaborations with other entities to utilize their mature marketing and distribution capabilities, but we may be unable to enter into marketing agreements on favorable terms, if at all. If our future collaborators do not commit sufficient resources to commercialize our future products, if any, and we

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are unable to develop the necessary marketing capabilities on our own, we may be unable to generate sufficient product sales revenue to sustain our business. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without a significant internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

Our future profitability, if any, depends in part on our and our collaborators' ability to penetrate global markets, where we would be subject to additional regulatory burdens and other risks and uncertainties associated with international operations that could materially adversely affect our business.

Our future profitability, if any, will depend in part on our ability and the ability of our collaborators to commercialize any products that we or our collaborators may develop in markets throughout the world. Commercialization of products in various markets could subject us to risks and uncertainties, including:

- obtaining, on a country-by-country basis, the applicable marketing authorization from the competent regulatory authority;
- the burden of complying with complex and changing regulatory, tax, accounting, labor and other legal requirements in each jurisdiction that we or our collaborators pursue;
- reduced protection for intellectual property rights;
- differing medical practices and customs affecting acceptance in the marketplace;
- import or export licensing requirements;
- governmental controls, trade restrictions or changes in tariffs;
- economic weakness, including inflation, or political instability in particular non-U.S. economies and markets;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers;
- foreign currency exchange rate fluctuations;
- reimbursement, pricing and insurance regimes; and
- the interpretation of contractual provisions governed by local laws in the event of a contract dispute.

We do not have prior experience in all of these areas, and the experience we do have in some of these areas is limited. Our collaborators may have limited experience in these areas as well. Failure to successfully navigate these risks and uncertainties may limit or prevent market penetration for any products that we or our collaborators may develop, which would limit their commercial potential and our revenues.

Even if we obtain regulatory approval for our product candidates, the products may not gain the market acceptance among physicians, patients, hospitals, cancer treatment centers and others in the medical community necessary for commercial success.

Even with the requisite approvals, the commercial success of our products will depend in part on the medical community, patients, and third-party or governmental payors accepting immunotherapies in general, and our products in particular, as medically useful, cost-effective and safe. Any product that we bring to the market may not gain market acceptance by physicians, trial participants, third-party payors, and others in the medical

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community. Additionally, ethical, social and legal concerns about genetic research could result in additional regulations restricting or prohibiting the products and processes we may use. If these products do not achieve an adequate level of acceptance, we may not generate significant product sales revenue and may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the potential efficacy and potential advantages over alternative treatments;
- the ability to offer our products, if approved, at competitive prices;
- the prevalence and severity of any side effects, including any limitations or warnings contained in a product's approved labeling;
- the prevalence and severity of any side effects resulting from checkpoint inhibitors or other drugs or therapies with which our products are administered;
- relative convenience and ease of administration;
- any restrictions on the use of our products, if approved, together with other medications;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments; and
- sufficient third-party insurance coverage or reimbursement, and patients' willingness to pay out-of-pocket in the absence of third-party coverage or adequate reimbursement.

Even if a potential product displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be known until after it is launched. Our efforts to educate the medical community and third-party payors on the benefits of the products may require significant resources and may never be successful. Our efforts to educate the marketplace may require more resources than are required by the conventional technologies marketed by our competitors due to the complexity and uniqueness of our programs.

Commercial success of any approved products will also depend in large part on the availability of coverage and adequate reimbursement from third-party payors, including government payors such as the Medicare and Medicaid programs and entry into managed care organizations, which may be affected by existing and future healthcare reform measures designed to reduce the cost of healthcare. Third-party payors could require us to conduct additional studies, including post-marketing studies related to the cost effectiveness of a product, to qualify for reimbursement, which could be costly and divert our resources. If government and other healthcare payors do not provide adequate coverage and reimbursement levels for any of our products once approved, whether due to healthcare reform legislation or otherwise, market acceptance and commercial success would be reduced.

In addition, if any of our products are approved for marketing, we or a collaborator will be subject to significant regulatory obligations regarding the submission of safety and other post-marketing information and reports for such product, and will need to continue to comply (or ensure that our third-party providers comply) with GMP and current good clinical practices, or GCP, for any clinical trials that we or a collaborator conduct post-approval. In addition, there is always the risk that we or a collaborator or regulatory authority might identify previously unknown problems with a product post-approval, such as adverse events of unanticipated severity or frequency. Compliance with these requirements is costly, and any such failure to comply or other issues with our product candidates identified post-approval could have a material adverse impact on our business, financial condition and results of operations.

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our product candidates, if approved, profitably.

Successful sales of our product candidates, if approved, depend on the availability of coverage and adequate reimbursement from third-party payors including governmental healthcare programs, such as Medicare and Medicaid, managed care organizations and commercial payors, among others. Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In addition, because our product candidates represent new approaches to the treatment of cancer, we cannot accurately estimate the potential revenue from our product candidates.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Obtaining coverage and adequate reimbursement from third-party payors is critical to new product acceptance.

Third-party payors decide which drugs and treatments they will cover and the amount of reimbursement. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. Even if we obtain coverage for a given product, if the resulting reimbursement rates are insufficient, hospitals may not approve our product for use in their facility or third-party payors may require co-payments that patients find unacceptably high. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates. Separate reimbursement for the product itself may or may not be available. Instead, the hospital or administering physician may be reimbursed only for providing the treatment or procedure in which our product is used. Further, from time to time, CMS revises the reimbursement systems used to reimburse health care providers, including the Medicare Physician Fee Schedule and Outpatient Prospective Payment System, which may result in reduced Medicare payments. In some cases, private third-party payors rely on all or portions of Medicare payment systems to determine payment rates. Changes to government healthcare programs that reduce payments under these programs may negatively impact payments from private third-party payors, and reduce the willingness of physicians to use our product candidates.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

We intend to seek approval to market our product candidates in the United States, the European Union and other selected jurisdictions. If we obtain approval for our product candidates in any particular jurisdiction, we will be subject to rules and regulations in that jurisdiction. In some countries, particularly those in Europe, the pricing of biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. Some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product

candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new products into the marketplace. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if government and other third-party payors fail to provide coverage and adequate reimbursement. We expect downward pressure on pharmaceutical pricing to continue. Further, coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

The advancement of healthcare reform legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize any product candidates we or our collaborators develop and may adversely affect the prices for such product candidates.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the ACA was passed, which substantially changes the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and promoted a new Medicare Part D coverage gap discount program. Considerable uncertainty remains regarding the implementation and impact of the ACA.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges. The Tax Cuts and Jobs Act of 2017, or the TCJA, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Further, on October 13, 2017, an executive order was signed terminating the cost-sharing reduction, or CSR, subsidies that reimburse insurers under the ACA. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. Another executive order was signed directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. With the current presidential administration and Congress, there may be additional administrative or legislative changes, including modification, repeal or replacement of all, or certain provisions of, the ACA. However, it remains to be seen whether new legislation modifying the ACA will be enacted and, if so, precisely what the new legislation will provide, when it will be enacted and what impact it will have on the availability of healthcare and containing or lowering the cost of healthcare. The implications of a potential repeal or replacement of the ACA, for our and our collaborators’ business and financial condition, if any, are not yet clear.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction

of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year. These reductions will remain in effect through 2025 unless additional congressional action is taken.

The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than European Union, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most European Union member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing European Union and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities, and affect our ability to commercialize any products for which we obtain marketing approval.

We expect that additional healthcare reform measures or proposals will be adopted in the future, any of which could limit the amounts that governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. In the event that the pricing structures for healthcare products, such as the product candidates we are developing, change materially and limit payments for such product candidates, our business will be adversely impacted as our products may no longer be commercially viable based on their expected net present value; we may have invested significant resources in products that cannot be commercially developed; or we may determine that assets that have reached an early phase of development cannot or will not be taken into further development, notwithstanding their clinical viability. In addition, development assets or clinical programs that are part of our collaborations may no longer be deemed commercially viable to pursue based on our collaborators' assessments of the impact of any proposed, announced, or legislated pricing reforms.

We cannot predict what healthcare reform initiatives may be adopted in the future. Further legislative and regulatory developments are likely, and we expect ongoing initiatives to increase pressure on drug pricing. Such reforms could have an adverse effect on anticipated revenues from product candidates that we may successfully develop and for which we may obtain regulatory approval, and may affect our overall financial condition and ability to develop product candidates.

European Union drug marketing and reimbursement regulations may materially affect our ability to market and receive coverage for our products in the European Union member states.

We intend to seek approval to market our product candidates in both the United States and in other selected jurisdictions. If we obtain approval for our product candidates in a particular jurisdiction, we will be subject to rules and regulations in that jurisdiction. In some countries, particularly those in the European Union, the pricing of biologics is subject to governmental control and other market regulations that could put pressure on the pricing and usage of our product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future healthcare reform measures.

In addition, in most countries outside the United States, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can

further reduce prices. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In some countries, we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of any of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and, generally, prices tend to be significantly lower in the European Union. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales by us or our collaborators and the potential profitability of any of our product candidates in those countries would be negatively affected.

Risks Related to our Reliance on Third Parties

We have entered into several arrangements with a related party for the performance of nonclinical research programs, and these arrangements present potential conflicts of interest.

We have had a longstanding relationship with Translational Oncology at the University Medical Center of the Johannes Gutenberg University Mainz (Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH), or TRON, a non-profit limited liability company engaged in biopharmaceutical research. During 2018, we paid €11.2 million to TRON, and TRON's research has historically constituted a significant portion of our discovery pipeline and target discovery engine. Prof. Ugur Sahin, M.D., our co-founder and Chief Executive Officer, co-founded TRON and served as Managing Director at TRON until 2019 and currently serves as a Professor of Medicine at the University of Mainz. Additionally, Prof. Christoph Huber, M.D., a member of our Supervisory Board, served on TRON's supervisory board until his resignation in April 2019. We and TRON also share certain intellectual property.

The existence or appearance of a conflict of interest could depress the price of the ADSs or attract scrutiny from shareholders, regulators or other stakeholders. Additionally, any conflicts of interest would create the risk that our officers may favor their personal interests over those of our shareholders.

We rely on third parties in the conduct of significant aspects of our preclinical studies and clinical trials and intend to rely on third parties in the conduct of future clinical trials. If these third parties do not successfully carry out their contractual duties, fail to comply with applicable regulatory requirements or fail to meet expected deadlines, we may be unable to obtain regulatory approval for our product candidates.

We currently rely and expect to continue to rely on third parties, such as CROs, clinical data management organizations, collaborators, medical institutions and clinical investigators, to conduct various and significant elements of our clinical trials. We currently rely and expect to continue to rely on third parties to conduct certain research and preclinical testing activities. In some cases, these third parties may terminate their engagements with us. If we need to enter into alternative arrangements, it would delay our discovery or product development activities.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our regulatory or contractual responsibilities. We will be responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial.

Moreover, the FDA requires us to comply with GCP for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and

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confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity, and civil and criminal sanctions. For any violations of laws and regulations during the conduct of our preclinical studies and clinical trials, we could be subject to warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

We and our CROs will be required to comply with regulations, including GCP, for conducting, monitoring, recording and reporting the results of preclinical studies and clinical trials to ensure that the data and results are scientifically credible and accurate and that the trial participants are adequately informed, among other things, of the potential risks of participating in clinical trials. We also are responsible for ensuring that the rights of our clinical trial participants are protected. These regulations are enforced by the FDA, the competent authorities of the member states, and comparable regulatory authorities of other jurisdictions for any product candidates in clinical development. The FDA enforces GCP regulations through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable regulatory authorities of other jurisdictions may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our future clinical trials will comply with GCP. In addition, our clinical trials must be conducted with product candidates produced in accordance with the requirements of GMP regulations. Our failure or the failure of our CROs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action.

Although we intend to design the clinical trials for certain of our product candidates, our collaborators will design the clinical trials that they are managing (in some cases, with our input) and in the case of clinical trials controlled by us, we expect that CROs will conduct all of the clinical trials. As a result, many important aspects of our development programs, including their conduct and timing, will be outside of our direct control. Our reliance on third parties to conduct future preclinical studies and clinical trials will also result in less direct control over the management of data developed through preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also potentially lead to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- undergo changes in priorities or become financially distressed;
- form relationships with other entities, some of which may be our competitors;
- have human errors; or
- be subject to cyberattacks.

These factors may materially adversely affect the willingness or ability of third parties to conduct our preclinical studies and clinical trials and may subject us to unexpected cost increases that are beyond our control. If the CROs do not perform preclinical studies and clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development, regulatory approval and commercialization of our product candidates may be delayed, we may not be able to obtain regulatory approval and commercialize our product candidates, or our development programs may be materially and irreversibly harmed. If we are unable to rely on preclinical and clinical data collected by our CROs, we could be required to repeat, extend the duration of, or increase the size of any clinical trials we conduct and this could significantly delay commercialization and require significantly greater expenditures.

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We also expect to rely on other third parties to transport, store and distribute the required materials for our clinical trials. In the past certain of our third-party vendors have mishandled our materials, resulting in loss of full or partial lots of material. Any further performance failure on the part of these third parties could result in damaged products and could delay clinical development or marketing approval of any product candidates we may develop or commercialization of our medicines, if approved, producing additional losses and depriving us of potential product sales revenue, causing us to default on our contractual commitments, result in losses that are not covered by insurance, and damage our reputation and overall perception of our products in the marketplace.

Our existing collaborations, or any future collaboration arrangements that we may enter into, may not be successful, which could significantly limit the likelihood of receiving the potential economic benefits of the collaboration and adversely affect our ability to develop and commercialize our product candidates.

We have entered into collaborations under which our collaborators have provided, and may in the future provide, funding and other resources for developing and potentially commercializing our product candidates. We expect to enter into additional collaborations to access additional funding, capabilities and expertise in the future. Our existing collaborations, and any future collaborations we enter into, may pose a number of risks, including the following:

- collaborators may not perform or prioritize their obligations as expected;
- the clinical trials conducted as part of such collaborations may not be successful;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization of programs based on clinical trial results, changes in the collaborators' focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for clinical trials, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates developed in collaborations with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the development or commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of any such product;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation, or the preferred course of development of any product candidates, may cause delays or termination of the research, development or commercialization of such product candidates, may lead to additional responsibilities for us with respect to such product candidates, or may result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain, protect, defend or enforce our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- disputes may arise with respect to the ownership of intellectual property developed pursuant to our collaborations;

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- collaborators may infringe, misappropriate or otherwise violate the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- collaborations may be terminated for the convenience of the collaborator and, if terminated, the development of our product candidates may be delayed, and we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates;
- future relationships may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing shareholders, or disrupt our management and business;
- we could face significant competition in seeking appropriate collaborators, and the negotiation process is time-consuming and complex; and
- our international operations through any future collaborations, acquisitions or joint ventures may expose us to certain operating, legal and other risks not encountered in the United States.

If our collaborations do not result in the successful development and commercialization of programs, or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone, earn-out, royalty, or other contingent payments under the collaborations. If we do not receive the funding we expect under these agreements, our development of product candidates could be delayed and we may need additional resources to develop our product candidates. In addition, in general our collaborators have the right to terminate their agreements with us for convenience. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and the perception of us in the business and financial communities could be adversely affected. All of the risks relating to product development, regulatory approval and commercialization described in this prospectus apply to the activities of our collaborators.

If we are not able to establish collaborations on commercially reasonable terms, we may have to alter our research, development and commercialization plans.

Our research and product development programs and the potential commercialization of any product candidates we develop alone or with collaborators will require substantial additional cash to fund expenses, and we expect that we will continue to seek collaborative arrangements with others in connection with the development and potential commercialization of current and future product candidates or the development of ancillary technologies. We face significant competition in establishing relationships with appropriate collaborators. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include, among other things and as applicable for the type of potential product or technology, an assessment of the opportunities and risks of our technology, the design or results of studies or trials, the likelihood of approval, if necessary, of the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products and technologies and industry and market conditions generally.

Current or future collaborators may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us. Additionally, we may be restricted under existing collaboration agreements from entering into future agreements on certain terms or for certain development activities with potential collaborators. For example, we have granted exclusive rights or options to Pfizer for certain targets, and under the terms of our respective collaboration agreements with them we will be restricted from granting rights to other parties to use our mRNA technology to pursue potential products that address those targets. Similarly, our collaboration agreements have in the past and may in the future contain non-competition provisions that could limit our ability to enter into collaborations with future collaborators.

Collaborations are complex and time-consuming to negotiate and document. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we do enter into additional collaboration agreements, the negotiated terms may force us to relinquish rights that diminish our potential profitability from development and commercialization of the subject product candidates or others. If we are unable to enter into additional collaboration agreements, we may have to curtail the research and development of the product candidate or technology for which we are seeking to collaborate, reduce or delay research and development programs, delay potential commercialization timelines, reduce the scope of any sales or marketing activities or undertake research, development or commercialization activities at our own expense. If we elect to increase our expenditures to fund research, development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all.

We have entered into in-licensing arrangements and may form or seek to enter into additional licensing arrangements in the future, and we may not realize the benefits of such licensing arrangements.

We are a party to licenses that give us rights to third-party intellectual property, including patents and patent applications, that are necessary or useful for our business. In particular, we have obtained licenses from CellScript LLC and its affiliate, mRNA RiboTherapeutics, Inc., to patent rights claiming certain uses of modified RNA, as well as licenses from certain other parties for intellectual property useful in pharmaceutical formulations. We may enter into additional licenses to third-party intellectual property in the future.

The success of products developed based on in-licensed technology will depend in part on the ability of our current and future licensors to prosecute, obtain, maintain, protect, enforce and defend patent protection for our in-licensed intellectual property. Our current and future licensors may not successfully prosecute the patent applications we license. Even if patents issue in respect of these patent applications, our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than we would. Without protection for the intellectual property we license, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects. In addition, we sublicense our rights under various third-party licenses to our collaborators. Any impairment of these sublicensed rights could result in reduced revenues under our collaboration agreements or result in termination of an agreement by one or more of our collaborators.

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe, misappropriate or otherwise violate the intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other intellectual property rights to third parties under collaborative relationships;
- our diligence obligations with respect to the use of the licensed intellectual property and technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- the ownership of inventions, trade secrets, know-how and other intellectual property resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators; and
- the priority of invention of patented technology.

If disputes over intellectual property that we have in-licensed or other related contractual rights prevent or impair our ability to maintain our current licensing arrangements on favorable terms, we may be unable to successfully develop and commercialize the affected product candidates.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described below. If we, our co-owners or our licensors fail to adequately protect, defend, maintain or enforce this intellectual property, our ability to commercialize products could suffer.

We rely on third parties to manufacture certain of our clinical product supplies, and we may have to rely on third parties to produce and process our product candidates, if approved.

Although we expect to continue using our own clinical manufacturing facilities, we may need to rely on outside vendors to manufacture supplies and process our product candidates. We have not yet caused our product candidates to be manufactured or processed on a commercial scale and may not be able to achieve commercial-scale manufacturing and processing and may be unable to create an inventory of mass-produced, off-the-shelf product to satisfy demands for our product candidates.

We do not yet have sufficient information to reliably estimate the cost of the commercial manufacturing and processing of our product candidates, and the actual cost to manufacture and process our product candidates could materially and adversely affect the commercial viability of our product candidates. As a result, we may never be able to develop a commercially viable product.

In addition, our reliance on a limited number of third-party manufacturers exposes us to the following risks:

- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA or other regulatory authorities may have questions regarding any replacement contractor. This may require new testing and regulatory interactions. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of regulatory authority questions, if any;
- our third-party manufacturers might be unable to timely formulate and manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- CMOs may not be able to execute our manufacturing procedures appropriately;
- our future CMOs may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products;
- manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the U.S. Drug Enforcement Administration and corresponding state agencies and by regulatory authorities in other jurisdictions to ensure strict compliance with GMP and other government regulations and corresponding standards in other jurisdictions. We do not have control over third-party manufacturers' compliance with these regulations and standards;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our products;
- our third-party manufacturers could breach or terminate their agreement with us; and
- our CMOs would also be subject to the same risks we face in developing our own manufacturing capabilities, as described above.

Each of these risks could delay our clinical trials, the approval, if any, of our product candidates by the FDA or regulatory authorities in other jurisdictions or the commercialization of our product candidates, or result in higher costs or deprive us of potential product sales revenue. In addition, we will rely on third parties to perform release tests on our product candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm.

We are dependent on single-source suppliers for some of the components and materials used in, and the processes required to develop, our product candidates.

We currently depend on single-source suppliers for some of the components and materials used in, and manufacturing processes required to develop, our product candidates. We cannot ensure that these suppliers or service providers will remain in business, or have sufficient capacity or supply to meet our needs, or that they will not be purchased by one of our competitors or another company that is not interested in continuing to work with us. Our use of single-source suppliers of raw materials, components, key processes and finished goods exposes us to several risks, including disruptions in supply, price increases or late deliveries. There are, in general, relatively few alternative sources of supply for substitute components. These vendors may be unable or unwilling to meet our future demands for our clinical trials or commercial sale. Establishing additional or replacement suppliers for these components, materials and processes could take a substantial amount of time and it may be difficult to establish replacement suppliers who meet regulatory requirements. Any disruption in supply from any single-source supplier or service provider could lead to supply delays or interruptions which would damage our business, financial condition, results of operations and prospects.

If we have to switch to a replacement supplier, the manufacture and delivery of our product candidates could be interrupted for an extended period, which could adversely affect our business. Establishing additional or replacement suppliers for any of the components or processes used in our product candidates, if required, may not be accomplished quickly. If we are able to find a replacement supplier, the replacement supplier would need to be qualified and may require additional regulatory authority approval, which could result in further delay. While we seek to maintain adequate inventory of the single source components and materials used in our products, any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand for our product candidates.

In addition, as part of the FDA's approval of our product candidates, we will also require FDA review of the individual components of our process, which include the manufacturing processes and facilities of our single-source suppliers.

Our reliance on these suppliers, service providers and manufacturers subjects us to a number of risks that could harm our reputation, business and financial condition, including, among other things:

- delays to the development timelines for our product candidates;
- interruption of supply resulting from modifications to or discontinuation of a supplier's operations;
- delays in product shipments resulting from uncorrected defects, reliability issues, or a supplier's variation in a component;
- a lack of long-term supply arrangements for key components with our suppliers;
- inability to obtain adequate supply in a timely manner, or to obtain adequate supply on commercially reasonable terms;
- difficulty and cost associated with locating and qualifying alternative suppliers for our components in a timely manner;
- production delays related to the evaluation and testing of components from alternative suppliers, and corresponding regulatory qualifications;
- delay in delivery due to our suppliers' prioritizing other customer orders over ours;
- damage to our reputation caused by defective components produced by our suppliers; and
- fluctuation in delivery by our suppliers due to changes in demand from us or their other customers.

If any of these risks materialize, costs could significantly increase and our ability to meet demand for our products could be impacted.

Risks Related to Our Intellectual Property

If our efforts to obtain, maintain, protect, defend and/or enforce the intellectual property related to our product candidates and technologies are not adequate, we may not be able to compete effectively in our market.

Our commercial success depends in part on our ability to obtain, maintain, protect, defend and enforce patent and other intellectual property, including trade secret and know-how, protection for our product candidates, proprietary technologies and their uses, as well as our ability to operate, develop, manufacture and commercialize our product candidates without infringing, misappropriating or otherwise violating the intellectual property or other proprietary rights of our competitors or any other third parties, including any non-practicing entities or patent assertion entities. We generally seek to protect our intellectual property position by filing and/or licensing patent applications in the United States and abroad related to our product candidates, proprietary technologies (including methods of manufacture) and their uses that are important to our business. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent that the issued claims cover third parties' activities in the countries in which they are performed. We cannot be certain that the claims in any of our patent applications will be considered patentable by the United States Patent and Trademark Office, or the USPTO, courts in the United States or the patent offices and courts in other jurisdictions, including Europe, nor can we be certain that the claims in our issued patents will not be found invalid or unenforceable if challenged. Accordingly, there can be no assurance that our patent applications or those of our licensors will result in additional patents being issued or that issued patents will adequately cover our product candidates or otherwise afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around, invalidated or held unenforceable. Furthermore, we may not be able to apply for patents on certain aspects of our current or future product candidates, proprietary technologies and their uses in a timely fashion, at a reasonable cost, in all jurisdictions, or at all, and any potential patent protection we obtain may not be sufficient to prevent substantial competition.

Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings before various patent offices or in courts in the United States, Europe or other jurisdictions. The degree of future protection for our intellectual property and other proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. If we do not adequately obtain, maintain, protect, defend and enforce our intellectual property and proprietary technology, competitors may be able to use our product candidates and proprietary technologies and erode or negate any competitive advantage we may have, which could have a material adverse effect on our financial condition and results of operations.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our current or future licensors or collaborators will be successful in prosecuting, obtaining, protecting, maintaining, enforcing or defending patents and patent applications necessary or useful to protect our product candidates, proprietary technologies (including methods of manufacture) and their uses. These risks and uncertainties include, from time to time, the following:

- the USPTO and various other governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application or a finding that a patent is unenforceable, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- issued patents that we own (solely or jointly) or have in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;

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- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use, sell, import or otherwise exploit our product candidates or other technologies;
- other parties may have designed around our patent claims or developed technologies that may be related or competitive to our product candidates or other technologies, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent filings, either by claiming the same or overlapping methods, products, reagents or devices or by claiming subject matter that could dominate one or more of our patent claims;
- any successful opposition to any patents owned by or in-licensed to us could deprive us of rights necessary for the development and exploitation of our product candidates and other technologies or the successful commercialization of any product candidates and other technologies that we may develop;
- because patent applications in the United States and most other jurisdictions are confidential for a period of time after filing, we cannot be certain that we, our co-owners or our licensors were the first to file any patent application related to our product candidates, proprietary technologies and their uses;
- a court or patent office proceeding, such as a derivative action or interference, can be provoked or instituted by a third party or a patent office, and might determine that one or more of the inventions described in our patent filings, or in those we licensed, was first invented by someone else, so that we may lose rights to such invention(s);
- a court or other patent proceeding, such as an *inter partes* review, post grant review or opposition, can be instituted by a third party to challenge the inventorship, scope, validity and/or enforceability of our patent claims and might result in invalidation or revision of one or more of our patent claims, or in a determination that such claims are unenforceable;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing competitors a better opportunity to create, develop and market competing product candidates.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. The standards that the USPTO and its counterparts use to grant patents are not always applied predictably or uniformly and can change. Similarly, the ultimate degree of protection that will be afforded to biotechnology inventions, including ours, in the United States and other countries, remains uncertain and is dependent upon the scope of the protection decided upon by patent offices, courts and lawmakers. Moreover, there are periodic changes in patent law, as well as discussions in the Congress of the United States and in international jurisdictions about modifying various aspects of patent law. There is no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in pharmaceutical or biotechnology patents. In certain countries, for example, methods for the medical treatment of humans are not patentable. More generally, the laws of some countries do not protect intellectual property rights to the same extent as U.S. laws, and those countries may lack adequate rules and procedures for granting, maintaining, protecting, defending and enforcing our intellectual property rights.

Furthermore, the patent prosecution process is also expensive and time-consuming, and we may not be able to file, prosecute, maintain, protect, defend, enforce or license all necessary or desirable patents or patent applications, as applicable, at a reasonable cost or in a timely manner. It is possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter

into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. We also rely to a certain extent on trade secrets, know-how, and technology, which are not protected by patents, to maintain our competitive position. If any trade secret, know-how or other technology not protected by a patent were to be disclosed to or independently developed by a competitor, our business and financial condition could be materially adversely affected.

The issuance of a patent is not conclusive as to its inventorship, priority date, scope, term, validity or enforceability so that any patents that may issue or that we may license may be challenged in the courts or patent offices in the United States, Europe and other jurisdictions. Once granted, patents may remain open to a variety of challenges, including opposition, interference, re-examination, post-grant review, *inter partes* review, nullification or derivation action in court or before patent offices or similar proceedings, and furthermore, may be challenged as a defense in any enforcement action that we might bring. Such challenges may result in loss of exclusivity or in patent claims being narrowed, terminated, disclaimed, invalidated, assigned to others or held unenforceable, any or all of which could limit our ability to stop others from using or commercializing similar or identical products, or limit the scope and/or term of patent protection of our products and product candidates and/or eliminate it altogether, thus hindering or removing our ability to limit third parties from making, using or selling products or technologies that are similar or identical to ours, and/or reduce or eliminate royalty payments to us from our licensees. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Furthermore, our pending and future patent applications may not result in patents being issued which protect our technology or product candidates or which effectively prevent others from commercializing competitive technologies and product candidates. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Our ability to enforce our owned and in-licensed patent and other intellectual property rights depends on our ability to detect infringement, misappropriation and other violation of such patents and other intellectual property. It may be difficult to detect infringers, misappropriators and other violators who do not advertise the components or methods that are used in connection with their products and services. Moreover, it may be difficult or impossible to obtain evidence of infringement, misappropriation or other violation in a competitor's or potential competitor's product or service, and in some cases we may not be able to introduce obtained evidence into a proceeding or otherwise utilize it to successfully demonstrate infringement. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

In addition, proceedings to enforce or defend our owned or in-licensed patents could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. If any of our owned or in-licensed patents covering our product candidates or other technologies are narrowed, invalidated or found unenforceable, or if a court found that valid, enforceable patents held by third parties covered one or more of our product candidates or other technologies, our competitive position could be harmed or we could be required to incur significant expenses to protect, enforce or defend our rights. If we initiate lawsuits to protect, defend or enforce our patents, or litigate against third-party claims, such proceedings would be expensive and would divert the attention of our management and technical personnel, even if the eventual outcome is favorable to us.

The degree of future protection for our intellectual property and other proprietary rights is uncertain, and we cannot ensure that:

- any of our patents, or any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect our product candidates and other technologies;
- any of our pending patent applications or those of our licensors may issue as patents;
- others will not or may not be able to make, use, offer to sell or sell products that are the same as or similar to our own but that are not covered by the claims of the patents that we own or license;
- we will be able to successfully commercialize our products on a substantial scale, if approved, before the relevant patents that we own or license expire;
- we were the first to make the inventions covered by each of the patents and pending patent applications that we own or license;
- we, our co-owners or our licensors were the first to file patent applications for these inventions;
- others will not develop similar or alternative products or technologies that do not infringe the patents we own or license;
- any of the patents we own or license will be found to ultimately be valid and enforceable;
- any patents issued to us or our licensors will provide a basis for an exclusive market for our commercially viable product candidates and other technologies or will provide us with any competitive advantages;
- a third party may not challenge the patents we own or license and, if challenged, a court would hold that such patents are valid, enforceable and infringed;
- we may develop or in-license additional proprietary technologies that are patentable;
- the patents of others will not have an adverse effect on our business;
- our competitors do not conduct research and development activities in countries where we do not have enforceable patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we will develop additional proprietary technologies or product candidates that are separately patentable; or
- our development and commercialization activities, including our manufacturing processes, or products will not infringe upon the patents of our competitors or any other third parties, including any non-practicing entities or patent assertion entities.

Other companies or organizations may challenge our intellectual property rights or may assert intellectual property rights that prevent us from developing and commercializing our product candidates and other technologies.

We practice in new and evolving scientific fields, the continued development and potential use of which has resulted in many different patents and patent applications from organizations and individuals seeking to obtain intellectual property protection in the fields. We own and in-license patent applications and issued patents that describe and/or claim certain technologies, including products, reagents, formulations and methods including uses and manufacturing methods, or features or aspects of any of these. These issued patents and pending patent applications claim certain compositions of matter and methods relating to the discovery, development, manufacture and commercialization of therapeutic modalities and our delivery technologies, including LNPs. If we, our co-owners or our licensors are unable to obtain, maintain, protect, defend or enforce patent protection with respect to our product candidates and other technology and any product candidates and technology we develop, our business, financial condition, results of operations and prospects could be materially harmed.

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As the scientific fields mature, our known competitors and other third parties have filed, and will continue to file, patent applications claiming inventions in the field in the United States and abroad. There is uncertainty about which patents will issue, and, if they do, as to when, to whom and with what claims. With respect to both in-licensed and owned intellectual property, we cannot predict whether the patent applications we and our licensors are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors.

We, our co-owners or our licensors may in the future become a party to patent proceedings or priority disputes in the United States, Europe or other jurisdictions. The Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, included a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent through USPTO-administered post-grant proceedings, including post-grant review, *inter partes* review and derivation proceedings. We expect that our competitors and other third parties will institute litigation and other proceedings, such as interference, reexamination and opposition proceedings, as well as *inter partes* and post-grant review proceedings against us and the patents and patent applications that we own and in-license. We expect that we will be subject to similar proceedings or priority disputes, including oppositions, in Europe or other foreign jurisdictions relating to patents and patent applications in our portfolio.

If we, our co-owners or our licensors are unsuccessful in any interference proceedings or other priority or validity disputes, including any derivations, post-grant review, *inter partes* review or oppositions, to which we or they are subject, we may lose valuable intellectual property rights through the narrowing or loss of one or more patents owned or in-licensed, or our owned or in-licensed patent claims may be narrowed, invalidated or held unenforceable. In many cases, the possibility of appeal exists for either us or our opponents, and it may be years before final, unappealable rulings are made with respect to these patents in certain jurisdictions. The timing and outcome of these and other proceedings is uncertain and may adversely affect our business if we are not successful in defending the patentability and scope of our pending and issued patent claims. In addition, third parties may attempt to invalidate our intellectual property rights. Even if our rights are not directly challenged, disputes could lead to the weakening of our intellectual property rights. Our defense against any attempt by third parties to circumvent or invalidate our intellectual property rights could be costly to us, could require significant time and attention of our management and could have a material adverse impact on our business and our ability to successfully compete against our current and future competitors.

There are many issued and pending patent filings that claim aspects of technologies that we may need for our mRNA product candidates or other product candidates, including patent filings that relate to relevant delivery technologies. There are also many issued patents that claim targeting genes or portions of genes that may be relevant for immunotherapies we wish to develop. In addition, there may be issued and pending patent applications that may be asserted against us in a court proceeding or otherwise based upon the asserting party's belief that we may need such patents for the development, manufacturing and commercialization of our product candidates. Thus, it is possible that one or more organizations, ranging from our competitors to non-practicing entities or patent assertion entities, has or will hold patent rights to which we may need a license, or hold patent rights which could be asserted against us. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If those organizations refuse to grant us a license to such patent rights on reasonable terms or a court rules that we need such patent rights that have been asserted against us and we are not able to obtain a license on reasonable terms or at all, we may be unable to perform research and development or other activities or market products covered by such patents, and we may need to cease the development, manufacture and commercialization of one or more of the product candidates we may develop. Any of the foregoing could result in a material adverse effect on our business, financial condition, results of operations or prospects.

We may not be successful in obtaining, maintaining, protecting or defending the necessary intellectual property rights to allow us to identify and develop product candidates, product components and manufacturing processes for our development pipeline.

We currently have rights to certain intellectual property, through our owned and in-licensed patents and other intellectual property rights, relating to identification and development of our product candidates or other technologies. As our pipeline may involve additional product candidates that could require the use of intellectual property and other proprietary rights held by third parties, the growth of our business could depend in part on our ability to acquire, in-license or use such intellectual property and proprietary rights. In addition, our product candidates may require specific formulations to work effectively and efficiently and these intellectual property and other proprietary rights may be held by others. We may be unable to secure such licenses or otherwise acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary, on reasonable terms, or at all, for product candidates and other technologies that we may develop. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, cash resources, and greater clinical development and commercialization capabilities.

For example, we sometimes collaborate with academic institutions in certain aspects of our preclinical research or development under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. However, these institutions may not honor our option and right of first negotiation for intellectual property rights or we may otherwise be unable to negotiate a license within the specified time frame or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program or otherwise continue to develop certain product candidates or other technologies.

Moreover, some of our owned patents and patent applications are, and may in the future be, co-owned with third parties. If we are unable to obtain, or continue to maintain, exclusive rights to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technologies. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

In addition, third parties that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain, protect, defend or enforce the existing intellectual property rights we have, we may have to abandon the development and commercialization of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

The lifespans of our patents may not be sufficient to effectively protect our product candidates, technologies and business.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first effective non-provisional filing date, assuming maintenance fees are timely paid after the patent has issued. Most foreign jurisdictions also provide a 20-year nominal patent term, though many require payment of regular, often annual, annuities to maintain pendency of an application or viability of an issued patent. In some

jurisdictions, one or more options for extension of a patent term may be available, but even with such extensions, the lifespan of a patent, and the protection it affords, is limited. Even if patents covering our product candidates, proprietary technologies and their uses are obtained, once the patent term has expired, we may be subject to competition from third parties that can then use the inventions included in such patents to create competing products and technologies. In addition, although upon issuance in the United States a patent's life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such candidates are commercialized. If any patents that we own or in-license expire, we would not be able to stop others from using or commercializing similar or identical technology and products, and our competitors could market competing products and technology. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

If we do not obtain patent term extension and data exclusivity for any product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We are heavily reliant upon licenses to certain intellectual property and other proprietary rights from third parties that are important or necessary to the development and commercialization of our technology and product candidates, and we expect to enter into similar license agreements in the future. Licensing of intellectual property is important to our business and involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. Our licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in any or all of our licenses.

Where we obtain licenses from, or collaborate with, third parties, in some circumstances we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications covering the technology that we license from third parties, or such activities, if controlled by us, may require the input of such third parties. In some cases, patent prosecution of our in-licensed intellectual property is controlled solely by the licensor. We may also require the cooperation of our licensors and collaborators to enforce or defend any in-licensed patent rights, and such cooperation may not be provided.

Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, protected, enforced or defended in a manner consistent with the best interests of our business. Any patents or patent applications that we in-license may be challenged, narrowed, circumvented, invalidated or held unenforceable, or our licensors may not properly maintain such patents or patent applications and they may expire. If our licensors fail to obtain, maintain, defend, protect or enforce the intellectual property we license from them, we could lose our rights to the intellectual property and our competitors could market competing products using the inventions in such intellectual property. In certain cases, we control the prosecution of patents included from in-licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our collaborators. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Moreover, any failure to satisfy obligations or any material breach under any of our licenses to third-party intellectual property could give the licensor the right to terminate the license. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone and royalty payment, exclusivity and other obligations on us. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, the licensor may have the right to terminate the license agreement, in which event we would not be able to develop, market and commercialize product candidates covered by the license agreement. In spite of our best efforts and even if we disagree, our licensors might still conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize the product candidates covered by these license agreements. In the event that any of our license agreements were to be terminated by the licensor, we may need to negotiate new or reinstated agreements, which may not be available to us on equally favorable terms, or at all. If these license agreements are terminated, or if the underlying patents or other intellectual property fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market and commercialize, products similar or identical to ours. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing license agreements in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described in this section. If we, our co-owners or our licensors fail to adequately protect this intellectual property, our ability to develop, market and commercialize our product candidates could suffer. Moreover, if disputes over intellectual property that we have in-licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop, market and commercialize the affected product candidates, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Some of our in-licensed intellectual property has been discovered through government-funded programs and thus may be subject to federal regulations such as “march-in” rights and certain reporting requirements, and compliance with such regulations may limit our exclusive rights and our ability to contract with manufacturers.

Certain intellectual property rights that have been in-licensed, including patent applications and patents that we in-license from the University of Pennsylvania and the Louisiana State University, have been generated through the use of U.S. government funding and are therefore subject to certain federal regulations. As a result, the U.S. government may have certain rights to intellectual property embodied in our current or future product candidates pursuant to the Bayh-Dole Act of 1980, or the Bayh-Dole Act. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require the licensor to grant exclusive, partially exclusive or non-exclusive licenses to any of these inventions to a third party if it determines that (i) adequate steps have not been taken to commercialize the invention, (ii) government action is

necessary to meet public health or safety needs or (iii) government action is necessary to meet requirements for public use under federal regulations (also collectively referred to as “march-in rights”). The U.S. government also has the right to take title to these inventions if the licensor fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Any exercise by the government of such rights could harm our competitive position, business, financial condition, results of operations and prospects. Intellectual property generated under a government-funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources.

In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture the products substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. We may not be able to obtain a waiver of this preference for U.S. industry, and this preference may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of our owned or in-licensed future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply. If we are unable to comply with these manufacturing requirements, we may experience a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Our current proprietary position for certain product candidates depends upon our owned or in-licensed patent filings covering components of such product candidates, manufacturing-related methods, formulations and/or methods of use, which may not adequately prevent a competitor or other third party from using the same product candidate for the same or a different use.

Composition of matter patent protection is generally considered to be desirable because it provides protection without regard to any particular method of use or manufacture or formulation. While we have obtained patent protection covering components of certain product candidates, manufacturing-related methods, formulations and/or methods of use, we do not currently have any claims in our owned or in-licensed issued U.S. patents that cover, for example, the overall construct used in our iNeST product candidates, and we cannot be certain that claims in any future patents issuing from our pending owned or in-licensed patent applications or our future owned or in-licensed patent applications will cover the composition of matter of our current or future product candidates.

Method of use patents protect the use of a product for the specified method and formulation patents cover formulations to deliver therapeutics. These types of patents do not prevent a competitor or other third party from developing, marketing or commercializing a similar or identical product for an indication that is outside the scope of the patented method or from developing a different formulation that is outside the scope of the patented formulation. Moreover, with respect to method of use patents, even if competitors or other third parties do not actively promote their product for our targeted indications or uses for which we may obtain patents, physicians may recommend that patients use these products off-label, or patients may do so themselves. Although off-label use may infringe or contribute to the infringement of method of use patents, the practice is common and this type of infringement is difficult to prevent or enforce. Consequently, we may not be able to prevent third parties from practicing our inventions in the United States or abroad.

Intellectual property rights of third parties could adversely affect our ability to commercialize our product candidates, and we might be required to litigate or obtain licenses from third parties in order to develop or market our product candidates.

Because our product candidates are still in early developmental stages, and one or more features of the product candidates or related technologies such as their manufacture, formulation or use, may still change, we cannot be confident that we are aware of all third-party intellectual property that might be relevant to products

that we eventually hope to commercialize. Various third-party competitors practice in relevant spaces, and may have issued patents, or patent applications that will issue as patents in the future, that will impede or preclude our ability to commercialize products. Furthermore, while U.S. patent laws provide a “safe harbor” to our clinical product candidates under 35 U.S.C. § 271(e)(1), which exempts from patent infringement activities related to pursuing FDA approval for a drug product, that exemption expires when an NDA is submitted. Given the uncertainty of clinical trials, we cannot be certain of the timing of their completion and it is possible that we might want to submit an NDA at a time when one or more relevant third-party patents is in force. Thus, it is possible that at the time that we commercialize our product candidates, one or more third parties may have issued patent claims that cover our products or critical features of their production or use. We may not be able to commercialize our products if patents issued to third parties or other third-party intellectual property rights cover, or may be alleged to cover, our products or elements thereof, or their methods of manufacture or use at the time that we seek to commercialize them. In such cases, we may not be in a position to develop or commercialize product candidates unless we successfully pursue litigation to nullify or invalidate the third-party intellectual property right concerned, successfully design around their claims, or enter into a license agreement with the intellectual property right holder(s). Such litigation or licenses could be costly or not available on commercially reasonable terms or at all, and design-around could be prohibitively expensive or impossible.

It is also possible that we have failed to identify relevant third-party patents that cover, or applications that will mature into patents that cover, one or more aspects of our platform or product candidates. Given that, in most jurisdictions, a patent application is confidential when initially filed, and typically remains so until it is published about 18 months after the initial filing, it may not be possible for us to identify certain relevant filings in time to avoid using the technology that they claim. Additionally, the claims of pending patent applications can, subject to certain limitations, be amended over time, so that even patent applications whose claims did not cover our products or activities when published could be amended to cover one or more aspects of our platform or product candidates over time, and we might not be aware that such amendment had been made.

We may be involved in lawsuits to protect or enforce our intellectual property or the intellectual property of our licensors, or to defend against third-party claims that we infringe, misappropriate or otherwise violate such third party’s intellectual property, each of which could be expensive, time consuming and unsuccessful.

There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, *ex parte* reexaminations, post-grant review, and *inter partes* review proceedings before the USPTO and corresponding European and other non-U.S. patent offices. Competitors and other third parties may infringe, misappropriate or otherwise violate our intellectual property rights or those of our licensors. To prevent infringement, misappropriation or other unauthorized use, we may be required to file claims, which can be expensive and time-consuming. In certain instances, we have instituted and may in the future institute *inter partes* review proceedings against issued U.S. patents and opposition proceedings against European patents owned by third parties in the field of immunotherapy. We have a number of these opposition proceedings ongoing at the European Patent Office against third-party patents related to mRNA technologies. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

In addition, in a patent infringement proceeding, our owned or in-licensed patents may be challenged and a court may decide that a patent we own or in-license is not valid, is unenforceable and/or is not infringed. If we or any of our potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at one of our product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution.

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Third parties may also raise similar claims before the USPTO, even outside the context of litigation. Similar mechanisms for challenging the validity and enforceability of a patent exist in ex-U.S. patent offices and may result in the revocation, cancellation or amendment of any ex-U.S. patents we hold in the future. The outcome following legal assertions of invalidity and unenforceability is unpredictable, and prior art could render our patents or those of our licensors invalid. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on such product candidate. Such a loss of patent protection would have a material adverse impact on our competitive position, business, financial conditions, results of operations and prospects.

Third parties, ranging from our competitors to non-practicing entities or patent assertion entities, may assert that we are employing their intellectual property and other proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use, development, manufacture or commercialization of our product candidates. As patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that our technologies infringe upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may obtain injunctive or other equitable relief, which could effectively block our ability to develop and commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms, or at all, or may be non-exclusive.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same intellectual property and technology. Our defense of litigation, interference, derivation or similar proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development or manufacturing collaborations that would help us bring our product candidates to market.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

In the event of a successful claim of infringement, misappropriation or other violation against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products, or obtain one or more licenses from third parties, which may not be made available on commercially favorable terms, if at all, or may require substantial time and expense.

Such licenses are likely to be non-exclusive and, therefore, our competitors may have access to the same intellectual property and technology licensed to us. If we fail to obtain a required license and are unable to design around a patent, we may be unable to effectively market some of our technology and product candidates, which could limit our ability to generate revenues or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations. Moreover, certain of our collaborations provide, and we expect additional collaborations to provide, that royalties payable to us for licenses to our intellectual property may be offset by amounts paid by our collaborators to third parties for licenses to such third parties' intellectual property in the relevant fields, which could result in significant reductions in our revenues from products developed through collaborations.

In addition, in connection with certain license and collaboration agreements, we have agreed to indemnify certain third parties for certain costs incurred in connection with litigation relating to intellectual property rights or the subject matter of the agreements. The cost to us of any litigation or other proceeding relating to intellectual property rights, even if resolved in our favor, could be substantial.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments in any litigation or other intellectual property proceedings. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of the ADSs.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees, and various other governmental fees on patents and applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents or applications. We have systems in place to remind us to pay these fees and we employ an outside firm and rely on our outside counsel to pay these fees due to non-U.S. patent agencies; however, we cannot guarantee that we will successfully pay these fees. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our in-licensed intellectual property, and we cannot guarantee that they will do so. In such an event, our competitors might be able to enter the market with similar or identical products or technology, and this would have a material adverse impact on our business, financial condition, results of operations and prospects.

Changes in patent law in the United States or in other countries could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biotechnology companies, our success is heavily dependent on our intellectual property rights, particularly patents that we own and in-license. Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity, and therefore obtaining and enforcing biotechnology patents is costly, time-consuming and inherently uncertain. Moreover, there are periodic changes in patent law. For example, after March 2013, under the America Invents Act, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was

the first to invent the claimed invention. The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. The America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, and their equivalents in other jurisdictions, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to obtain, maintain, protect, defend or enforce our intellectual property in the future.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patent protection for some of our technology and product candidates, we also seek to rely on trade secret protection and confidentiality agreements to maintain our competitive position and protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets and know-how may be difficult to protect.

We seek to protect these trade secrets, know-how and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants and require all of our employees and key consultants who have access to our trade secrets, proprietary know-how, information or technology to enter into confidentiality agreements. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Despite our best efforts, any of these parties may breach the agreements and we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. We may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret or know-how is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets and know-how. If any of our trade secrets or know-how were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results, financial condition and prospects.

We may be subject to claims that we have wrongfully hired an employee from a competitor, or that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

We have received confidential and proprietary information from third parties in the course of our research and other collaborations with others in the industry, academic institutions and other third parties. In addition, many of our employees, consultants and advisors are currently or were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although

we try to ensure that our employees, consultants, independent contractors and advisors do not use the confidential or proprietary information, trade secrets or know-how of others in their work for us, we may be subject to claims that we have inadvertently or otherwise used or disclosed confidential or proprietary information, trade secrets or know-how of these third parties, or that our employees, consultants, independent contractors or advisors have inadvertently or otherwise used or disclosed confidential information, trade secrets or know-how of such individual's current or former employer. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees. Claims that we, our employees, consultants or advisors have misappropriated the confidential or proprietary information, trade secrets or know-how of third parties could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may in the future be subject to claims that current or former employees, consultants, independent contractors, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. While it is our policy to require our employees, consultants, independent contractors, collaborators and other third parties who may be involved in the conception, development or reduction to practice of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives, develops or reduces to practice such intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached. For example, we may have inventorship disputes arise from conflicting obligations of employees, consultants, independent contractors, collaborators or other third parties who are involved in developing and commercializing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business, operating results and financial condition. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Furthermore, the laws of some other countries do not protect intellectual property and other proprietary rights or establish ownership of inventions to the same extent or in the same manner as the laws of the United States. A majority of our employees work in Germany and are subject to German employment law. Ideas, developments, discoveries and inventions made by such employees and consultants are subject to the provisions of the German Act on Employees' Inventions, which regulates the ownership of, and compensation for, inventions made by employees. We face the risk that disputes can occur between us and our employees or former employees pertaining to alleged non-adherence to the provisions of this act that may be costly to defend and take up our management's time and efforts whether we prevail or fail in any such dispute. There is a risk that the compensation we provided to employees who assign patents to us may be deemed to be insufficient and we may be required under German law to increase the compensation due to such employees for the use of the patents. In those cases where employees' rights have not been assigned to us, we may need to pay compensation for the use of those patents. If we are required to pay additional compensation or face other disputes under the German Act on Employees' Inventions, our business, results of operations and financial condition could be adversely affected.

We will not seek to protect our intellectual property rights in all jurisdictions throughout the world, and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

Filing, prosecuting and defending patents on product candidates and product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some countries do not protect intellectual property rights to the same extent as laws in Germany and the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and to the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own product candidates and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement, misappropriation or other violation of our patents and other intellectual property or development, marketing and commercialization of competing products in violation of our intellectual property and other proprietary rights generally. Proceedings to enforce our intellectual property rights in such jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or in-license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential collaborators or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and trade names by our licensees may jeopardize our rights in or diminish the goodwill associated with our

trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, know-how, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make personalized cancer immunotherapies that are similar to any product candidates we may develop and commercialize or utilize similar technologies that are not covered by the claims of the patents that we now or may in the future own or have exclusively in-licensed;
- we, our co-owners or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or have exclusively in-licensed;
- we, our co-owners or our licensors or future collaborators might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or in-licensed intellectual property rights;
- it is possible that our pending patent applications or those that we may own or in-license in the future will not lead to issued patents;
- issued patents that we own or have exclusively in-licensed may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may have an adverse effect on our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Government Regulation

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, and other healthcare laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

We may be subject to additional healthcare regulation and enforcement by the U.S. federal government and by authorities in the United States, the European Union and other jurisdictions in which we conduct our business. If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations will be directly, or indirectly through our prescribers, customers and purchasers, subject to various federal and state fraud and abuse laws and regulations, including, without limitation, the federal Health Care Program Anti-Kickback Statute, the federal civil and criminal False Claims Act, and the

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Physician Payments Sunshine Act and regulations. Many states and other jurisdictions have similar laws and regulations, some of which may be broader in scope. These laws will impact, among other things, our proposed sales, marketing and educational programs. In addition, we may be subject to patient privacy laws enacted by both the federal government and the states in which we conduct our business. The laws that will affect our operations include, but are not limited to the following:

- The federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in return for the purchase, recommendation, leasing or furnishing of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers, and formulary managers on the other. The ACA amends the intent requirement of the federal Anti-Kickback Statute to provide that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it.
- The federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment or approval from Medicare, Medicaid or other government payors. The ACA provides, and recent government cases against pharmaceutical and medical device manufacturers support, the view that federal Anti-Kickback Statute violations and certain marketing practices, including off-label promotion, may implicate the False Claims Act.
- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit a person from knowingly and willfully executing a scheme or making false or fraudulent statements to defraud any healthcare benefit program, regardless of the payor (*e.g.*, public or private).
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and their implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization by entities subject to the rule, such as health plans, health care clearinghouses and health care providers.
- The U.S. Federal Food, Drug, and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices.
- the U.S. Public Health Service Act, which prohibits, among other things, the introduction into interstate commerce of a biological product unless a biologics license is in effect for that product.
- Federal transparency laws, including the federal Physician Payment Sunshine Act, which require disclosure of payments and other transfers of value provided to physicians and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations.
- State law equivalents of each of the above federal laws, state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, and state laws governing the privacy and security of health information in certain circumstances which are also applicable to us, and many of them differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts in certain circumstances.
- the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, U.S. companies and their employees and agents, as well as non-U.S. companies that are registered with the Securities and Exchange Commission, or the SEC, from authorizing, promising, offering or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof; and

- similar healthcare laws and regulations in the European Union and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

Due to the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the European Union. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of European Union member states, such as the U.K. Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain European Union member states must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization or the regulatory authorities of the individual European Union member states. These requirements are provided in the national laws, industry codes, or professional codes of conduct, applicable in the European Union member states. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

We are subject to certain anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.

Among other matters, anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, which are collectively referred to as "trade laws", prohibit companies and their employees, agents, CROs, legal counsel, accountants, consultants, contractors and other collaborators from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of trade laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, intellectual property (including patents) and other regulatory approvals, and we can be held liable for the corrupt or other illegal activities of our personnel, agents or collaborators, even if we do not explicitly authorize or have prior knowledge of such activities.

We are subject to stringent privacy laws, information security policies and contractual obligations governing the use, processing, and cross-border transfer of personal information and our data privacy and security practices.

We receive, generate and store significant and increasing volumes of sensitive information, such as employee, personal and patient data. We are subject to a variety of local, state, national and international laws, directives and regulations that apply to the collection, use, storage, retention, protection, disclosure, transfer and other processing of personal data, collectively referred to as "data processing", in the different jurisdictions in which we operate, including comprehensive regulatory systems in the United States and Europe. Legal requirements relating to data processing continue to evolve and may result in ever-increasing public scrutiny and escalating levels of enforcement, sanctions and increased costs of compliance.

Compliance with U.S. and international data protection laws and regulations could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. Moreover, complying with these various laws could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend, could result in adverse publicity and could have a material adverse effect on our business, financial condition and results of operations.

The collection and use of personal health data in the European Union had previously been governed by the provisions of the Data Protection Directive, which has been replaced by the European Union General Data Protection Regulation, or GDPR. While the Data Protection Directive did not apply to organizations based outside the European Union, the GDPR has expanded its reach to include any business, regardless of its location, that provides goods or services to residents in the European Union. The GDPR imposes strict requirements on controllers and processors of personal data, including special protections for "sensitive information" which includes health and genetic information of data subjects residing in the European Union. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States and other countries. In addition, the GDPR provides that European Union member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data.

Since we are located in the European Union, we are subject to the GDPR. Additionally, as the GDPR applies extraterritorially, we are also subject to the GDPR even where our data processing activities occur outside of the European Union if such activities involve the personal data of individuals located in the European Union. GDPR regulations have imposed additional responsibility and liability in relation to the personal data that we process and we may be required to put in place additional mechanisms to ensure compliance with the new data protection rules. This may be onerous and may interrupt or delay our development activities, and adversely affect our business, financial condition, results of operations and prospects.

Other jurisdictions outside the European Union are similarly introducing or enhancing privacy and data security laws, rules and regulations, which could increase our compliance costs and the risks associated with non-compliance. We cannot guarantee that we are, or will be, in compliance with all applicable international regulations as they are enforced now or as they evolve. For example, our privacy policies may be insufficient to protect any personal information we collect, or may not comply with applicable laws, in which case we may be subject to regulatory enforcement actions, lawsuits or reputational damage, all of which may adversely affect our business. There is significant uncertainty related to the manner in which data protection authorities will seek to enforce compliance with the GDPR, especially with regard to clinical trial conduct. For example, it is not clear if the authorities will conduct random audits of companies doing business in the European Union, or if the authorities will wait for complaints to be filed by individuals who claim their rights have been violated. Enforcement uncertainty and the costs associated with ensuring GDPR compliance may be onerous and adversely affect our business, financial condition, results of operations and prospects. If we fail to comply with the GDPR and the applicable national data protection laws of the European Union member states, or if regulators assert we have failed to comply with these laws, it may lead to regulatory enforcement actions, which can result in monetary penalties of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties. If any of these events were to occur, our business and financial results could be significantly disrupted and adversely affected.

Although we take measures to protect sensitive data from unauthorized access, use or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other malicious or inadvertent disruptions. Any such breach or interruption could

compromise our networks and the information stored there could be accessed by unauthorized parties, manipulated, publicly disclosed, lost or stolen. Any such access, breach or other loss of information could result in legal claims or proceedings, and liability under federal or state laws that protect the privacy of personal information, as well as regulatory penalties. In the United States, notice of breaches must be made to affected individuals and the U.S. Secretary of HHS, and for extensive breaches, notice may need to be made to the media or U.S. state Attorneys General. Such a notice could harm our reputation and our ability to compete. HHS has the discretion to impose penalties without attempting to resolve violations through informal means. In addition, U.S. state Attorneys General are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. Although we have implemented security measures to prevent unauthorized access to patient data, such data is currently accessible through multiple channels, and there is no guarantee we can protect our data from breach. Unauthorized access, loss or dissemination could also damage our reputation or disrupt our operations, including our ability to conduct our analyses, deliver test results, process claims and appeals, provide customer assistance, conduct research and development activities, collect, process and prepare company financial information, provide information about our tests and other patient and physician education and outreach efforts through our website, and manage the administrative aspects of our business.

If we or our third-party suppliers fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We will become subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations will involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also may produce hazardous waste products. We generally anticipate contracting with third parties for the disposal of these materials and wastes. We will not be able to eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from any use by us of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations.

If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly and time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

General Risks Related to our Business

Our future success depends on our ability to retain key employees, consultants and advisors and to attract, retain and motivate qualified senior management and scientific personnel.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent upon members of our management and scientific teams. We may not be able to retain these persons due to the competitive environment in the biotechnology industry. The loss of any of these persons' services may adversely impact the achievement of our research, development, financing and commercialization objectives. We currently do not have "key person" insurance on any of our employees.

In addition, we rely on consultants, contractors and advisors, including scientific and clinical advisors, to assist us in formulating our research and development, regulatory approval and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. The loss of the services of one or more of our current employees or advisors might impede the achievement of our research, development, regulatory approval and commercialization objectives. In addition, we have flexibly grown our workforce through the use of contractors and part-time workers. We may not be able to retain the services of such personnel, which might result in delays in the operation of our business.

Recruiting and retaining other qualified employees, consultants and advisors for our business, including scientific and technical personnel, also will be critical to our success. Competition for skilled personnel, including in mRNA research, clinical operations, regulatory affairs, therapeutic area management and manufacturing, is intense and the turnover rate can be high. We may not be able to attract and retain personnel on favorable terms given the competition among numerous pharmaceutical and biotechnology companies and academic institutions for individuals with similar skill sets. In addition, adverse publicity, failure to succeed in preclinical studies or clinical trials or applications for marketing approval may make it more challenging to recruit and retain qualified personnel. The inability to recruit, or loss of services of certain executives, key employees, consultants or advisors, may impede the progress of our research, development and commercialization objectives and have a material adverse impact on our business, financial condition, results of operations and prospects.

Our employees, principal investigators and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading, which could have an adverse effect on our results of operations.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators and consultants. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in the European Union and other jurisdictions, provide accurate information to the FDA, the EMA and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, but it is

not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions.

Employee litigation and unfavorable publicity could negatively affect our future business.

Our employees may, from time to time, bring lawsuits against us regarding injury, creating a hostile work place, discrimination, wage and hour disputes, sexual harassment or other employment issues. In recent years there has been an increase in the number of discrimination and harassment claims generally. Coupled with the expansion of social media platforms and similar devices that allow individuals access to a broad audience, these claims have had a significant negative impact on some businesses. Certain companies that have faced employment- or harassment-related lawsuits have had to terminate management or other key personnel, and have suffered reputational harm that has negatively impacted their business. If we were to face any employment-related claims, our business could be negatively affected.

We and our collaborators or other contractors or consultants depend on information technology systems, and any failure of these systems could harm our business. Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business, results of operations and financial condition.

Our internal computer systems and those of our current and any future collaborators, vendors, and other contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, cybersecurity threats, war, and telecommunication and electrical failures. If any such material system failure, accident or security breach were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from one or more ongoing or completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, because of our approach to running multiple clinical trials in parallel, any breach of our computer systems may result in a loss of data or compromised data integrity across many of our programs in many stages of development. Any such breach, loss or compromise of clinical trial participant personal data may also subject us to civil fines and penalties, including under the GDPR and relevant member state law in the European Union, and HIPAA and other relevant state and federal privacy laws in the United States. To the extent that any disruption or security breach were to result in a loss of, or damage to, data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed.

While we have not experienced any material system failures, accidents or security breaches to date, we and a vendor have separately in the past been subject to a security breach resulting in us unknowingly making payments to third parties that were able to gain unauthorized access to our and the vendor's email systems. We have since put systems and procedures in place to minimize the likelihood of such incidents reoccurring; however, we cannot guarantee that third parties will not be able to gain unauthorized access to or otherwise breach our systems in the future. Any such unauthorized access or breach could adversely affect our business, results of operations and financial condition.

Our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

We recognize the need for, and are in the early stages of, developing disaster recovery, business continuity and document retention plans that would allow us to be operational despite casualties or unforeseen events

impacting our corporate headquarters or distribution center. Without disaster recovery, business continuity and document retention plans, if we encounter difficulties or disasters with our manufacturing facilities or at our corporate headquarters, our critical systems, operations and information may not be restored in a timely manner, or at all, and this could have an adverse effect on our business.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of our current or future product candidates.

We face an inherent risk of product liability exposure related to the testing of any of our current or future product candidates in clinical trials, and we may face an even greater risk if we commercialize any product candidate that we may develop. If we cannot successfully defend ourselves against claims that our product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidate that we may develop;
- loss of revenue;
- substantial monetary awards to patients, healthy volunteers or their children;
- significant time and costs to defend the related litigation;
- withdrawal of clinical trial participants;
- the inability to commercialize any product candidates that we may develop; and
- injury to our reputation and significant negative media attention.

We carry clinical trial insurance, including product liability insurance, which we believe to be sufficient in light of our current clinical programs; however, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs or medical treatments that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause the price of the ADS to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

If our products become subject to a product recall it could harm our reputation, business and financial results.

The FDA and similar governmental authorities in other jurisdictions have the authority to require the recall of certain commercialized products. In the case of the FDA, the authority to require a recall of a biologic product must be based on an FDA finding that a batch, lot or other quantity of the biologic product presents an imminent or substantial hazard to the public health. In addition, some governmental bodies outside the United States have the authority to require the recall of any product candidate in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a product is found. A government-mandated or voluntary recall by us could occur as a result of manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our product candidates would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. A recall announcement could harm our reputation with customers and negatively affect our sales, if any.

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If we engage in future acquisitions, joint ventures or collaborations, this may increase our capital requirements, dilute our shareholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks. We may not realize the benefits of these acquisitions, joint ventures or collaborations.

We may evaluate various acquisitions and collaborations, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any potential acquisition, joint venture or collaboration may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, we may utilize our cash, issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense.

Moreover, we may not be able to locate suitable acquisition or collaboration opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

Risks Related to Ownership of the ADSs and this Offering

The price of the ADSs may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of the ADSs in this offering.

The market price of the ADSs is likely to be volatile. The stock market in general, and the market for biopharmaceutical companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell the ADSs at or above the initial public offering price. The market price for the ADSs may be influenced by many factors, including:

- results of clinical trials of our product candidates or those of our competitors;
- the success of competitive products or technologies;
- commencement or termination of collaborations;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents, or other intellectual property or proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;

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- the results of our efforts to discover, develop, acquire or in-license additional product candidates;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the numerous programs in our pipeline, the development of which could each generate news or significant adverse events that could impact financial results or recommendations by securities analysts.

If our semi-annual or annual results fall below the expectations of investors or securities analysts, the price of the ADSs could decline substantially. Furthermore, any semi-annual or annual fluctuations in our results may, in turn, cause the price of the ADSs to fluctuate substantially. We believe that period-to-period comparisons of our results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

In the past, following periods of volatility in the market price of a company's securities, securities class-action litigation often has been instituted against that company. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such claims and divert management's attention and resources, which could seriously harm our business, financial condition, results of operations and prospects.

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives. We will be subject to financial reporting and other requirements for which our accounting and other management systems and resources may not be adequately prepared. We may fail to comply with the rules that apply to public companies, including Section 404 of the Sarbanes-Oxley Act of 2002, which could result in sanctions or other penalties that would harm the business.

As a public company, and particularly after we are no longer an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the federal securities laws, including the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and rules subsequently implemented by the SEC and the Nasdaq Stock Market LLC, or Nasdaq, have imposed various requirements on public companies, including requirements to file annual and event-driven reports with respect to our business and financial condition, and to establish and maintain effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance. We may not be able to produce reliable financial statements or file these financial statements as part of a periodic report in a timely manner with the SEC or comply with Nasdaq listing requirements. In addition, we could make errors in our financial statements that could require us to restate our financial statements.

Pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, we will be required to furnish a report by our management on our internal control over financial reporting, including the attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm in our annual filings with

the SEC. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants, and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as “say on pay” and proxy access. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years from the pricing of this offering. We intend to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Shareholder activism, the current political environment, and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives.

We have identified a material weakness in our internal control over financial reporting and may identify additional material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements in our financial statements. If we fail to remediate our material weakness, we may not be able to report our financial results accurately or to prevent fraud.

Our management is responsible for establishing and maintaining internal control over financial reporting, disclosure controls, and compliance with the other requirements of the Sarbanes-Oxley Act and the rules promulgated by the SEC thereunder. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with international financial reporting standards. A material weakness is defined as a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company’s annual or interim financial statements will not be prevented or detected by the company’s internal controls on a timely basis.

Prior to this offering, we have operated as a private company that was not required to comply with the obligations of a public company with respect to internal control over financial reporting. We have historically operated with limited accounting personnel and other resources with which to address our internal control over financial reporting.

In connection with the audit of our 2018 and 2017 financial statements in preparation for this offering, we and our auditors identified a material weakness primarily related to (i) a lack of sufficient accounting and supervisory personnel who have the appropriate level of technical accounting experience and training, (ii) a lack of supervision over external consultants and (iii) a lack of consistent application of accounting processes and procedures by our accounting personnel. These deficiencies constitute a material weakness in our internal control over financial reporting in both design and operation. As a result of the material weakness, management failed to identify audit adjustments in various areas, including but not limited to revenue, capitalization of tangible and intangible assets, and share-based compensation. We have relied on the assistance of outside advisors with expertise in these matters to assist us in the preparation of our financial statements and in our compliance with SEC reporting obligations related to this offering, and we expect to continue to do so while we remediate this material weakness.

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We have begun to develop a remediation plan to address the material weakness; however, our overall control environment is still immature and may expose us to errors, losses or fraud. Our remediation plan includes the hiring of additional staff. Additionally, we intend to document and implement consistent accounting policies and procedures and provide additional training to our accounting and finance staff. While we are working to remediate the material weakness as quickly and efficiently as possible, we cannot at this time provide an estimate of the costs we expect to incur or the expected timeline in connection with implementing our remediation plan. These remediation measures may be time-consuming and costly, and might place significant demands on our financial and operational resources. If we are unable to successfully remediate this material weakness or successfully supervise and rely on outside advisors with expertise in these matters to assist us in the preparation of our financial statements, our financial statements could contain material misstatements that, when discovered in the future, could cause us to fail to meet our future reporting obligations and cause the price of our ADSs to decline.

We are an “emerging growth company” and the reduced disclosure requirements applicable to emerging growth companies may make our ordinary shares and the ADSs less attractive to investors.

We are an “emerging growth company” under the JOBS Act, and we will remain an emerging growth company until the earlier of:

- the last day of the first fiscal year in which our annual gross revenues exceed \$1.07 billion;
- the date on which we have issued more than \$1 billion in nonconvertible debt securities during the previous three years;
- the date on which we are deemed to be a large accelerated filer under the rules of the SEC, which means the first day of the year following the first year in which, as of the last business day of our most recently completed second fiscal quarter, the market value of our common equity held by non-affiliates exceeds \$700 million; and
- the last day of the fiscal year following the fifth anniversary of the date of the completion of this offering.

For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of reduced reporting burdens in this prospectus. In particular, we have not included all of the executive compensation information that would be required if we were not an emerging growth company. We cannot predict whether investors will find the ADSs less attractive if we rely on certain or all of these exemptions. If some investors find the ADSs less attractive as a result, there may be a less active trading market for the ADSs and the price per ADS may be more volatile.

In addition, the JOBS Act provides that an emerging growth company may take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth

company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. Such provisions are only applicable under U.S. GAAP. As a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required or permitted by the IASB.

As a “foreign private issuer,” we are exempt from a number of rules under the U.S. securities laws, as well as Nasdaq rules, and we are permitted to file less information with the SEC than are U.S. companies. This may limit the information available to holders of the ADSs and may make our ordinary shares and the ADSs less attractive to investors.

We are a “foreign private issuer,” as defined in the rules and regulations of the SEC, and, consequently, we are not subject to all of the disclosure requirements applicable to companies organized within the United States. For example, we are exempt from certain rules under the U.S. Securities Exchange Act of 1934, as amended, or the Exchange Act, that regulate disclosure obligations and procedural requirements related to the solicitation of proxies, consents or authorizations applicable to a security registered under the Exchange Act. In addition, our officers and directors are exempt from the reporting and “short-swing” profit recovery provisions of Section 16 of the Exchange Act and related rules with respect to their purchases and sales of our securities. Moreover, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. public companies. Accordingly, there may be less publicly available information concerning our company than there is for U.S. public companies.

As a foreign private issuer, we will file an annual report on Form 20-F within four months of the close of each fiscal year ending December 31 and reports on Form 6-K relating to certain material events promptly after we publicly announce these events. Additionally, we rely on a provision in the Nasdaq Stock Market’s Listed Company Manual that allows us to follow German company law and European law applicable to European stock corporations in general and the German Stock Corporation Act (*Aktiengesetz*), the Council Regulation (EC) No 2157/2001 of October 8, 2001 on the Statute for a European company (SE), or the SE Regulation, and the German Act on the Implementation of Council Regulation (EC) No 2157/2001 of October 8, 2001 on the Statute for a European company (SE) (*Gesetz zur Ausführung der Verordnung (EG) NR. 2157/2001 des Rates vom 8. Oktober 2001 über das Statut der Europäischen Gesellschaft (SE)*) (*SE-Ausführungsgesetz—SEAG*), in particular with regard to certain aspects of corporate governance. This allows us to follow certain corporate governance practices that differ in significant respects from the corporate governance requirements applicable to U.S. companies listed on Nasdaq.

For example, we are exempt from regulations of Nasdaq that require a listed U.S. company to:

- have a majority of the board of directors consist of independent directors;
- require non-management directors to meet on a regular basis without management present;
- adopt a code of conduct and promptly disclose any waivers of the code for directors or executive officers that should address certain specified items;
- have an independent compensation committee;
- have an independent nominating committee;
- solicit proxies and provide proxy statements for all shareholder meetings;
- review related party transactions; and
- seek shareholder approval for the implementation of certain equity compensation plans and issuances of ordinary shares.

As a foreign private issuer, we are permitted to follow home country practice in lieu of the above requirements. We therefore intend to continue to follow German corporate governance practices in lieu of the

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corporate governance requirements of Nasdaq in certain respects. In particular, we intend to follow German corporate governance practices in connection with the distribution of annual and interim reports to shareholders, the application of our code of conduct to our Supervisory Board, proxy solicitation in connection with shareholders' meetings, and obtaining shareholder approval in connection with the issuance of shares in connection with an acquisition, change of control transactions, the establishment or material amendment to any equity-based compensation plans and the issuance of shares in a private placement in excess of 20% of the outstanding share capital at less than the greater of book or market value.

In accordance with our Nasdaq listing, our audit committee is required to comply with the provisions of Section 301 of the Sarbanes-Oxley Act, and Rule 10A-3 of the Exchange Act, both of which are also applicable to U.S. companies listed on Nasdaq. As we are a foreign private issuer, however, our audit committee is not subject to additional requirements of the Nasdaq applicable to listed U.S. companies, including an affirmative determination that all members of the audit committee are "independent," using more stringent criteria than those applicable to us as a foreign private issuer.

Due to the above exemptions for foreign private issuers, our shareholders will not be afforded the same protections or information generally available to investors holding shares in public companies organized in the United States, some investors may find the ADSs less attractive as a result, and there may be a less active trading market for the ADSs.

A significant portion of our total outstanding ordinary shares after this offering will be restricted from immediate resale but may be sold in the near future. The large number of shares eligible for sale or subject to rights requiring us to register them for sale could cause the market price of the ADSs to drop significantly, even if our business is performing well.

Sales of a substantial number of ordinary shares or the ADSs could occur at any time, subject to certain restrictions described below. These sales, or the perception in the market that holders of a large number of shares intend to sell shares, could reduce the market price of the ADSs. Based on the number of our ordinary shares outstanding as of _____, 2019, we will have _____ ordinary shares outstanding after this offering (or _____ ordinary shares if the underwriters exercise their option to purchase additional ADSs in full).

In connection with our initial public offering, we, all of our directors and officers, and substantially all of our shareholders have entered into lock-up agreements with the underwriters and/or are subject to market standoff agreements or other agreements with us under which we and they agreed, subject to specific exceptions, not to sell any of our shares for at least 180 days following the date of our initial public offering. The remaining ordinary shares will be available for sale after this offering since they are not subject to contractual and legal restrictions on resale. Any or all of the shares subject to lock-up agreements may be released prior to the expiration of the lock-up period at the discretion of the lead underwriters for this offering. To the extent shares are released before the expiration of the lock-up period and these shares are sold into the market, the market price of the ADSs could decline.

We intend to file one or more registration statements on Form S-8 under the Securities Act of 1933, as amended, or the Securities Act, to register all ordinary shares issued or issuable under our equity plans. Any such Form S-8 registration statements will automatically become effective upon filing. Accordingly, shares registered under such registration statements will be available for sale in the open market following the expiration of the applicable lock-up period. See "Shares and ADSs Eligible for Future Sale" appearing elsewhere in this prospectus for a more detailed description of the restrictions on selling shares.

Sales of ADSs or our ordinary shares as restrictions end or pursuant to registration rights may make it more difficult for us to finance our operations through the sale of equity securities in the future at a time and at a price that we deem appropriate. These sales also could cause the trading price of the ADSs to fall and make it more difficult for you to sell the ADSs.

If you purchase ADSs in this offering, you will incur immediate and substantial dilution in the book value of your investment.

You will suffer immediate and substantial dilution in the net tangible book value of the ADSs if you purchase ADSs in this offering. Based on an assumed initial public offering price of \$ per ADS, which is the midpoint of the price range set forth on the cover page of this prospectus, after giving effect to this offering, purchasers of ADSs in this offering will experience immediate dilution in net tangible book value of \$ per ADS. In addition, after giving effect to this offering, investors purchasing ADSs in this offering will contribute % of the total amount invested by shareholders since inception but will only own % of the ordinary shares outstanding. See “Dilution” for a more detailed description of the dilution to new investors in the offering.

Holders of the ADSs are not treated as shareholders of our company and will not have the same voting rights as our shareholders, which may affect the value of the ADSs.

By participating in this offering, you will become a holder of ADSs with underlying ordinary shares in a European stock corporation (*Societas Europaea*). Holders of ADSs are not treated as our shareholders unless they withdraw the ordinary shares underlying the ADSs from the depositary, which is the holder of the ordinary shares underlying the ADSs. Holders of ADSs, therefore, do not have any rights as shareholders of our company, other than the rights that they have pursuant to the deposit agreement. As such, holders of ADSs will not be able to directly vote underlying ordinary shares. Holders of ADSs may instruct the depositary how to vote the ordinary shares underlying their ADSs. If we ask it to, the depositary will send out information about shareholder meetings and solicit voting instructions and will try to carry out voting instructions it receives. However, we are not required to instruct the depositary to take action with respect to shareholder meetings. If we do not do so, holders of the ADSs can still send voting instructions to the depositary, and the depositary may try to carry out those instructions, but it is not required to do so. Holders of the ADSs may not become aware of shareholder meetings if the depositary does not send out information. Even if the depositary does solicit voting instructions, holders of ADSs may not receive the information in time. As a result of these factors, holders of ADSs may not be able to effectively exercise voting rights that they would have if they held our ordinary shares directly.

If we sell our ordinary shares or ADSs in future financings, holders of ADSs may experience immediate dilution and, as a result, the price of the ADSs may decline.

We may from time to time issue additional ordinary shares or ADSs at a discount from the current trading price of our ordinary shares or ADSs. As a result, holders of ADSs would experience further immediate dilution upon the purchase of any ordinary shares or ADSs sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, ordinary shares or ADSs. If we issue ordinary shares or securities convertible or exchangeable into ordinary shares, such as ADSs, holders of the ADSs would experience additional dilution and, as a result, the price of the ADSs may decline.

Raising additional capital may cause dilution to our existing shareholders, restrict our operations, or require us to relinquish rights to our technologies or product candidates.

We may seek additional capital through a combination of public and private equity offerings, debt financings, collaborations and licensing arrangements. To the extent that we raise additional capital through the sale of equity or debt securities, your ownership interest will be diluted and the terms may include liquidation or other preferences that adversely affect your rights as a holder of ADSs. The incurrence of indebtedness would result in increased fixed payment obligations and could involve restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through collaborations and licensing arrangements with third parties or through asset sales, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us.

Holders of the ADSs may not be able to participate in any future preemptive subscription rights issues or elect to receive dividends in shares, which may cause additional dilution to their holdings.

Under German law, the existing shareholders of a company have a preemptive right to subscribe for shares offered in proportion to the amount of shares they hold in connection with any offering of shares. However, a shareholders' meeting may vote, by a majority representing at least three-quarters of the share capital represented at the meeting, to waive this preemptive right provided that, from the company's perspective, there exists good and objective cause for such waiver.

Certain non-German shareholders may not be able to exercise their preemptive subscription rights in our future offerings due to the legislation and regulations of their home country. For example, ADS holders in the United States will not be entitled to exercise or sell such rights unless we register the rights and the securities to which the rights relate under the Securities Act or an exemption from the registration requirements is available. In addition, the deposit agreement provides that the depository need not make rights available to you unless the distribution to ADS holders of both the rights and any related securities are either registered under the Securities Act or exempted from registration under the Securities Act. We are under no obligation to file a registration statement with respect to any such rights or securities or to endeavor to cause such a registration statement to be declared effective. Moreover, we may not be able to establish an exemption from registration under the Securities Act. Accordingly, ADS holders may be unable to participate in our rights offerings and may experience dilution in their holdings. In addition, if the depository is unable to sell rights that are not exercised or not distributed or if the sale is not lawful or reasonably practicable, it will allow the rights to lapse, in which case you will receive no value for these rights.

U.S. holders of ADSs may suffer adverse tax consequences if we are characterized as a passive foreign investment company.

A non-U.S. corporation will be classified as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes for any taxable year, if either (i) 75% or more of its gross income for such year consists of certain types of "passive" income or (ii) 50% or more of the value of its assets (determined on the basis of a quarterly average) during such year produce or are held for the production of passive income. Passive income generally includes dividends, interest, royalties, rents, annuities, net gains from the sale or exchange of property producing such income and net foreign currency gains. In addition, a non-U.S. corporation will be treated as owning its proportionate share of the assets and earning its proportionate share of the income of any other corporation in which it owns, directly or indirectly, more than 25% (by value) of the stock. Based on certain estimates of our gross income and gross assets, the latter determined by reference to the expected value of the ADSs and our ordinary shares, we believe that we will not be classified as a PFIC for the taxable year ending December 31, 2019 and we do not expect to be treated as a PFIC in any future taxable year. However, because PFIC status is based on our income, assets and activities for the entire taxable year, which we expect may vary substantially over time, it is not possible to determine whether we will be characterized as a PFIC for any taxable year until after the close of the taxable year. Moreover, we must determine our PFIC status annually based on tests that are factual in nature, and our status in future years will depend on our income, assets and activities in each of those years. There can be no assurance that we will not be considered a PFIC for any taxable year. If we were to be or become a PFIC for any taxable year during which a U.S. holder (defined below in "Taxation—Material United States Federal Income Tax Considerations") holds ADSs, certain adverse U.S. federal income tax consequences could apply to such U.S. holder. See "Taxation—Material United States Federal Income Tax Considerations—Passive Foreign Investment Company Considerations."

The interpretation of the treatment of ADSs by the German tax authorities is subject to change.

The specific treatment of ADSs under German tax law is based on administrative provisions by the fiscal authorities, which are not codified law and are subject to change. Tax authorities may modify their interpretation and the current treatment of ADSs may change, as the circular issued by the German Federal Ministry of Finance

(*BMF-Schreiben*), dated November 8, 2017, reference number IV C 1 – S 1980-1/16/10010 :10, shows. According to this new circular, ADSs are not treated as capital participation (*Kapitalbeteiligung*) within the meaning of Section 2 Para. 8 of the Investment Tax Code (*Investmentsteuergesetz*). Such changes in the interpretation by the fiscal authorities may have adverse effects on the taxation of investors.

U.S. investors may have difficulty enforcing civil liabilities against our company and members of our Supervisory Board and Management Board and the experts named in this prospectus.

We are incorporated under the laws of Germany as a European stock corporation (*Societas Europaea*) pursuant to the SE Regulation. The majority of our assets are located outside the United States and all of the members of our Management Board and Supervisory Board reside outside of the United States. As a result, it may not be possible for investors to effect service of process within the United States upon such persons or to enforce against them or us in U.S. courts' judgments predicated upon the civil liability provisions of the federal securities laws of the United States. In addition, awards of punitive damages in actions brought in the United States or elsewhere may be unenforceable in Germany. An award for monetary damages under the U.S. securities laws would be considered punitive if it does not seek to compensate the claimant for loss or damage suffered and is intended to punish the defendant. The enforceability of any judgment in Germany will depend on the particular facts of the case as well as the laws and treaties in effect at the time. We have been advised by Freshfields Bruckhaus Deringer LLP, our German counsel, that there is currently no treaty between the United States and Germany providing for reciprocal recognition and enforceability of judgments rendered in connection with civil and commercial disputes and, accordingly, a final judgment rendered by a U.S. court based on civil liability would, except where explicitly ruled enforceable by a competent German court, not be enforceable in Germany as such. However, a U.S. court's judgment may carry evidentiary value in any proceedings for civil liability brought in the German courts. Litigation in Germany is also subject to rules of procedure that differ from the U.S. rules, including with respect to the taking and admissibility of evidence, the conduct of the proceedings and the allocation of costs. Proceedings in Germany would have to be conducted in the German language, and all documents submitted to the court would, in principle, have to be translated into German. For these reasons, it may be difficult for a U.S. investor to bring an original action in a German court predicated upon the civil liability provisions of the U.S. federal securities laws against us or any members of our Management or Supervisory Boards.

German and other non-U.S. courts may refuse to hear a U.S. securities law claim because such courts may not be the most appropriate forums in which to bring such a claim. Even if a non-U.S. court agrees to hear a claim, it may determine that the law of the jurisdiction in which the court resides, and not U.S. law, is applicable to the claim. Further, if U.S. law is found to be applicable, the content of applicable U.S. law must be proved as fact, which can be a time-consuming and costly process, and certain matters of procedure would still be governed by the law of the jurisdiction in which the foreign court resides.

The rights of shareholders in a stock corporation subject to German law differ in material respects from the rights of shareholders of corporations incorporated in the United States.

We are a European stock corporation (*Societas Europaea*) with our registered office in Germany. Our corporate affairs are governed by the laws governing stock corporations and European stock corporations incorporated in Germany, the SE Regulation and our articles of association. The rights of shareholders may be different from the rights and obligations of shareholders in companies governed by the laws of U.S. jurisdictions. Among other differences in shareholder rights, under German law, certain important resolutions, including, for example, capital decreases, measures under the German Transformation Act (*Umwandlungsgesetz*), such as mergers, conversions and spin-offs, the issuance of convertible bonds or bonds with warrants attached and the dissolution of the German stock corporation apart from insolvency and certain other proceedings, require the vote of a 75% majority of the capital present or represented at the relevant shareholders' meeting. Therefore, the holder or holders of a blocking minority of 25% or, depending on the attendance level at the shareholders'

meeting, the holder or holders of a smaller percentage of the shares in a German stock corporation may be able to block any such votes, possibly to our detriment or the detriment of other shareholders.

As a general rule under German law, in the case of a two-tier European stock corporation a shareholder has no direct recourse against the members of the management board and the supervisory board, in the event that it is alleged that they have breached their duty of loyalty or duty of care to the corporation. Apart from insolvency or other special circumstances, only the European stock corporation itself has the right to claim damages from members of the management and supervisory boards. A European stock corporation may waive or settle these damages claims only if at least three years have passed and the shareholders approve the waiver or settlement at the shareholders' meeting with a simple majority of the votes cast, provided that a minority holding, in the aggregate, 10% or more of the European stock corporation's share capital does not have its opposition formally noted in the minutes maintained by a German civil law notary.

In addition, the responsibilities of members of our Management Board and Supervisory Board may differ from the duties of directors of U.S. corporations. For example, in the performance of their duties, our Management Board and Supervisory Board may take into account a broad range of considerations, including our interests, the interests of our shareholders, employees, creditors and, to a limited extent, the general public. It is possible that some of these parties will have interests that are different from, or in addition to, your interests as a holder of ADSs.

For more information, we have provided summaries of relevant German corporation law and of our articles of association under "Management" and "Description of Share Capital and Articles of Association (*Satzung*)."

An active trading market for the ADSs may not develop.

Prior to this offering, there has been no public market for ADSs representing our ordinary shares. The initial public offering price for the ADSs was determined through negotiations with the underwriters. Although we have applied to list the ADSs on the Nasdaq Global Select Market, an active trading market for the ADSs may never develop or be sustained following this offering. If an active market for the ADSs does not develop, it may be difficult for you to sell ADSs you purchase in this offering without depressing the market price for the ADSs, or at all.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of the ADSs, the price of the ADSs could decline.

The trading market for the ADSs will rely, in part, on the research and reports that industry or financial analysts publish about us or our business. We do not currently have, and may never obtain, research coverage by industry or financial analysts. If no, or few, analysts commence coverage of us, the trading price of the ADSs would likely decrease. Even if we do obtain analyst coverage, if one or more of the analysts covering our business downgrade their evaluations of the ADSs, the price of the ADSs could decline. If one or more of these analysts cease to cover the ADSs, we could lose visibility in the market for the ADSs, which in turn could cause price of the ADSs to decline.

Our principal shareholders and management own a significant percentage of our ordinary shares and will be able to exert significant control over matters subject to shareholder approval.

Our executive officers, directors, five percent shareholders, and their affiliates beneficially own approximately 84.67% of our ordinary shares and, upon closing of this offering, that same group will beneficially own approximately % of our outstanding ordinary shares. Therefore, even after this offering, these shareholders will have the ability to influence us through their ownership positions. For example, these shareholders, acting together, may be able to exert significant influence over matters such as elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our ordinary shares that you may believe are in your best interest as one of our shareholders.

We have broad discretion in the use of our cash, cash equivalents and investments, including the net proceeds from this offering, and we may not use them effectively.

Our management will have broad discretion in the application of our cash, cash equivalents and investments, including the net proceeds from this offering, and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our ordinary shares. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse impact on our business, cause the price of the ADSs to decline, and delay the development of our product candidates. Pending their use, we may invest our cash, cash equivalents and investments, including the net proceeds from this offering, in a manner that does not produce income or that loses value. See “Use of Proceeds” for more information.

Because we do not currently pay cash dividends on our ordinary shares and do not anticipate paying any cash dividends on our ordinary shares in the foreseeable future, capital appreciation, if any, will be your sole source of gain on your investment in the ADSs.

We do not currently intend to declare or pay cash dividends on our ordinary shares. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, on the ADSs will be your sole source of gain for the foreseeable future.

If we were to pay dividends, holders of the ADSs may be unable to claim tax credits with respect to, or tax refunds to reduce German withholding tax applicable to, the payment of such dividends, or such dividends may effectively be taxed twice.

As a German tax resident company, if we were to pay dividends, such dividends will be subject to German withholding tax. Currently, the applicable German withholding tax rate is 26.375% of the gross dividend. This German tax can be reduced to the applicable U.S.-Germany income tax treaty, or Treaty, rate, which is generally 15%, if the applicable taxpayer is eligible for such Treaty rate and files an application containing a specific German tax certificate with the German Federal Central Tax Office (*Bundeszentralamt für Steuern*). If such a tax certificate cannot be delivered to the ADS holder due to applicable settlement mechanics or lack of information regarding the ADS holder, holders of the ADSs may be unable to benefit from the double tax treaty relief (including “Eligible U.S. Holders” as defined under the Treaty) and may be unable to file for a credit of such withholding tax in its jurisdiction of residence. Further, the payment made to the ADS holder equal to the net dividend may, under the tax law applicable to the ADS holder, qualify as taxable income that is in turn subject to withholding, which could mean that a dividend is effectively taxed twice. There can be no guarantee that the information delivery requirement can be satisfied in all cases, which could result in adverse tax consequences for affected ADS holders. ADS holders should note that the applicable interpretation circular (*Besteuerung von American Depositary Receipts (ADR) auf inländische Aktien*) issued by the German Federal Ministry of Finance (*Bundesministerium der Finanzen*), dated May 24, 2013 (reference number IV C 1-S2204/12/10003), or the ADR Tax Circular, is not binding on German courts, and there is no certainty as to whether a German tax court will follow the ADR Tax Circular in determining the German tax treatment of the ADSs. In addition, the ADR Tax Circular does not include details on how an ADR program should be designed. If the ADSs were determined not to fall within the scope of application of the ADR Tax Circular, or a German tax court did not follow the ADR Tax Circular, and profit distributions made with respect to the ADSs were not treated as a dividend for German tax purposes, a holder of the ADSs would not be entitled to a refund of any taxes withheld on the dividends under German tax law and profit distributions made with respect to the ADSs may be effectively taxed twice.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biopharmaceutical companies have experienced significant price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management’s attention and resources, which could harm our business.

ADS holders may not be entitled to a jury trial with respect to claims arising under the deposit agreement, which could result in less favorable outcomes to the plaintiffs in an action of that kind.

The deposit agreement governing the ADSs representing our ordinary shares provides that, to the fullest extent permitted by law, ADS holders waive the right to a jury trial of any claim they may have against us or the depository arising out of or relating to our ordinary shares, the ADSs or the deposit agreement, including any claim under U.S. federal securities laws.

If we or the depository opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable based on the facts and circumstances of that case in accordance with the applicable state and federal law. To our knowledge, the enforceability of a contractual pre-dispute jury trial waiver in connection with claims arising under the federal securities laws has not been finally adjudicated by the United States Supreme Court. However, we believe that a contractual pre-dispute jury trial waiver provision is generally enforceable, including under the laws of the State of New York, which govern the deposit agreement, by a federal or state court in the City of New York, which has non-exclusive jurisdiction over matters arising under the deposit agreement. In determining whether to enforce a contractual pre-dispute jury trial waiver provision, courts will generally consider whether a party knowingly, intelligently and voluntarily waived the right to a jury trial. We believe that this is the case with respect to the deposit agreement and the ADSs. It is advisable that you consult legal counsel regarding the jury waiver provision before entering into the deposit agreement.

If you or any other ADS holders bring a claim against us or the depository in connection with matters arising under the deposit agreement or relating to the ADSs, including claims under federal securities laws, you may not be entitled to a jury trial with respect to such claims, which may have the effect of limiting and discouraging lawsuits against us or the depository. If a lawsuit is brought against us or the depository under the deposit agreement, it may be heard only by a judge or justice of the applicable trial court, which would be conducted according to different civil procedures and may result in different outcomes than a trial by jury would have had, including results that could be less favorable to the plaintiffs in that action.

Nevertheless, if this jury trial waiver provision is not permitted by applicable law, an action could proceed under the terms of the deposit agreement with a jury trial.

No condition, stipulation or provision of the deposit agreement or the ADSs serves as a waiver by any ADS holder or by us or the depository of compliance with any substantive provision of the U.S. federal securities laws and the rules and regulations promulgated thereunder.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business operations and financial performance and condition. Many of the forward-looking statements contained in this prospectus can be identified by the use of forward-looking words such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “potential,” “should,” “target,” “would” and other similar expressions that are predictions of or indicate future events and future trends, although not all forward-looking statements contain these identifying words.

Forward-looking statements are based on our management’s beliefs and assumptions and on information currently available to our management. Such statements are subject to risks and uncertainties, and actual results may differ materially from those expressed or implied in the forward-looking statements due to a variety of factors, including, but not limited to, those identified in the section titled “Risk Factors” in this prospectus. These risks and uncertainties include factors relating to:

- the initiation, timing, progress, results, and cost of our research and development programs and our current and future preclinical studies and clinical trials, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available and our research and development programs;
- the timing of and our ability to obtain and maintain regulatory approval for our product candidates;
- our ability to identify research opportunities and discover and develop investigational medicines;
- the ability and willingness of our third-party collaborators to continue research and development activities relating to our development candidates and investigational medicines;
- our expectations regarding the size of the patient populations for our product candidates, if approved for commercial use;
- our estimates of our expenses, ongoing losses, future revenue and capital requirements and our needs for or ability to obtain additional financing;
- our ability to identify, recruit and retain key personnel;
- our and our collaborators’ ability to protect and enforce our intellectual property protection for our proprietary and collaborative product candidates, and the scope of such protection;
- the development of and projections relating to our competitors or our industry;
- our ability to commercialize our product candidates, if approved;
- the pricing and reimbursement of our investigational medicines, if approved;
- the rate and degree of market acceptance of our investigational medicines;
- the amount of and our ability to use net operating losses and research and development credits to offset future taxable income;
- our ability to manage our development and expansion;
- regulatory developments in the United States and foreign countries;
- our ability to manufacture our product candidates with advantages in turnaround times or manufacturing cost;
- our ability to implement, maintain and improve effective internal controls;
- our use of the proceeds from this offering; and

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- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act and a foreign private issuer.

The preceding list is not intended to be an exhaustive list of all of our forward-looking statements. The forward-looking statements contained in this prospectus speak only as of the date of this prospectus, and unless otherwise required by law, we do not undertake any obligation to update them in light of new information or future developments or to release publicly any revisions to these statements in order to reflect later events or circumstances or to reflect the occurrence of unanticipated events.

USE OF PROCEEDS

We estimate that the net proceeds to us from this offering will be approximately \$ (or approximately \$ if the underwriters exercise in full their options to purchase an additional ADSs), assuming an initial public offering price of \$ per ADS, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ per ADS, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the net proceeds to us from this offering by approximately \$ million, assuming the number of ADSs offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of ADSs we are offering. An increase (decrease) of in the number of ADSs offered by us would increase (decrease) the net proceeds to us from this offering by approximately \$ million, assuming no change in the assumed initial public offering price and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

As of December 31, 2018, we had cash and cash equivalents of €411.5 million. We currently intend to use the net proceeds from this offering as follows:

- approximately \$ million to complete our ongoing and currently planned clinical trials for our FixVac product candidates BNT111, BNT113 and BNT114, as well as to fund our portion of the research and development expenses for each of the following: RO7198457 (BNT122), which is being developed in collaboration with Genentech, SAR441000 (BNT131), which is being developed in collaboration with Sanofi, and GEN1046 (BNT311), which is being developed in collaboration with Genmab;
- approximately \$ to advance additional product candidates through Phase 1 clinical trials, including for our CAR T, RiboMabs and RiboCytokines platforms in oncology, and for our infectious disease and rare disease programs;
- approximately \$ to advance additional preclinical product candidates, develop additional product candidates leveraging our current therapeutic platforms and fund the further development of our core technologies; and
- approximately \$ million to fund the further expansion of our manufacturing and laboratory capacity and the continued development of our infrastructure.

We expect to use the remainder of any net proceeds from this offering, as well as our existing cash and cash equivalents, for general corporate purposes. We may also use a portion of the net proceeds to in-license or acquire or invest in complementary technologies, products, businesses or assets, either alone or together with a collaborator. However, we have no current plans, commitments or obligations to do so.

Our expected use of net proceeds from this offering represents our current intentions based on our present plans and business condition, which could change as our plans and business conditions evolve. The amounts and timing of our actual use of net proceeds will vary depending on numerous factors, including the progress of our clinical development of our product candidates, including our ongoing clinical trials. As a result, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the closing of this offering or the amounts that we will actually spend on the uses set forth above. Our management will have broad discretion in the application of the net proceeds from this offering.

We expect that we will need to raise significant additional funds beyond this offering in order to continue to advance our pipeline. In particular, we will need additional funds in order to advance our product candidates through Phase 3 clinical trials and to potential commercialization. We may seek to raise capital through public or private equity or debt financing, government or other third-party grants or funding, sales of assets, marketing and distribution arrangements, other collaborations or a combination of these approaches.

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Based on our planned use of the net proceeds of this offering and our existing cash and cash equivalents described above, we estimate that such funds will be sufficient to enable us to fund our operating expenses and capital expenditure requirements through at least the next months. We have based this estimate on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect.

Pending our use of the net proceeds from this offering, we plan to invest the net proceeds in short- and intermediate-term interest-bearing financial instruments.

DIVIDEND POLICY

We have never paid or declared any cash dividends on our ordinary shares, and we do not anticipate paying any cash dividends on our ordinary shares in the foreseeable future. We intend to retain all available funds and any future earnings to fund the development and expansion of our business. All of the shares represented by the ADSs offered by this prospectus will generally have the same dividend rights as all of our other outstanding shares.

Under German law, we may pay dividends only from the distributable profit (*Bilanzgewinn*) reflected in our unconsolidated financial statements (as opposed to the consolidated financial statements for us and our subsidiaries) prepared in accordance with the principles set forth in the German Commercial Code (*Handelsgesetzbuch*) and adopted by our management board (*Vorstand*) and the supervisory board (*Aufsichtsrat*), or, as the case may be, by our shareholders in a shareholders' meeting. See "Description of Share Capital and Articles of Association (*Satzung*)," which explains in more detail the procedures we must follow and the German law provisions that determine whether we are entitled to declare a dividend.

CAPITALIZATION

The table below sets forth our cash and cash equivalents and our total capitalization as of December 31, 2018:

- on an actual basis; and
- on an as adjusted basis to give effect to our issuance and the sale of ADSs by us in this offering, assuming an initial public offering price of \$ _____ per ADS, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

Our capitalization following the offering will be adjusted based on the actual offering price and other terms of the offering determined at pricing, including the amount by which actual offering expenses are higher or lower than estimated. You should read this table in conjunction with our consolidated financial statements and related notes included in this prospectus as well as the sections titled “Use of Proceeds,” “Selected Consolidated Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

(in thousands except share and per share data)	As of December 31, 2018	
	Actual	As Adjusted
Cash and cash equivalents ⁽¹⁾	€ 411,495	€ _____
Total debt	5,600	
Equity		
Ordinary shares, no par value per share: 10,738,632 shares, actual; _____ shares, as adjusted		
Share capital ⁽¹⁾	10,739	
Capital reserve ⁽¹⁾	526,672	
Accumulated profit/(losses)	(245,771)	
Other reserves	(25,487)	
Equity attributable to equity holders of the parent	266,153	
Non-controlling interests	847	
Total equity ⁽¹⁾	267,000	_____
Total capitalization ⁽¹⁾	€ 272,600	€ _____

- (1) Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ _____ per ADS, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) each of cash and cash equivalents, capital reserve, total equity and total capitalization by approximately \$ _____ million, assuming the number of ADSs offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of ADSs we are offering. An increase (decrease) of _____ in the number of ADSs offered by us would increase (decrease) each of cash and cash equivalents, share capital, capital reserve, total equity and total capitalization by approximately \$ _____ million, assuming no change in the assumed initial public offering price and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The number of our ordinary shares to be outstanding after this offering is based on 10,738,632 ordinary shares outstanding as of December 31, 2018 and excludes:

- 658,109 ordinary shares issuable upon the exercise of options outstanding as of December 31, 2018; and
- _____ ordinary shares available for future issuance under our Employee Stock Ownership Plan.

DILUTION

If you invest in our ADSs in this offering, your interest will be diluted immediately to the extent of the difference between the initial public offering price per ADS and our as adjusted net tangible book value per ADS after completion of the offering.

As of December 31, 2018, we had a historical net tangible book value of €179 million (\$ million), corresponding to a net tangible book value per ordinary share of € (\$) (equivalent to € (\$) per ADS). Our net tangible book value per ADS represents the amount of our total assets less our total liabilities, excluding intangible assets, divided by the number of our ordinary shares outstanding as of December 31, 2018, and multiplied by (one ADS represents ordinary shares).

After giving effect to the issuance and sale of ADSs in this offering at an assumed initial offering price of \$ per ADS, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value as of December 31, 2018 would have been € million (\$ million), corresponding to a net tangible book value per ordinary share of € (\$) (equivalent to € (\$) per ADS). This represents an immediate increase in net tangible book value of € () per ordinary share to existing shareholders and immediate dilution of € (\$) per ordinary share (equivalent to € (\$) per ADS) to new investors purchasing ADSs in this offering. Dilution per ADS to new investors is determined by subtracting our as adjusted net tangible book value per ADS from the assumed initial public offering price per ADS paid by new investors.

The following table illustrates this dilution on a per-ADS basis:

Assumed initial public offering price per ADS	\$
Historical net tangible book value per ADS as of December 31, 2018	\$
Increase in net tangible book value per ADS attributable to new investors participating in this offering	\$
As adjusted net tangible book value per ADS after this offering	\$
Dilution per ADS to new investors participating in this offering	\$

Each \$1.00 increase (decrease) in the assumed initial offering price of \$ per ADS, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) our as adjusted net tangible book value as of December 31, 2018 by € (\$) per ADS, and would increase (decrease) dilution to new investors in this offering by € (\$) per ADS, assuming that the number of ADSs offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. An increase (decrease) of in the number of ADSs offered by us would increase (decrease) our as adjusted net tangible book value after this offering by approximately € (\$) per ADS, and would decrease (increase) dilution to investors in this offering by approximately € (\$) per ADS, assuming no change in the assumed initial public offering price per ADS and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise in full their option to purchase additional ADSs, our as adjusted net tangible book value per ADS would be € (\$), representing an immediate increase in as adjusted net tangible book value to existing shareholders of € (\$) per ADS and immediate dilution of € (\$) per ADS to new investors, assuming no change in the assumed initial public offering price per ADS and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The as adjusted information is illustrative only, and we will adjust this information based on the actual initial public offering price and other terms of this offering determined at pricing.

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The following table sets forth, on an as adjusted basis as of December 31, 2018, the number of ordinary shares owned by existing shareholders and to be owned by new investors purchasing ADSs in this offering, the total consideration paid to us, the average price per ordinary share paid by our existing shareholders and the average price per ADS to be paid by new investors purchasing ADSs in this offering. The calculation below is based on an assumed initial public offering price of \$ _____ per ADS, which is the midpoint of the price range set forth on the cover page of this prospectus, before deducting underwriting discounts and commissions and estimated offering expenses payable by us:

	Ordinary Shares Purchased		Total Consideration		Average Price Per Share	Average Price Per ADS
	Number	Percent	Amount	Percent		
Existing shareholders		_____%	\$ _____	_____%	\$ _____	\$ _____
New investors		_____%	\$ _____	_____%	\$ _____	\$ _____
Total		100%		100%	\$ _____	\$ _____

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ _____ per ADS, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the total consideration paid by new investors by \$ _____ million and increase (decrease) the percentage of total consideration paid by new investors by approximately _____%, assuming that the number of ADSs offered by us, as set forth on the cover page of this prospectus, remains the same, and before deducting underwriting discounts and commissions and estimated offering expenses payable by us. An increase (decrease) of _____ in the number of ADSs offered by us would increase (decrease) the total consideration paid by investors participating in this offering, total consideration paid by all shareholders and the average price per share paid by all shareholders by approximately \$ _____ million, \$ _____ million and \$ _____, respectively, assuming no change in the assumed initial public offering price and before deducting underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise their option to purchase additional ADSs in full, our existing shareholders would own _____ ordinary shares, or _____% in the aggregate, and our new investors would own _____ ordinary shares, or _____% in the aggregate.

The number of our ordinary shares to be outstanding after this offering is based on 10,738,632 ordinary shares outstanding as of December 31, 2018 and excludes:

- 658,109 ordinary shares issuable upon the exercise of options outstanding as of December 31, 2018; and
- _____ ordinary shares available for future issuance under our Employee Stock Ownership Plan.

We may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of such securities may result in further dilution to our shareholders.

SELECTED CONSOLIDATED FINANCIAL DATA

The following tables present selected consolidated financial data as of and for the years ended December 31, 2018 and 2017. We derived the selected consolidated statements of operations for the years ended December 31, 2018 and 2017 and the selected consolidated balance sheet data as of December 31, 2018 and 2017 from our audited consolidated financial statements included elsewhere in this prospectus. We present our consolidated financial statements in Euros and in accordance with IFRS as issued by the IASB.

The selected consolidated financial data below should be read together with our consolidated financial statements and related notes included elsewhere in this prospectus, as well as the sections of this prospectus titled “Capitalization” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

	For the Years Ended December 31,	
	2018	2017
(in thousands except per share data)		
Consolidated statement of operations:		
Revenues from contracts with customers	€ 127,575	€ 61,598
Cost of sales	(13,690)	(9,318)
Gross profit	113,885	52,280
Research and development expenses	(143,040)	(85,496)
Sales and marketing expenses	(3,041)	(6,603)
General and administrative expenses	(26,334)	(23,520)
Other operating income	5,396	2,349
Other operating expenses	(720)	(288)
Operating loss	(53,854)	(61,277)
Finance income	8,046	2,133
Finance expense	(48)	(26,007)
Interest expense related to lease liability	(1,721)	(676)
Share of loss of equity method investees	(84)	(78)
Loss before tax	(47,662)	(85,905)
Income taxes	(600)	(45)
Loss for the year	€ (48,262)	€ (85,950)
Loss attributable to non-controlling interests	(243)	(297)
Loss attributable to equity holders of the parent	€ (48,019)	€ (85,653)
Basic and diluted loss per share	€ (4.53)	€ (9.28)

	As of December 31,	
	2018	2017
(in thousands)		
Consolidated statement of financial position:		
Cash and cash equivalents	€ 411,495	€ 172,106
Total assets	652,986	374,713
Share capital	10,739	9,265
Total liabilities	385,986	422,920
Accumulated losses	(245,771)	(197,753)
Total equity	267,000	(48,206)

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with the information in "Selected Consolidated Financial Data" and our financial statements and related notes included elsewhere in this prospectus. The following discussion is based on our financial information prepared in accordance with the International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB, which may differ in material respects from generally accepted accounting principles in other jurisdictions, including U.S. GAAP. The following discussion includes forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including but not limited to those described in "Risk Factors" and elsewhere in this prospectus. Please also see "Cautionary Note Regarding Forward-Looking Statements."

BioNTech was founded in 2008 on the understanding that every cancer patient's tumor is unique and that in order to effectively address this challenge, we must create individualized treatments for each patient. To realize this vision, we combine decades of groundbreaking research in immunology, cutting-edge therapeutic platforms, and a suite of patient profiling and bioinformatic tools to develop individualized immunotherapies for cancer as well as other diseases. We leverage powerful new therapeutic mechanisms and exploit a diverse array of biological targets to harness the power of each patient's immune system to address the unique molecular signature of each patient's underlying disease. We believe we are uniquely positioned to develop and commercialize the next generation of immunotherapies with the potential to significantly improve clinical outcomes for patients and usher in a new era of individualized medicine.

Our clinical stage pipeline includes seven product candidates in eight ongoing clinical trials. Our immunotherapy drug classes consist of mRNA therapeutics, engineered cell therapies, antibodies and small molecule immunomodulators, and our product candidates span oncology, infectious diseases and rare diseases.

We have assembled an exceptional team of over 1,000 employees and have established relationships with seven pharmaceutical collaborators, which comprise Genentech, Inc., or Genentech, Sanofi S.A., or Sanofi, Genmab A/S, or Genmab, Genevant Sciences, or Genevant, Eli Lilly and Company, or Eli Lilly, Bayer AG, or Bayer, and Pfizer Inc., or Pfizer. We have built out comprehensive in-house manufacturing capabilities and aim to strengthen our position as a leader in the highly automated, on-demand manufacturing of individualized therapies.

We have raised \$1.3 billion of capital in private placements of our shares and from our collaborators. We use the capital we have raised to fund operations and investing activities across research for technology creation, drug discovery and clinical development programs, infrastructure (including digital infrastructure), creation of our portfolio of intellectual property, and administrative support.

Since we were founded we have incurred significant operating losses. Our net losses were €48.3 million and €86.0 million for the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018 and 2017, our accumulated losses were €245.8 million and €197.8 million, respectively. We expect to continue to incur significant expenses and operating losses for the foreseeable future. In addition, we anticipate that our expenses will increase significantly in connection with our ongoing activities as we:

- continue or expand our research or development of our programs in preclinical development;
- continue or expand the scope of our clinical trials for our product candidates;
- initiate additional preclinical studies or clinical or other trials for our product candidates, including under our collaboration agreements;
- continue to invest in our immunotherapy platforms to conduct research to identify novel technologies;
- change or add to internal manufacturing capacity or capability;

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- change or add additional suppliers;
- add additional infrastructure to our quality control, quality assurance, legal, compliance and other groups to support our operations as we progress our product candidates toward commercialization;
- attract and retain skilled personnel;
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts, including expansion of sites in Germany and new sites in the United States;
- seek marketing approvals and reimbursement for our product candidates;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- seek to identify and validate additional product candidates;
- acquire or in-license other product candidates and technologies;
- make milestone or other payments under any in-license agreements;
- maintain, protect, defend, enforce and expand our intellectual property portfolio; and
- experience any delays or encounter issues with any of the above.

We do not expect to generate revenue from the sale of our product candidates unless and until we successfully complete clinical development and obtain regulatory approval for such product candidates. If we seek to obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses.

As a result, we will need substantial additional funding to support our continued operations and pursue our growth strategy. Until we can generate significant revenue from pharmaceutical product sales, if ever, we expect to finance our operations through a combination of public or private equity offerings and debt financings, government funding arrangements, collaborations and marketing, distribution and licensing arrangements. We may be unable to raise additional funds or enter into such other agreements on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our programs.

Because of the numerous risks and uncertainties associated with pharmaceutical development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate revenues from the sale of our products, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and may be forced to reduce our operations.

Information About Our Business Units and Operating Segments

Our business is managed in two business units: our biotech business unit and our external services business unit. Our biotech business unit is comprised of the following three operating segments:

- The **Clinical** segment contains all development activities relating to clinical programs. Clinical trials include testing the product candidates on humans. Clinical trials are an essential part of the development and licensing of the pharmaceutical products and are performed before the respective product can be placed on the market. We are actively engaged in many collaborations and licensing deals with leading pharmaceutical companies and academic collaborators.
- The **Technology Platform** segment contains all development activities relating to preclinical programs. Preclinical development is the stage of research that begins before clinical trials. It is performed to determine the desired pharmacological effects and to identify any unwanted effects that may cause adverse reactions during human exposure.

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- The **Manufacturing** segment is an essential part of the research and development process as it comprises the manufacturing unit of mRNA and engineered cell therapies. All of the medical substances and tools that form the basis for the research studies performed by BioNTech are manufactured in this segment (*i.e.*, the manufacturing segment contains only internally produced substances and tools).

Our biotech business unit also includes our business services operations. Our business services operations comprise our central administrative functions, such as finance, procurement, human resources, legal and intellectual property. Revenue and Expenses relating to a program are attributed to the Technology Platform segment until the program commences late-stage preclinical studies, including IND-enabling studies, at which time the program revenues and expenses are attributed to the clinical segment. In addition, the majority of our Manufacturing segment revenue and expenses are related to the development of our clinical product candidates.

Our external services business unit comprises the external services segment, which includes activities related to the sales of diagnostic products, peptides, retroviral vectors for clinical supply, and development and manufacturing services that are sold to third-party customers.

Financial Operations Overview

The following table summarizes our consolidated statements of operations for each period presented (in thousands):

	Year Ended December 31,	
	2018	2017
Revenue	€ 127,575	€ 61,598
Cost of sales	(13,690)	(9,318)
Gross profit	113,885	52,280
Research and development expenses	(143,040)	(85,496)
Sales and marketing expenses	(3,041)	(6,603)
General and administrative expenses	(26,334)	(23,520)
Other operating income	5,396	2,349
Other operating expenses	(720)	(288)
Operating loss	(53,854)	(61,277)
Finance income	8,046	2,133
Finance expense	(48)	(26,007)
Interest expense related to lease liability	(1,721)	(676)
Share of loss of equity method investees	(84)	(78)
Loss before tax	(47,662)	(85,905)
Income taxes	(600)	(45)
Loss for the year	€ (48,262)	€ (85,950)

Revenue

To date, we have not generated any revenue from the sale of pharmaceutical products. Our revenue has been primarily derived from our collaborations and the sale of diagnostic products, peptides, retroviral vectors for clinical supply, and development and manufacturing services that are sold to third-party customers.

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The following is a summary of revenue recognized for the years ended December 31, 2018 and 2017 (in thousands):

	Year Ended December 31,	
	2018	2017
Revenue:		
Collaboration revenue	€ 101,837	€ 42,333
Other sales transactions	25,738	19,265
Total revenue	€ 127,575	€ 61,598

The following table summarizes our collaboration revenue for the years ended December 31, 2018 and 2017 (in thousands):

	Year Ended December 31,	
	2018	2017
Collaboration revenue:		
Eli Lilly	€ 676	€ 2,074
Genentech	49,536	27,829
Genmab	2,740	6,765
Pfizer	7,174	—
Sanofi	41,712	5,665
Total collaboration revenue	€ 101,837	€ 42,333

Our collaboration revenue consists of milestone payments, upfront licensing payments and reimbursement of development expenses. Certain of these payments are initially recorded on our statement of financial position and are subsequently recognized as revenue in accordance with our accounting policy as described further in “—Critical Accounting Policies and Use of Estimates” and Note 2.3.4 to our consolidated financial statements included elsewhere in this prospectus. Our collaborations with Bayer and Genevant did not result in any revenue in 2018 and 2017.

Our revenue from other sales transactions consists of sales of diagnostic products, peptides, retroviral vectors for clinical supply, and development and manufacturing services sold to third-party customers.

Our ability to generate revenue from sales of pharmaceutical products and become profitable depends upon our and our collaborators’ ability to successfully commercialize our product candidates. For the foreseeable future, we do not expect revenue from pharmaceutical product sales. To the extent that existing or potential future collaborations generate revenue, our revenue may vary due to many uncertainties in the development of our product candidates and other factors.

For further information on our revenue recognition policies, see “—Critical Accounting Policies and Use of Estimates—Revenue Recognition.”

Cost of Sales

Our cost of sales includes personnel-related expenses, social security expenses, laboratory supplies, purchased services, depreciation and other expenses incurred in connection with the manufacturing of our external products.

The following table summarizes our cost of sales for the years ended December 31, 2018 and 2017 (in thousands):

	Year Ended December 31,	
	2018	2017
Cost of sales:		
Wages	€ 5,582	€ 5,115
Social security expenses	1,144	990
Laboratory supplies	1,368	2,849
Purchased services	2,514	—
Depreciation	1,367	—
Other	1,715	364
Total cost of sales	€ 13,690	€ 9,318

Research and Development Expenses

The nature of our business and primary focus of our activities generate a significant amount of research and development expenses. All research and development expenses are expensed as incurred. Research and development expenses include our share of expenses payable by us under the terms of our collaboration agreements and 100% of the expenses for our wholly owned product candidates. Research and development expenses represent costs incurred by us for the following:

- cost to develop our platforms;
- discovery efforts leading to product candidates;
- clinical development expenses for our programs;
- cost to develop our manufacturing technology and infrastructure; and
- digital infrastructure costs.

The costs above comprise the following categories:

- personnel-related expenses, including salaries, benefits, share-based compensation expense and social security expense;
- expenses incurred under agreements with third parties, such as consultants, investigative sites, contract research organizations, or CROs, that conduct our preclinical studies and clinical trials, and in-licensing arrangements;
- costs of acquiring, developing and manufacturing materials for preclinical studies and clinical trials, including both internal manufacturing and third-party contract manufacturing organizations, or CMOs;
- expenses incurred for the procurement of materials, laboratory supplies and non-capital equipment used in the research and development process; and
- facilities, depreciation and amortization, and other direct and allocated expenses incurred as a result of research and development activities.

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The following table summarizes our research and development expenses for the years ended December 31, 2018 and 2017 (in thousands):

	Year Ended December 31,	
	2018	2017
Research and development expenses:		
Wages and social security expenses (excluding share-based compensation)	€ 38,882	€ 26,403
Share-based compensation	6,786	5,567
Purchased services	42,079	22,686
Laboratory supplies	22,921	15,762
Depreciation	18,312	9,859
Other	14,060	5,219
Total research and development expenses	€ 143,040	€ 85,496

Our “other” research and development expenses comprise expenses in relation to clinical studies, travel costs, incidental rental costs, and lease and lease-related costs.

The largest component of our total operating expenses has historically been our investment in research and development activities, including development of our platforms and manufacturing technologies. We cannot reasonably estimate the nature, timing and amount of research and development expenses required to complete the development of the product candidates we are currently developing or may develop in the future. There are numerous risks and uncertainties associated with the research and development of such product candidates, including, but not limited to:

- scope, progress and expense of developing ongoing and future product candidates;
- entry in and completion of related preclinical studies;
- enrollment in and completion of subsequent clinical trials;
- safety and efficacy of product candidates resulting from these clinical trials;
- changes in laws or regulations relevant to the investigational medicines in development;
- receipt of the required regulatory approvals; and
- commercialization, including establishing manufacturing and marketing capabilities.

A change in expectations or outcomes of any of the known or unknown risks and uncertainties may materially impact our expected research and development expenditures. Continued research and development is central to the ongoing activities of our business. Product candidates in later stages of clinical development generally have higher development expenses than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect these costs to continue to increase in the future as our product candidates progress through the development phases and as we identify and develop additional programs. However, we do not believe that it is possible at this time to accurately project total program-specific expenses through commercialization. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will impact our clinical development programs and plans.

Sales and Marketing Expenses

Our sales and marketing expenses consist of personnel-related costs, purchased services, travel costs, social security, transport costs and depreciation. If we obtain regulatory approval for any of our product candidates and do not enter into any third-party commercialization collaborations, we expect to incur significant expenses related to building a sales and marketing team to support sales, marketing and distribution activities.

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Our sales and marketing expenses amounted to €3.0 million in 2018, €0.8 million of which constituted expenses for purchased services. Our sales and marketing expenses amounted to €6.6 million in 2017, €2.8 million of which constituted expenses for purchased services.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related costs (including share-based compensation) for finance, legal, human resources, business development and other administrative and operational functions, professional fees, accounting and legal services, information technology and facility-related costs. These costs relate to the operation of the business, unrelated to the research and development function or any individual program.

The following table summarizes our general and administrative expenses for the years ended December 31, 2018 and 2017 (in thousands):

	Year Ended December 31,	
	2018	2017
General and administrative expenses:		
Wages and social security expenses (excluding share-based compensation)	€ 7,854	€ 6,363
Share-based compensation	728	3,498
IT and office equipment	3,774	2,706
Purchased services	5,177	3,544
Office costs	608	1,611
Depreciation	2,284	630
Other	5,908	5,167
Total administrative expenses	€ 26,334	€ 23,520

Our “other” general and administrative expenses are mainly comprised of travel costs, job advertisement expenses, contract staffing expenses, training expenses and incidental rental costs.

We anticipate general and administrative expenses will increase as research and development expands. These increases will likely relate to additional personnel and increased costs related in part to finance, legal and intellectual property-related matters along with increased expenses related to operating as a publicly traded company, such as fees related to audit, legal and tax services, regulatory compliance programs and investor relations.

Other Operating Income (Expenses)

Our other operating income consists primarily of government grants. In 2018, our other operating income amounted to €5.4 million, €4.2 million of which constituted government grants. In 2017, our other operating income amounted to €2.4 million, €2.3 million of which constituted government grants.

In 2018, no impairment loss was recognized. In 2017, we suffered an impairment loss of €281 thousand as a result of a write-down of a software program which was no longer usable.

Finance Income (Expenses)

Our finance income consists of interest income on cash and foreign exchange gains. In 2018, finance income amounted to €8.0 million, €6.1 million of which were attributable to unrealized foreign exchange gains. In 2017, no foreign exchange gains were reported under finance income and our finance income amounted to €2.1 million.

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Our finance expense consists of the amortized cost of financial instruments and foreign exchange losses. In 2018, no foreign exchange losses were reported under finance expense and our finance expense amounted to €48 thousand. In 2017, our finance expense amounted to €26.0 million, almost all of which was attributable to unrealized foreign exchange losses resulting from unhedged U.S. dollar cash accounts.

Tax Losses

We have accumulated tax losses with respect to corporate tax and trade tax. We had accumulated tax losses of €179.3 million with respect to corporate tax and €176.4 million with respect to trade tax as at December 31, 2018. We had accumulated tax losses of €178.5 million with respect to corporate tax and €176.0 million with respect to trade tax as at December 31, 2017.

Biotech Business Unit

The following table summarizes the statements of operations of our biotech business unit, consisting of the clinical, platform technology and manufacturing segments and the associated business services operations for each period presented (in thousands):

	Year Ended December 31,	
	2018	2017
Revenue	€ 108,662	€ 42,657
Cost of sales	(40)	—
Gross profit	108,622	42,657
Research and development expenses	(142,448)	(83,583)
Sales and marketing expenses	(2,106)	(4,904)
General and administrative expenses	(23,791)	(21,094)
Other result	4,065	1,598
Operating loss	(€ 55,659)	(€ 65,326)

Comparison of the Years Ended December 31, 2018 and 2017

Revenue

The following table summarizes the revenue of our biotech business unit broken down by segment for each period presented (in thousands):

	Year Ended December 31,		Change	
	2018	2017	€	%
Clinical	€ 36,750	€ 25,721	11,029	43
Technology Platform	46,235	14,828	31,407	212
Manufacturing	25,635	2,108	23,527	1,116
Business Services	42	—	42	—
Total unit revenue	€ 108,662	€ 42,657	66,005	155

The total revenue of our biotech business unit increased by €66.0 million, or 155% from €42.7 million to €108.7 million, due to a significant increase in the revenue recognition of our collaboration revenue, particularly with respect to our collaborations with Genentech (in the Clinical and Manufacturing segments) and Sanofi, as well as revenue from our collaboration with Pfizer, which was entered into in 2018. In the segment Technology Platform, 2018 revenue included €3.9 million for outlicensing patents and know-how to a third party. No further payments are due.

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Research and Development Expenses

The following table summarizes the research and development expenses of our biotech business unit for each period presented (in thousands):

	Year Ended December 31,		Change	
	2018	2017	€	%
Clinical	€ 48,641	€25,099	23,542	94
Technology Platform	60,320	37,019	23,301	63
Manufacturing	31,508	14,764	16,744	113
Business Services	1,979	6,701	(4,722)	(70)
Total unit research and development expenses	€ 142,448	€83,583	58,865	70

The research and development expenses of our biotech business unit increased by €58.9 million, or 70%, to €142.4 million in 2018 from €83.6 million in 2017. This increase was primarily due to increase in clinical development activities, manufacturing for the iNeST clinical study supply and increased headcount.

The following table summarizes our clinical research and development expenses, broken down by drug class and selected platforms, for the years ended December 31, 2018 and 2017 (in thousands):

	Year Ended December 31,	
	2018	2017
Clinical:		
FixVac	€3,018	€2,539
iNeST	13,335	17,223
Other mRNA	9,441	3,124
mRNA	25,794	22,886
Engineered Cell Therapies	653	2,213
Antibodies	14,353	—
Small Molecule Immunomodulators	1,497	—
Other	6,344	—
Total clinical research and development expenses	€48,641	€25,099

Sales and Marketing Expenses

The sales and marketing expenses of our biotech business unit consist of sales and marketing expenses which are not directly attributable to one of our operating segments and are allocated to business services.

The sales and marketing expenses of our biotech business unit decreased by €2.8 million, or 57%, to €2.1 million in 2018 from €4.9 million in 2017. This decrease was primarily due to a reduction of purchased sales and marketing services.

General and Administrative Expenses

The general and administrative expenses of our biotech business unit are attributable to the manufacturing segment and business services.

The general and administrative expenses of our biotech business unit increased by €2.7 million, or 13%, to €23.8 million in 2018 from €21.1 million in 2017. This increase was primarily due to increased purchased administrative services, information technology and office equipment as well as increased depreciation.

Other Result

The other result of our biotech business unit mostly relates to government grants. This income increased by €2.5 million, or 154%, to €4.1 million in fiscal year 2018 from €1.6 million in fiscal year 2017. This increase was primarily attributable to an increase in government grants.

External Services Business Unit

The following table summarizes the statements of operations of our external services business unit for each period presented (in thousands):

	Year Ended December 31,	
	2018	2017
Revenue	€ 18,914	€ 18,941
Cost of sales	(13,358)	(9,318)
Gross profit	5,556	9,623
Research and development expenses	(884)	(1,912)
Sales and marketing expenses	(935)	(1,698)
General and administrative expenses	(2,542)	(2,427)
Other result	559	463
Operating profit	€ 1,753	€ 4,049

Our external services business unit's operating profit decreased by €2.3 million, or 57%, during the year ended December 31, 2018, compared to the prior year. The decrease was primarily attributable to an increase in cost of sales by €4.0 million, or 43%, partially offset by a decrease in research and development and sales and marketing expenses in 2018 by €1.8 million, or 50%.

Liquidity and Capital Expenditures

We have historically funded our operations primarily from private placements of our ordinary shares, proceeds from collaborators and services and proceeds from secured bank loans. As of December 31, 2018, we had cash and cash equivalents of €411.5 million. Cash and cash equivalents are invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation, and consist primarily of cash in banks and on hand and short-term deposits with an original maturity of three months or less, which are stated at fair value.

We maintain two secured credit facilities with Deutsche Bank AG, or Deutsche Bank, to finance the buildout of our JPT Peptide Technologies GmbH facility and Innovative Manufacturing Services GmbH (IMFS) facility. Our €10.0 million secured credit facility, entered into with Deutsche Bank by our subsidiary BioNTech Innovative Manufacturing Services GmbH, bears interest at a rate of 2.15% and matures on December 30, 2027. We have drawn €4.0 million under this facility as of December 31, 2018. The loan is repayable in equal quarterly installments of €312.5 thousand commencing on March 31, 2020. Our €9.45 million secured credit facility, entered into with Deutsche Bank by our subsidiary JPT Peptide Technologies GmbH, bears interest at a rate of 2.08% and matures on September 30, 2028. We have drawn €1.6 million as of December 31, 2018. The loan is repayable by quarterly installments of €286.4 thousand commencing on September 30, 2020. The loan is drawn as construction costs are incurred, and we expect the loan to be fully drawn at January 15, 2020. Each of these facilities is secured by liens over our property.

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Cash Flow

The following table summarizes the primary sources and uses of cash for each period presented (in thousands):

	Year Ended December 31,	
	2018	2017
Net cash flows from (used in):		
Operating activities	(€58,180)	(€52,562)
Investing activities	(67,148)	(52,549)
Financing activities	365,177	(1,643)
Exchange rate differences	(459)	(24,820)
Total cash inflow (outflow)	<u>€239,389</u>	<u>(€131,573)</u>

Operating Activities

We derive cash flows from operations primarily from collaborations, the sale of products and services rendered. Our cash flows from operating activities are significantly influenced by our use of cash for operating expenses and working capital to support the business. We have historically experienced negative cash flows from operating activities as we have invested in the development of our technologies and manufacturing capabilities, as well as for clinical and preclinical development of our product candidates.

Net cash used in operating activities in 2018 was €58.2 million, comprising a loss before tax of €47.7 million, non-cash adjustments of €30.5 million, and a net negative change in assets and liabilities of €41.0 million. Non-cash items primarily included depreciation and share-based compensation expenses. The net negative change in assets and liabilities was primarily due to an increase in trade receivables and a decrease in payables and liabilities.

Net cash used in operating activities for the year ended December 31, 2017 was €52.6 million, comprising a loss before tax of €85.9 million, non-cash adjustments of €43.1 million, and a net negative change in assets and liabilities of €9.8 million. Non-cash items primarily included depreciation and share-based compensation expenses and exchange rate differences. The net negative change in assets and liabilities was primarily due to a decrease in payables and liabilities.

Investing Activities

Net cash used in investing activities in 2018 was €67.1 million, of which €37.3 million was attributable to the purchase of intangible assets, including payment for the license agreement for the CellScript, LLC patent, and €30.6 million was attributable to the purchase of property, plant and equipment, partially offset by proceeds from the sale of property, plant and equipment amounting to €705 thousand.

Net cash used in investing activities in 2017 was €52.5 million, of which €33.4 million was attributable to the purchase of intangible assets, including payment for the license agreement for the CellScript, LLC patent, and €24.3 million was attributable to the purchase of property, plant and equipment, partially offset by proceeds from the sale of property, plant and equipment amounting to €5.2 million.

Financing Activities

Our primary financing activities consist of issuances of share capital, proceeds from bank loans and payments of finance lease liabilities.

During the year ended December 31, 2018, we generated cash from financing activities of €365.2 million, primarily from proceeds from the issuance of shares in the amount of €361.7 million and proceeds from loans and borrowings in the amount of €5.6 million, partially offset by the payment of finance lease liabilities in the amount of €2.1 million.

We had insignificant financing activities in 2017.

Operation and Funding Requirements

Since our inception, we have incurred significant losses and negative cash flows from operations due to our significant research and development expenses and our investment in our manufacturing capabilities. We have an accumulated losses of €245.8 million as of December 31, 2018. We expect to continue to incur significant losses in the foreseeable future and expect our expenses to increase in connection with our ongoing activities, particularly as we continue research and development and clinical activities for our product candidates. In addition, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company. Our expenses will also increase if, and as, we:

- continue or expand our research or development of our programs in preclinical development;
- continue or expand the scope of our clinical trials for our product candidates;
- initiate additional preclinical studies or clinical or other trials for our product candidates, including under our collaboration agreements;
- continue to invest in our immunotherapy platforms to conduct research to identify novel technologies;
- change or add to internal manufacturing capacity or capability;
- change or add additional suppliers;
- add additional infrastructure to our quality control, quality assurance, legal, compliance and other groups to support our operations as we progress our product candidates toward commercialization;
- attract and retain skilled personnel;
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts, including expansion of sites in Germany and new sites in the United States;
- seek marketing approvals and reimbursement for our product candidates;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- seek to identify and validate additional product candidates;
- acquire or in-license other product candidates and technologies;
- make milestone or other payments under any in-license agreements;
- maintain, protect, defend, enforce and expand our intellectual property portfolio; and
- experience any delays or encounter issues with any of the above.

We are subject to all of the risks related to the development and commercialization of pharmaceutical products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. We believe that our cash and cash equivalents as of December 31, 2018, together with the proceeds of this offering, will be sufficient to enable us to fund our operating expenses and capital expenditure requirements through at least the next months.

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Our future funding requirements will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of preclinical or nonclinical studies and clinical trials for our product candidates;
- the results of research and our other platform activities;
- the clinical development plans we establish for our product candidates;
- the terms of any agreements with our current or future collaborators;
- the number and characteristics of product candidates that we develop or may in-license;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, EMA and other comparable regulatory authorities;
- the cost of filing, prosecuting, obtaining, maintaining, protecting, defending and enforcing our patent claims and other intellectual property rights, including actions for patent and other intellectual property infringement, misappropriation and other violations brought by third parties against us regarding our product candidates or actions by us challenging the patent or intellectual property rights of others;
- the effect of competing technological and market developments, including other products that may compete with one or more of our product candidates;
- the cost and timing of completion and further expansion of clinical and commercial scale manufacturing activities sufficient to support all of our current and future programs; and
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive marketing approval and reimbursement in regions where we choose to commercialize our products on our own.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2018 and the effects that such obligations are expected to have on our liquidity and cash flows in future periods (in thousands):

	Payments Due by Period				
	Total	Less than 1 year	1 – 3 years	3 – 5 years	More than 5 years
Leases	€ 73,669	3,813	6,999	6,333	56,524
Loans	5,600	—	5,350	250	—
Total contractual cash obligations	€ 79,269	3,813	12,349	6,583	56,524

We have lease agreements for land and buildings in all of our locations, which will expire from 2019 to 2027. In addition, we have various leases for equipment and cars which will expire in 2019 and 2020. The amounts in the table above represent our fixed contractual lease obligations and do not include the optional extensions.

In addition to the above obligations, we enter into a variety of agreements and financial commitments in the normal course of business. The terms generally allow us the option to cancel, reschedule and adjust our

requirements based on our business needs, prior to the delivery of goods or performance of services. It is not possible to predict the maximum potential amount of future payments under these agreements due to the conditional nature of our obligations and the unique facts and circumstances involved in each particular agreement.

Critical Accounting Policies and Use of Estimates

Our consolidated financial statement for the fiscal year ending December 31, 2018 have been prepared in accordance with IFRS, as issued by the IASB.

The preparation of the consolidated financial statements for the fiscal year ended December 31, 2018 in accordance with IFRS required the use of estimates and assumptions by the management that affect the value of assets and liabilities—as well as contingent assets and liabilities—as reported on the balance sheet date, and revenues and expenses arising during the fiscal year. The main areas in which assumptions, estimates and the exercising of a degree of discretion are appropriate relate to the determination of the useful lives of non-current assets and the formation of provisions, as well as income taxes. We based our assumptions and estimates on parameters available when the consolidated financial statements were prepared. Existing circumstances and assumptions about future developments, however, may change due to market changes or circumstances arising that are beyond our control. Hence, our estimates may vary from the actual values.

We believe that the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our consolidated financial statements. We have reviewed these critical accounting policies and estimates with the audit committee of our Supervisory Board.

Revenue Recognition

We recognize revenue through collaboration and license agreements, rendering of services and sales of products.

Under our collaboration and license agreements, described in more detail in “Business—XIV. Third-Party Strategic Collaborations,” we receive milestone payments, up-front licensing payments and reimbursement of development expenses, for committing to collaborate with the respective collaborator to research and develop certain pharmaceutical products. Such collaboration agreements also include licenses of certain of our intellectual property to the respective collaborators. As these agreements comprise several promises, it must be assessed whether these promises are capable of being distinct within the context of the contract. For some agreements, this results in us accounting for all goods and services promised in a collaboration and license agreement as a single performance obligation with a single measure of progress. We determined that the grant of the license is the predominant promise within the (combined) performance obligation and the promise to grant a license is accounted for as a performance obligation satisfied over time as our customer simultaneously receives and consumes the benefits from our performance. Up-front licensing payments and reimbursement for development expenses are initially deferred on our statement of financial position and subsequently recognized as revenue over time, either as costs are incurred or over the length of the agreement, as above. Milestone payments are included in the transaction price at the amount stipulated in the respective agreement and recognized as revenue if the occurrence of reaching the future milestone is highly probable.

The collaboration and license agreements may also provide for additional profit-sharing or royalty income, to the extent a pharmaceutical product is successfully commercialized. To date, no such income has been recognized.

We provide development and manufacturing services to customers and recognize revenue over time using an input-based method to measure progress toward complete satisfaction of the service because the customer simultaneously receives and consumes the benefits provided. We recognize such revenue based on a fixed agreed amount and therefore it is not subject to estimation.

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We recognize revenue from the sale of medical products (*e.g.*, peptides and retroviral vectors for clinical supply) when control has been transferred. The transaction price is quoted in the relevant price lists in force at the date of the customer placing the respective order for such products, and is not subject to significant discounts or rebates.

For further information regarding our revenue recognition policy, please refer to Note 2.3.4 of our consolidated financial statements included elsewhere in this prospectus.

Research and Development Expenses

Research and development expenses are expensed as incurred.

Share-Based Compensation

Employees (and others providing similar services) receive remuneration in the form of share-based payments which are settled in equity instruments (equity-settled transactions). In addition, in the past, employees and others providing similar services were granted share appreciation rights which were settled in equity instruments (equity-settled transactions).

The cost of equity-settled transactions is determined by the fair value at the grant date. These costs are recognized in research and development expenses, sales and marketing expenses or general and administrative expenses, together with a corresponding increase in equity (other capital reserves), over the period in which the service is provided (the vesting period). The cumulative expense recognized for equity-settled transactions at each reporting date until the vesting date reflects the extent to which the vesting period has expired and our best estimate of the number of equity instruments that will ultimately vest. The expenses or credits in the statement of profit or loss for a period represent the movement in cumulative expense recognized as at the beginning and end of that period.

Fair Value of Share-Based Awards

Employee Stock Ownership Plan

On November 15, 2018, we established a share option program that grants selected employees options to receive shares in the Company. The program is designed as an Employee Stock Ownership Plan and option grants are classified as share-based equity-settled remuneration. As at December 31, 2018, we had 658,109 share options outstanding with a weighted-average exercise price of €182.53.

The following share options were issued to the management board:

Name	Number of Ordinary Shares Underlying Options	Option Exercise Price (€)
Prof. Ugur Sahin, M.D.	101,686	182.53
Sean Marett	33,895	182.53
Dr. Sierk Poetting, Ph.D.	33,895	182.53
Dr. Özlem Türeci, M.D.	108,463	182.53

The fair value of the employee share options has been measured using a binomial model. Service conditions were not taken into account in measuring the fair value.

The share options can only be exercised if as of the date of exercise the current price is at least equal to a certain threshold amount. The threshold amount constitutes the exercise price increased by 8 basis points on each anniversary of the allocation date (September 26, 2018). Moreover, the share options can only be exercised if we have completed a public offering in the United States. Both of these conditions have been incorporated into the fair value at grant date.

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The inputs used in the measurement of the fair values at grant date of the Employee Stock Ownership Plan were as follows:

	Grant date November 15, 2018
Fair value at grant date	€ 133.40
Share price at grant date	€ 259.28
Exercise price	€ 182.53
Expected volatility (%)	46%
Expected life (years)	5.84
Expected dividends (%)	0%
Risk-free interest rate (%)	0.05%

The share price at grant date was determined by reference to an observable transaction. We involved an independent third-party appraiser to confirm that the transaction selected was appropriate for the purposes of determining fair value. Expected volatility was based on an evaluation of the historical and the implied volatilities of comparable companies over the historical period commensurate with the expected term. The expected term was based on general optionholder behavior for employee options.

Share Appreciation Rights

On December 1, 2017, we granted 32,373 shares to selected employees under the share appreciation rights (SAR) program. The shares vested immediately at the grant date (December 2017) as there were no vesting conditions.

Income Taxes

Current income tax assets and liabilities are measured at the amount expected to be recovered from or paid to the taxation authorities. The tax rates and tax laws used to compute the amount are those that are enacted or substantively enacted at the reporting date in the countries where we operate and generate taxable income. Management periodically evaluates positions taken in the tax returns with respect to situations in which applicable tax regulations are subject to interpretation and establishes provisions where appropriate.

Deferred tax is provided using the liability method on temporary differences between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes at the reporting date. As long as taxable profit is not probable, no tax assets are recognized.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply in the year when the asset is realized or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted at the reporting date. Deferred tax items are recognized in correlation with the underlying transaction either in other comprehensive income or directly in equity.

We offset deferred tax assets and deferred tax liabilities if and only if we have a legally enforceable right to set off current tax assets and current tax liabilities and the deferred tax assets and deferred tax liabilities relate to income taxes levied by the same taxation authority on either the same taxable entity or different taxable entities which intend either to settle current tax liabilities and assets on a net basis, or to realize the assets and settle the liabilities simultaneously, in each future period in which significant amounts of deferred tax liabilities or assets are expected to be settled or recovered.

Recently Issued Accounting Pronouncements

The following standards and interpretations were recently issued but were not effective as of December 31, 2018. We intend to adopt these new and amended standards and interpretations, if applicable. We do not expect a significant impact of the application of these standards.

Standards/Interpretation		Date of application
IFRIC 23	Uncertainty over income tax treatment	January 1, 2019
Amendments to IFRS 9	Prepayment features with negative compensation	January 1, 2019
Amendments to IAS 19	Plan amendment, curtailment or settlement	January 1, 2019
Amendments to IAS 28	Long-term interests in associates and joint ventures	January 1, 2019
Annual improvements 2015 -2017 Cycle	Annual improvement cycle to IFRS 2015 -2017	January 1, 2019

Quantitative and Qualitative Disclosures About Market Risk

We are exposed to various risks in relation to financial instruments, including liquidity risk and currency risk. Our risk management is coordinated by our executive board. We do not engage in the trading of financial assets for speculative purposes. The most significant financial risks to which we are exposed include the risks discussed below.

Currency risk

We are subject to currency risk, as our income and expenditures are denominated in Euro and the U.S. dollar. As such, we are exposed to exchange rate fluctuations between these currencies. We aim to match U.S. dollar cash inflows with U.S. dollar cash outflows where possible, and we do not hedge this exposure. If we increase sales of our products in the United States, we would expect to have significant increases in cash balances, revenues and sales and marketing expenses denominated in U.S. dollars, while we would expect the majority of our development and operating expenses to remain denominated in Euro.

We publish our consolidated financial statements in Euro. Revenue and expenses incurred in U.S. dollars will be translated into Euro when they are reported in our consolidated financial statements. As a result, any substantial future appreciation or decline of the U.S. dollar against the Euro could have a material effect on our revenue and profitability. As an example, if the U.S. dollar weakens by 10% against the Euro, cash and cash equivalents as of December 31, 2018 would decrease by €16.0 million, or 4%.

Material Weakness

Historically, we have been a private company and did not maintain the internal accounting and financial reporting resources necessary to comply with the obligations of a public reporting company, including maintaining effective internal control over financial reporting. We identified a material weakness primarily related to (i) our lack of sufficient accounting and supervisory personnel with the appropriate level of technical accounting experience/training and (ii) our lack of consistent application of its accounting processes and procedures, particularly in the areas of share-based compensation, revenue from collaborators and capitalization of tangible and intangible assets. As of consequence of point (i) above, management relies on the assistance of outside advisors with expertise in these matters to assist in the preparation of IFRS financial statements and compliance with SEC reporting obligations in relation to our anticipated U.S. public offering. However, our lack of sufficient accounting and supervisory personnel also means there has also been a lack of supervision over external consultants. We identified several other audit adjustments including leasing, inventory and accruals, which indicate difficulties in properly applying accounting policies and processes consistently throughout the organization and omission of assessment of critical accounting guidance for complex areas or areas requiring judgments indicating inadequate supervision of its external consultants.

We have begun to develop a remediation plan to address this material weakness. Our remediation plan includes the hiring of additional staff, documenting and implementing consistent accounting policies and procedures and providing additional training to our accounting and finance staff. While we are working to remediate the material weakness as quickly and efficiently as possible, we cannot at this time provide a timeline on such remediation. See our risk factor on this material weakness in “Risk Factors—Risks Related to Ownership of the ADSs and this Offering.”

JOBS Act and Emerging Growth Company Status

In April 2012, the JOBS Act was enacted. The exemptions and reduced reporting requirements under the JOBS Act for emerging growth companies include presentation of only two years of audited financial statements in a registration statement for an initial public offering, an exemption from the requirement to provide an auditor’s report on internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act, an exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation, and less extensive disclosure about our executive compensation arrangements. Additionally, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Such provisions are only applicable under U.S. GAAP. As a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required or permitted by the IASB.

We will remain classified as an emerging growth company until the earlier of (i) the last day of the fiscal year following the fifth anniversary of the date of the completion of this offering, (ii) the last day of the first fiscal year in which our annual gross revenues exceed \$1.07 billion, (iii) the date on which we have issued more than \$1 billion of non-convertible debt securities during the previous three years, or (iv) the date on which we are deemed a large accelerated filer under the rules of the SEC, which means the first day of the year following the first year in which, as of the last business day of our most recently completed second fiscal quarter, the market value of our common equity that is held by non-affiliates exceeds \$700 million.

BUSINESS

I. Overview

BioNTech was founded in 2008 on the understanding that every cancer patient's tumor is unique and that in order to effectively address this challenge, we must create individualized treatments for each patient. To realize this vision, we combine decades of groundbreaking research in immunology, cutting-edge therapeutic platforms, and a variety of patient profiling and bioinformatic tools to develop individualized immunotherapies for cancer as well as other diseases. We leverage powerful new therapeutic mechanisms and exploit a diverse array of biological targets to harness the power of each patient's immune system to address the unique molecular signature of each patient's underlying disease. We believe we are uniquely positioned to develop and commercialize the next generation of immunotherapies with the potential to significantly improve clinical outcomes for patients and usher in a new era of individualized medicine.

We and our collaborators have advanced a development pipeline of over 20 product candidates, of which seven have entered into eight ongoing clinical trials. While we believe our approach is broadly applicable across a number of therapeutic areas, our most advanced programs are focused on oncology, where we have treated over 250 patients across 17 tumor types to date. Our immunotherapy drug classes consist of messenger ribonucleic acid, or mRNA, therapeutics, engineered cell therapies, antibodies and small molecule immunomodulators. Our product candidates span oncology, infectious diseases and rare diseases.

We have assembled an exceptional team of over 1,000 employees and have established relationships with seven pharmaceutical collaborators, including Genentech, Inc., or Genentech, Sanofi S.A., or Sanofi, Genmab A/S, or Genmab, Genevant Sciences, or Genevant, Eli Lilly and Company, or Eli Lilly, Bayer AG, or Bayer, and Pfizer Inc., or Pfizer. We have built out comprehensive highly automated, on-demand in-house manufacturing capabilities that complement the development of our individualized immunotherapies.

Our programs are based on our pioneering development of numerous immunotherapeutic platforms, designed to provide patients with highly tailored treatment options. Our platforms leverage the following four drug classes:

- **mRNA Therapeutics.** We are utilizing messenger ribonucleic acid, or mRNA, to deliver genetic information to cells, where it is used to express proteins for therapeutic effect. We are developing a portfolio of immunotherapies that utilize four different mRNA formats and three different formulations to derive five distinct platforms for the treatment of cancer. Three of these platforms are currently in human testing: (i) our off-the-shelf shared antigen immunotherapy, or FixVac; (ii) our individualized neoantigen specific immunotherapy, or iNeST, in collaboration with Genentech; and (iii) our intratumoral immunotherapy, in collaboration with Sanofi. In addition, we are developing two platforms in which we use mRNA to express directly in the patient either (a) particular antibodies, or RiboMabs, or (b) specific cytokines, or RiboCytokines. In collaboration with Pfizer and Genevant, we are also leveraging our mRNA technology beyond oncology to treat influenza and rare diseases.
- **Engineered Cell Therapies.** We are developing a range of novel cell therapies in which the patient's T cells are modified to target cancer-specific antigens. These include two platforms for the treatment of solid tumors: chimeric antigen receptor, or CAR, T cells and T cell receptor, or TCR, programs. We are also combining our mRNA FixVac platform with our first CAR T product candidates to enhance the persistence of CAR-T cells *in vivo*.
- **Antibodies.** We are developing, in collaboration with Genmab, next-generation bispecific antibodies that are designed to target immune checkpoints that modulate the patient's immune response to cancer. We are also exploring additional targeted cancer antibody approaches utilizing our in-house and recently acquired antibody capabilities.
- **Small Molecule Immunomodulators.** We use small molecules to augment the activity of other drug classes by inducing specific and discrete patterns of immunomodulation. We are developing a small molecule toll-like receptor 7, or TLR7, immunomodulator for the treatment of solid tumors.

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We have leveraged these four drug classes to build a robust pipeline of product candidates. Our pipeline includes seven product candidates in eight ongoing clinical trials. Our most advanced programs are focused on oncology, where we have to-date treated over 250 patients across 17 solid tumor types. We also are developing more than 10 additional preclinical programs and expect to initiate clinical testing with several of them in the near future. We expect to have up to 10 clinical-stage programs by the end of 2019, and are targeting the advancement of five product candidates into the clinic per year in 2019 and 2020, with meaningful clinical data updates for up to five programs expected by the end of 2020. In our Phase 1 trials, we have observed antigen-specific immune responses in over 90% of advanced melanoma patients treated with BNT111, our lead FixVac off-the-shelf product candidate, as a single agent. In addition, we have observed single-agent antigen-specific immune responses in patients treated with BNT121, the precursor to RO7198457 (BNT122), our lead iNeST product candidate. In both trials, we have observed durable objective responses (reduction in tumor volume) in both the monotherapy and checkpoint-combination settings.

We have established multiple collaborations to advance our science and development capabilities and provide non-dilutive capital. We have entered into selective collaborations with leading pharmaceutical companies where a collaborator may bring incremental expertise or resources that we currently do not possess in-house. To date, we have formed relationships with seven pharmaceutical companies, which comprise Genentech, Sanofi, Genmab, Genevant, Eli Lilly, Bayer and Pfizer. We have entered into some of these collaborations in order to advance our technologies and business outside of our initial focus on cancer. We are collaborating with Pfizer to develop an influenza vaccine through our mRNA-based immunotherapy technology and have a collaboration with Genevant to develop protein replacement therapies in up to five rare disease indications. We have also collaborated with the University of Pennsylvania, or Penn, to develop mRNA-based vaccines in up to 10 additional infectious disease indications. In addition, we have a relationship with Translational Oncology at the University Medical Center of the Johannes Gutenberg University Mainz (Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH), or TRON, to further our immunotherapy research. We either wholly own or retain significant rights to all of our clinical stage programs, either in the form of a global share of profit and co-commercialization rights with our collaborators in certain markets or significant royalties and milestones.

Our ability to develop, control and optimize the manufacturing process is a core strategic pillar and competitive advantage across our portfolio, in particular for our individualized product candidates. We operate three Good Manufacturing Practice, or GMP, certified manufacturing facilities in Germany, where we manufacture mRNA therapeutics and engineered cell therapies for our own pipeline and for external customers. We operate a fourth manufacturing facility in Germany where we manufacture custom peptides to support our extensive immuno monitoring activities within our development programs. We have collaborated with Siemens AG, or Siemens, to develop efficient, semi-automated processes to produce our individualized mRNA immunotherapies on demand.

We were founded in 2008, and to date we have raised \$1.3 billion of capital in private placements of our shares and from our collaborators. Our investors include the Strüngmann Family Office, which is our majority shareholder, MIG Fonds, Fidelity Management & Research Company, Redmile Group, Janus Henderson Investors and the Invus Group, LLC.

Our Team

Our team combines proven biotechnology entrepreneurs, world-renowned immunologists and sophisticated biopharma investors. We were founded in 2008 by our scientific founders, Prof. Ugur Sahin, M.D., Prof. Christoph Huber, M.D. and Özlem Türeci, M.D., with a seed investment of €150 million from the Strüngmann family, through its investment vehicle AT Impf, and MIG Fonds, or MIG. Andreas and Thomas Strüngmann are serial entrepreneurs, having co-founded Hexal AG, a German pharmaceutical firm, which they built and sold to Novartis, along with their majority stake in Eon Labs, Inc., a U.S. public pharmaceutical firm, for a combined €5.6 billion (at the time, \$8.3 billion). After selling Hexal, they founded a family office focused on healthcare.

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The Strüngmann family office and MIG have invested in, helped build and sold, either on their own or together, a number of biotechnology and healthcare companies, such as SuppreMol, Ganymed AG, or Ganymed, CorImmune, Sivantos (former Siemens hearing aid business), Press Ganey (surgery survey company) and Apceth (cell therapy manufacturing company). Helmut Jeggle and Michael Motschmann, on behalf of the Strüngmann family and MIG, respectively, along with Dr. Huber, were founding members of our Supervisory Board.

BioNTech has been supported since its inception by Prof. Rolf Zinkernagel, M.D., Ph.D and Prof. Hans Hengartner, Ph.D., who serve on our Scientific Advisory Board. Dr. Zinkernagel is a Professor Emeritus at the University of Zurich, University Hospital, and former head of the Institute of Experimental Immunology in Zurich. Prof. Zinkernagel was awarded the Nobel Prize in 1996 for the discovery of how the immune system recognizes virus-infected cells. Prof. Hengartner is a world-renowned immunologist and Professor Emeritus at the Federal Institute of Technology ETH Zurich and the University of Zurich.

At the time of BioNTech's founding, Dr. Sahin and Dr. Türeci were the Chief Scientific Officer and the Chief Medical Officer, respectively, of Ganymed, a private biotechnology company that was founded in 2001 and was focused on developing a monoclonal antibody targeting CLDN18.2 (zolbetuximab). The Strüngmann family and MIG were majority investors in Ganymed. When Dr. Sahin became Chief Executive Officer of BioNTech, he stepped down from the management board of Ganymed and became the chair of its Scientific Advisory Board. Dr. Türeci continued to lead Ganymed as its Chief Executive Officer until it was sold to Astellas Pharma Inc. in 2016 for up to \$1.4 billion.

Our initial group of scientific founders have been joined by experienced pharmaceutical executives, immunologists and biotechnology specialty investors. Sean Marett, our Chief Business Officer and Chief Commercial Officer, led the business development teams at Evotec, and previously was an executive at GlaxoSmithKline in the United States. Dr. Sierk Poetting, our Chief Financial Officer and Chief Operating Officer, joined us from Sandoz, where he served as the Chief Financial Officer in North America. We have also attracted talented scientists such as Katalin Karikó, our Senior Vice President & Head of RNA Protein Replacement, who has more than 30 years of experience working with RNA, has published more than 70 peer-reviewed papers and is co-inventor on mRNA-related patents, including a foundational patent relating to modified mRNA. In addition to the Strüngmann family and MIG, our investors include Fidelity Management & Research Company, Redmile Group, Janus Henderson Investors, the Invus Group, LLC, Salvia GmbH, Eli Lilly, Sanofi and Pfizer. Since our founding, we have raised \$1.3 billion of capital in private placements of our shares and through collaborations.

A. Our Pipeline of Product Candidates

We are advancing a deep and broad portfolio of product candidates derived from our four drug classes focused on the treatment of cancer, infectious and rare diseases:

Oncology									
Drug Class	Platform	Product Candidate	Indication (Targets)	Preclinical	Phase 1	Phase 2	Phase 3	Rights/ Collaborator	
mRNA	FixVac (fixed combination of shared cancer antigens)	BNT111	Advanced Melanoma (Adjuvant & Metastatic)	█	█			Global	
		BNT112	Prostate Cancer	█				Global	
		BNT113	HPV+ Head and Neck Cancer ¹	█				Global	
		BNT114	Triple Negative Breast Cancer	█				Global	
		BNT115, BNT116	Other Cancers, including Ovarian Cancer	█				Global	
	iNeST (patient-specific cancer antigen therapy)	RO7198457 (BNT122)	1L Melanoma with CPI ²	█	█			Genentech (Global 50:50 profit/loss share)	
			Multiple Solid Tumors	█					
	Intratumoral Immunotherapy	SAR441000 (BNT131)	Solid Tumors (<i>IL-12sc</i> , <i>IL-15sushi</i> , <i>GM-CSF</i> , <i>IFNα</i>)	█	█			Sanofi (Global profit/loss share)	
	RiboMabs (mRNA-encoded antibodies)	BNT141	Multiple Solid Tumors	█				Global	
		BNT142	Multiple Solid Tumors (<i>CD3+CLDN6</i>)	█				Global	
	RiboCytokines (mRNA-encoded cytokines)	BNT151	Multiple Solid Tumors (<i>Optimized IL-2</i>)	█				Global	
		BNT152	Multiple Solid Tumors (<i>IL-7</i>)	█				Global	
		BNT153	Multiple Solid Tumors (<i>IL-2</i>)	█				Global	
	Engineered Cell Therapies	CAR-T Cells	BNT211	Multiple Solid Tumors (<i>CLDN6</i>)	█				Global
			BNT212	Pancreatic, Other Cancers (<i>CLDN18.2</i>)	█				Global
TCRs		To be selected	Solid Tumors	█				Eli Lilly (Exclusive license option)	
		To be selected	All Tumors	█				Global	
Antibodies	Next-Gen CP ³ Immuno-modulators	GEN1046 (BNT311)	Multiple Solid Tumors (<i>PD-L1</i> × <i>4-1BB</i>)	█	█			Genmab (Global 50:50 profit/loss share)	
		BNT312	Multiple Solid Tumors (<i>CD40</i> × <i>4-1BB</i>)	█					
	Targeted Cancer Antibodies	MVT-5873 (BNT321)	Pancreatic Cancer (<i>sLe^x</i>)	█	█			Global	
SM Immunomodulators	Toll-Like Receptor Binding	BNT411	Solid Tumors (<i>TLR7</i>)	█				Global	
Other									
Drug Class	Platform	Product Candidate	Indication (Targets)	Preclinical	Phase 1	Phase 2	Phase 3	Rights/ Collaborator	
mRNA	Infectious Disease Immunotherapies	BNT161	Influenza	█				Pfizer	
			Up to 10 Indications	█				Penn ⁴	
	Rare Disease PRT ⁵	To be selected	5 Rare Disease Indications	█				Genevant (Global 50:50 profit/loss share)	

¹ BNT113 is currently being studied in an investigator-initiated Phase 1 trial

² Checkpoint Inhibitor

³ Checkpoint

⁴ We are eligible to receive worldwide licenses

⁵ Protein Replacement Therapy

1. Oncology

FixVac. Our FixVac product candidates contain selected combinations of unmodified, pharmacologically optimized mRNA encoding known cancer-specific shared antigens. They feature our proprietary immunogenic mRNA backbone and proprietary RNA-lipoplex, or RNA-LPX, delivery formulation, designed to enhance stability and translation, target dendritic cells and trigger both innate and adaptive immune responses. We are currently evaluating three FixVac product candidates in clinical trials, including BNT111 in a Phase 1 trial in metastatic melanoma, BNT113 in a Phase 1 trial in HPV+ head and neck cancers and BNT114 in a Phase 1 trial in triple negative breast cancer.

As of the July 2019 interim cut-off, 89 patients with metastatic melanoma had been dosed at least once in our Phase 1 clinical trial of BNT111. Forty-two of these patients had macroscopic tumor lesions at the time they were enrolled, and these patients were evaluated for preliminary clinical activity, with 25 receiving BNT111 as a monotherapy and 17 receiving BNT in combination with a checkpoint inhibitor. Four of the 25 patients who received BNT111 as a monotherapy demonstrated a partial response and seven had stable disease following treatment. Six of the 17 patients who received BNT111 in combination with a checkpoint inhibitor demonstrated a partial response and two had stable disease following treatment.

We expect to initiate a Phase 2 trial for BNT111 in metastatic melanoma in the first half of 2020 and a Phase 1 trial for BNT112, our FixVac product candidate targeting prostate cancer, in the second half of 2019. In addition, we are planning to initiate a Phase 2 study for BNT113 in HPV+ cancers by the first half of 2020.

Individualized neoantigen specific immunotherapy (iNeST). Our iNeST immunotherapies contain unmodified, pharmacologically optimized mRNA encoding up to 20 patient-specific neoantigens, and also feature our proprietary RNA-LPX formulation. We are conducting, in collaboration with Genentech, two clinical trials of our iNeST product candidate, RO7198457 (BNT122), including a randomized Phase 2 trial in first-line metastatic melanoma in combination with pembrolizumab, a checkpoint inhibitor, and a Phase 1a (monotherapy)/1b (in combination with atezolizumab) trial in multiple solid tumors. In a previous Phase 1 trial of BNT121, an earlier version of our iNeST product candidate that was administered intranodally, in 13 patients with metastatic melanoma, we observed stable progression-free survival in nine patients for up to 41 months following surgery and treatment with BNT121. In addition, we observed an objective response in three out of five patients, two with iNeST alone and one patient who also received checkpoint immunotherapy. We also observed a significant decrease in the cumulative recurrence rate post-treatment as compared to pre-treatment. We and Genentech expect to report a data update from our RO7198457 (BNT122) Phase 1 trial in multiple solid tumors, and interim data from our RO7198457 (BNT122) Phase 1 trial in first-line metastatic melanoma, in the second half of 2020.

mRNA intratumoral immunotherapy. In collaboration with Sanofi, we are conducting a Phase 1 trial of BNT131, our first mRNA-based intratumoral immunotherapy, encoding the IL-12sc, IL-15sushi, GM-CSF and INF α cytokines, in solid tumors.

CLDN6 CAR-T cell immunotherapy. We are developing a proprietary chimeric antigen receptor T cell, or CAR T, product candidate, BNT211, targeting Claudin-6, or CLDN6, a novel solid tumor-specific antigen. We developed BNT211 utilizing our target discovery engine, and we plan to administer it along with a FixVac “primer” to boost the immune response and promote CAR-T cell persistence. We expect to initiate a Phase 1/2 clinical trial for BNT211 in the first half of 2020.

Next-generation checkpoint immunomodulators. We are developing, in collaboration with Genmab, novel next-generation bispecific antibodies that are designed for conditional activation of immunostimulatory checkpoint molecules. Our first bispecific candidates are GEN1046 (BNT311), which targets PD-L1 in conjunction with 4-1BB, and BNT312, which targets CD40 in conjunction with 4-1BB. While 4-1BB is a known immune checkpoint target that is expressed on T cells and natural killer, or NK, cells, prior attempts to target 4-1BB with monoclonal antibodies have been severely limited by liver toxicities. Our 4-1BB targeting product candidates are designed to avoid toxicities by conditionally activating a 4-1BB receptor only together with the binding of either PD-L1 or CD40. We have initiated a Phase 1 trial of GEN1046 (BNT311) in solid tumors, and expect to initiate a Phase 1 trial for BNT312 in the second half of 2019.

Targeted Cancer Antibodies. We recently acquired an antibody with a novel mode of action, MVT-5873 (BNT321). BNT321 is a fully human IgG1 monoclonal antibody targeting sialyl Lewis A (sLe^a), a novel epitope expressed specifically in pancreatic and other solid tumors. MVT-5873 (BNT321) is currently in Phase 1 clinical development in pancreatic cancer, which we intend to resume in the second half of 2019. Positive interim data were announced in February 2018.

In addition, we have several other cancer immunotherapy programs in development, including:

- *RiboMabs:* novel classes of mRNA-based therapeutics that are designed to encode antibodies directly in the patient's body. We expect to initiate a Phase 1 clinical trial for our first RiboMab product candidate, BNT141, in the first half of 2020, and for our second product candidate, BNT142, in the second half of 2020.
- *RiboCytokines:* novel classes of mRNA-based therapeutics that are designed to encode cytokines directly in the patient's body. We expect to initiate a Phase 1 clinical trial for our first two RiboCytokine product candidates, BNT151 and BNT152, in the first half of 2020.
- *TCR therapy:* T cells with engineered TCRs that are designed to specifically target cancer cells.
- *Small molecule immunomodulators:* novel intratumoral agents that trigger inflammation and improvement of antigen presentation by antigen-presenting cells. We expect to initiate a Phase 1 clinical trial for our first small molecule immunomodulator product candidate, BNT411, in the first half of 2020.

2. *Infectious Diseases*

We have collaborated with third parties to exploit the immunotherapeutic properties of our mRNA drug class for the treatment and prevention of infectious diseases. We expect to advance our first programs into the clinic by the end of 2020.

- *Flu vaccine:* In August 2018, we entered into a collaboration with Pfizer to develop mRNA-based immunotherapies for the prevention of influenza.
- *Infectious diseases:* In October 2018, we entered into a research collaboration with Penn, under which we have the exclusive option to develop and commercialize mRNA immunotherapies for the treatment of up to 10 infectious disease indications.

3. *Rare Diseases*

In 2018, we collaborated with Genevant in order to capitalize on opportunities for our mRNA technology in rare disease indications potentially featuring expedited paths to market. We will combine our mRNA technology with Genevant's lipid nanoparticle, or LNP, delivery technology to create up to five mRNA protein replacement therapies for the treatment of rare diseases with high unmet medical needs. We expect our first compound to enter the clinic by the end of 2020.

II. *Our Strengths*

We are developing a broad portfolio of technologies and product candidates that we believe position us at the forefront of the next generation of targeted, specific immunotherapies. Our key strengths include:

We are a next-generation immunotherapy powerhouse pioneering individualized immunotherapies to address the shortcomings of existing treatments for cancer and other indications with significant unmet need.

- We have established leadership and expertise in immunology and oncology. Through 11 years of rigorous scientific investigation and clinical translation, we have developed a portfolio of disruptive immunotherapy technologies designed to address the challenges of disease heterogeneity and patient variability.

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- Our team have consistently been first-movers and have published over 150 scientific papers in leading peer reviewed journals. We were the first to develop an intravenously delivered mRNA-based human therapeutic, the first to advance an individualized mRNA-based cancer immunotherapy into clinical trials, and the first to establish scaled in-house manufacturing for such a product candidate.
- Since our founding in 2008, we have advanced four of our therapeutic platforms into human clinical trials, generated promising early evidence of clinical activity in several cancer types, raised over \$1.3 billion of capital from renowned global biopharmaceutical investors, formed collaborations with seven leading pharmaceutical companies, and acquired complementary assets ranging from research and manufacturing units to clinical programs.
- Our efforts are driven by a group of over 1,000 employees including over 400 scientists, overseen by our founders who are internationally recognized thought leaders in their disciplines.

We are developing product candidates addressing highly specific immuno-oncology targets, employing a technology-agnostic approach.

- Our portfolio includes four drug classes, spanning mRNA therapeutics, engineered cell therapies, antibodies and small molecule immunomodulators, which can potentially be used alone or in combination to enhance therapeutic effect.
- Our oncology pipeline includes seven product candidates in eight ongoing clinical trials, and more than 10 preclinical programs.
- We have developed significant expertise in the selection of optimal combinations of targets for the specific and individualized treatment of particular cancers. We have assembled libraries of more than 200 proprietary or known shared antigens and have developed predictive algorithms capable of efficiently identifying multiple neoantigens on an individualized basis for any patient.
- Our approach enables real-time monitoring of therapeutic effect on the immune system in a feedback loop of biological surveillance that we believe has the potential to further enhance the success of individualized immunotherapy approaches.

We have tested our lead mRNA candidates in over 250 patients and have already demonstrated signs of single-agent clinical activity in our two lead programs.

- Our most advanced programs are focused on oncology where we have to-date dosed over 250 patients across 17 solid tumor types.
- In our Phase 1 trials, we observed single-agent antigen specific immune responses in over 90% of advanced melanoma patients treated with BNT111, our lead off-the-shelf immunotherapy product candidate leveraging our wholly owned FixVac platform. In addition, we observed single-agent antigen specific immune responses in patients treated with BNT121, the precursor to our lead individualized neoantigen specific immunotherapy product candidate derived from our iNeST platform. For both candidates, we have observed durable objective responses in both the monotherapy and checkpoint combination settings.

We have developed a very broad and advanced mRNA therapeutic portfolio for the treatment of cancer.

- We have over a decade of experience pioneering the use of mRNA as a drug class, yielding five distinct mRNA platforms in oncology, each with the potential to generate multiple first-in-class product candidates.
- We have developed four distinct mRNA formats, each tailored to specific therapeutic applications. We have also developed and optimized multiple delivery formulations for our mRNA product candidates, including our proprietary non-viral RNA-LPX, to deliver our mRNA systemically and target it to relevant organs in the body.

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- The combination of these platforms, formats and delivery formulations is designed to address a wide range of disease targets, and tailor drug product for systemic or intratumoral delivery, as well as directly encode mAbs or cytokines *in vivo*.
- This broad mRNA expertise is a core strategic asset of our company. It is protected by a global patent portfolio and our proprietary technical knowledge and trade secrets.

We have a deep, diversified pipeline and expect data updates for up to five oncology programs by the end of 2020.

- We have already advanced our portfolio to a critical stage of maturity with multiple programs progressing in parallel. We expect numerous near-term product candidate development updates, including:
 - data updates in up to five clinical programs by the end of 2020;
 - advancement of up to five product candidates into the clinic per year in 2019 and 2020; and
 - up to 10 different product candidates in clinical trials by the end of 2019.
- Our preclinical oncology pipeline is progressing rapidly. By the end of 2019, we expect to have initiated clinical trials for our lead CAR T and checkpoint immunomodulator antibody product candidates.
- We expect to report our target indications and first product candidates for our infectious and rare disease platforms in 2020.

We have formed multiple collaborations with leading pharmaceutical companies and have retained significant development, commercial and financial rights across our portfolio.

- We have chosen to form collaborations in oncology to rapidly advance our science and enhance our development capabilities, bring our potentially disruptive therapies to patients more quickly and provide non-dilutive capital.
- We are currently collaborating with four pharmaceutical companies with expertise in oncology, including Genentech, Sanofi, Genmab and Eli Lilly, and have retained significant rights in each of our collaborations.
- In addition, we have formed collaborations with leading pharmaceutical companies to broaden our footprint beyond oncology. Our collaboration with Pfizer focuses on influenza, and includes our product candidate BNT161 for influenza. We are collaborating with Penn to develop mRNA-based immunotherapies for up to 10 additional infectious disease indications. We have also formed a collaboration with Genevant for up to five rare disease indications.
- We have retained worldwide rights to all product candidates under our FixVac, RiboMabs, RiboCytokines and CAR T platforms.

We have created a vertically integrated business with comprehensive in-house manufacturing capabilities.

- We believe that to successfully bring individualized immunotherapies to patients, it is critical to control the manufacturing and supply processes. We therefore have chosen to invest early in scaling our in-house capabilities.
- We currently operate four manufacturing facilities in Germany spanning mRNA and peptide production, viral vectors and engineered T cells, and we continue to invest significant human and financial capital into these activities.
- In collaboration with Siemens, we are optimizing our iNeST production process, reducing turnaround time from over three months to less than six weeks currently, with the goal of delivering on-demand commercial supply.

Our Company's scientific DNA, which is the foundation of the BioNTech approach, has attracted a talented team from nearly 50 countries around the world.

- Prof. Ugur Sahin, M.D., our co-founder and Chief Executive Officer, and Özlem Türeci, M.D., our Chief Medical Officer, are physicians, scientists and innovators. They have made groundbreaking scientific and technological contributions in the field of personalized cancer immunotherapy and are co-inventors on more than 100 patents. Their daily work is motivated by their experience as researchers and cancer physicians aiming to exploit scientific insights and drive technological progress to develop commercially viable products that could help individual patients, an attitude and culture that has become the DNA of BioNTech.
- Our DNA, with a deep culture of intellectual curiosity and innovation, has made us a destination of choice for scientific pioneers. This culture has attracted an exceptionally talented team from nearly 50 countries around the world.

III. Our Strategy

Our vision is to harness the power of the human immune system to develop truly individualized and patient-centric therapies for cancer and other serious diseases. We aim to rapidly develop, manufacture and, if approved, commercialize a portfolio of novel immunotherapies, including both off-the-shelf drugs and individualized treatments. The key elements of our strategy to achieve this vision are as follows:

Rapidly advance our potential first-in-class product candidates derived from our FixVac and iNeST platforms toward market approvals in oncology, either on our own or with our collaborators.

- We are conducting three Phase 1 clinical trials with our wholly owned off-the-shelf FixVac mRNA immunotherapy and plan to initiate an additional Phase 1/2 clinical trial in the second half of 2019. Our most advanced current FixVac product candidate, BNT111, is currently being evaluated in 115 patients with advanced melanoma, and we expect to initiate a Phase 2 trial in the first half of 2020.
- We are also advancing, in collaboration with Genentech, our iNeST individualized neoantigen specific mRNA immunotherapy in two clinical trials, targeting more than eight tumor types. Our most advanced iNeST program is a Phase 2 trial of our product candidate, RO7198457 (BNT122), in 132 patients with metastatic melanoma, evaluating iNeST in combination with pembrolizumab as a first-line therapy.
- We believe both FixVac and iNeST have therapeutic potential in a wide variety of solid tumors. We have identified significant market opportunities in additional indications and plan to pursue potentially expedited routes to market approval.

Progress additional product candidates through clinical development, leveraging our multiple drug classes and the synergies between them in order to expand our oncology pipeline.

- In addition to FixVac and iNeST, we are also conducting a Phase 1 clinical trial of our intratumoral immunotherapy product candidate SAR441000 (BNT131) in collaboration with Sanofi, as a monotherapy in patients with advanced melanoma and as a combination therapy with an anti-PD-1/PD-L1 checkpoint inhibitor in patients with certain solid tumors.
- Beyond mRNA, we plan to rapidly advance other product candidates from our immunotherapy drug classes into clinical proof of concept studies in solid tumor indications.
- In collaboration with Genmab, we have initiated a Phase 1/2 clinical trial for our product candidate GEN1046 (BNT311) in solid tumors and intend to initiate an additional Phase 1/2 clinical trial in the second half of 2020 for BNT312 in solid tumors. These product candidates are based on our novel checkpoint immunomodulator bispecific monoclonal antibodies, which we believe have potential in a broad range of cancers.

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- We also plan to initiate a Phase 1/2 clinical trial in the first half of 2020 for our wholly owned CAR T product candidate, BNT211, in multiple solid tumors, targeting a novel solid-tumor specific antigen, CLDN6.

Maximize the potential and leverage the broad applicability of our mRNA drug class in additional therapeutic areas beyond cancer, including through selective collaborations.

- Beyond oncology, we intend to leverage our mRNA technology to direct the immune system to fight a range of infectious diseases and address missing or defective proteins in certain rare diseases.
- Our collaborations with Pfizer in influenza and with Genevant in rare diseases underscore the potential of our approach. We intend to continue to seek value added collaborations with leading industry players who contribute their competencies and know-how to complement our powerful suite of technologies to address challenging diseases outside of our core therapeutic focus on oncology.

Strengthen our position as a leader in the highly automated, on-demand manufacture of individualized therapies with the goal of delivering our therapies globally.

- We will continue to invest to reduce cycle times and increase the automation of our processes, and to expand our manufacturing capacity across all platforms to support the efficient progression of our product candidates into late-stage clinical trials and commercialization.
- We will continue to invest in and scale up our advanced, in-house GMP manufacturing capabilities and capacity across mRNA and cell therapy production.

Establish a commercial organization to bring our portfolio of cancer immunotherapies to patients.

- We believe that developing our own commercial infrastructure will be key to maximizing the value of our programs. We intend to jointly participate in the commercialization of our collaborative programs where we retain significant commercial rights.
- We plan to expand our footprint to support our global clinical development activities and intend to establish operations in the United States by the end of 2020.

Expand our current technology suite by continuing to develop existing and new drug classes and platforms, and selectively in-licensing technologies that are complementary to our existing pipeline.

- As our understanding of immunology and oncology evolves, we plan to continue developing existing as well as new drug classes and platforms that are consistent with our strategy, with particular focus on those that can benefit from our in-house expertise.
- As evidenced by our recent acquisition of MabVax Therapeutics, we also continuously assess the external environment for novel drug classes, platforms and product candidates that can further expand and improve our pipeline of innovative immunotherapeutics, and help us to execute our strategy.

Maintain our culture of scientific excellence to continue to drive future innovation.

- We are committed to maintaining close ties to the scientific and academic community by fostering our many long-standing university relationships.
- We also intend to continue our leadership in the Association for Cancer Immunotherapy, or CIMT, which provides us potential new sources of innovation and academic collaboration opportunities.

IV. Immunotherapy in Cancer

The immune system has evolved over hundreds of millions of years to identify and eradicate what is foreign to the body with a high level of efficiency. The immune system's efficacy is attributable to approximately

one trillion highly diversified immune cells that constantly travel throughout the body and interact in a coordinated manner. They are able to detect and eliminate diseased cells and pathogens with high precision by relying on a broad range of immune recognition receptors. Their powerful mechanisms both synergize and regulate each other.

The goal of immunotherapy in the field of oncology is to harness the power of the immune system to recognize malignant cells as “foreign,” overcome immune evasion mechanisms employed by cancers, eradicate cancer cells and thereby eliminate tumors.

Immunotherapy approaches in cancer have a long history. Recent years have seen an acceleration of scientific advancements and clinical breakthroughs in this field. The introduction over the last decade of checkpoint inhibitors such as Yervoy, Opdivo and Keytruda, and CAR T therapies such as Yescarta and Kymriah has demonstrated that even leveraging one single mechanism to harness the immune system may result in unprecedented, significantly improved clinical outcomes for a subset of patients.

While these first-generation immunotherapies have ignited the paradigm shift toward immuno-oncology, they also have limitations. For example, less than 40% of patients respond to checkpoint inhibitors, while CAR T therapies have been primarily limited to blood cancers in subsets of patients, and have been hampered by toxicities.

Realizing the full potential of immunotherapy is the objective of the next generation of immuno-oncology drugs to be developed.

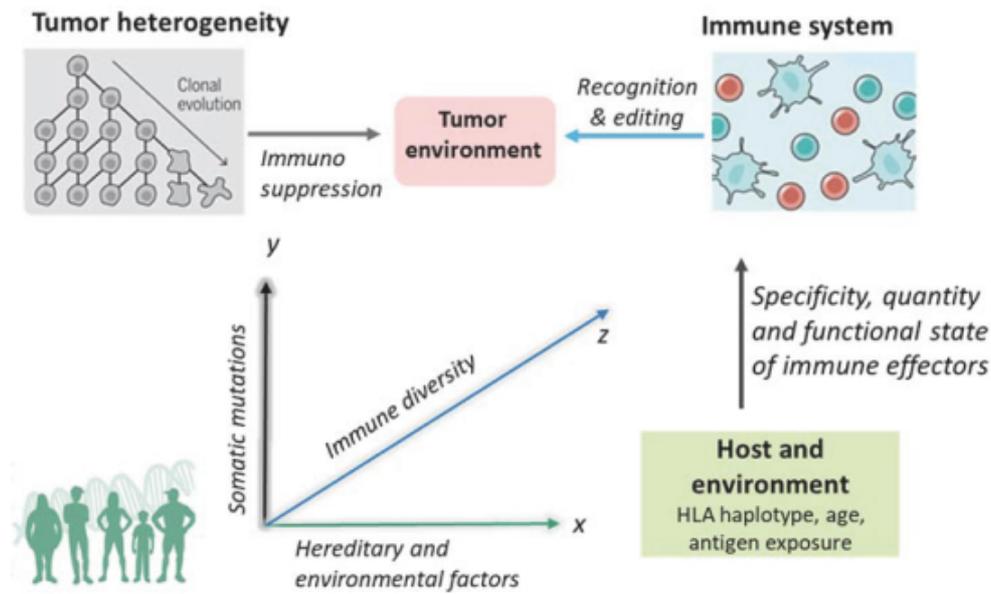
V. Challenges and Opportunities of Cancer Therapies

Cancer results from an accumulation of abnormalities, known as somatic mutations, in the genome of cells over time leading to malignant transformation, combined with a failure by the immune system to detect and eradicate such transformed cells. Due to their random nature, the vast majority of these aberrations are unique to the individual patient.

As a consequence, heterogeneity is an intrinsic hallmark of cancer, posing a key challenge for cancer therapy:

- **Interindividual tumor heterogeneity.** Tumors, even within the same cancer type, differ at the molecular level. For example, two patients with the same type of cancer usually share less than five percent of their mutations. As a result, patients often respond very differently to the same drug.
- **Intratumor heterogeneity.** Within the same patient, cancer also evolves over time so that different tumor cell clones co-exist, in a manner known as clonal evolution. As a result, a patient’s cancer may be intra-tumorally as well as inter-tumorally heterogeneous. Therapies might target only a subfraction of tumor cell clones. This can lead to immune escape and therapy failure.
- **Cancer evolution and immune escape.** Cancer cells can adapt to therapeutic pressure, which results in treatment resistance. During immunotherapy, tumor cell clones may evolve that no longer express T cell recognized antigens or have defects in their antigen presentation machinery.
- **Tumor microenvironment.** Tumors induce various forms of immunosuppressive microenvironment that prevent T cells from proliferating and executing their anti-tumor effector function.
- **Host, environment and immune system.** The functional state of each patient’s immune system is dependent on the patient’s age, genetic makeup and environmental exposures. For example, the HLA haplotype, or the genetic makeup that encodes the major histocompatibility complex, is highly individual and decisive for which epitopes of an antigen are presented to T cells. Whereas a given tumor antigen might be a good target in one patient, a second patient might not be able to respond to it at all.

The graphic below depicts the interaction between these types of heterogeneity, the immune system and cancer:



The interconnected dimensions of cancer heterogeneity. The interaction between cancer and immune system is shaped by various host, tumor and environmental factors. The complex interplay of these sources of interpatient heterogeneity affects both the course of disease and the efficacy of immunotherapy.

Together, these factors make cancer an extremely complex and heterogeneous disease. As a consequence, in the majority of cancer types, less than 40% of treated individuals benefit from highly potent approved therapies, and responses are often not durable. While these hallmarks of cancer are a challenge for cancer therapy, they also present opportunities for immunotherapy. These interconnected layers of complexity and variability require a deep understanding of an individual cancer and call for a patient-centric approach in order to find an optimal treatment.

Transformation of Cancer Therapies

We believe the recent convergence of breakthrough technologies in life sciences has enabled innovative concepts to address the immunobiology of cancer at its core. One of these breakthroughs has been the establishment of cancer immunotherapy in the armamentarium of cancer treatments. Another has been the emerging progress towards individualized medicine. Technologies such as next-generation sequencing, or NGS, have confirmed beyond doubt the problematic diversity of tumors on the inter-patient level. At the same time, NGS enables fast, cost-efficient and precise high-resolution mapping of each patient's individual disease. We believe the application of these breakthrough technologies has the potential to change drug development and profoundly alter the oncology treatment landscape.

The ability to translate a comprehensive molecular map of an individual tumor into treatment decisions, and make individually tailored therapeutics available, have become the focus of the next generation of cancer therapy. The technology necessary for leapfrog advancements in oncology now exists, but to realize its potential, a radical paradigm shift is required in drug development.

VI. The BioNTech Approach

We are focused on bringing cancer immunotherapy into the next generation. We believe that we can accomplish this by applying the following principles:

- **Exploiting the full potential of the immune system.** Our broad pipeline includes mRNA-based immune activators, antigen-targeting T cells and antibodies, and defined immunomodulators of various immune cell mechanisms. This portfolio is designed to mirror the evolution of the immune system to rely on multiple complementary pathways.
- **Broadening the universe of patients benefiting from cancer immunotherapy.** We discover and exploit novel targets and target combinations. Our aim is to extend the utility of immunotherapy to patient populations that are not currently amenable or do not benefit from the targets of current immunotherapies. One example are patients with low mutational load tumors, such as pancreatic and prostate cancer, which we address with tumor-associated antigens.
- **Improving the success rate.** We engineer and develop highly potent drug candidates designed to avoid compromising precision for the specific target. We further augment activity and counteract resistance mechanisms by combining compounds with non-overlapping, synergistic mechanisms of action, such as combining our FixVac immunotherapy with our novel CAR T therapies.
- **Focusing on curative approaches.** The root cause of recurrence or for lack of tumor eradication is interindividual variability and cancer heterogeneity. Addressing this biological reality is one of the mandatory design aspects of the product candidates we develop. For example, each of our cancer immunotherapies incorporates multiple targets in order to account for this variability.

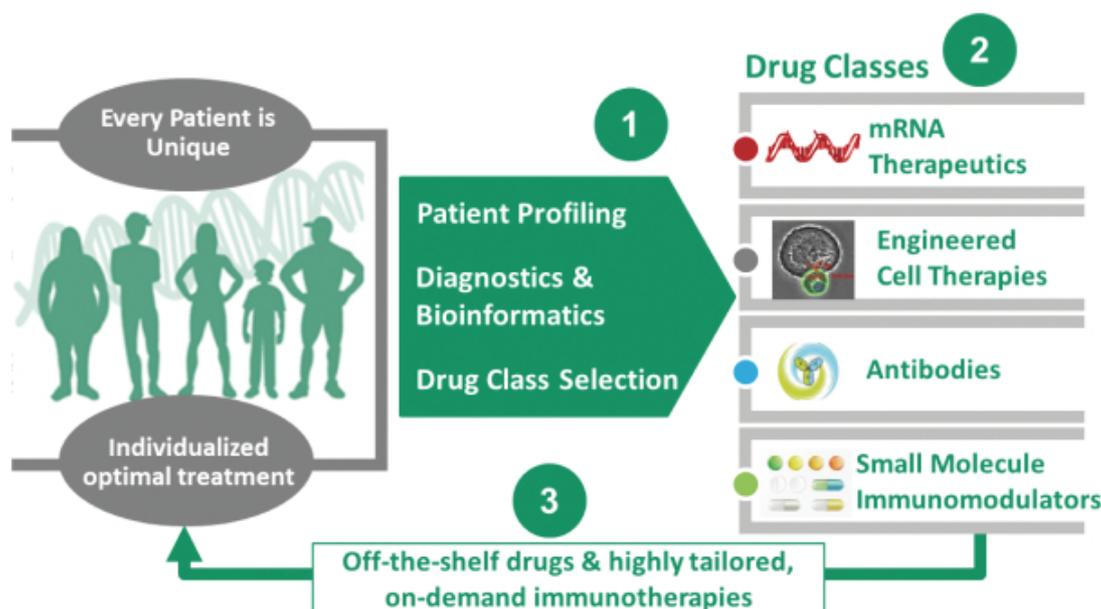
We have applied these four guiding principles to a broad suite of therapeutic platforms optimized for a distinct mode of action, high precision targeting, high potency and efficacy. We expect each platform to yield a pipeline of drug candidates for further development.

We believe this technology-agnostic range of platforms and product candidates positions us to remain at the forefront of the shift toward an individually tailored, patient-centric therapeutic approach in oncology.

Patient-Centric Model

We believe the next generation of cancer immunotherapy will start from the perspective of the molecular changes that have occurred in an individual patient, and then will provide a specific therapy *for that patient*. We believe that BioNTech is ideally positioned to drive this transformation.

Our patient-centric model is based on three pillars:



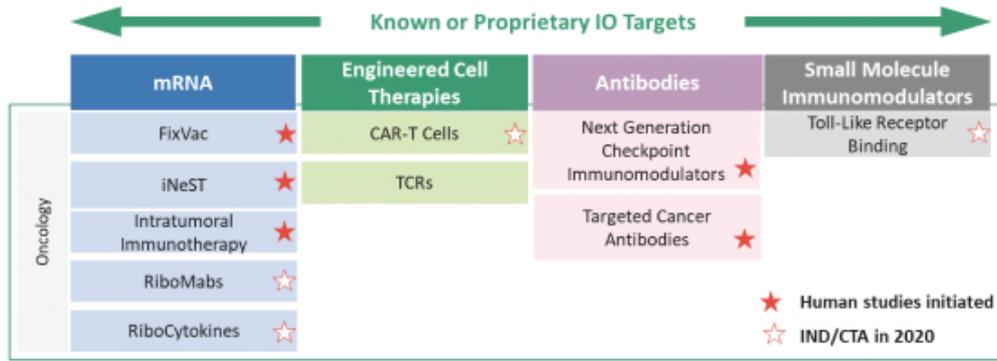
Our patient-centric model. Utilizing patient profiling, diagnostics and bioinformatics, we select from our suite of drug classes to provide optimal individualized treatment.

1. We develop and leverage our competencies in target discovery, biomarker science and computational medicine to thoroughly profile a patient's tumor sample and immune cells for the selection of suitable targets and treatments. Combined with our deep domain expertise in immunoncology and product vision, we are able to use this data to develop next-generation product candidates.
2. We have developed and are iteratively optimizing next-generation therapeutic platforms leveraging four drug classes. Each therapeutic platform bundles innovations designed to deliver a distinct mode of action with high-precision targeting, high potency and efficacy. Each platform is being developed to provide a pipeline of drug candidates with complementary and potentially synergistic modes of action.
3. Our drug platforms are highly versatile and support the fast development of scalable manufacturing processes. We develop and establish highly digitalized and automated manufacturing technologies and quality controlled processes enabling fast delivery of customized therapies comprising off the shelf drugs, on-demand immunotherapies, and combinations thereof.

We invest in innovation whenever we encounter technology barriers which may constrain clinical success. We are technology-agnostic and we seek to utilize the technology that is most suited for the respective purpose. By focusing on the three pillars discussed above over the last decade, we have integrated all of the building blocks of immunotherapy under one roof, enabling an approach with the potential to optimize patient outcomes.

Broad and Potentially Synergistic Suite of Platforms

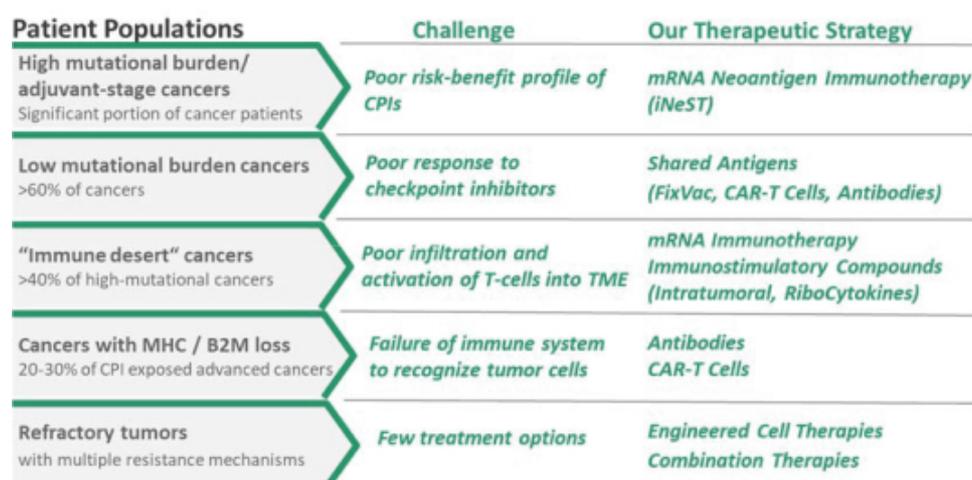
We believe the depth and breadth of our understanding of immune system and cancer biology allows us to create an extensive pipeline of specific and potentially efficacious product candidates. We are exploiting a comprehensive repertoire of known and proprietary therapeutically relevant immunology targets and are developing a diverse spectrum of immunotherapeutic approaches, as shown in the chart below.



We believe that harnessing complementary, potentially synergistic modes of action increases the likelihood of therapeutic success, reduces the risk of emergence of secondary resistance mechanisms, and also unlocks a larger potential market. Critically, this approach allows us to pursue a technology agnostic approach, providing the most appropriate therapeutic platform or a combination thereof for the intended patient and purpose.

For example, we believe our neoantigen immunotherapies are particularly well-suited to treat high mutation load cancers in the adjuvant setting to prevent the tumor from spreading or recurring following initial treatment such as surgery. In this setting, tumor volumes tend to be low and there remains the potential for strong T cell responses since the patient’s immune system has not been weakened by prior lines of treatment, and checkpoint inhibition alone often offers a poor risk-benefit profile or low response rate. Similarly, we believe our FixVac, CAR T and next-generation checkpoint immunomodulator platforms may have especially strong potential in lower mutation burden tumors such as ovarian or prostate cancers, which comprise a significant proportion of tumors and often also have a poor response to checkpoint inhibition. Likewise, we believe that monoclonal targeted cancer antibodies and CAR-T cell therapies are particularly well-suited for tumors that have defects in their antigen-presentation machinery.

We believe our technology breadth is greater than the sum of its parts in that it positions us to combine modes of action in a coordinated way to treat cancer in a more efficacious manner than current existing therapies. We further believe that our patient-centric approach and our broad, potentially synergistic portfolio of drug platforms place us at the forefront of the paradigm shift toward individualized immunotherapies.



Diversity of cancer patient populations, challenges and our therapeutic strategies. We believe our diversified portfolio allows us to potentially address a large share of cancer patients. Abbreviations: TME, tumor microenvironment; B2M, beta-2 microglobulin, a component of MHC.

VII. Selection of Therapeutic Targets and Therapies

Immunotherapy targets can be categorized as *antigens* for targeted immunotherapy with antibody- or T cell-based effector mechanisms and *immunomodulatory targets* to be exploited to improve the anti-tumoral function of immune cells.

A. Targeting Cancer Antigens

In order to address the broadest possible number of patients, our therapeutically targeted cancer antigen library comprises tumor associated antigens, viral neoantigens and mutant neoantigens:

1. Tumor Associated Antigens

Tumor associated antigens, or TAAs, are cancer selective targets that typically have a highly restricted expression pattern in normal tissues but are frequently expressed in a wide range of human cancers. Over the last 15 years, we have built up a database of approximately 200 cancer-selective antigens, including proprietary disease targets that could be used as targets for immunotherapy-based approaches.

- Cancer-Germline and Cancer-Embryo-Fetal Antigens, which are normally expressed during embryonal development and silenced after birth or restricted to germline cells. These antigens are aberrantly expressed in a variety of human malignancies and are generally not expressed in healthy tissue, making them particularly suitable for our FixVac-, antibody- and CAR-T cell-based therapeutic approaches.
- Differentiation antigens, which are normally expressed in a highly tissue-specific manner in normal tissues (*e.g.*, on melanocytes or on prostate cells) but are also present in a high proportion of tumors derived from these tissues, are well-suited for therapeutic targeting with FixVac and antibody approaches.

- Tumor-associated carbohydrate antigens are carbohydrate-based cell surface tumor antigens generated by cancer cell-specific aberrant glycosylation that enable the development of antibody and CAR-T cell therapies.

2. Viral Neoantigens

Viral oncoproteins, or viral neoantigens, are virus derived proteins that drive the oncogenic transformation of infected cells by viruses that can cause cancer. Examples are the E6 and E7 oncoproteins from human papilloma virus, or HPV. Viral oncoproteins are commonly acknowledged as safe and promising targets for immunotherapy as they are (i) absent from any non-infected tissue, (ii) highly immunogenic since they are not prone to central tolerance mechanisms and (iii) not subject to immune escape by gene silencing as they are crucial to maintaining the transformed state of the tumor cells. We leverage viral neoantigens as targets for our BNT113 FixVac program in HPV16+ head and neck cancer.

3. Mutant Neoantigens

Somatic mutations, or mutations of non-germline cells, are a hallmark of cancer. Driver mutations promote the oncogenic process, whereas passenger mutations are considered as functionally irrelevant. Both types of mutations, however, can alter the sequence of proteins and create new epitopes which are processed and presented on specialized MHC molecules. Mutated epitopes that are recognized by T cells are called neoepitopes and the sequence-altered proteins they are derived from are neoantigens. They are promising targets for cancer immunotherapy as (i) activation of the immune system against such antigens is highly specific (they are only expressed on cancer cells) and (ii) mutant neoantigens are exempt from central tolerance and thus T-cell affinity for neoantigens may be significantly superior. We utilize individualized mutant neoantigens as targets for our iNeST product candidates.

B. Immunomodulatory Targets

The activity of immune cells can be controlled or manipulated by the targeting of receptors that control key biological processes in these cells, known as immunomodulation. Immunomodulatory targeting strategies include:

1. Checkpoint Inhibition

Checkpoint inhibition is a therapeutic approach by which T cell function is stimulated with mAbs that block their inhibitory receptors, which can be exploited by cancer cells to shut down T cell activity. Examples of checkpoint targets are PD-1, PD-L1, CTLA-4, TIGIT, LAG3 and many others. The concept is known as “releasing the brakes” and has been shown to be therapeutically effective in tumors with strong pre-existing immune cell infiltration. Our GEN1046 (BNT311) product candidate is a next-generation bispecific checkpoint immunomodulator, with one arm targeting PD-L1.

2. Immunostimulation

Immunostimulatory approaches are directed against receptors known to directly activate immune cells. Examples of these targets include co-stimulatory molecules such as CD40, and 4-1BB or cytokine receptors such as IL-2R, IL-7R and IL-12R. Immunostimulatory approaches provide a powerful opportunity to enhance immune activation, even in types of cancer that are not responsive to checkpoint inhibition due to lack of immune cell infiltration. However, this approach is often limited by a narrow therapeutic window associated with dose-limiting toxicity.

We believe that both concepts can be combined in a potentially synergistic and safe fashion by developing precisely engineered molecules, such as our BNT151 RiboCytokine program or BNT312, our next-generation bispecific checkpoint immunomodulator targeting both CD40 and 4-1BB.

C. Our computational approach to individualized immunotherapy

Bioinformatics are critical in the production of individualized therapies. We have accumulated a high level of experience in bioinformatics of mutation detection, cancer genomics and immunotherapy through our ongoing research and preclinical studies and clinical trials.

Our validated patient-centric bioinformatic process, as illustrated below, allows the application of complex algorithms to the patient’s data in the context of drug manufacture. Our bioinformatics processes are robust and scalable, incorporating our experience handling genomic data in a high throughput environment, as we target making on-demand production of individualized immunotherapies commercially viable.



From Patient to Analysis. Our bioinformatic process for the selection of neoepitopes.

1. Sequencing

We sequence the patient’s tumor and healthy tissue samples using NGS technology. Comparison of the patient’s sequenced tumor and healthy samples provides us with the data from which we can identify targets for the design of an individualized cancer immunotherapies. This is a multi-step process in which mutation detection and neoantigen prediction are particularly important.

2. Mutation detection

Mutation detection, which defines which tumor-specific mutations are present in any cancer, is the starting point for defining targets for individualized immunotherapy. Determining mutations from NGS data with high precision and sensitivity is challenging because numerous factors can lead to false positives, which can mask mutations. Despite advances in the field, commonly used mutation detection algorithms still exhibit high false positive mutation detections. In order to address these challenges, we have exclusively licensed a technology from TRON that combines tumor modeling with mutation detection, called MyMUT. MyMUT is a next-generation mutation detection system, which we believe has the following key characteristics:

- **High specificity and robustness.** By combining tumor modeling, sophisticated statistical and genomic filters, and replicate sampling, MyMUT achieves clinical precision in detecting mutations with comparable sensitivity to state-of-the-art mutation detection systems. Higher specificity translates to potentially more effective immunotherapies, with faster and cheaper production. MyMUT is designed to deliver uniform performance for all patients regardless of tumor complexity, mutation burden or sample purity. MyMUT’s performance with low mutation tumors also allows us to offer individualized immunotherapies to patients with low tumor mutation burdens.
- **Intratumor heterogeneity.** By performing tumor modeling, MyMUT can also identify clonal and subclonal mutations with high precision, allowing us to prioritize the former in neoantigen-directed immunotherapies and address intratumoral heterogeneity by targeting mutations that are common in a higher proportion of cancer cells within a tumor.
- **Quality control (QC).** By analyzing the genomic properties of sequenced samples, MyMUT can detect errors that pass standard sequencing QC, ensuring the quality and safety of individualized immunotherapies.

3. *Neopeptide selection*

Only a portion of mutated peptides (neopeptides) are suitable for raising an immune response *in vivo*. Our approach focuses on evoking responses involving both CD8⁺ T cells and CD4⁺ T cells. We do this by discerning the likelihood of presentation of the neopeptide to the T cell receptor as an MHC peptide complex using data from mRNA expression levels and MHC binding affinity predictions, among other factors. For example, in our first individualized neopeptide immunotherapy clinical study, all 13 stage III and IV melanoma patients selected for treatment developed a CD4⁺ and/or CD8⁺ T cell response, achieving an overall 60% immune response rate to predicted neopeptides.

Presentation of a neopeptide on an MHC molecule does not, however, guarantee recognition by T cells, and an integrated view combining several properties impacting immunogenicity is necessary. Our algorithms are continuously being improved and extended with data collections from various sources such as our past and current clinical studies as well as HLA data. By using machine learning approaches applied to these large datasets we aim to further improve prediction of overall presentation of neopeptides tailored to patients' specific HLA types.

VIII. Our mRNA Drug Class

At a glance: mRNA as a Therapeutic Drug Class

- Natural molecule found universally within cells, with well-characterized properties.
- Suitable to encode for antibodies, antigens, cytokines and any other type of protein.
- Transient, with adaptable activity and half-life. Avoids genomic integration problems sometimes seen in gene therapy, potentially resulting in a better safety profile.
- Can be designed and optimized pharmacologically and immunologically, making it suitable for a broad range of applications.
- Fast manufacturability, making it an inexpensive and flexible therapeutic to produce.

In the last decade mRNA has progressed into a promising new class of medicine, with the potential to treat a wide variety of diseases with high unmet medical needs. mRNA is a long, polymeric molecule, composed of four different building blocks called nucleotides. In mRNA, hundreds or thousands of these nucleotides are linked in a unique order to convey genetic information to cells, where it is used to express proteins with biological effects.

Considering that all mRNA is generated with four different building blocks, but with unique sequence order, all therapeutic mRNAs have highly similar compositions, while having the capacity to encode a variety of different proteins. These characteristics allow for rapid development of mRNA therapeutics that are broadly applicable for treatment of many diseases, including cancer, infectious diseases and rare diseases. Our mRNA pipeline addresses all of these therapeutic areas.

A. **General principles of mRNA Pharmacology**

As a drug, manufactured mRNA provides instruction to a target cell to produce a desired therapeutic protein. The mRNA drug will temporarily change the status of the target cell where these instructions are translated into proteins. Based on the information encoded by the mRNA, the proteins will be either secreted or remain intracellular. The mRNA drug will eventually be degraded and eliminated from the body.

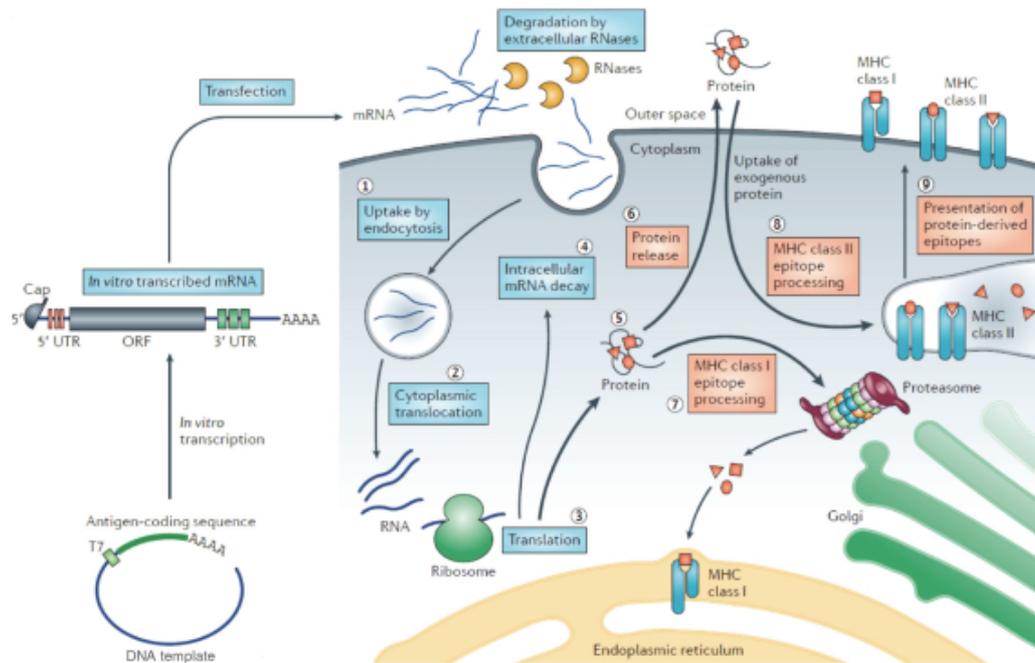
Our mRNA drugs are synthesized from a DNA template. With the exception of the 5' cap, the template determines all structural elements of the mRNA. The mRNA molecule comprises:

- an open reading frame, or ORF, which encodes for the protein of interest;

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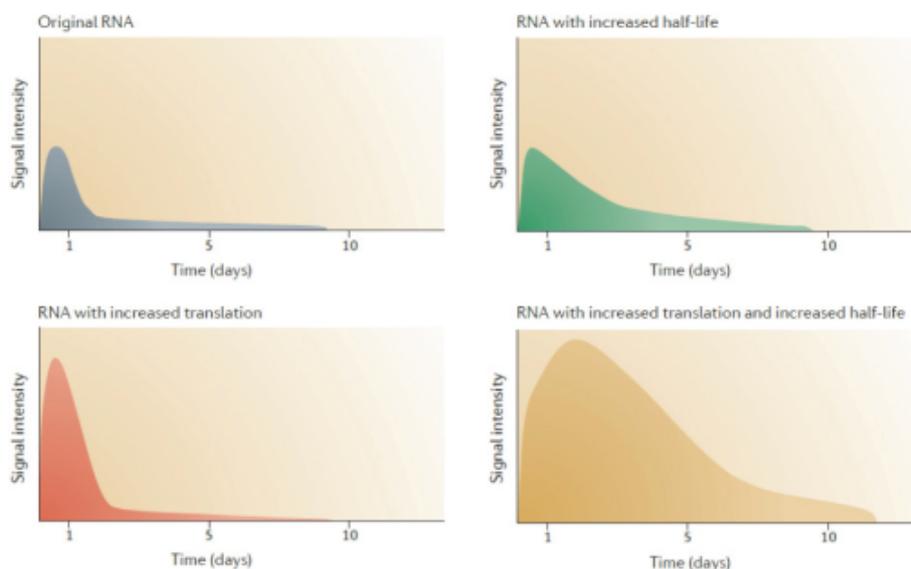
- untranslated regions, or UTRs, which flank the ORF; and
- the cap and the polyA tail, which are the two terminal structures of the linear mRNA, and are responsible for increased stability and translational efficiency of mRNA.

The mRNA drug needs to be appropriately formulated in order to protect it from breakdown by extracellular RNases. The formulation is selected based on the intended application and route of delivery. After uptake into the target cell, the mRNA molecules are loaded into ribosomes, where translation into protein takes place. Subsequently, the mRNA is degraded by cellular mechanisms. In case of an immunotherapy application, the protein is degraded into immunogenic epitopes. These are loaded onto specialized molecules, namely MHC I or MHC II. These molecules present the epitopes to immune cells to provoke the desired immune response. In the case of other mRNA applications, the mRNA encodes proteins that are secreted from the cells, such as antibodies, and function extracellularly.



General principles of mRNA pharmacology. Step 1: Exogenous mRNA escapes degradation by RNases and is taken up by cells. Step 2: Release mechanisms of mRNA into the cytoplasm are not fully understood. Step 3: Translation of mRNA uses the protein synthesis machinery of host cells. Step 4: Termination of translation by degradation of mRNAs. Step 5: The translated protein product acts in the cell in which it has been generated. Step 6: Alternatively, the protein product is secreted and may act via autocrine, paracrine or endocrine mechanisms. Step 7: For immunotherapeutic use of mRNA, the protein product is degraded into epitopes, which are loaded onto MHC molecules, which ensure surface presentation of these antigens to immune effector cells. Cytoplasmic proteins are loaded on MHC class I molecules to be presented to CD8⁺ T cells. Step 8: In antigen-presenting cells, to obtain cognate T cell help for a more potent and sustainable immune response, the protein product can be routed to MHC class II molecules through signal-encoding sequences in the mRNA. Step 9: Protein-derived epitopes can then be presented on the cell surface by both MHC class I and MHC class II molecules.

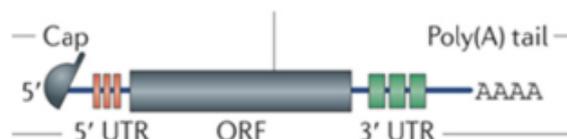
The structural elements of the mRNA have an impact on its performance. This includes potential immunogenicity, efficacy of translation and stability of the molecule. We leverage our extensive experience to design, synthesize, manufacture and formulate our therapeutic mRNA, and adapt its composition to suit the desired application.



The impact of increasing the translation and half-life of mRNA. We have optimized our mRNA in order to maximize its therapeutic effect.

B. Our mRNA backbone concepts and technologies

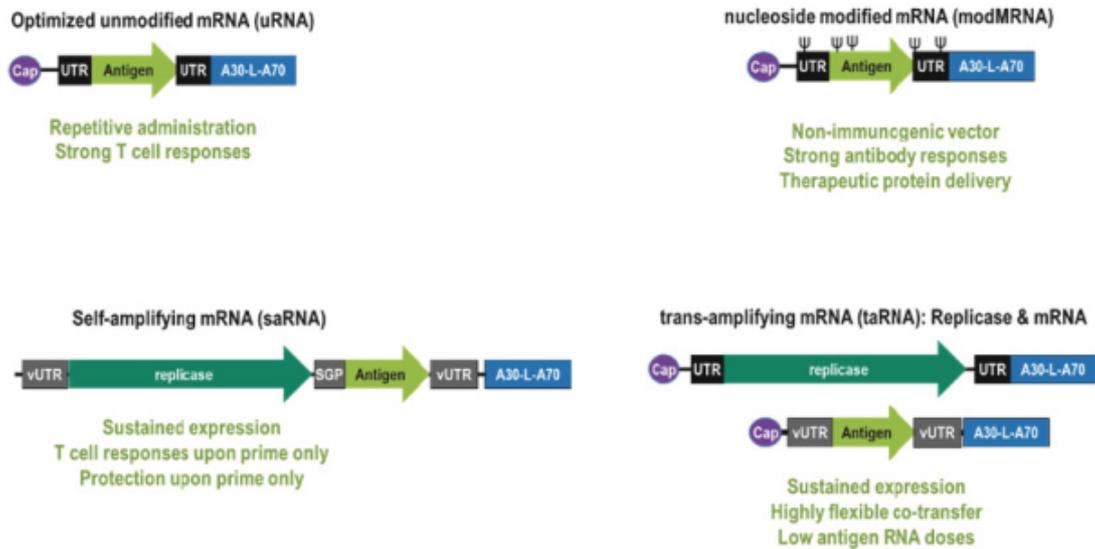
Our mRNAs all contain basic structural elements, including the 5' cap, the untranslated regions and the polyA tail, in addition to a coding sequence, that are all encoded by our DNA template.



- The cap is added to the 5' end of the mRNA during its synthesis. Our studies have demonstrated that incorporation of a unique cap analogue into the mRNA helps to achieve superior translational performance by stabilizing the mRNA molecule and directing the immune response. This unique cap analogue is extremely useful for our immunotherapy approaches.
- The composition and structure of the 3' untranslated regions of the mRNA molecule are important determinants of the intracellular stability of mRNA. As a result of rigorous screening of different mRNA sequences, we identified specific 3' UTRs that promote protein translation for long duration.
- We have performed extensive research on the structure of the polyA tail and the translational performance of mRNA and customized our template design accordingly.

The translational performance of mRNA can be increased by removing contaminating double-stranded RNA from the mRNA. We have extensive expertise in different mRNA purification procedures. We have also invented

a novel mRNA purification method that greatly impacts translatability of our mRNA. Depending on the protein characteristics needed for treatment of a disease, we optimize the DNA template through a proprietary codon optimization process, changing the nucleotide sequence of the template without altering the amino acid composition of the encoded protein. We make further adjustments during mRNA production. We believe these fine tunings of the respective molecules are essential for the purpose-adapted performance of our mRNA.



Our mRNA formats. As shown above, we have developed four mRNA formats, each optimized for different therapeutic applications.

Our mRNA formats include:

1. Optimized unmodified mRNA (uRNA)

The nucleotide sequence of mRNA determines the amino acid sequence of the protein. In addition, the nature of nucleosides used for production of mRNA drugs can also influence recognition of the molecule by the immune system. Presence of naturally occurring uridine (U) in our optimized mRNA makes it immunogenic by activating immune sensors. We have further optimized our unmodified mRNA for immunogenicity (augmented antigen presentation on MHC I and MHC II) and pharmacological activity (enhanced stability and translational efficiency). Immunogenicity of the mRNA is an added benefit when mRNA is used for immunotherapy applications, by acting as an immunotherapy adjuvant. This makes our therapeutics for iNeST and FixVac even more potent.

2. Nucleoside-modified mRNA (modRNA)

Immunogenic reaction against mRNA drugs needs to be avoided in applications where therapeutic proteins are produced, such as in our RiboMab and RiboCytokine platforms. We have profound expertise in incorporating naturally-occurring modified nucleosides into our therapeutic mRNAs. We have demonstrated that the presence of a variety of modified nucleosides in the manufactured mRNA suppresses its intrinsic immune activation, while leading to superior protein production for long duration. Deimmunizing mRNA by incorporating modified nucleosides helps to avoid production of anti-drug antibodies and broaden the therapeutic application of these types of mRNA drugs. We believe this customization has resulted in therapeutic mRNA that is both potent and well tolerated.

3. Self-amplifying mRNA (saRNA)

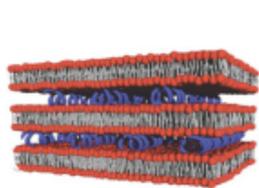
Our self-amplifying mRNA, or saRNA, drugs use the concept of viral replication, while not being an infectious, disease-causing agent itself. saRNA resembles conventional mRNA encoding the protein of interest, but also encoding a polymerase, called replicase, that multiplies part of the mRNA within the target cell. During self-amplification inside the cell, a double-stranded RNA intermediate is generated, which is recognized by intracellular immune sensors. This makes saRNA a very potent activator of the immune system and therefore an excellent category of immunotherapy. As we have demonstrated, our saRNA ensures high levels of sustained antigen production with a small amount of initial mRNA input. Our scientific team has designed this mRNA technology to act as a potent tool for prophylactic vaccination, with the potential application in infectious diseases with high medical needs.

4. Trans-amplifying mRNA (taRNA)

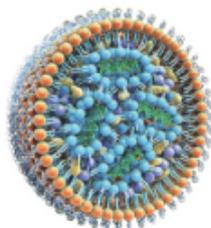
We have also expanded on our self-amplifying mRNA capabilities, developing a novel mRNA amplification technology by separating the target mRNA to be amplified and the replicase encoding mRNA. This advancement broadens the spectrum of applications by making the development of therapeutic mRNAs even more flexible, as the replicase can amplify mRNA encoding of not only one protein, but several different ones. In the case of vaccines, this allows us to produce the replicase in advance for use with different vaccines. Our trans-amplifying mRNA is a proprietary mRNA format that is particularly well-suited for prophylactic vaccines to prevent infectious diseases.

C. Our mRNA delivery formulation technologies

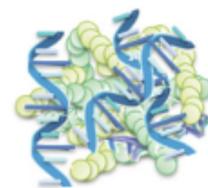
We have deep and broad expertise in the targeted delivery of mRNA therapeutics. We are convinced that our development of suitable delivery formulations in conjunction with our own therapeutic mRNAs is a key competitive advantage.



Lipoplexes
(FixVac, iNeST)



LNPs
(RiboMabs, RiboCytokines,
Rare Disease)



Polyplexes
(Discovery Programs)

Our mRNA delivery formulation technologies. We utilize a range of mRNA delivery formulations for different therapeutic needs.

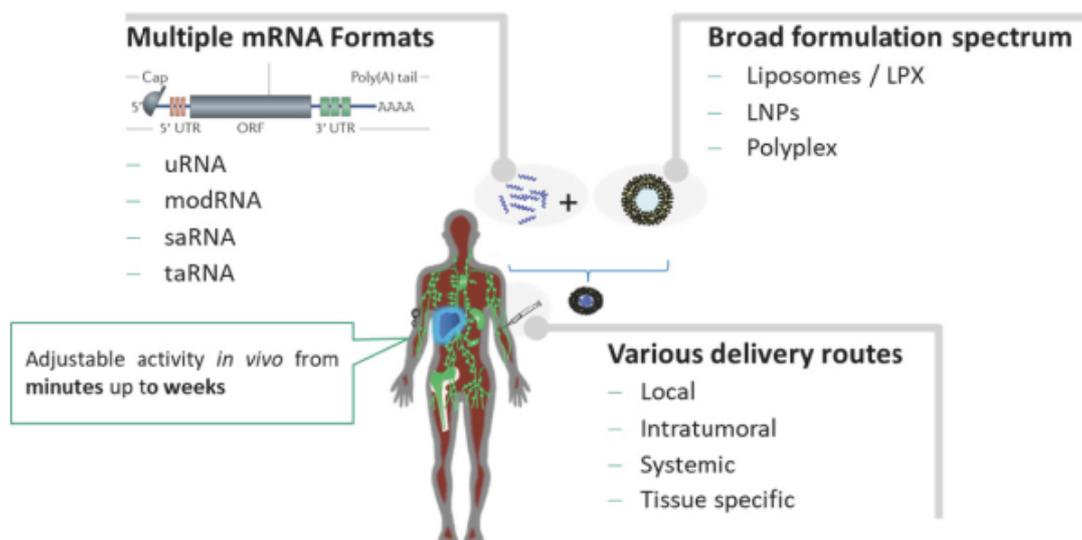
We employ multiple mRNA delivery formulations, each designed for different functions and optimized for therapeutic product needs:

- **Lipoplex:** Our lipoplex formulation, or LPX, embeds the mRNA between a lipid bilayer, which is used for our FixVac and iNeST platforms. We use a proprietary size- and charge-based non-viral mRNA lipoplex that was developed to deliver mRNA to dendritic cells in lymphoid compartments such as the spleen for optimal antigen presentation and immune response activation.
- **LNPs:** For other applications, we encapsulate our mRNA in lipid nanoparticles, or LNPs. These formulations are suitable for our RiboMab, RiboCytokine and rare disease protein replacement platforms. Our LNP formulations can be adjusted according to our needs for delivery to particular target tissues, such as the liver in the case of our rare disease protein replacement platform.

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- **Polyplexes:** Our portfolio also comprises polyplexes, which are being utilized in certain of our discovery programs, in which the mRNA is bound to a polymer and then forms nanoparticles.

As shown in the graphic below, our mRNA platforms utilize our wide range of mRNA formats, mRNA delivery formulations and mRNA delivery routes to optimize and tailor treatments.

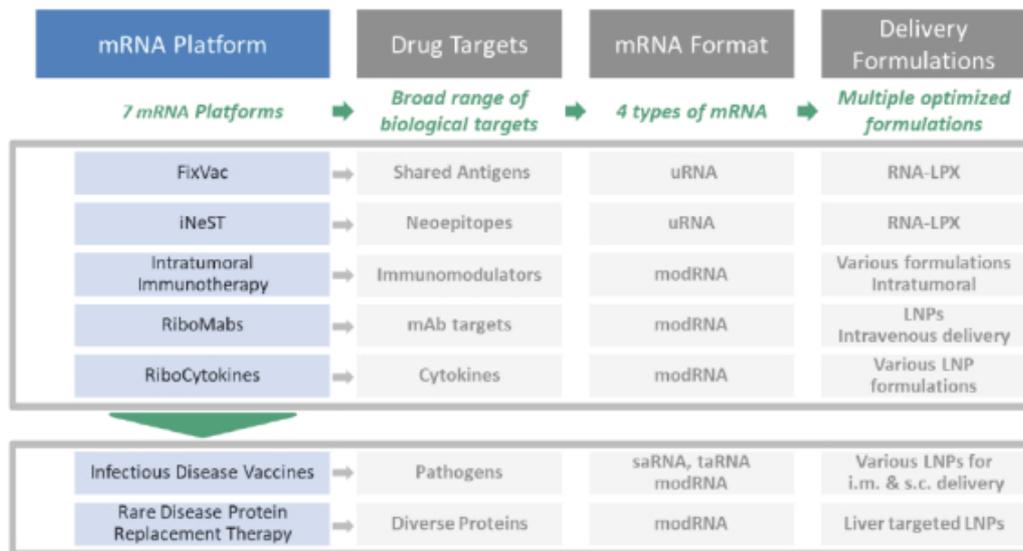


Our therapeutic mRNA technology toolbox. Our product candidates utilize multiple mRNA formats, a broad spectrum of delivery formulations and applications using various delivery routes.

D. Our mRNA Platforms

We are developing multiple mRNA-based therapeutic platforms. These include FixVac, iNeST, mRNA-based intratumoral immunotherapy, RiboMabs and RiboCytokines in the oncology space. In addition, we have implemented mRNA platforms for the development of infectious disease vaccines and protein replacement therapies for rare diseases.

Importantly, each of these platforms enables the development of multiple pharmaceutical product candidates or programs.



Our mRNA Platforms. We have multiple mRNA-based platforms utilizing different mRNA formats and delivery formulations, directed at a range of biological targets in oncology and infectious and rare diseases.

1. Cancer Immunotherapies

Our goal is to develop safe, potent, efficacious and cost-effective cancer immunotherapies which stimulate and potentially expand tumor cell specific CD4⁺ and CD8⁺ T cells in cancer patients. Our cancer immunotherapies development integrates our competencies in mRNA backbone optimization, formulation development and immunological research.

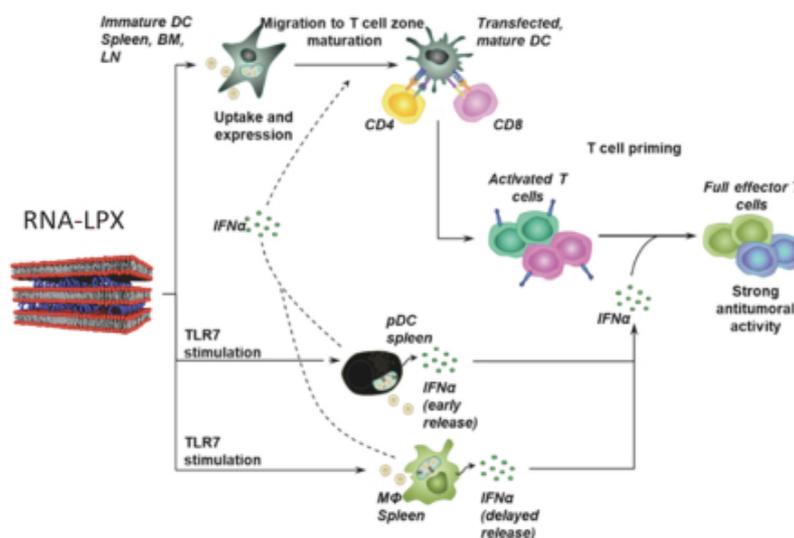
We have developed novel immunotherapy approaches to replicate the highly potent and effective natural activation of the immune system in response to a viral infection. Our first generation mRNA cancer immunotherapies were delivered as naked mRNA by ultrasound guided injection into a patient’s lymph node and induced T cell responses and antitumoral activity when targeting mutant neoantigens in advanced melanoma patients. To further improve this potency and antigen specificity we have developed a nano-particulate mRNA lipoplex immunotherapy for intravenous delivery.

RNA-LPX technology

At a glance: RNA-LPX Cancer Immunotherapy Technology

- Potential first-in-class clinical intravenous nano-particulate mRNA immunotherapy, allowing systemic delivery.
- Strong potency by systemic targeting to dendritic cells in lymphoid tissues.
- Universally applicable for all cancer antigens.
- Opportunity to deliver multiple antigens in parallel, enabling the induction of poly-specific T cell responses.
- Synchronized adjuvant effect mediated by toll-like receptor 7 (TLR7)-triggering and type-I interferon-driven innate and adaptive immune stimulation.
- Preclinical anti-tumoral activity demonstrated against multiple tumors.
- Unprecedented clinical immune responses against shared TAAs.
- Beneficial clinical activity demonstrated in advanced melanoma patients.

To advance from local to systemic dendritic cell, or DC, targeting, we developed an innovative liposome-based RNA-lipoplex formulation, RNA-LPX, that allows for intravenous administration of our mRNA cancer immunotherapies. We have demonstrated in the clinic that systemic DC targeting by mRNA cancer immunotherapies can result in potent activity at very low doses. Consequently, less material is required for treating high patient numbers, making manufacturing more cost-effective.



Our RNA-LPX technology. Our proprietary RNA-LPX formulation is designed to target dendritic cells in the spleen and other lymphoid compartments. Abbreviations: BM, bone marrow; LN, lymph node; DC, dendritic cell; pDC, plasmacytoid dendritic cell; MΦ, macrophage; IFN α , interferon alpha.

RNA-LPX protects mRNA from degradation outside of the cell and mediates its efficient uptake and expression of encoded antigens in various dendritic cell populations.

The versatility of the RNA-LPX technology allows us to target a wide variety of antigens and address cancer patients with all possible HLA haplotypes. Utilizing RNA-LPX, we can target fixed groups of known shared antigens with our FixVac platform and a whole new class of patient-specific neoantigen targets with our iNeST platform.

a) FixVac

At a glance: Our FixVac Platform

- **Concept:** Cancer immunotherapies targeting shared antigens that we have identified to be frequently expressed across patients with a specific cancer type.
- **mRNA Format:** Optimized mRNA providing superior immunogenicity.
- **mRNA Delivery Formulation:** Proprietary size- and charge-based RNA-LPX targeting DCs.
- **Development Approach:** Worldwide rights; wholly owned.
- **Lead Candidate:** BNT111 for metastatic melanoma.
- **Data Highlights:** Four partial responses and seven stable diseases in 25 patients with metastatic lesions at enrollment, following BNT111 monotherapy.

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Our FixVac approach involves off-the-shelf mRNA immunotherapies targeting cancer cell-specific shared tumor associated antigens for selected patient populations. Our FixVac product candidates target TAAs which are commonly expressed by a significant portion of patients in a given cancer type. We have developed a sophisticated target selection process which enables us to produce poly-specific FixVac immunotherapies that cover up to 95% of patients with a given cancer type. The use of off-the-shelf FixVac immunotherapies allows for large-batch manufacturing and prompt supply to patients with ready-to-use medication, ensuring a straight-forward cost- and time-efficient manufacturing process with favorable logistics.

Besides targeting commonly expressed TAAs, our target selection strategy facilitates the identification of suitable viral oncoproteins for the treatment of virus-induced cancers like HPV+ head and neck cancer. Patient stratification, if needed, can easily be performed at the clinical site or a central lab using standard biotechnological methods, thereby reducing treatment costs. As the viral genome is comparatively small, encoding only for a few proteins, we believe our FixVac approach is ideally suited for the treatment of virus-induced cancers.

Our FixVac Development Plan

We currently have seven FixVac programs in development, with three in human trials: our ongoing Phase 1 trial in advanced melanoma, a Phase 1 trial in HPV+ head and neck cancer and a Phase 1 trial in triple negative breast cancer. In the first half of 2020, we expect to progress our advanced melanoma program into Phase 2 clinical trials, and we expect to initiate a Phase 1 trial in prostate cancer in the second half of 2019. In addition, we are planning to initiate a Phase 2 study for FixVac in HPV+ cancers in the first half of 2020.

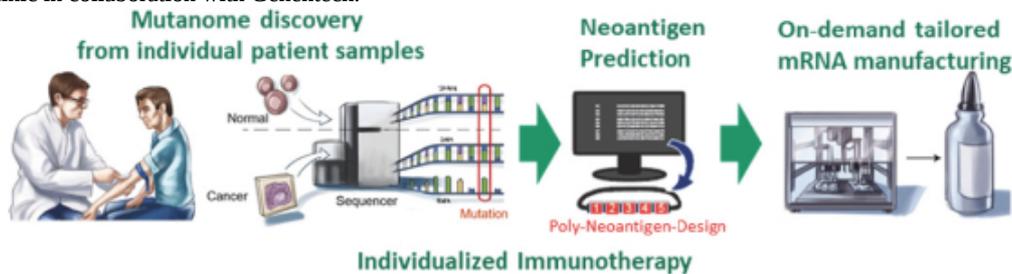
<u>Candidate</u>	<u>Antigens</u>	<u>Development Phase</u>	<u>Next Potential Milestone</u>
BNT111	Melanoma-specific antigens: NY-ESO-1, tyrosinase, MAGE-A3 and TPTE	Phase 1: Metastatic melanoma	Report Phase 1 data and initiate Phase 2 trial in 2020
BNT112	Five prostate cancer-specific antigens, including PAP and three internally identified antigens	Preclinical	Initiate Phase 1/2 trial in 2H 2019
BNT113	HPV E6 and E7 oncoproteins	Phase 1: HPV+ head and neck cancer (IST)	Initiate Phase 2 trial in 1H 2020
BNT114	Selected breast cancer-specific antigens	Phase 1: TNBC	Report data update in 1H 2020 and assess antigen immunogenicity
Multiple trials or ISTs; ovarian cancer, small cell lung cancer	Multiple	Preclinical	—

b) Individualized Neoantigen Specific Immunotherapy (iNeST)

At a glance: Our iNeST Platform

- **Concept:** Individualized cancer immunotherapy targeting neoantigens identified on a patient by patient basis and selected for immunogenicity.
- **mRNA Format:** Optimized mRNA providing superior immunogenicity.
- **mRNA Delivery Formulation:** Proprietary size- and charge-based RNA-LPX targeting DCs.
- **Development Approach:** 50:50 cost share with Genentech.
- **Lead Indication:** RO7198457 (BNT122) as a first-line melanoma therapy in combination with pembrolizumab.
- **Data Highlights:** In a previous Phase 1 trial of BNT121, we observed first-in-human data in 13 patients with metastatic melanoma demonstrating stable progression-free survival in nine patients for up to 41 months, and additional objective responses in three of five patients with metastatic disease at time of treatment with iNeST, including one patient receiving combination therapy. We also observed a significant decrease in the cumulative recurrence rate post-treatment as compared to pre-treatment.

We are a pioneer and global leader in developing fully individualized cancer immunotherapies. We have developed a first of its kind, on-demand manufacturing process to treat each individual patient based on the mutation profile of the patient's tumor. We have validated this treatment approach in the clinic in collaboration with Genentech.



Our iNeST process. The figure above depicts our iNeST process for the on-demand production of individualized mRNA cancer immunotherapies.

Our iNeST process is summarized below:

- A blood sample and tumor biopsy is taken from the patient to obtain healthy cells and tumor tissue. We extract healthy cells from the patient's blood sample and tumor cells from the tumor sample. We use NGS to analyze genetic material (DNA and RNA) of these cells to identify which mutations are present in the cancer cells compared to healthy cells.
- We apply proprietary bioinformatic algorithms to identify tumor specific mutations. The mutations within a cancer cell differ widely from patient to patient and form a unique signature for each tumor. This genomic information can be further utilized to analyze tumor heterogeneity and microenvironment as well as individual aspects of the immune system like the HLA type.
- Based on these bioinformatic algorithms, we then select mutations that are the most promising therapeutic targets. The specific traits of the patient's immune system, including HLA type, are key to the selection of the most appropriate targets. Picking multiple mutations increases the chance to induce potent T cell responses and reduces the risk that the tumor evades T cell attack over time. We account for heterogeneity of each tumor by preferentially selecting mutations that are expressed on all tumor cells. Importantly, the selected mutations are intended to ensure both CD4⁺ and CD8⁺ T cell induction.

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- Following mutation selection, we design the structure for the iNeST product. The chosen mutations have to be arranged in a certain order and the DNA sequence of the mutations has to be optimized. This is important to ensure a robust production of the starting material, or DNA matrix, for the GMP manufacturing of the iNeST product.
- Next we produce the patient-specific iNeST product under GMP conditions and the iNeST product undergoes numerous different quality control tests.
- The iNeST product is transferred to the hospital and injected into the same patient by the physician.
- This process has been designed for the on-demand delivery of our iNeST products, and currently takes approximately six weeks.

Our iNeST Development Plan

We are currently developing iNeST therapeutics for the treatment of metastatic melanoma and multiple solid tumors. We are conducting two clinical trials of iNeST in collaboration with Genentech, including one randomized Phase 2 trial in first-line melanoma in combination with pembrolizumab and a Phase 1a/1b trial monotherapy in patients with locally advanced or metastatic tumors (including in melanoma, non-small cell lung cancer, bladder cancer and other solid tumors) as a monotherapy and in combination with atezolizumab. We expect to announce a data update from the Phase 1a/1b trial in solid tumors in the second half of 2020.

Candidate	Antigens	Development Phase	Next Potential Milestone
RO7198457 (BNT122)	Up to 20 neoantigens selected on a patient by patient basis	Phase 2: first-line melanoma in combination with pembrolizumab Phase 1a/1b: multiple solid tumors	Report interim data in 2H 2020 Report data update in 2H 2020

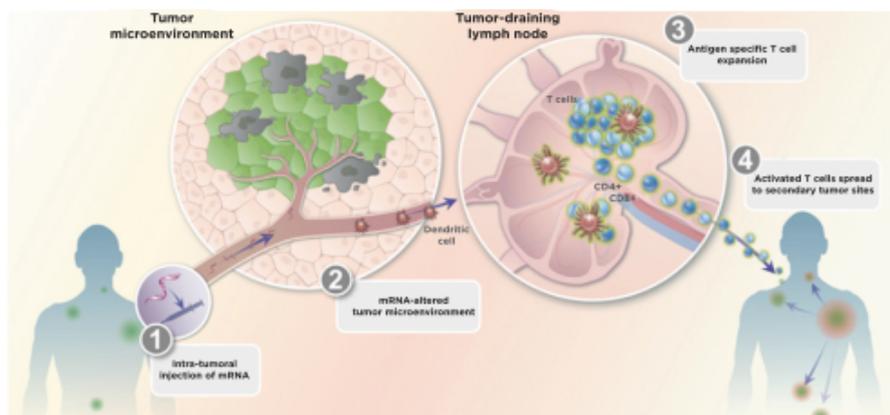
c) Intratumoral mRNA Immunotherapy

At a glance: Our Intratumoral mRNA Platform

- **Concept:** Immunomodulator-encoding mRNA injected directly into the tumor in order to avoid off-target toxicities.
- **mRNA Format:** Nucleoside-modified mRNA engineered for minimal immunogenicity in order to avoid immune detection and allow translation of the encoded cytokines to occur within the cells.
- **mRNA Delivery Formulation:** Various formulations, delivered by intratumoral injection.
- **Development Approach:** Co-development and co-commercialization, at our option, in collaboration with Sanofi.
- **Lead Candidate:** SAR441000 (BNT131) for advanced solid tumors as a monotherapy and in combination with cemiplimab.

We are leveraging our mRNA technology to develop intratumoral immunotherapies for the treatment of solid tumors. Intratumoral immunotherapy is designed to promote innate and adaptive immune responses against tumors, without toxicities related to systemic administration. Our intratumoral immunotherapy involves injection of cytokine-encoding mRNA directly into a tumor in order to alter the tumor microenvironment and promote greater T cell activity. This approach has been found in preclinical studies to boost cancer-specific immune responses locally, while also producing tumor responses in remote parts of the body due to the circulation of properly activated antitumor immune cells, known as an abscopal effect. We believe intratumoral immunotherapy may provide an alternative to surgical cancer treatments. We are developing our mRNA-based intratumoral platform in collaboration with Sanofi.

Our lead intratumoral immunotherapy product candidate, SAR441000 (BNT131), consists of a modified mRNA that encodes for the IL-15sushi, IL-12sc, GM-CSF and IFN- α cytokines. Our intratumoral immunotherapy product candidate is injected directly into the tumor, where it promotes high levels of local cytokine expression within the tumor microenvironment in order activate innate and adaptive immune responses against tumors.



Therapeutic mode of action of intratumoral mRNA immunotherapy. The figure above demonstrates how SAR441000 (BNT131) promotes cytokine expression within the tumor itself.

Our Intratumoral Development Plan

Our first intratumoral mRNA product candidate is being investigated in a Phase 1 clinical trial with 264 patients with advanced solid tumors, as a monotherapy and in combination with cemiplimab, in four sites in Europe. We expect to report a data update from this study in the second half of 2020.

Candidate	Encoded Cytokines	Development Phase
SAR441000 (BNT131)	IL-15sushi, IL-12sc, GM-CSF and IFN- α	Phase 1: Advanced solid tumors as a monotherapy and in combination with cemiplimab

2. Infectious Disease Vaccines

At a glance: Our Infectious Disease Vaccine Platform

- **Concept:** mRNA-based vaccines targeting infectious disease pathogens.
- **mRNA Format:** Self-amplifying mRNA providing high immunogenicity with smaller amounts of mRNA.
- **mRNA Delivery Formulation:** LNPs.
- **Development Approach:** Collaboration with Pfizer and exclusive option arrangement with Penn.
- **Lead Candidate:** Influenza vaccine.

Expanding beyond our research in oncology, we are leveraging our mRNA technologies to direct the immune system more effectively against infectious diseases. Our infectious disease vaccine candidates contain self-replicating or transreplicating, modified mRNA-encoding antigens specific to a target pathogen, delivered in various LNP formulations in order to activate and direct T cells and B cells to fight the pathogen.

Influenza Vaccine

We are collaborating with Pfizer to develop an influenza vaccine using our mRNA-based immunotherapy technology. Current influenza vaccines consist of antigens from inactivated influenza viruses, recombinant influenza haemagglutinin, or HA, proteins or live attenuated influenza viruses and are available as trivalent (containing two influenza A strains and one influenza B strain) or quadrivalent (containing two influenza A strains and two influenza B strains) vaccines. Currently available influenza vaccines are produced in chicken eggs or cell culture and take about five to six months to produce. This requires the composition of the coming season's vaccine to be selected by the World Health Organization, or WHO, far in advance for the vaccine to be available on time, which reduces the reliability of that prediction.

Our mRNA based vaccine can be manufactured within three months from the time the recommendation is published, including cloning and production and therefore the WHO's review of the vaccine components can occur closer to the influenza season to obtain a more reliable prediction. The flexibility of the mRNA vaccine platform allows for rapid generation of vaccines against genetically drifted seasonal viruses or pandemic strains. We expect to initiate a Phase 1 clinical trial for our influenza vaccine product candidate, BNT161, in the second half of 2020.

Other Infectious Diseases

In October 2018, we entered into a research collaboration with Penn, under which we have the exclusive option to develop and commercialize prophylactic mRNA immunotherapies for the treatment of up to 10 infectious disease indications. We expect to report our first product candidates under this collaboration, and advance our first product candidate into the clinic, in the first half of 2021.

3. mRNA-based protein replacement platform for rare diseases

At a glance: Our Protein Replacement Platform for Rare Diseases

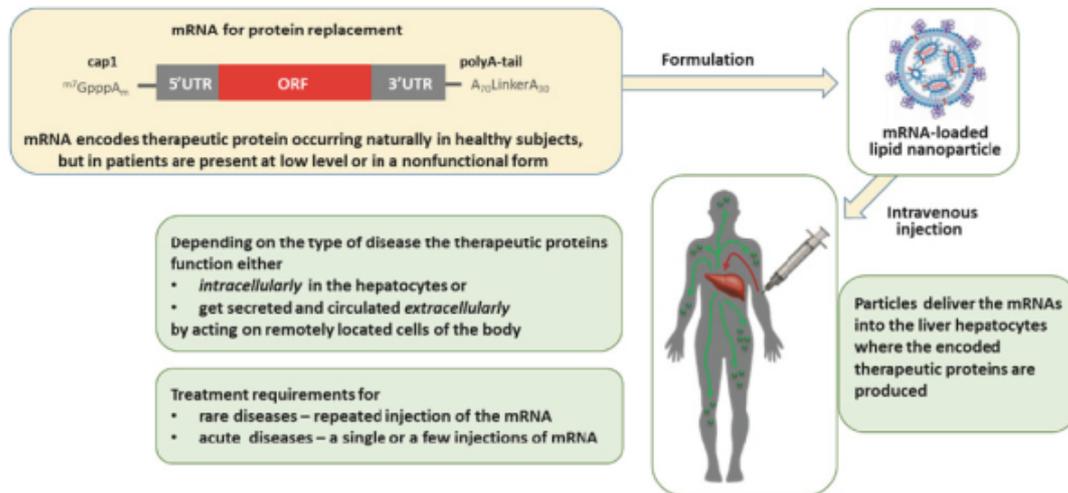
- **Concept:** Therapeutic proteins encoded by mRNA and produced in the patient as an alternative to recombinant protein replacement.
- **mRNA Format:** Nucleoside-modified mRNA, deimmunized to avoid immune activation in order to allow for translation of the therapeutic protein in the cells.
- **mRNA Delivery Formulation:** Liver-targeting LNPs.
- **Development Approach:** 50:50 cost and profit share with Genevant.

By incorporating modified nucleosides into our mRNA, we are able to reduce the immunogenicity of our product candidates, thereby allowing their use for therapeutic protein production. In addition, we utilize advanced mRNA delivery methods to protect the mRNA cargo *en route* to its target and promote its uptake into liver cells. Current protein-based replacement therapies were developed to treat rare diseases by administering recombinant proteins. Such therapies are limited to diseases where the missing protein function is extracellular. However, mRNA-based protein replacement therapy also has the potential to treat illnesses with intracellular protein defects, as long as the mRNA can be delivered into the affected cells.

Our mRNA-based protein replacement therapy features:

- **Nucleoside-modified mRNA.** Replacing uridines in mRNA with modified analogues is important to avoid immune activation that can provoke anti-drug antibody production and would limit efficacy of the treatment.
- **Liver targeted expression.** mRNA encoding therapeutic proteins are formulated into LNPs using in-licensed clinically-validated LNP delivery technology owned by Genevant. The mRNA-loaded LNPs are

less than 100nm in size. When injected intravenously, these particles are selectively taken up by hepatocytes, the major cell component of the liver.



Our mRNA-based protein replacement technology. The illustration above depicts our mRNA-based protein replacement process for the treatment of rare diseases.

Our protein replacement technology is designed for the treatment of:

- Genetic disorders that manifest due to a missing or defective protein, where mRNA would need to be administered regularly for a lifetime.
- Acute diseases caused by transient depletion of a protein, such as a hormone, where treatment of such diseases with a single or a few doses of the encoding mRNA could be curative.

Therapeutic proteins encoded by the mRNA can either act intracellularly or be secreted and act extracellularly, in order to produce the desired therapeutic effect.

mRNA-based protein replacement technology has several advantages over recombinant proteins:

- **No need to develop procedure for protein purification.** The development of recombinant proteins is a laborious and expensive procedure due to the requirement for a unique purification protocol for each protein. During mRNA-based protein replacement the protein is produced by the patient, which we believe avoids the need for purification and also accelerates drug development.
- **The protein has proper post-translational modification.** To function properly, most recombinant proteins need to be modified after synthesis. Proteins produced in patients from mRNA are more likely to obtain the correct modifications than recombinant proteins produced in cultured bacterial or mammalian cells.
- **Continuous *in vivo* supply of encoded protein.** Recombinant proteins, especially those with short half-lives, can be cleared from the body very quickly, thereby limiting therapeutic effect. During mRNA-based therapy, the encoded therapeutic protein is produced for a longer duration (*e.g.*, 10-14 days).
- **Production of intracellular proteins.** Recombinant proteins have limited intracellular therapeutic effects. In contrast, proteins encoded by mRNA can reach any cellular compartment and potentially help to cure diseases where the therapeutic protein needs to function in different subcellular locations, including the mitochondria, nucleus or cell membrane.

Our Protein Replacement Development Plan in Rare Diseases

We expect to initiate our first rare disease clinical trial in the second half of 2020.

4. RiboMabs

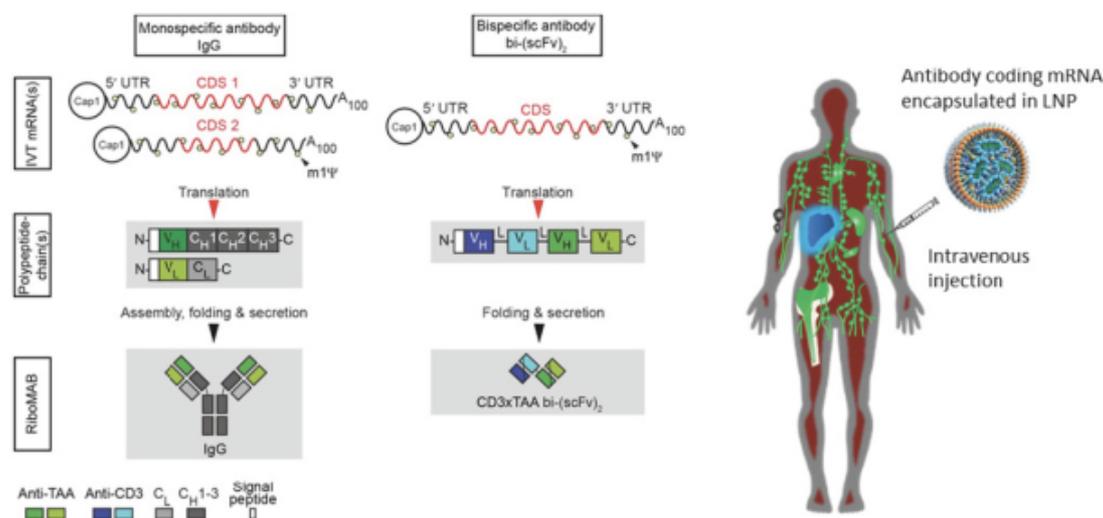
At a glance: Our RiboMab Platform

- **Concept:** Antibodies encoded by mRNA and produced in the patient as an alternative to recombinant antibodies.
- **mRNA Format:** Nucleoside-modified mRNA engineered for minimal immunogenicity in order to avoid immune detection and allow translation of the encoded antibodies to occur within the cells.
- **mRNA Delivery Formulation:** Various liver-targeting LNP formulations, delivered intravenously, to ensure systemic availability and prolonged production of the antibody *in vivo*.
- **Development Approach:** Worldwide rights; wholly owned.
- **Lead Candidate:** BNT141 in multiple solid tumors.

We believe our RiboMab technology represents the next generation of antibody-based drugs. Antibody drugs are a leading class of biologics for the treatment of various diseases, but have a number of limitations. The development of antibodies is currently challenged by demanding and costly procedures of production, purification and formulation of a recombinant protein, which we believe hampers the rapid development and clinical testing of new drugs in this class. Recombinant protein antibodies require development of a cell line, establishment and adaptation of processes for production, purification and analytical testing. The whole process typically takes 18 to 30 months to optimize, scale-up and produce first clinical batches. Some of these antibodies are produced in low yields making them unsuitable for therapeutic application.

By contrast, mRNA not only involves a simpler and less expensive manufacturing process, but also is effective in much lower volumes than are required to produce similar effects using recombinant proteins. RiboMabs simply involve the encoding of a sequence in the mRNA, and the body does the production work itself. This simplicity allows for both shorter development times and a greater diversity of druggable targets. For efficient RiboMab production, the encoding mRNA is encapsulated in LNPs that deliver the mRNA to the liver cells. For cancer treatment, we focus on tumor-associated antigens to keep adverse effects for the patients as low as possible. We believe we can integrate any antibody sequence in our RiboMab-encoding mRNA.

We have demonstrated the feasibility of our RiboMab technology for a variety of antibody formats, such as full immunoglobulins (Ig), primarily IgG, or different bispecific antibody variants, all of which engage the patient’s own immune cells to eradicate antigen-positive tumor cells.



Our RiboMab technology. The figure above depicts the structure of *in vitro* transcribed (IVT) IgG and bi-(scFv)₂ RiboMab. IVT-mRNA encoding the therapeutic antibody is encapsulated in LNPs and injected intravenously into patients. The mRNA is delivered to the liver where it is translated into antibodies and secreted into the blood stream. Abbreviations: A100, poly adenosine tail; bi-(scFv)₂, bispecific single chain variable fragment; C, C-terminus; CH, constant heavy domain; CL, constant light domain; IgG, immunoglobulin G; IVT, *in vitro* transcribed; L, linker; LNP, lipid nanoparticles; m1y, 1-methylpseudouridine; N, N-terminus; TAA, tumor-associated antigen; VH, variable heavy domain; VL, variable light domain; UTR, untranslated region.

We believe our broad portfolio of antibody formats will enable us to produce mRNAs encoding the appropriate antibody format for the individual patient’s medical need and the desired treatment regimen (*e.g.*, monotherapy or combination therapy).

Our RiboMab Development Plan

Our first development candidate, BNT141, is an IgG antibody, which we expect to enter the clinic in the first half of 2020 in a basket trial targeting multiple solid tumor types. We are also currently evaluating multiple additional RiboMab development candidates in the preclinical setting, including RiboMabs encoding bispecific antibodies, one of which, BNT142, we expect to enter the clinic in the second half of 2020.

Candidate	Target	Development Phase	Next Potential Milestone
BNT141 (monospecific)	Undisclosed	Preclinical	Initiate Phase 1 trial in 1H 2020
BNT142 (bispecific)	CD3xCLDN6	Preclinical	Initiate Phase 1 trial in 2H 2020

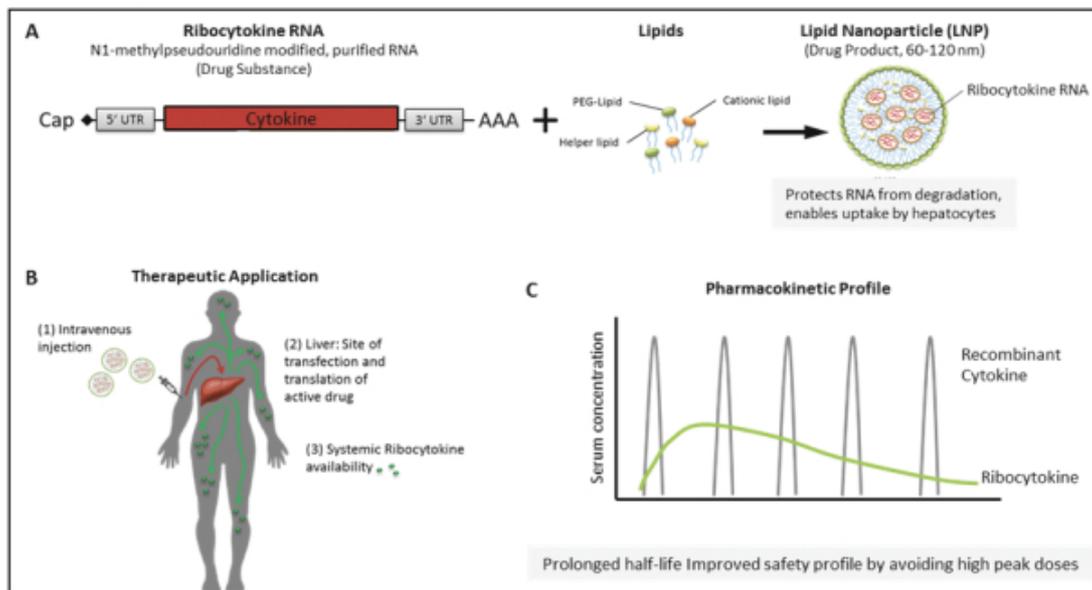
5. RiboCytokines

At a glance: Our RiboCytokine Platform

- **Concept:** Cytokines encoded by mRNA and produced in the patient as an alternative to recombinant cytokines.
- **mRNA Format:** Nucleoside-modified mRNA engineered for minimal immunogenicity in order to avoid immune detection and allow translation of the encoded cytokines to occur within the cells.
- **mRNA Delivery Formulation:** Various liver-targeting LNP formulations, delivered intravenously, to ensure systemic availability and prolonged production of the cytokine *in vivo*.
- **Development Approach:** Worldwide rights; wholly owned.
- **Lead Candidate:** BNT151 in multiple advanced malignancies.

Cytokines represent a large group of relatively small proteins (<30 kDa) that regulate a variety of biological functions as they elicit signaling for immune and non-immune cells. In particular, cytokines play a pivotal role in orchestrating the initiation, execution and extinction of innate and adaptive immunity against pathogens as well as malignant cells. Due to their natural role as immunomodulators, recombinant cytokines are currently used for the treatment of a number of infectious, inflammatory, autoimmune and malignant diseases. One of the major challenges associated with the therapeutic use of cytokines relates to their short serum half-life and low bioavailability. This impedes therapeutic efficacy as it necessitates high and frequent dosing, which often results in dose-limiting toxicities.

We have developed a wholly owned, novel mRNA-based platform technology called RiboCytokines, designed to address the limitations of recombinantly expressed cytokines.



Concept of our RiboCytokine technology. The graphic above depicts our RiboCytokine technology, including mRNA formulated in LNPs and administered by injection, having a beneficial pharmacokinetic profile.

Our RiboCytokine platform allows for sustained delivery of the encoded cytokines with prolonged half-life, including through:

- **Usage of N1-methylpseudouridine modified mRNA.** N1-methylpseudouridine as a nucleoside analogue prevents the recognition of mRNA by TLRs, avoiding immune attack against the mRNA drug.
- **Liver targeted expression.** mRNA-encoded cytokines are formulated as LNPs using in-licensed clinically validated LNP delivery technology owned by Genevant. LNPs selectively target the liver resulting in high-level expression.

We believe that apart from a beneficial pharmacokinetic profile, our mRNA-based RiboCytokine technology has a number of additional advantages over other types of cytokine therapies:

- **Less immunogenic than recombinant cytokines.** Expression of self and foreign antigens in the liver is associated with immune tolerance due to a unique anti-inflammatory microenvironment. We expect RiboCytokines to be less likely to trigger an immune response when compared to their recombinant counterparts.

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- **Shorter development times and greater diversity.** The development of recombinant cytokines is a challenge due to demanding and costly CMC procedures of production, purification and formulation. The simplicity of our mRNA manufacturing allows for both shorter development times and a greater diversity of druggable targets.

We believe that our RiboCytokine technology is particularly well-suited to identify candidates for combination treatment with our proprietary CAR T cell and cancer immunotherapies platforms.

Our RiboCytokine Development Plan

We expect our first two RiboCytokine product candidates, BNT151 and BNT152, to enter the clinic in the first half of 2020, in basket trials targeting multiple advanced malignancies.

<u>Candidate</u>	<u>Cytokines</u>	<u>Development Phase</u>	<u>Next Potential Milestone</u>
BNT151	Modified IL-2	Preclinical	Initiate Phase 1 trial in 1H 2020
BNT152	IL-7	Preclinical	Initiate Phase 1 trial in 1H 2020
BNT153	IL-2	Preclinical	—

IX. Our Engineered Cell Therapies Drug Class

The tailored reprogramming of autologous T cells from cancer patients to recognize and attack their tumors has become a disruptive medical innovation. Retargeting of T cells can be achieved via introduction of tumor-specific receptors into patient-derived T cells. For that purpose, T cells are mostly engineered by retroviral gene transfer to express either T cell receptors, or TCRs, or chimeric antigen receptors, or CARs. Recently, CAR expressing T cells, or CAR-T cells, became the first engineered T cell therapy to obtain FDA approval for some B cell derived hematological malignancies.

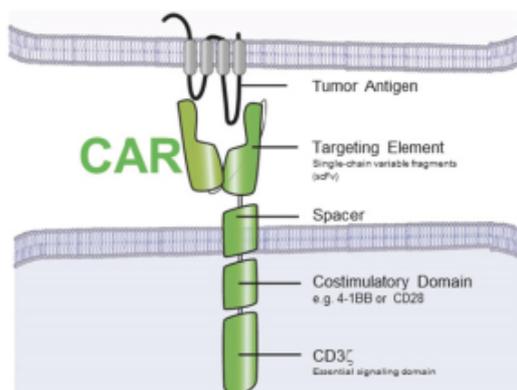
A. CAR-T cells

At a glance: Our CAR T Platform

- **Concept:** Second-generation CAR T therapy designed to overcome the shortcomings of CAR T therapy in solid tumors.
- **Mechanism:** T cells with CARs engineered to target cancer-specific antigens, including novel antigens selected from our proprietary antigen library and administered with a FixVac immune booster to enhance CAR-T cell expansion and persistence.
- **Development Approach:** Worldwide rights; wholly owned.
- **Lead Candidate:** BNT211 for multiple solid tumors.

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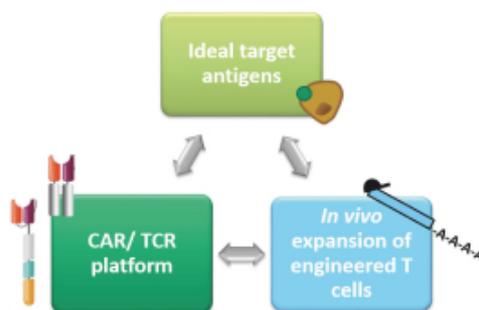
CARs are artificial receptors that consist of an antigen recognition domain derived from a tumor-specific antibody linked to intracellular T cell signaling domains. CARs redirect T cells to eradicate tumors through specific recognition of native surface proteins expressed on tumor cells in a non-MHC-restricted manner. Therefore, CAR-T cells can be used for the treatment of all individuals whose tumor expresses the respective target, independent of the individual's HLA genotype. CARs can be used for redirection of both CD4⁺ and CD8⁺ T cells.



Second-generation CAR. The figure above illustrates the basic structure of a second-generation CAR, such as those included in our BNT211 and BNT212 product candidates.

While CAR T therapy has shown potent anti-tumor responses in patients with B cell malignancies, clinical efficacy in solid tumors so far is limited. The main hurdles for application of CAR T therapies in solid tumors are:

- Lack of highly tumor selective targets, which are needed for safe and effective tumor targeting; and
- Low anti-tumoral activity due to insufficient expansion of engineered T cells.



Our platforms for development of next-generation engineered T cell therapies. Our engineered cell therapies combine our antigen selection capabilities with our FixVac immunotherapy to enhance T cell activation and expansion.

We are developing the next generation of engineered T cell therapies that:

- target novel and known tumor-specific antigens, including mutant neoantigens, and a broad spectrum of tumor-associated antigens expressed in a wide range of cancers; and
- leverage our proprietary FixVac technology for controlled *in vivo* stimulation, activation and expansion of engineered T cells.

The powerful characteristics of CAR-T cells, including their potential to eradicate targeted tumor cells in combination with their potentially life-long persistence in the host, require careful target selection. We believe the essential features of an ideal antigen for T cell-based immunotherapy are:

- Absence of expression from any toxicity-relevant non-malignant tissue, to prevent off-tumor/on-target toxicity; and
- Expression on the cell surface of tumor cells at sufficient levels to allow for recognition and lysis by CAR-T cells.

We are developing CAR T programs targeting two different members of the Claudin family, namely CLDN6 and CLDN18.2. Claudins, or CLDNs, are central components of tight junctions that regulate epithelial-cell barrier function and polarity. Most of the CLDNs are broadly expressed, while CLDN6 and CLDN18.2 are exclusively expressed in different high medical need cancers. Disturbance and dysregulation of tight junction molecules is a frequent hallmark of cancer cells and often associated with malignant transformation and metastasis and, hence, disease progression.

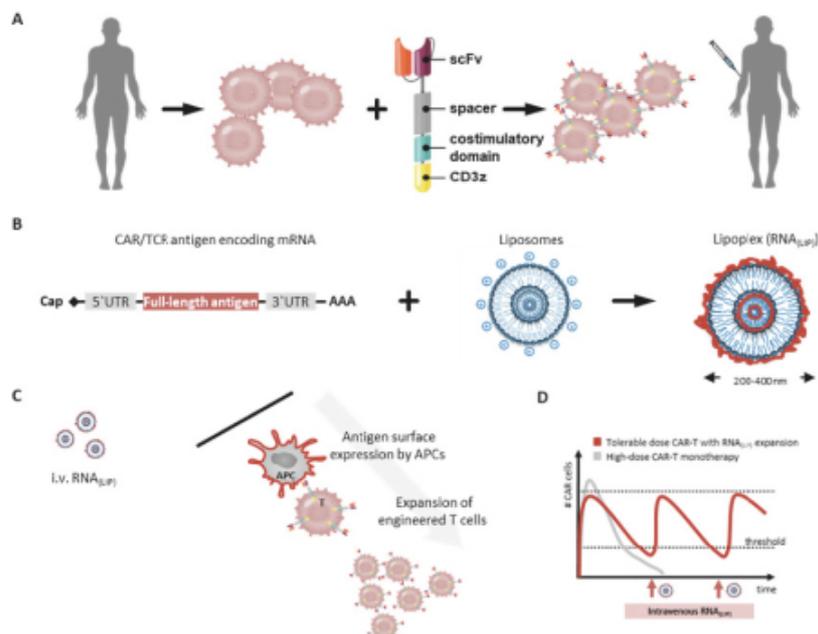
CLDN6 is an oncofetal cell surface antigen expressed in embryonic stem cells during fetal development. The gene encoding CLDN6 is strictly silenced and not expressed in healthy adult tissues but re-activated in different cancers with a high medical need including ovarian, endometrial, testicular and lung cancers.

In contrast to CLDN6, CLDN18.2 is a tissue restricted marker that is exclusively expressed in short-lived differentiated cells of the gastric mucosa. CLDN18.2 is observed in a large fraction of gastric cancers. In addition, CLDN18.2 is aberrantly activated in a variety of tumor entities, including esophageal cancer, pancreatic adenocarcinoma and cholangiocarcinoma.

In vivo expansion of engineered T cells using liposomally formulated mRNA

Besides targeting an ideal tumor-specific antigen, the frequency and the persistence of CAR-T cells in the respective patient is a critical factor determining antitumor efficacy. A positive correlation between clinical outcome and CAR-T cell engraftment and persistence has been shown in several CD19-targeting CAR T trials. Both tend to be much more limited in the solid tumor setting, likely due to the lack of circulating antigen-presenting cells, or APCs, such as dendritic cells expressing the target CAR antigen.

To address this critical factor, we developed an approach for *in vivo* stimulation of CAR-T cells that relies on our proprietary FixVac technology for systemic mRNA delivery in combination with our CAR T product candidates. Intravenous administration of a FixVac encoding for the tumor antigen induces expression of the desired target on antigen-presenting cells in secondary lymphoid tissues. FixVac treatment facilitates *in vivo* expansion of CAR-T cells in a dose-dependent manner. Moreover repetitive administration of FixVac results in an improved CAR-T cell persistence as well as increased anti-tumor activity.



Our CAR-T cell immunotherapies combined with FixVac-mediated *in vivo* expansion. (A) Autologous T cells engineered to express a CAR are adoptively transferred into the patient. (B) Full-length CAR target-encoding mRNA is complexed with liposomes to form lipoplexes (FixVac). (C) Intravenously administered FixVac selectively targets APCs in secondary lymphoid organs facilitating uptake, antigen expression and maturation of APCs. Exposure of CAR-T cells to their target results in CAR-T cell *in vivo* expansion. (D) FixVac can be administered repetitively to achieve controlled expansion and persistence of CAR-T cells within the therapeutic window.

Our CAR T Development Plan

Our first CAR T product candidate, BNT211, includes a second-generation CAR directed against CLDN6. Our second product candidate is BNT212, which includes a CLDN18.2-targeting CAR. We expect to initiate a Phase 1/2 basket trial of our novel combination CLDN6 CAR-T cell and CLDN6 FixVac product candidate in multiple solid tumors in the first half of 2020.

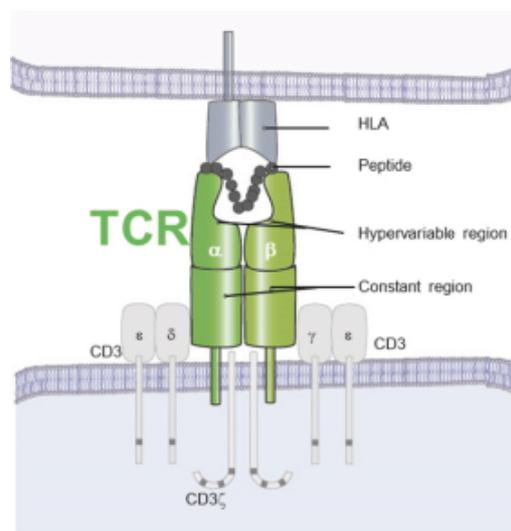
<u>Candidate</u>	<u>Antigen Target</u>	<u>Development Phase</u>	<u>Next Potential Milestone</u>
BNT211	CLDN6	Preclinical	Initiate Phase 1/2 trial in 1H 2020
BNT212	CLDN18.2	Preclinical	—

B. TCRs

The TCR is part of a complex signaling machinery, which includes the TCR α and β chains that are responsible for antigen recognition, the coreceptor CD4⁺ or CD8⁺ and the CD3 signal transduction complex. TCRs recognize antigens presented on the cell surface as small peptides loaded on the patients' HLA molecules.

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Those peptides are derived from proteins after intracellular degradation. In contrast to CARs that recognize solely native membrane proteins, the repertoire of suitable TCR target antigens include TAAs and mutant neoantigens.



TCR complex. The illustration above shows the basic structure of a TCR complex.

Our TCR discovery and validation platform

We have developed an integrated technology platform for the systematic identification of functional, fully human TCRs from single antigen-reactive T cells. This technology consists of a proprietary high-throughput approach for the fast retrieval, cloning and rapid validation of novel paired T cell receptor sequences. Our approach facilitates the isolation of tumor cell specific TCRs against multiple antigens and various HLA class I and II alleles.

We believe our TCR discovery technology has the potential to unlock an array of patient and tumor specific TCRs suitable for clinical use. We believe this technology has potential utility for:

- therapeutic TCR products encompassing single TCRs for targeting a specific antigen;
- a therapeutic TCR warehouse encompassing multiple TCRs for targeting of one or more tumor antigens; or
- individualized T cell therapy involving on-demand identification and timely manufacturing of customized, engineered T cells with autologous TCRs against neoepitopes for adoptive transfer.

Our TCR Development Plan

We and our collaborator Eli Lilly are studying potential TCR product candidates in preclinical studies.

X. Our Antibodies Drug Class

In the past decades, monoclonal antibodies, or mAbs, have transformed from scientific tools to powerful human therapeutics. As one of the fastest growing classes of drugs, to date, more than 40 mAbs have been approved to treat a variety of diseases including cancer, inflammation, autoimmune diseases and others. In addition, identified antigen binding domains are also fundamental elements for the construction of novel therapeutic formats and formulations, such as CAR-T cells, bispecific therapeutics and targeted nanoparticles.

We have developed and integrated multiple complementary antibody and antibody-mimetic protein technologies into our overall portfolio of treatment approaches.

A. Our next-generation checkpoint immunomodulators

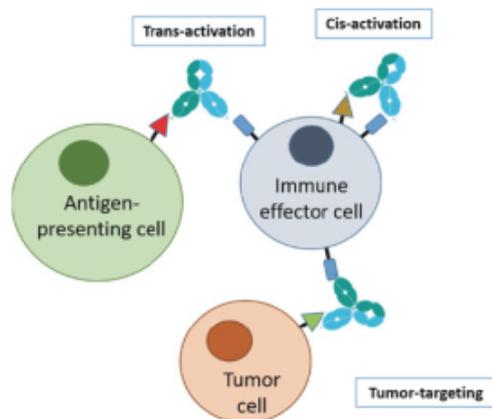
At a glance: Our Next-generation Checkpoint Immunomodulators

- **Concept:** Bispecific antibodies for dual immunomodulation, initially targeting 4-1BB, an immune checkpoint that is expressed on T cells and NK cells and can enhance immune cell proliferation and activation, in combination with simultaneous checkpoint inhibition.
- **Mechanism:** Conditional activation of 4-1BB checkpoint only upon simultaneous binding of PD-L1 or CD40 (in the case of our initial candidates), potentially avoiding toxicities seen in prior attempts at 4-1BB agonism by localizing 4-1BB activation to the tumor environment.
- **Development Approach:** 50:50 cost and profit share with Genmab, combining our and Genmab's immunostimulatory antibodies and extensive immunology expertise with Genmab's DuoBody bispecific antibody platform.
- **Lead Candidate:** GEN1046 (BNT311), our PD-L1x4-1BB product candidate for multiple solid tumors.

Following the success of immune checkpoint blocking antibodies targeting CTLA-4, PD-1 or PD-L1 in cancer treatment, bispecific antibody formats represent the next generation of emerging immunotherapies with the potential to further improve clinical efficacy. In addition to bispecific T cell engager formats, which redirect T-cell cytotoxicity to malignant cells, bispecific antibodies can be formatted as tumor-targeted immunomodulators and dual immunomodulators. Tumor-targeted immunomodulators direct potent immune costimulation to the tumor-infiltrating immune cells, whereas dual immunomodulators simultaneously address two immunomodulating targets, resulting in blockade of inhibitory targets, depletion of suppressive cells or activation of immune effector cells.

We are developing, in collaboration with Genmab, bispecific antibodies that function as dual immunomodulators, applying Genmab's proprietary DuoBody technology in combination with our target identification expertise. These next-generation checkpoint immunomodulators are thought to induce beneficial co-stimulation, promoting specific T cell activation, survival, proliferation and T cell effector functions. Our collaboration encompasses three potential classes of immunotherapeutic bispecific antibodies:

- Tumor-targeted DuoBody molecules are bispecific antibodies targeting a tumor-specific antigen expressed by the malignant cell, and an immunomodulatory receptor expressed by tumor-infiltrating immune cells. This is expected to induce powerful activation of tumor-specific effector immune cells with reduced risk of immune-related adverse events.
- Cis-activating DuoBody molecules are bispecific antibodies that bind two distinct immunomodulating targets presented on the same cell. Addressed targets are specifically expressed on activated immune cells with the rationale to boost existing immune responses by additive or synergistic effects of dual immunomodulation.
- Trans-activating DuoBody molecules are bispecific antibodies that bind two distinct immunomodulating targets expressed on two separate cell subsets. By simultaneously targeting, for example, effector immune cells and antigen-presenting cells, these compounds are thought to amplify the immune cell priming process and augment subsequent effector responses.



Next-generation checkpoint immunomodulators. Our collaboration with Genmab potentially includes bispecific antibodies from three different classes: trans-activating, cis-activating and tumor-targeting antibodies.

Our Next-generation Checkpoint Immunomodulator Development Plan

We are currently developing two next-generation checkpoint immunomodulator product candidates: GEN1046 (BNT311), our anti-PDL1x4-1BB bispecific antibody, and BNT312, our CD40x4-1BB bispecific antibody.

Candidate	Targets	Development Phase	Next Potential Milestone
GEN1046 (BNT311)	PD-L1x4-1BB	Phase 1/2 basket trial in multiple solid tumors	—
BNT312	CD-40x4-1BB	IND filed	Commence Phase 1 trial in 2H 2019

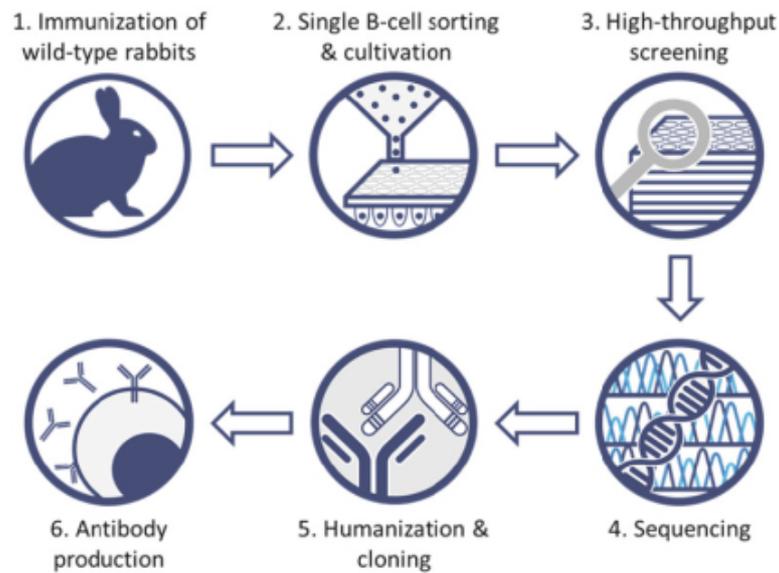
B. Our antibody discovery engines

We believe that our multiple antibody discovery engines significantly expand our targeting repertoire and enable us to directly, rapidly and efficiently produce new mAb candidates. In addition, antigen-binding domain sequences identified through our antibody discovery engines also feed into our proprietary CAR T cell and mRNA-encoded RiboMab platforms as well as our next-generation checkpoint immunomodulator collaboration. For instance, binders to human 4-1BB were identified from a previous antibody generation campaign and are currently under clinical and preclinical development as part of our next-generation checkpoint immunomodulator collaboration with Genmab. HuMab, our human antibody discovery engine acquired from MabVax Therapeutics in 2019, led to the clinical development of our fully human IgG1 monoclonal antibody product candidate targeting Sialyl Lewis^a (sLea^a), a carbohydrate moiety that is present in over 90% of pancreatic and a large percentage of gastrointestinal cancers.

1. Our rabbit-based antibody discovery engine

With the acquisition of MAB Discovery GmbH’s antibody generation unit in 2019, we integrated a unique and proprietary rabbit-based antibody discovery platform that can generate and develop high quality, functional mAbs targeting traditional proteins and receptors as well as a wide variety of more challenging targets. Rabbit monoclonal antibodies are highly diverse and do not require affinity maturation, due to consistently high affinities. They often recognize epitopes on human antigens that are not immunogenic in rodents, thus increasing the total number of targetable epitopes. The mechanisms of antibody diversification in rabbits allow an easy and quick translation of preclinical data into the clinic with an improved probability of success. We established a

streamlined semi-automated process of rabbit immunization for the efficient production of high-affinity rabbit mAbs.

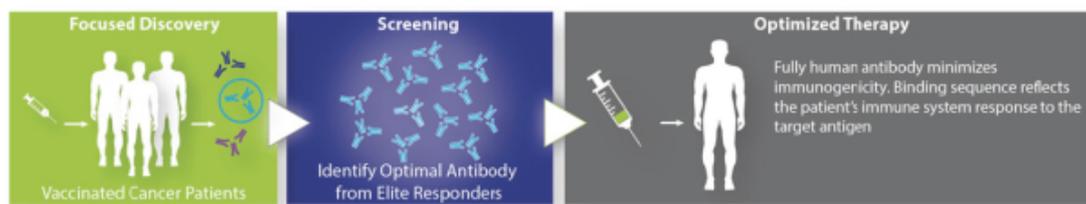


Our rabbit-based antibody discovery engine. The figure above depicts our semi-automated process for the discovery and production of high-affinity rabbit mAbs.

2. Our fully human antibody discovery engine

Our HuMab discovery technology focuses on abnormal carbohydrate targets upregulated on solid tumors. Aberrant glycosylation is a common phenotypic change of cancer cells that mainly affects the outer part of glycans. These abnormal carbohydrate structures are known as tumor-associated carbohydrate antigens, or TACAs, and are associated with malignancy grade, invasion, metastasis and poor prognosis. TACAs are considered promising novel targets for therapeutic intervention using, in particular, mAbs or CAR-T cells. However, TACAs usually induce only low-affinity humoral immune responses, since carbohydrate moieties do not trigger the necessary T cell responses.

Using B cell sorting, hit identification, sequencing, antibody production and high-throughput antibody screening, we are able to select optimal TACA-specific antibodies from multiple clinically confirmed immunotherapy responders. All antibodies emanating from this platform are fully human with no need for additional humanization at minimal risk for immunogenicity.



Our fully human antibody discovery engine. The figure above shows our proprietary approach to the discovery and development of novel fully human antibody therapeutic and diagnostic agents.

Our targeted cancer antibody development plan

<u>Candidate</u>	<u>Targets</u>	<u>Development Phase</u>	<u>Next Potential Milestone</u>
MVT-5873 (BNT321)	sLea	Phase 1 basket trial in multiple solid tumors; currently paused	Resume Phase 1 trial in 2H 2019

XI. Our Small Molecule Immunomodulator Drug Class

At a glance: Our Small Molecule Immunomodulators

- **Concept:** Small molecule therapies, with a specific focus on TLRs, that can be used synergistically with other cancer therapeutics, including other product candidates in our portfolio.
- **Development Approach:** Worldwide rights; wholly owned.
- **Lead Candidate:** BNT411, our TLR7 agonist product candidate intended for combination therapies.

Small molecule cancer therapeutics can be used to regulate cancer growth, halt blood vessel formation in tumors, deliver toxins to cancer cells and mark cancer cells for destruction by the immune system. Unlike larger antibody-based cancer therapies, small molecule compounds are often developed for targets located within cells since they can enter the cells more easily as a result of their physical properties and low molecular weight. Small molecules also often have other intrinsic benefits including relative ease and cost of production compared to larger compounds, as well as more frequently having the potential for oral administration to patients. They can also often be used synergistically in combination with other therapeutics such as mRNA, checkpoint inhibitors, radiation therapy and chemotherapy.

We aim to discover and develop the next generation of small molecule immunomodulatory compounds to improve the standard of care. We have a team of approximately 25 scientists and technicians, with extensive small molecule experience, focused on drug discovery.

Our immunomodulatory small molecule product class focuses on a range of endosomal and intracellular targets that are known to stimulate the activity of a wide range of immune cells. We have a particular emphasis on TLRs. TLRs are a family of pattern recognition receptors that function as primary sensors of the innate immune system to recognize pathogens. We believe TLRs represent a promising target class for cancer immunotherapy, particularly for inflammatory re-programming of the tumor microenvironment. In many cancers, tumors are protected by an anti-inflammatory environment, which reduces the ability of the immune system to attack the cancer cells. TLR7 agonists are able to initiate a direct cellular immune response, for example, by activating immature dendritic cells, cytotoxic T cells and NK cells, as well as stimulating the release of signal molecules such as cytokines and chemokines including IFN- α and IP-10, which can be directed against tumor cells. The activation of the innate and adaptive immune system and the release of cytokines and chemokines, for instance by our small molecule TLR7 agonist, results in the potent stimulation of antigen specific T cells, B cells and innate immune cells such as NK cells and macrophages.

Our initial focus is on small molecule product candidates that activate the innate and adaptive immune system via TLR7 and are designed to be used in combination with chemotherapeutics as well as checkpoint inhibitors.

Our Small Molecule Immunomodulator Development Plan

Our initial development candidate is a potent TLR7 agonist, which we plan to develop as a combination therapy for small cell lung cancer and other solid tumors.

<u>Candidate</u>	<u>Target</u>	<u>Development Phase</u>	<u>Next Potential Milestone</u>
BNT411	TLR7	Preclinical	Initiate Phase 1 trial in 1H 2020

XII. OUR PRODUCT CANDIDATES

We are developing a broad and deep pipeline of over 20 product candidates across our four drug classes. Our product candidates are currently being investigated in eight clinical trials, and we expect to have up to 10 product candidates in the clinic by the end of 2019.

Oncology								
Drug Class	Platform	Product Candidate	Indication (Targets)	Preclinical	Phase 1	Phase 2	Phase 3	Rights/ Collaborator
mRNA	FixVac (fixed combination of shared cancer antigens)	BNT111	Advanced Melanoma (Adjuvant & Metastatic)					Global
		BNT112	Prostate Cancer					Global
		BNT113	HPV+ Head and Neck Cancer ¹					Global
		BNT114	Triple Negative Breast Cancer					Global
		BNT115, BNT116	Other Cancers, including Ovarian Cancer					Global
	iNeST (patient-specific cancer antigen therapy)	RO7198457 (BNT122)	IL Melanoma with CPI ²					Genentech (Global 50:50 profit/loss share)
			Multiple Solid Tumors					
	Intratumoral Immunotherapy	SAR441000 (BNT131)	Solid Tumors (<i>IL-12sc</i> , <i>IL-15sushi</i> , <i>GM-CSF</i> , <i>IFNα</i>)					Sanofi (Global profit/loss share)
	RiboMabs (mRNA-encoded antibodies)	BNT141	Multiple Solid Tumors					Global
			BNT142	Multiple Solid Tumors (<i>CD3+CLDN6</i>)				Global
	RiboCytokines (mRNA-encoded cytokines)	BNT151	Multiple Solid Tumors (Optimized <i>IL-2</i>)					Global
			BNT152	Multiple Solid Tumors (<i>IL-7</i>)				Global
			BNT153	Multiple Solid Tumors (<i>IL-2</i>)				Global
	Engineered Cell Therapies	CAR-T Cells	BNT211	Multiple Solid Tumors (<i>CLDN6</i>)				Global
			BNT212	Pancreatic, Other Cancers (<i>CLDN18.2</i>)				Global
TCRs		To be selected	Solid Tumors					Eli Lilly (Exclusive license option)
		To be selected	All Tumors					Global
Antibodies	Next-Gen CP ³ Immunomodulators	GEN1046 (BNT311)	Multiple Solid Tumors (<i>PD-L1</i> × <i>4-1BB</i>)				Genmab (Global 50:50 profit/loss share)	
		BNT312	Multiple Solid Tumors (<i>CD40</i> × <i>4-1BB</i>)					
SM Immunomodulators	Targeted Cancer Antibodies	MVT-5873 (BNT321)	Pancreatic Cancer (<i>sLe^x</i>)				Global	
	Toll-Like Receptor Binding	BNT411	Solid Tumors (<i>TLR7</i>)				Global	
Other								
Drug Class	Platform	Product Candidate	Indication (Targets)	Preclinical	Phase 1	Phase 2	Phase 3	Rights/ Collaborator
mRNA	Infectious Disease Immunotherapies	BNT161	Influenza					Pfizer
			Up to 10 Indications					Penn ⁴
	Rare Disease PRT ⁵	To be selected	5 Rare Disease Indications					Genevant (Global 50:50 profit/loss share)

¹ BNT113 is currently being studied in an investigator-initiated Phase 1 trial

² Checkpoint Inhibitor

³ Checkpoint

⁴ We are eligible to receive worldwide licenses

⁵ Protein Replacement Therapy

A. Our mRNA Product Class in Oncology

1. FixVac

FixVac is our wholly owned systemic off-the-shelf mRNA-based cancer immunotherapy platform, from which we are developing several first-in-human and potential first-in-class product candidates. FixVac product candidates are designed to trigger both innate and adaptive immune responses by encoding selected combinations of shared, tumor-associated antigens.

a) BNT111: Our FixVac Cancer Immunotherapy for the Treatment of Advanced Melanoma

We are developing our mRNA-based FixVac product candidate BNT111 for the treatment of advanced melanoma in patients with metastatic tumors and as an adjuvant treatment after tumor resection. We are currently studying BNT111 in an ongoing Phase 1 clinical trial.

Melanoma

Melanoma is an increasingly prevalent, deadly form of skin cancer in which melanocytes, which are the cells that color the skin, form malignant cells. With 132,000 new cases diagnosed globally each year, melanoma constitutes less than five percent of all skin cancers. In recent decades, however, the incidence rate of melanoma has risen faster than almost any other cancer type, on average by 1.5% per year over the last 10 years. In 2018, approximately 91,000 new melanoma cases were diagnosed in the United States, representing 5.3% of all new cancer cases in the United States.

Melanoma is the most lethal form of skin cancer, accounting for the majority of skin cancer deaths. There were an estimated 9,300 deaths from melanoma in the United States in 2018. While the five-year survival rate for melanoma, regardless of disease stage, is approximately 91.8%, patients with stage III melanoma have a five-year survival rate of approximately 63%. The five-year survival rate for metastatic melanoma (stage IV) is approximately 20%.

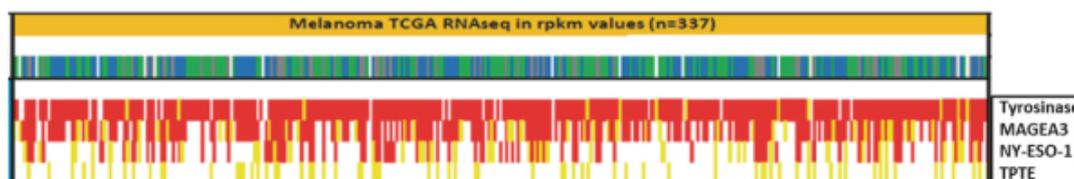
The current treatment regimen involves surgical removal for earlier stages, while a number of targeted therapies, such as BRAF and MEK inhibitors, and checkpoint inhibitors are approved for advanced disease. Checkpoint inhibitors include nivolumab (Opdivo) for advanced or metastatic melanoma after resection, and pembrolizumab (Keytruda) in unresectable or metastatic disease.

Our BNT111 Targets

BNT111 is designed to elicit an immune response to the following four antigens that have each been found to be associated with melanoma:

- New York esophageal squamous cell carcinoma 1, or NY-ESO-1, a well-known cancer-testis antigen that is also expressed in numerous cancers, including melanoma;
- melanoma-associated antigen A3, or MAGE-A3, which is not expressed in normal tissues, except the testis and the placenta;
- tyrosinase, an enzyme that is required for melanin production and that is produced in increased levels in melanoma; and
- trans-membrane phosphatase with tensin homology, or TPTE, a novel cancer-testis antigen that we discovered internally.

We sequenced over 300 melanoma tumors and detected at least one of these four antigens in over 90% of melanoma tumors.



BNT111 antigens detected in over 90% of melanoma tumors. The graphic above shows expression of BNT111 target antigens on a patient by patient basis. Each row at the bottom of the graphic represents an antigen, and each vertical line represents a patient, depicting whether or not that patient expressed each antigen.

Our BNT111 Clinical Trials

Ongoing Phase 1 trial in advanced melanoma patients (LIPOMERIT study)

We are conducting a multi-center, open-label, first-in-human, Phase 1 dose escalation study evaluating the safety and tolerability of multiple intravenous administrations of BNT111 in patients with advanced melanoma. This is the first clinical trial worldwide in which an mRNA-based cancer immunotherapy is administered intravenously for systemic treatment.

The trial employs a conventional 3+3 design, in which patients are dosed in groups of three at incrementally greater dosages until the maximum tolerated dose is identified, during the dose escalation phase, which is then followed by expanded dose cohorts. Patients are treated with doses from 7.2µg up to the highest administered dose of 400µg total mRNA.

July 2019 Interim Data

As of July 2019, 89 patients had been dosed at least once at one of four centers in Germany. Baseline and demographic characteristics were largely as expected for a trial recruiting advanced stage IIIB-IIIC and stage IV melanoma patients with and without measurable disease. Approximately half of the patients were resected and had radiographically non-evaluable disease at baseline. The other half of the patients had radiographically evaluable disease at baseline and most of these patients were heavily pretreated. Only the subset of patients with evaluable disease at baseline was assessed for preliminary clinical activity.

Immunogenicity. Immune responses induced by BNT111 were assessed using various orthogonal assay systems by analyzing T cells against each vaccine antigen in pre- and post-treatment blood samples of patients. Approximately half of the dosed patients have been analyzed for immune responses. A first analysis in a subset of 18 patients evaluated vaccine antigen reactivity of CD4+ and CD8+ T cells by IFNγ ELISpot after *in vitro* stimulation. All tested patients showed either a *de novo* or an augmented (as compared to baseline) immune response against at least one of the BNT111-encoded tumour antigens. Most patients exhibited either CD4+ or concurrent CD4+ and CD8+ T cell responses against the individual vaccine targets. A second analysis looked at the magnitude of immune responses on the individual level by using an *ex vivo* IFNγ ELISpot, which due to its sensitivity level would only capture very strong T cell responses. This analysis showed that more than 75% of patients exhibited vaccine-induced CD4+ or CD8+ T cell responses. The kinetics of *de novo*-induced CD8+ T cells were further characterized in selected patients of interest by a third method using *ex vivo* MHC peptide multimer staining of blood samples collected at baseline and at different time points after start of vaccination. Antigen-specific T cell counts generally demonstrated a rapid ramp-up from being undetectable at baseline to levels ranging from 1,000 to more than 100,000 per million circulating CD8+ T cells within the first 4-8 weeks of treatment. Under monthly maintenance treatment, frequencies of individual antigen-specific T cells continued to slowly increase or remained stable up to over one year. In patients who did not continue on maintenance vaccination, robust memory T cell responses were detectable up to six months after the last vaccination.

Clinical activity. As of July 2019, in our review of interim data, we assessed 42 patients with radiographically evaluable, measurable disease at baseline for preliminary clinical activity according to Response Evaluation Criteria in Solid Tumors, Version 1.1, or RECIST v1.1. 25 of these 42 patients received BNT111 as a monotherapy, and 17 patients received BNT111 in combination with an anti-PD-1 checkpoint inhibitor, or CPI (either pembrolizumab or nivolumab).

In the BNT111 monotherapy cohort, we observed clinical activity for all 25 patients. All of these patients had received at least one line of prior treatment with a CPI, and 24 of the 25 patients had failed prior sequential or combination treatment with anti-PD-1 and anti-CTLA4 antibodies. Four of 25 patients (16%) showed a partial response, or PR, and seven patients (28%) demonstrated stable disease. The clinical benefit rate, or CBR, is 44%. Two of the PRs manifested early on during treatment (at imaging day 90); the two others manifested at imaging days 180 and 360, respectively.

In the BNT111 in combination with anti-PD-1 CPI cohort, 16 of the 17 patients had prior treatment with CPI. Six patients (35%) showed a partial response, and two patients (12%) demonstrated stable disease. The CBR is 47%. Objective responses were observed across all dose levels explored in expansion cohorts (14µg, 50 µg and 100µg). Five of 10 (50%) patients who received the highest target dose of 100µg demonstrated a PR.

Completed Phase 1 trial in patients with advanced melanoma (MERIT study)

In 2016, we published results of a first-in-human dose escalation study evaluating the safety and tolerability of intranodal administration of an earlier generation of BNT111 in patients with advanced melanoma. In this study, the earlier formulation of BNT111 targeted only NY-ESO-1 and tyrosinase.

This international, multi-center, open-label interventional study's primary endpoints were the maximum tolerated dose for multiple dosing, safety and adverse reactions and tolerability profile of multiple dosing. The secondary endpoints were (i) to observe immunotherapy-induced immune responses following multiple treatment cycles and (ii) clinical benefit (complete response, partial response and stable disease).

Five dosages were administered to patients sequentially: 50µg, 100µg, 300µg, 600µg, and 1,000µg. The sample size for the first three doses was three each. The 600µg dose cohort was comprised of 13 patients and the 1,000µg dose cohort was comprised of seven patients. In the 100µg, 300µg and 600µg dose cohorts, seven patients in total received continued treatment. The overall individual treatment period was 43 to 51 days and comprised eight treatment cycles of ultrasound-guided intranodal injections on days one, four, eight, 11, 15-17, 22-26, 29-35 and 43-51. In case of an optional continued treatment for patients who neither exhibited unacceptable drug-related toxicity nor disease progression, four additional treatment cycles were administered at the same dosage that the patient had received in his or her cohort. The first cycle of continued treatment was scheduled 14-42 days after the last visit, with the second and third additional treatment cycles following after a one-month interval each. The fourth treatment cycle then followed after an interval of three months.

The occurrence of new measurable lesions was observed in only one patient of the 1,000µg dose cohort, while new non-measurable lesions were identified in seven patients. Twenty-one patients, or 75%, were classified as having immune-related stable disease and six patients, or 21.4%, had immune-related progressive disease.

The most frequent adverse events included administration site conditions, infections and infestations, musculoskeletal and connective tissue disorders, nasopharyngitis, fatigue, headache and back pain. No life-threatening adverse events nor deaths occurred in this study. Thirteen severe adverse events were reported, including infections and infestations and vascular disorders. Sixteen patients were affected by adverse events with a suspected relationship to the study drug. These were most frequently fatigue, application site erythema and application site pain. None of the drug-related adverse events was categorized as serious. No dose-limiting toxicities were observed.

Next Steps

We expect to report Phase 1 data from the LIPOMERIT trial and to initiate a Phase 2 clinical trial for BNT111 in the first half of 2020.

b) BNT112: Our FixVac Cancer Immunotherapy for the Treatment of Prostate Cancer

We are developing BNT112 for the treatment of prostate cancer.

Prostate Cancer

Prostate cancer is the second most common cancer amongst men worldwide and the fourth most commonly occurring cancer overall, with around 1.3 million new cases recorded worldwide in 2018 and 174,650 cases expected in 2019 in the United States alone. The stage of the prostate cancer (I-IV), alongside the prostate-specific antigen and Gleason score, are the key factors for defining the treatment options for individual cases. Surgical or radiation based approaches are often used in first-line therapy, however after relapse (up to 30-40% of patients), androgen-deprivation therapies are employed, which in turn also often become redundant (metastatic castration-resistant prostate cancer, or mCRPC) at which point patients are treated with either further hormonal agents or chemotherapy.

Our BNT112 Targets

BNT112 is designed to elicit an immune response to five prostate cancer-specific antigens, including prostate-specific antigen, or PSA, a transmembrane protein that is expressed by virtually all prostate cancers, prostatic acid phosphatase, or PAP, and three undisclosed antigens.

Our BNT112 Clinical Trials

Planned Phase 1/2 Clinical Trial

We plan to initiate an open-label, multi-center, first-in-human Phase 1/2 individual dose titration study of BNT112 in patients with mCRPC and high-risk localized prostate cancer, or LPC, in the second half of 2019. Eligible patients will have newly diagnosed high-risk localized prostate cancer and will be treated with BNT112 as a single agent, in combination with cemiplimab and goserelin acetate or in combination with goserelin acetate alone. We anticipate a total enrollment of 60 to 80 patients at up to 20 investigational sites.

The study is designed to evaluate the safety, tolerability, immunogenicity and preliminary efficacy of BNT112 in mCRPC and LPC patients. The primary objective of this study will be to establish the safety and tolerability of BNT112 alone, or in combination with goserelin acetate with or without cemiplimab. The secondary objectives of the trial will be to examine the immunogenicity of BNT112 alone or in combination with goserelin acetate with or without cemiplimab, and to evaluate anti-tumor activity based on levels of prostate-specific antigen, or PSA.

The study will consist of three arms. The first arm will start with a dose titration phase for the initial safety assessment and recommended expansion dose range assessment. We anticipate enrollment of approximately 20 patients in arm one who will receive BNT112 alone, with up to nine patients participating in the dose titration part of the arm (with staggered starting groups of three patients one week apart). Titration will continue until unacceptable toxicity or disease progression. Efficacy in the first arm will be assessed by on-treatment imaging and in the second and third arms by tumor volume measurement.

After at least six patients are treated and evaluable for at least one treatment cycle, we plan to commence enrollment of the second and third arms, each enrolling approximately 20 patients with newly diagnosed LPC. Patients in the second arm will receive BNT112 combined with goserelin acetate and cemiplimab, and patients in

the third arm will receive BNT112 combined with goserelin acetate alone. Treatment periods in the second and third arms will last until unacceptable toxicity or until the end of the eighth cycle, which will be followed by planned radical prostatectomy.

Next Steps

We expect to initiate a Phase 1/2 trial for BNT112 in the second half of 2019.

c) BNT113: Our FixVac Cancer Immunotherapy for the Treatment of HPV+ Head and Neck Cancer

We are developing BNT113 for the treatment of HPV+ head and neck cancer. BNT113 is currently being studied by the University of Southampton in an ongoing investigator-sponsored Phase 1/2 basket study in HPV+ cancers, including head and neck cancer.

HPV+ Head and Neck Cancer

Head and neck cancer defines an heterogeneous group of tumors originating in the squamous cells that line the moist, mucosal surfaces inside the head and neck. Head and neck cancer is the sixth most common malignancy worldwide, accounting for approximately 6% of all cancer cases, and is responsible for 1-2% of all cancer deaths. An increasing percentage of this cancer is now attributed to HPV infection in the United States and Europe, particularly those arising from the oropharynx. In the U.S., HPV-related oropharynx cancer, or OPC, is one of only five cancers with rising incidence and prevalence. The percentage of OPC related to HPV rose from approximately 16% in 1984 to 1989 to approximately 72% during 2000 to 2004. Early stage H&N cancer is typically either treated with surgery or radiation alone, however approximately 66% of patients present with advanced disease and fewer than 30% of these are cured. The management of advanced disease consists of multiple-modality therapy with surgery, radiation and chemotherapy. Long-term survival rates in these patients have not increased significantly in the past 30 years: five-year survival rates are 60-80%.

Our BNT113 Targets

BNT113 is designed to elicit an immune response against the well-characterized HPV16-derived oncoproteins E6 and E7, which are strongly immunogenic, viral neoantigens that are found in HPV16+ solid cancers such as head and neck squamous cell carcinoma.

Our BNT113 Clinical Trials

Ongoing Phase 1/2 Basket Study (Investigator Sponsored)

BNT113 is being studied in an investigator sponsored open-label, Phase 1/2 dose escalation basket study with two different arms in approximately 44 patients with HPV+ head and neck and other cancers. The first arm will perform dose escalation in patients with previously treated HPV+ head and neck cancer using two dose cohorts to establish a safe, tolerable and recommended dose of BNT113. The second arm will perform dose escalation in patients with advanced HPV+ cancers, including head and neck, anogenital, penile and cervical cancers, using a single cohort to establish a safe, tolerable and recommended dose.

Next Steps

We intend to initiate a Phase 2 trial of BNT113 in HPV+ cancers in the first half of 2020.

d) BNT114: Our FixVac Cancer Immunotherapy for the Treatment of Triple Negative Breast Cancer

We are currently studying antigens selected for BNT114 in a three-arm clinical trial as both a monotherapy and in combination with our RO7198457 (BNT122) individualized iNeST immunotherapy in patients with triple negative breast cancers.

Triple Negative Breast Cancer

Breast cancer is the most commonly occurring cancer in women and the second most common cancer overall with over two million new cases globally in 2018 with an expected 268,600 cases in 2019 in the United States alone. There are three broadly defined categories of breast cancer. About 80% of breast cancers are defined as ER+, meaning that they grow in response to the hormone estrogen, while 65% of these are also defined as PR+, as they also grow in response to another hormone, progesterone. Such cancers can be identified by the presence of estrogen receptors, or ER, and/or progesterone receptors, or PR, on the cancer cell surface and are more likely to be treatable by hormone therapies than cancers that are ER or PR negative. In about 20% of cancers, the tumor can be identified by its production of an excess of the HER2 protein. Such HER2+ cancers tend to be aggressive and fast moving. Breast cancers that neither express ER or PR, nor over-express HER2-, are known as triple negative breast cancers, or TNBCs. TNBC patients represent approximately 12-15% of all breast cancer cases, however it remains an area of high unmet medical need given it is typically the most aggressive form of breast cancer. There are currently no effective treatments for TNBC. While initial treatment options include surgery or chemotherapy, TNBC is characterized by rapid resistance to chemotherapy, and few remaining treatment options remain thereafter.

Our BNT114 Targets

BNT114 is designed to elicit an immune response to selected antigens that are found in breast cancers.

Our BNT114 Clinical Trials

Ongoing Phase 1 Clinical Trial (BNT114 monotherapy and in combination with RO7198457 (BNT122))

We are currently conducting an international, multi-center, open-label, three-arm Phase 1 study of BNT114 as a monotherapy and in combination with our RO7198457 (BNT122) individualized iNeST immunotherapy in 39 TNBC patients who had previously received the standard of care therapy (*i.e.*, surgery, chemotherapy and/or radiotherapy). The primary endpoints of the study are to assess safety and tolerability. Safety will be analyzed by adverse event documentation and clinical observation and tolerability will be analyzed based on patients' vital signs and clinical chemistry. The secondary endpoint of the study is the observation of the treatment-induced immune responses, expressed as treatment-induced T cell responses, resulting from multiple treatment cycles.

Patients in the first arm receive BNT114, patients in the second arm receive BNT114 in combination with RO7198457 (BNT122) and patients in the third arm receive BNT114 in combination with mRNA encoding tetanus-toxin help epitopes.

Next Steps

We expect to report a data update in the first half of 2020 and assess the immunogenicity of the selected antigens.

e) Other FixVac Indications

We are also exploring FixVac development candidates in other cancer indications, including ovarian cancer.

2. Individualized Neoantigen Specific Immunotherapy (iNeST)

Our iNeST product candidate is an individualized cancer immunotherapy that targets specific neoantigens that are present on a patient's tumors. We are developing our iNeST cancer immunotherapy in collaboration with Genentech.

a) BNT122: Our iNeST Cancer Immunotherapy for Multiple Potential Indications

We and our collaborator Genentech are developing RO7198457 (BNT122) for the treatment of metastatic melanoma and other solid tumors. In a previous Phase 1 trial of BNT121, an earlier version of our iNeST product candidate that was administered intranodally, in 13 patients with metastatic melanoma, we observed stable progression-free survival in nine patients for up to 41 months following surgery and treatment with BNT121. We are currently conducting a randomized Phase 2 trial of RO7198457 (BNT122) in collaboration with Genentech in first-line melanoma in combination with pembrolizumab. We are also studying RO7198457 (BNT122) as a monotherapy and in combination with atezolizumab in a Phase 1a/1b basket study of patients with locally advanced or metastatic solid tumors (including in melanoma, non-small cell lung cancer, bladder cancer as well as other solid tumors).

Our RO7198457 (BNT122) Targets

RO7198457 (BNT122) is an individualized neoantigen specific immunotherapy. Each RO7198457 (BNT122) dose includes up to 20 different neoepitopes, selected on a patient-by-patient basis. We believe that neoepitope-specific T cells induced by RO7198457 (BNT122) can enhance the therapeutic efficacy of immune checkpoint blockade.

Our RO7198457 (BNT122) Clinical Trials

Ongoing Phase 2 Clinical Trial (First-line with pembrolizumab)

In January 2019, we and Genentech initiated a Phase 2, open-label, multi-center, randomized clinical trial investigating the safety and efficacy of RO7198457 (BNT122) in combination with pembrolizumab in 132 patients with previously untreated metastatic melanoma. Patients in the experimental arm will receive pembrolizumab by intravenous infusion every three weeks, plus a selected dose of RO7198457 (BNT122) at defined intervals. Patients in the active comparator arm will receive 200mg of pembrolizumab by intravenous infusion every three weeks. Following treatment in the comparator arm, patients will be permitted to cross over to combination therapy with RO7198457 (BNT122).

The co-primary endpoints are:

- progression-free survival, or PFS, of patients treated with RO7198457 (BNT122) compared with patients receiving pembrolizumab alone, at up to approximately 24 months, according to RECIST v1.1; and
- objective response rate, or ORR, in patients treated with RO7198457 (BNT122) compared with patients receiving pembrolizumab alone, defined as the proportion of participants with complete response, or CR, or PR, at up to approximately 24 months.

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Secondary endpoints include:

- overall survival, or OS, of patients treated with RO7198457 (BNT122) compared with patients receiving pembrolizumab only;
- duration of response according to RECIST v1.1 of patients treated with iNeST compared with patients receiving pembrolizumab only;
- mean change in health-related quality of life, scores of patients treated with iNeST compared with patients receiving pembrolizumab only;
- percentage of patients with CR or PR following cross-over from pembrolizumab monotherapy to combination therapy at up to 12 months following cross-over, according to RECIST v1.1; and
- incidence and severity of adverse events.

Ongoing Phase 1 Clinical Trial

We and Genentech are currently conducting a global Phase 1a/1b open-label, global dose-escalation basket study to assess the safety, tolerability, immune response and pharmacokinetics of RO7198457 (BNT122) as a single agent and in combination with Tecentriq (atezolizumab), an anti-PD-L1 mAb, in patients with locally advanced or metastatic tumors, including in melanoma, non-small cell lung cancer, bladder cancer, colorectal cancer, TNBC, renal cancer, H&N cancer and other solid cancers. We expect to enroll over 770 patients in this study and expect initial data in 2020.

In the Phase 1a portion of the study, patients receive RO7198457 (BNT122), administered intravenously every 21 days at escalating doses. In the Phase 1b portion, patients receive RO7198457 (BNT122), administered intravenously every 21 days at escalating dosages, in combination with atezolizumab at a fixed dose of 1,200mg.

In addition, we are investigating RO7198457 (BNT122) in three Phase 1b arms in combination with atezolizumab at a fixed dose of 1200mg, in (i) patients with non-small cell lung cancer that have received cancer checkpoint inhibitors, (ii) patients with selected tumor types who consent to optional serial biopsies and (iii) patients with different indications as per inclusion criteria.

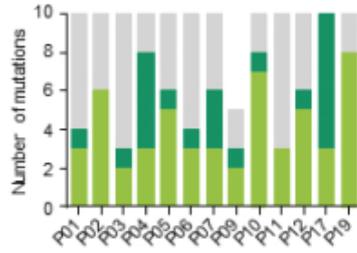
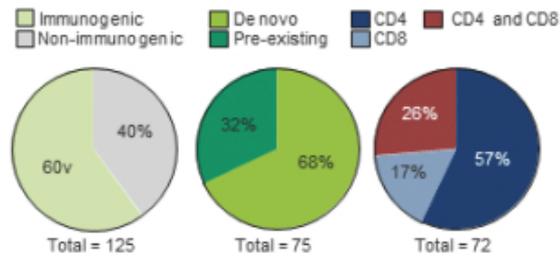
Completed Phase 1 Clinical Trial (First Generation iNeST)

In 2017, we published the results of a 13-patient, first-in-human trial of our first generation intranodal iNeST product candidate, BNT121, in patients with late-stage malignant melanoma. The objective of this clinical trial was to study the feasibility, safety, tolerability, immunogenicity and potential anti-tumoral activity of iNeST. All patients had stable disease at enrollment with a high risk for relapse.

All 13 patients developed T cell immune responses against multiple immunotherapy neoepitopes at up to high single-digit percentages. As shown below, 60% of the selected neoepitopes elicited a T cell response. The detected immune response was elicited by both CD4⁺ and CD8⁺ T cells and the majority was induced *de novo*, which we believe to be an important requirement for an effective immune response and an added benefit beyond checkpoint inhibition alone.

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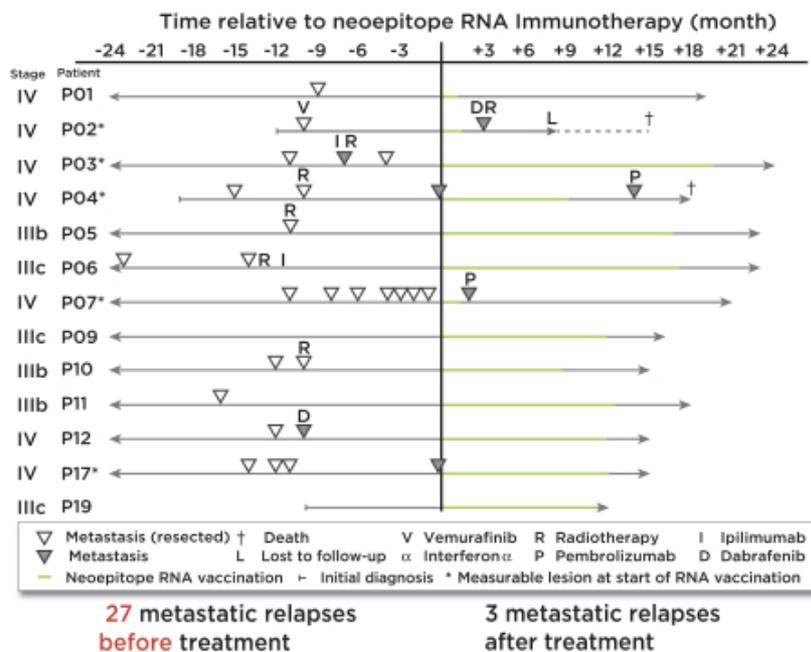
No severe adverse drug reactions were reported in the study. Common adverse events included flu-like symptoms.



Immune responses documented in our prior BNT121 study. Patients showed immune responses, including both CD4+ and CD8+ responses, against multiple neoantigens.

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In addition, metastases resected from two patients following treatment with BNT121 demonstrated evidence of treatment-induced infiltration with BNT121-induced neoepitope-specific T cells and neoepitope-specific killing of tumor cells. The cumulative rate of metastatic events was significantly reduced after the start of treatment, resulting in a sustained progression-free survival. Of the 13 patients entering the trial, eight patients that had no radiologically detectable lesions at start of neo-epitope vaccination were relapse free and remained recurrence-free for the whole follow-up period (12 to 23 months). Five patients experienced melanoma relapses shortly after inclusion in the trial and despite initiation of standard treatment had progressing metastases at start of their neoepitope treatment. Of these, two patients developed neoepitope treatment-related objective clinical responses. One of these patients exhibited a complete response and remained relapse-free for 26 months. The other patient had an immunotherapy-related partial response. This patient had a late relapse owing to outgrowth of β 2-microglobulin-deficient melanoma cells as an acquired resistance mechanism. A third patient developed a complete response to treatment in combination with PD-1 blockade therapy.



Metastatic relapses before and after treatment with BNT121. The chart above shows the metastatic relapses of patients before and after treatment with BNT121. Each horizontal line represents the time course of a single patient. The vertical line indicates the treatment start of BNT121.

Next Steps

We expect to report interim data from our RO7198457 (BNT122) first-line Phase 2 melanoma trial, and report a data update from our RO7198457 (BNT122) Phase 1a/1b solid tumor trial, in the second half of 2020.

3. Intratumoral Immunotherapy

We, in collaboration with Sanofi, are developing intratumoral immunotherapies utilizing our proprietary mRNA technology. These immunotherapies are designed to be administered directly into the tumor in order to alter the tumor microenvironment and enhance the immune system's ability to recognize and fight cancer within the tumor (proximal) as well as in other untreated locations (distal).

a) SAR441000 (BNT131): Our Initial Intratumoral Immunotherapy for the Treatment of Solid Tumors

We and Sanofi are developing SAR441000 (BNT131) as an intratumoral immunotherapy for the treatment of solid tumors. SAR441000 (BNT131) is being studied in a Phase 1 basket clinical trial as a monotherapy in patients with advanced melanoma and in combination with an anti-PD-1/PD-L1 checkpoint inhibitor in patients with advanced melanoma and certain solid tumors.

Our SAR441000 (BNT131) Targets

SAR441000 (BNT131) utilizes mRNA to encode the cytokines IL-12sc, IL-15sushi, IFN α and GM-CSF. By increasing the concentration of these cytokines in the tumor microenvironment, the immune system may more easily recognize and fight cancer.

Our SAR441000 (BNT131) Clinical Trials

Ongoing Phase 1 Clinical Trial

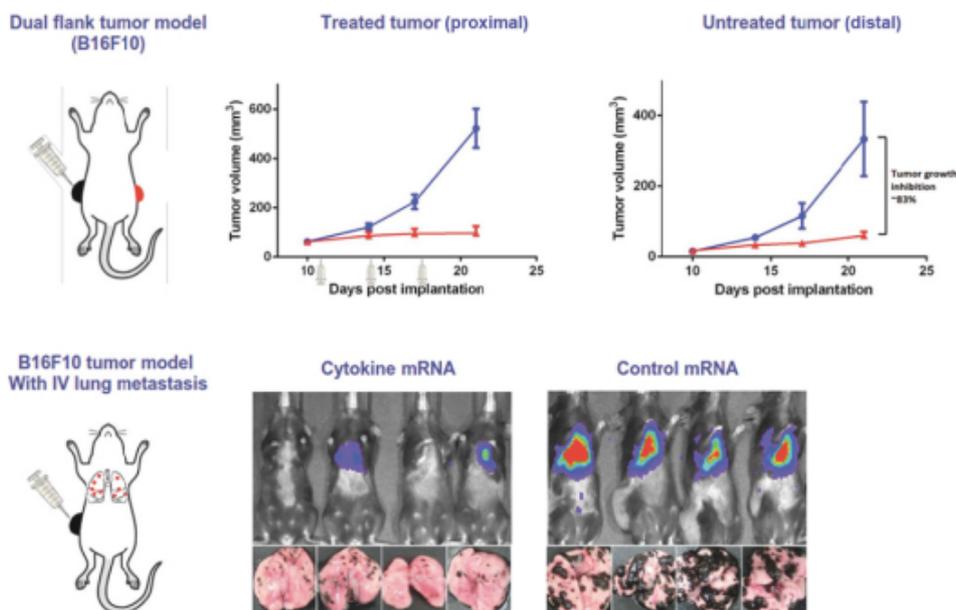
We and Sanofi have commenced a first-in-human, multi-center, open-label, Phase 1, dose escalation and expansion basket study to evaluate the safety, pharmacokinetics, pharmacodynamics and anti-tumor activity of SAR441000 (BNT131) administered intratumorally as monotherapy and in combination with cemiplimab, in 264 patients with advanced solid tumors.

Our SAR441000 (BNT131) Preclinical Studies

We conducted a preclinical study of SAR441000 (BNT131) in mouse tumor models. In these *in vivo* models, the anti-tumor activity of cytokines encoded by mRNA was driven by the action of T cells as well as NK cells and was accompanied by robust intratumoral induction of interferon gamma, systemic expansion of antigen-specific T cells and increased granzyme B positive CD8⁺ T cell infiltration.

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SAR441000 (BNT131) was shown to form immunological memory toward both dominant and subdominant antigens, which protected long-term survivors from re-challenge with autologous tumors. Importantly, although cytokine mRNAs were administered intratumorally, resulting in local target expression, anti-tumor activity extended beyond the injected tumor to effectively control the growth of distal tumors in both a dual-tumor model and an experimental lung metastasis model. Finally, SAR441000 (BNT131) demonstrated improved overall survival and higher incidence of complete tumor regressions across several preclinical models.



Systemic anti-tumor effects in mouse model. As shown above, BNT131 demonstrated local and systemic anti-tumor effects of intratumoral cytokine mRNA. In this study, mice were implanted with a tumor on each of the right and left flank. One tumor was injected with intratumoral cytokine mRNA (or control mRNA) while the other was not. The top center figure shows the tumor volume of the treated tumor (red line) against the control (blue line). The top right figure shows an anti-tumor effect on the untreated tumor (red line) against the control (blue line). The figures on the bottom show the abscopal effect of an intratumoral cytokine mRNA (center bottom) on distal lung metastases compared to the control mRNA (right bottom).

Based on these preclinical results, we believe we can leverage our robust and versatile synthetic mRNA technology to deliver localized cytokine-based cancer immunotherapy with broad anti-tumor activity against treated and untreated lesions.

4. RiboMabs

RiboMab product candidates consist of our proprietary nucleoside-modified mRNA that is designed to minimize the immunomodulatory activity of the mRNA, and these candidates are formulated using liver-targeting LNP for intravenous delivery.

Our RiboMab product candidates are designed to encode secreted antibodies for expression *in vivo* by the patient's cells. RiboMabs potentially addresses the limitations of recombinant antibodies, including costly manufacturing processes and unfavorable pharmacokinetics, such as short plasma half-life. We are conducting preclinical studies for two development candidates, and have shown compelling preclinical data.

RiboMab Preclinical Studies

We have generated RiboMabs targeting different tumor antigens and tested their therapeutic potency in mice engrafted with human tumors that were repopulated with human immune cells. We demonstrated in preclinical studies that injection with a RiboMab product candidate encoding bispecific RiboMabs directed against CD3 and CLDN6 antigens resulted in elimination of aggressively growing, large tumors. Intravenously administering a microgram dose of mRNA encoding RiboMabs resulted in bispecific RiboMab production in the liver cells and rapid secretion into circulation, reaching peak plasma concentration within hours and remaining at therapeutically effective levels for one week. The dosage and frequency of dosing of recombinant bispecific antibodies required to produce similar effects was substantially greater. This was the first preclinical study to demonstrate *in vivo* application of mRNA-encoded antibodies for the successful treatment of cancer.

a) BNT141: Our Initial RiboMab for the Treatment of Solid Tumors

BNT141 is our RiboMab product candidate for the treatment of solid tumors. BNT141 is designed to encode secreted IgG antibodies.

Our BNT141 Targets

BNT141 is designed to encode secreted antibodies that target multiple epithelial solid tumors, including gastric and pancreatic cancers.

Next Steps

We expect to initiate a Phase 1 basket trial of BNT141 for the treatment of various solid tumors, including gastrointestinal tumors, in the first half of 2020.

b) BNT142: Our Second RiboMab for the Treatment of Solid Tumors

BNT142 is our RiboMab product candidate for the treatment of solid tumors. BNT142 is designed to encode a secreted bispecific antibody that targets CD3 and CLDN6.

Our BNT142 Targets

BNT142 is designed to encode bispecific antibodies that target CD3, a T cell receptor that plays a key role in the activation of CD8⁺ and CD4⁺ T cells, and CLDN6, a highly specific oncofetal cell surface antigen that is found in solid tumors, but not in normal cells.

Next Steps

We expect to initiate a Phase 1 basket trial of BNT142 for the treatment of numerous solid tumors in the second half of 2020.

5. RiboCytokines

Our RiboCytokine product candidates utilize mRNA that encodes the desired cytokines. RiboCytokine product candidates consist of modified mRNA designed to encode secreted cytokines that are formulated to use liver-targeting LNP for intravenous delivery.

Our RiboCytokine product candidates are designed to address the limitations of recombinantly expressed cytokines, including limited serum half-life and production costs. We are developing RiboCytokines to be used primarily in combination with other drugs, including our other pipeline candidates.

a) BNT151: Our Initial RiboCytokine for the Treatment of Solid Tumors

We are developing BNT151, our RiboCytokine designed to encode a modified version of the human interleukin-2, or IL-2, cytokine for the treatment of solid tumors. BNT151 is designed to stimulate T cells without triggering immunosuppression in the tumor microenvironment.

Our BNT151 Target

BNT151 comprises our nucleoside-modified mRNA that encodes mRNA for a function-modified IL-2. IL-2 is a key cytokine in T cell immunity, supporting the differentiation, proliferation, survival and effector functions of T cells.

Recombinant IL-2, aldesleukin, was the first approved cancer immunotherapy, and has been marketed globally for the treatment of late stage melanoma and renal cell cancer for decades. Most patients with complete responses after IL-2 treatment remain regression free for more than 25 years after initial treatment, but overall response rates are low due in part to the limitations of recombinant cytokines. Recombinant IL-2 has a very short half-life, requiring high and frequent dosing and a partially unfavorable activity profile, which leads to increased side effects, thus limiting its utility as a cancer treatment.

Next Steps

We expect to initiate a Phase 1 clinical basket trial of BNT151 in the first half of 2020.

b) BNT152: Our Second RiboCytokine for the Treatment of Solid Tumors

We are developing BNT152, our RiboCytokine designed to encode IL-7 for the treatment of solid tumors.

Next Steps

We expect to initiate a Phase 1 clinical trial of BNT152 in the first half of 2020.

c) BNT153: Our IL-2 variant RiboCytokine for the Treatment of Solid Tumors

We are developing BNT153, our RiboCytokine designed to secrete IL-2 for the treatment of solid tumors.

B. Our Oncology Engineered Cell Therapy Product Candidates

1. CAR T

We are advancing multiple CAR T product candidates, the most advanced of which, BNT211, is targeting the novel and highly specific target CLDN6⁺ in solid tumors, and which we expect to enter the clinic in the second half of 2019 for the treatment of CLDN6⁺ solid tumors, including ovarian cancer. We plan to use our initial CAR-T cell product candidates in combination with a FixVac immunotherapy that encodes the same target as the CAR T. The FixVac selectively targets dendritic cells, which leads to uptake, antigen expression and maturation of the dendritic cells. The co-stimulation provided by dendritic cell maturation has been shown in preclinical studies to amplify and expand CAR-T cells *in vivo*, leading to increased persistence of the CAR T.

a) BNT211: Our CAR T cell Therapy for the Treatment of CLDN6⁺ Solid Tumors

BNT211 is our CAR T cell therapy for the treatment of CLDN6⁺ solid tumors. BNT211 targets CLDN6 and will initially be evaluated in combination with a FixVac that encodes CLDN6.

Our BNT211 Target

BNT211 targets Claudin 6, or CLDN6, a highly specific oncofetal cell surface antigen that is found in multiple cancers, including ovarian, testicular and lung cancers, but not in normal cells.

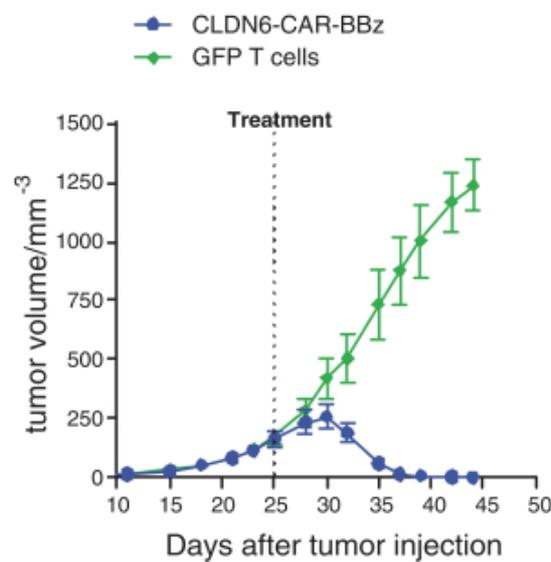
Our BNT211 Trials

Planned Phase 1/2 Clinical Trial

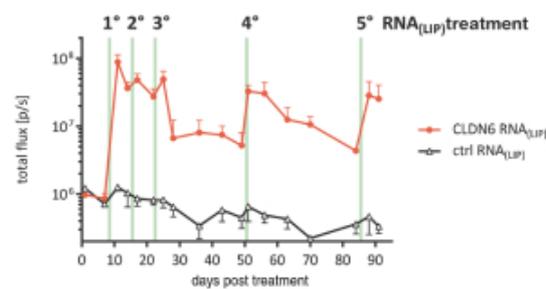
We anticipate initiating a Phase 1/2 open-label, multi-center dose escalation and dose expansion basket study of BNT211 with or without a CLDN6 FixVac immunotherapy in the first half of 2020. We anticipate enrolling patients with advanced solid tumor malignancies who express CLDN6. While our preclinical focus has been on ovarian cancer, we expect patients with uterine, testicular, lung and gastric cancers may also be enrolled in our upcoming CAR T trials.

Preclinical Studies

We have observed compelling preclinical data of BNT211 demonstrating potent anti-tumoral activity, including eradication of advanced tumors in an ovarian carcinoma xenograft model.



Potent anti-tumoral activity. As shown above, BNT211 demonstrated eradication of advanced tumors in a mouse model.



Effect of FixVac booster. The figure above depicts the effect of a CLDN6-encoding FixVac immune booster administered in combination with BNT211 on the number of CLDN6-specific T cells.

Next Steps

We are planning to initiate a Phase 1/2 clinical trial of the combination of BNT211 and a CLDN6 FixVac in the first half of 2020 for the treatment of CLDN6⁺ solid tumors.

b) BNT212: Our CAR T Cell Therapy for the Treatment of CLDN18.2⁺ Solid Tumors

BNT212 is our CAR-T cell therapy for the treatment of CLDN18.2-positive solid tumors. BNT212 will initially be evaluated in combination with a FixVac that encodes CLDN18.2.

Our BNT212 Target

BNT212 targets Claudin 18.2, or CLDN18.2, a highly specific target that is only expressed in cancer and in differentiated epithelial cells of the gastric mucosa, but it is absent from the gastric stem cell zone. CLDN18.2 is expressed in numerous epithelial solid tumors, including gastric, pancreatic, esophageal, ovarian and lung tumors.

C. Our TCR Product Candidates in Oncology

We are developing T cell receptor therapies for the treatment of cancer, including in collaboration with Eli Lilly. Under our collaboration, Eli Lilly has an exclusive option to pursue clinical development of certain potential TCR product candidates. We and Eli Lilly have concluded the research phase of the collaboration and Eli Lilly is evaluating whether to exercise its option.

D. Our Antibody Product Candidates in Oncology

1. Next-Generation Checkpoint Immunomodulators

In collaboration with Genmab, we are currently studying two bispecific antibody checkpoint immunomodulators.

a) GEN1046 (BNT311): Our Bispecific PD-L1x4-1BB Antibody for the Treatment of Solid Tumors

GEN1046 (BNT311), our PD-L1x4-1BB product candidate, is a potential first-in-class bispecific antibody combining PD-L1 checkpoint inhibition with 4-1BB checkpoint activation. We dosed the first patient in a Phase 1/2 basket study of GEN1046 (BNT311) for the treatment of malignant solid tumors in May 2019.

Our GEN1046 (BNT311) Targets

GEN1046 (BNT311) is a bispecific antibody designed to target PD-L1 and 4-1BB to block the inhibitory PD-1/PD-L1 axis and simultaneously activate essential co-stimulatory activity via 4-1BB. PD-L1 is a validated target that is expressed on tumor cells. 4-1BB is a trans-membrane receptor belonging to the TNF super-family, and is expressed predominantly on activated T cells.

Our GEN1046 (BNT311) Trials

Our Ongoing Phase 1/2 Clinical Trial

In collaboration with Genmab, we are conducting a Phase 1/2, open-label, single arm safety basket trial of GEN1046 (BNT311), which is expected to enroll approximately 192 patients with malignant solid tumors. The trial consists of a dose escalation portion and an expansion portion. The dose escalation portion will determine the safety profile of GEN1046 (BNT311) in subjects with certain relapsed or refractory, advanced and/or

metastatic malignant solid tumors who are no longer candidates for standard therapy. The expansion portion will be initiated once the recommended Phase 2 dose has been established in Phase 1. In the expansion portion, GEN1046 (BNT311) will be administered intravenously once every 21 days. The primary endpoints of the trial are dose-limiting toxicities, adverse events and safety laboratory parameters, including hematology, biochemistry, coagulation and endocrinology.

Preclinical Studies

In preclinical settings, GEN1046 (BNT311) promoted conditional T cell activation in a tumor-specific manner. Preclinical studies also indicated a release of T cell inhibition through the PD-1/PD-L1 axis.

b) BNT312: Our Bispecific CD40x4-1BB Antibody for the Treatment of Solid Tumors

BNT312, our CD40+4-1BB antibody product candidate, is a potential first-in-class bispecific antibody designed to induce conditional immune activation by crosslinking CD40 and 4-1BB positive cells.

Our BNT312 Targets

BNT312 is a bispecific antibody designed to activate an anti-tumor immune response through conditional CD40-mediated stimulation of antigen presenting cells crosslinked with conditional stimulation of 4-1BB⁺ T cells. The cell surface molecule CD40 is a member of the tumor necrosis factor receptor superfamily and is broadly expressed by a wide range of tumor cells.

Our BNT312 Preclinical Studies

BNT312 is designed to target CD40 and 4-1BB to enhance both DC and antigen-dependent T cell activation. In preclinical settings, BNT312 simultaneously activated antigen presenting cells and enhanced T cell activation. Preclinical studies also indicated the conditional activation and expansion of previously activated cytotoxic CD8⁺ T-cells, clonal expansion of T cells and cytokine production resulting from BNT312.

Next Steps

In the first half of 2019, we submitted a CTA to regulatory authorities in the United Kingdom, and we expect to initiate a Phase 1 clinical trial for BNT312 in the second half of 2019 for the treatment of solid tumors.

2. Targeted Cancer Antibodies

a) MVT-5873 (BNT321): Our Targeted Cancer Antibody for the Treatment of Pancreatic Cancer

In May 2019, we acquired certain antibody assets from MabVax Therapeutics Holding, Inc., including MVT-5873 (BNT321), a clinical stage targeted cancer antibody.

Pancreatic Cancer

The American Cancer Society estimates that approximately 56,770 people will be diagnosed with pancreatic cancer in the United States in 2019. Pancreatic cancer is an aggressive cancer, with a five-year survival rate from diagnosis, across all stages combined, of 9%.

Our MVT-5873 (BNT321) Target

MVT-5873 (BNT321) is a fully human IgG1 monoclonal antibody targeting sialyl Lewis A (sLe^a), an epitope on CA19-9 that is expressed in pancreatic and other gastrointestinal cancers that plays a role in tumor adhesion and metastasis formation, and is a marker of an aggressive cancer phenotype.

Our MVT-5873 (BNT321) Trials

MVT-5873 (BNT321) is being investigated in an open-label, multi-center, non-randomized dose escalation Phase 1/2 study evaluating the safety and recommended Phase 2 dose of MVT-5873 (BNT321) both as a monotherapy and in combination with a standard of care chemotherapy in approximately 68 subjects with pancreatic and other CA19-9 positive malignancies. Secondary objectives include evaluating tumor response rate by RECIST 1.1, duration of response, and determining pharmacokinetics. This study utilizes a conventional 3+3 design to identify the recommended Phase 2 dose.

Interim data for the combination cohort was reported in February 2018. In this cohort, MVT-5873 (BNT321) was given in combination with nab-paclitaxel and gemcitabine to patients newly diagnosed with CA19-9 positive pancreatic cancer. MVT-5873 (BNT321) at a dose of 0.125mg/kg when added to first-line chemotherapy was generally well tolerated by all subjects. All six patients evaluated had measurable tumor reductions by RECIST, with four patients meeting the criteria for partial response and two patients meeting the criteria for stable disease.

Next Steps

This trial is currently paused; however, we intend to resume the trial in the second half of 2019.

E. Our Oncology Small Molecule Immunomodulator Product Candidates

1. BNT411: Our Small Molecule TLR7 Agonist for the Treatment of Colorectal and Bladder Cancer

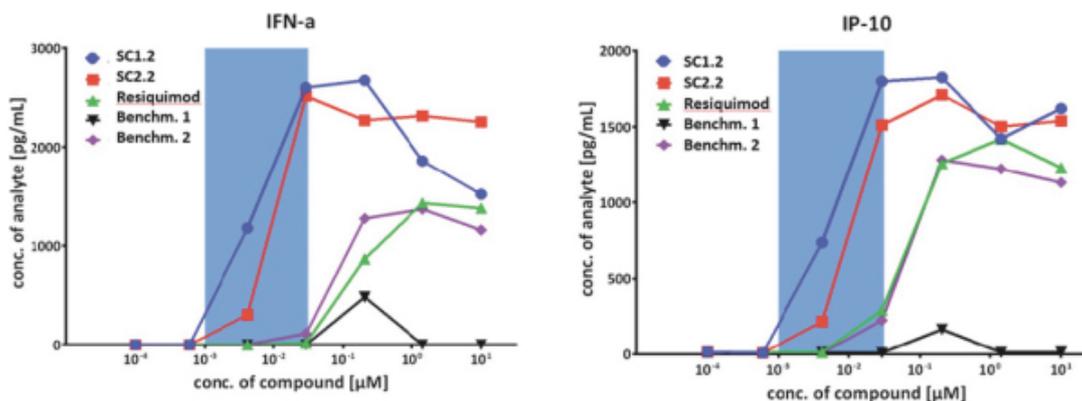
BNT411 is our novel small molecule TLR7 agonist product candidate. BNT411 is designed to activate both the adaptive and innate immune system through the TLR7 pathway. We are designing BNT411 to be used in combination with chemotherapy and checkpoint inhibitors.

Our BNT411 Target

BNT411 is a TLR7 agonist that is designed to activate both the adaptive and innate immune system through the TLR7 pathway. This activity and the release of cytokines and chemokines are designed to result in the potent stimulation of antigen specific CD8⁺ T cells, B cells and innate immune cells such as NK cells and macrophages.

Our BNT411 Preclinical Studies

In preclinical studies, BNT411 (SC1.2/Ago1.2) was shown to be more potent in the induction of IFN α compared to the clinical competitor compound resiquimod (R848), even at lower concentrations (minimal effective concentration of BNT411 *in vitro* is 4nM). In contrast to the tested competitor compound, BNT411 was shown to induce at low concentrations especially IFN α whereas other (pro-)inflammatory and CRS related cytokines (IL-6, IL-10, TNF α , IL-8) are only observed at higher concentrations.



Next Steps

We expect to initiate a Phase 1 clinical trial of BNT411 as a combination therapy in solid tumors in the first half of 2020.

F. Our Infectious Disease mRNA Product Candidates

1. BNT161: Our Prophylactic Vaccine for the Prevention of Influenza

We are collaborating with Pfizer to develop an influenza vaccine based on our mRNA drug classes. Our product candidate BNT161 will encode influenza virus antigens selected by the WHO in advance of the flu season.

Next Steps

We anticipate beginning a Phase 1 clinical trial in BNT 161 by the end of 2020.

2. Other Infectious Diseases

We have a research collaboration with Penn, under which we have the exclusive option to develop and commercialize prophylactic mRNA immunotherapies for the treatment of up to 10 infectious disease indications.

Next Steps

We are targeting initiating our first Phase 1 clinical trial under this collaboration in the first half of 2021.

G. Our Rare Disease Protein Replacement mRNA Product Candidates

We have collaborated with Genevant, combining our mRNA technology with Genevant’s LNP delivery technology, to create up to five mRNA protein replacement therapies for the treatment of rare diseases with high unmet medical needs. We expect our first compound from this collaboration to enter the clinic by the end of 2020.

H. Other

Our legacy commercial stage product, MammaTyper, is a molecular *in vitro* diagnostic test for the quantitative detection of the mRNA expression of ERBB2, ESR1, PGR and MK167 in breast cancer tissue. MammaTyper has been shown in a variety of scientific publications to offer superior diagnostics insights compared to conventional immunohistochemical detection methods.

XIII. Manufacturing

We are building a fully integrated biotechnology company, with operations spanning from research through clinical development, and manufacturing through sales and marketing. We operate three GMP-certified manufacturing facilities in Germany, where we manufacture mRNA therapeutics and engineered cell therapies for our own pipeline and for external customers. We operate a fourth facility in Germany where we manufacture custom peptides to support our extensive immunomonitoring activities within our development programs. Our subsidiary BioNTech Innovative Manufacturing Services GmbH, or BioNTech IMFS, has been manufacturing GMP-certified cellular products since 1999, was granted its first GMP license for manufacturing mRNA in 2011 and has been manufacturing individualized mRNA products since 2014.

We have expanded our capability to produce and supply drug products to support clinical development of our, and our collaborators', product candidates. To date, we have manufactured over 500 drug substance batches in our manufacturing facilities.

Our approach has been to proactively build capacity in anticipation of demand from internal research and development, as well as from our collaborators. We have done so by continuing to make significant investments in manufacturing infrastructure and increasingly expanding our capacity to manufacture mRNA, viral vectors, cellular products and peptides. We believe the development and optimization of our manufacturing processes in parallel to drug development is crucial to our success. We have also collaborated with Siemens to develop a process for the fully-automated, on-demand production of mRNA therapies.

Our Manufacturing Operations

mRNA. We believe manufacturing mRNA at scale can best be executed as part of a proprietary manufacturing approach, not as part of an outsourcing strategy. We believe this approach allows us to maintain control of our proprietary processes and gives us the flexibility we need for scheduling drug substance batch production to match our development plans as they evolve. Our mRNA manufacturing is conducted at our in-house BioNTech IMFS facility and our BioNTech East Wing facility, the latter being dedicated to iNeST manufacturing. Our mRNA manufacturing process involves standardized production of all mRNA constructs and minimal restrictions in construct length. We have the capacity to undertake sterile filtration and final filling in up to 1,200 vials of various sizes. Batch sizes range from a few mg for individualized applications (*i.e.*, iNeST) to 3g for standard mRNA applications (*i.e.*, FixVac and intratumoral immunotherapies), with batch sizes of up to 10g currently possible.

To date, we have produced more than 500 batches of mRNA drug substance to support our studies. We currently have infrastructure capable of producing more than 100 batches of mRNA drug substance and formulated drug product per month with a turnaround time of about 30 to 40 days from sequence identification to released product. We believe we currently have capacity to meet the product candidate supply needs of our in clinical trials up to registration.

In recent years, we have successfully decreased the time required to deliver individualized immunotherapy to patients. In 2014, it took us over three months to manually manufacture and deliver individualized immunotherapies to patients. Since December 2017, with the implementation of semiautomatic GMP manufacturing in collaboration with Siemens, we have been consistently delivering individualized immunotherapies in under six weeks. This advancement represents significant progress toward our commercial target turnaround time of less than 28 days. We believe this is achievable, and with our clinical process have already achieved turnaround times as low as 29 days for iNeST delivery. We plan to continue to develop additional process improvements which we expect will further reduce our turnaround times as we progress through clinical development.

Cell Therapy Products. We have end-to-end capabilities and over 20 years of experience in cell therapy manufacturing. Our manufacturing process for cellular products involves the isolation of primary human cells

and subpopulations, including CD34⁺ and CD3⁺ cells. We engage in the culturing, expansion and genetic modification of primary human cells as well as mammalian cell lines. Our processes include vector production for transfection of cells with CARs, cell banking and cryopreservation.

We have set up a broad range of quality control assays for the characterization of cell therapy products that allow us to certify the manufactured drug products in a short time. We are a leader in the production of gamma retroviral vectors. To date, we have produced more than 50 different cell therapy products.

Peptides. Our custom peptide synthesis business has developed unique technologies to produce several million peptides during the past three years to support our growing clinical pipeline. These include fast small scale manufacturing of peptides for target and epitope discovery as well as for neo epitope characterization and production of high content arrays. It is important to synthesize highly purified peptides in order to avoid false positives in immunomonitoring in our mRNA immunotherapy trials. We also use these peptides as starting material in our engineered cell therapies. We have developed know-how to produce highly complex and purified peptide pools that consist of overlapping peptides spanning entire antigens or neoepitopes. We plan to establish a new production facility, which will roughly double our current capacity.

Our Manufacturing Facilities

We operate four manufacturing and packaging facilities in Germany. In these facilities, we manufacture and package individualized mRNA, bulk mRNA, retroviral vectors, cellular products and peptides. In Mainz, we are currently constructing another facility for iNeST manufacturing at a commercial scale, which is planned to start manufacturing in 2022 and will supply markets mainly in Europe and the United States.

BioNTech IMFS. Our manufacturing operations for retroviral vectors, cell therapy products and mRNA are housed in our wholly-owned subsidiary, BioNTech IMFS. Founded in 1997, BioNTech IMFS specializes in services for innovative therapeutic approaches. In 2009, BioNTech IMFS became our wholly-owned subsidiary, giving us access to synergistic platforms and complementary expertise for development, testing and manufacturing services. BioNTech IMFS and its predecessors have had GMP-certified cell and gene therapy manufacturing capabilities since 1999, and obtained GMP manufacturing authorization for mRNA production in 2011. In 2017, BioNTech IMFS began automated manufacturing of the iNeST product candidate and entered into its first commercial supply contract for retroviral vectors. Located near Mainz, the BioNTech IMFS facility occupies over 30,000 square feet. Two hundred and twenty staff members are employed at this facility, with collective expertise in molecular biology, cell biology and virology.

BioNTech iNeST Clinical Manufacturing (East Wing). We dedicate our GMP-certified manufacturing facility at our headquarters building in Mainz, Germany to the production of iNeST immunotherapies. In 2015, our wholly owned subsidiary, BioNTech RNA Pharmaceuticals GmbH, or BioNTech RNA, and Siemens announced a collaboration for developing an automated, paperless and digitalized production site for individualized mRNA. We obtained our GMP manufacturing authorization for iNeST production at our East Wing facility in June 2018 and released our first drug product there the following month.

This facility contains approximately 17,000 square feet of laboratory and office space, including 4,300 square feet of GMP facilities. About 200 staff members are employed at this facility and operate it seven days per week. In its first year of operation the facility manufactured and released more than 250 batches of mRNA.

BioNTech Clinical Manufacturing. Our GMP-certified manufacturing facility in Kupferbergterrasse, Mainz, Germany is authorized to conduct secondary packing, labeling, storage and batch release of primary packed investigational medicinal products. This facility contains approximately 11,500 square feet of laboratory and office space, including 1,250 square feet of GMP facilities.

JPT. JPT, our peptide manufacturing facility, was established in 2004 and became a wholly owned subsidiary of BioNTech in 2008. JPT is located in Berlin, Germany and occupies over 16,000 square feet of clean rooms, laboratory and office space.

Other Certifications

BioNTech Diagnostics has a quality management system that is certified according to ISO 13485:2016 and JPT maintains a ISO 9001:2015 certified Quality Management System to allow production of European CE marked companion diagnostics.

Quality Assurance

We have implemented and maintain several Quality Assurance systems. BioNTech IMFS, BioNTech Clinical Manufacturing and BioNTech iNeST Clinical Manufacturing have implemented GMP-certified quality assurance systems. BioNTech Diagnostics has a quality management system that is certified according to ISO 13485:2016 and JPT maintains a ISO 9001:2015 certified Quality Management System.

Future Manufacturing Outlook

We are committed to the continued development of world-class manufacturing operations to support our clinical manufacturing needs, to prepare for commercial scale manufacturing of our product candidates, and to realize external commercial opportunities. We expect to commit approximately an additional €250 million through 2023. Our planned manufacturing investments include:

- two new buildings at our BioNTech IMFS facility, including three floors each of clean rooms and additional development and quality control laboratories;
- our planned commercial scale facility in Mainz, which will occupy more than 100,000 square feet and will house cleanrooms, laboratories and offices; and
- an expansion of our JPT facility, which is designed to more than double our capacity.

XIV. Third-Party Collaborations

We have forged productive collaborations with pharmaceutical companies and academic research institutions with area expertise and resources in an effort to advance and accelerate our discovery and development programs in oncology, and also to leverage our drug classes into additional disease indications while minimizing our incremental costs.

Our collaborations include:

- Genentech for our iNeST platform in our mRNA drug class;
- Sanofi for our intratumoral therapy platform in our mRNA drug class;
- Genmab for our next-generation checkpoint immunomodulator platform in our antibodies drug class;
- Pfizer for our influenza vaccine program, which leverages technology from our infectious disease mRNA-based platform;
- Penn for up to 10 prophylactic indications in our infectious disease mRNA-based platform; and
- Genevant for our rare disease protein replacement therapy platform in our mRNA drug class.

We either wholly own or retain significant rights to all of our clinical stage programs, either in the form of a global share of profit and co-commercialization rights with our collaborators in certain markets or significant royalties and milestones. We plan to continue to identify potential collaborators who can contribute meaningful resources and insights to our programs and allow us to more rapidly expand our impact to broader patient populations.

Genentech—iNeST Collaboration

Collaboration Agreement

On September 20, 2016, we and BioNTech RNA entered into a Collaboration Agreement with Genentech and F. Hoffman-La Roche Ltd, which we refer to as the Genentech Collaboration Agreement, to jointly research, develop, manufacture and commercialize certain pharmaceutical products that comprise neoepitope RNAs, or the Genentech Collaboration Products, which include our iNeST development candidates, for any use worldwide. Under the Genentech Collaboration Agreement, we and Genentech have agreed to perform joint research, with each party bearing its own costs, under a research plan to further improve our technology platform for the manufacturing of Genentech Collaboration Products.

We and Genentech must use commercially reasonable efforts to jointly develop one or more Genentech Collaboration Products in accordance with an agreed global development plan, with the costs of such development to be shared equally. We will continue certain clinical studies that were initiated prior to the execution of the Collaboration Agreement at our sole expense, and any future material changes in the operation of such clinical studies require Genentech's approval. Genentech may access and use any data generated in these ongoing clinical studies.

In addition to the clinical studies included in the global development plan, we may propose certain additional clinical studies for indications not included in the global development plan, and if the joint development committee formed by the parties does not elect to include the proposed studies in the global development plan, then we may conduct the study at our sole expense under certain conditions, and subject to certain restrictions. Genentech has the option to select any candidate in such studies for potential further joint development and/or commercialization by Genentech as a Genentech Collaboration Product. In the case that Genentech wishes to pursue the clinical development of a Genentech Collaboration Product in an indication that we are not interested in pursuing, then under certain conditions, we may opt out of the co-funding of such development and Genentech may continue to do so at its own costs, except that we are obligated to repay Genentech's development costs in the event that such product subsequently receives regulatory approval.

Genentech has the sole right to commercialize the Genentech Collaboration Products on a worldwide basis, with all profits and losses from such commercialization to be split equally with us. If we exercise our right to opt out of sharing equally in future development costs for any Genentech Collaboration Products, then we will no longer split all such profits and losses for such Genentech Collaboration Products equally with Genentech and will instead receive a royalty on annual worldwide net sales of such Genentech Collaboration Products that are covered by a valid claim included in certain of our patents and certain joint patents that arise out of the collaboration. Furthermore, for certain Genentech Collaboration Products for which we share co-promotion rights with Genentech, we have the option to assume a percentage to be determined of the total sales force in the United States and certain other countries, including Germany and other major European markets. In addition, under certain regulatory and other circumstances, we have the right to independently commercialize Genentech Collaboration Products in indications that the joint development committee declines to pursue and that Genentech does not subsequently elect to commercialize, provided that we market such Genentech Collaboration Products under a separate brand and trademark that is approved by the joint commercialization committee established by the parties as not confusingly similar to the Genentech Collaboration Products being commercialized by Genentech. Our ability to research, develop, co-promote and/or independently commercialize Genentech Collaboration Products may be terminated or limited in the event we undergo a change of control.

We granted to Genentech an exclusive license under certain of our intellectual property, and our interest in any jointly owned intellectual property developed under this agreement, to research, develop, make, sell and import any pharmaceutical products that comprise neoepitope RNA. Genentech granted to us an exclusive, non-transferable, sublicensable licenses under certain Genentech intellectual property, our intellectual property exclusively licensed to Genentech, and their interest in any jointly owned intellectual property developed under this agreement for the performance of our ongoing clinical studies and the exercise of our rights and obligations under the Genentech Collaboration Agreement.

Until September 20, 2019, we and Genentech are subject to certain exclusivity obligations under the Genentech Collaboration Agreement. In addition, until the first marketing approval for a Genentech Collaboration Product, we have granted Genentech the first right to negotiate an exclusive license to develop, manufacture and commercialize combination therapies involving pharmaceutical products based on neoepitope RNA and pharmaceutical products based on non-neoepitope RNA for the treatment of cancer in humans.

The Genentech Collaboration Agreement will remain in effect so as long as Genentech Collaboration Products are in development or commercialization, or until the date of the expiration of the last royalty term if BioNTech has exercised its option to opt-out of joint development of Genentech Collaboration Products. If the agreement expires, the licenses granted to Genentech become fully-paid up, royalty-free and irrevocable. Genentech may terminate the Collaboration Agreement if we fail to achieve certain milestone targets or at any time for convenience with or without reason upon 60 days' prior written notice. In the event of any such termination, all rights to the development and commercialization of Genentech Collaboration Products developed under the collaboration would revert to us and Genentech would grant us licenses under its intellectual property to further develop and commercialize Genentech Collaboration Products. We would be required to pay certain royalties to Genentech for such license(s). In addition, either party may terminate the agreement upon the other party's uncured material breach or insolvency.

Manufacturing Development and Supply Agreement

Concurrent with the Genentech Collaboration Agreement, we and BioNTech RNA entered into a Manufacturing Development and Supply Agreement with Genentech and F. Hoffman-La Roche Ltd, or the Genentech Manufacturing Agreement, which governs the manufacturing, related manufacturing development activities and supply of Genentech Collaboration Products. Pursuant to the Genentech Manufacturing Agreement, we are responsible for clinical manufacturing and supply, for developing and implementing manufacturing processes (including pursuant to specified target turnaround times), and for constructing, commissioning, qualifying and obtaining permits for the clinical facilities. We are permitted to subcontract certain steps in the clinical manufacturing process to our affiliate, BioNTech IMFS.

In addition, we are responsible for developing the commercial manufacturing process, which requires more stringent turnaround times than the clinical manufacturing process. Genentech will generally be responsible for commercial manufacturing. We are obligated to use commercially reasonable efforts to achieve certain predetermined clinical manufacturing capacity commitments.

Under the Genentech Manufacturing Agreement, we and Genentech will jointly develop a manufacturing network plan detailing the location, capacity, scale-out, associated timing and other appropriate details of the commercial manufacturing facilities. We may participate in commercial manufacturing through our right to include as part of the commercial manufacturing network one of our own facilities in the European Union or the United States and one of our own facilities in another region to be agreed upon with Genentech (provided that in each region our facility is not the first facility to be included in the commercial manufacturing network).

Sanofi—Intratumoral Therapy Collaboration

On November 2, 2015, BioNTech RNA entered into a Collaboration and License Agreement with Sanofi, which we refer to as the Sanofi Agreement. Pursuant to the Sanofi Agreement, we and Sanofi will collaborate on intratumorally administered mRNA-based therapeutics for the treatment of solid tumors in humans.

The Sanofi Agreement contemplates: (i) research, (ii) development and commercialization and (iii) possible co-development and co-commercialization activities with us.

During the research phase, the parties seek to identify, characterize and validate up to five "mixtures" of two or more mRNAs encoding different proteins administered together in the same solution. Sanofi at its sole discretion may select up to five mixtures created under the research plan for further development and commercialization, which we refer to as Sanofi Collaboration Products.

After selection of a Sanofi Collaboration Product, Sanofi would be responsible for all development and commercialization activities involving that product. We have the option, by payment of an exercise fee, to co-develop and co-commercialize up to two Sanofi Collaboration Products primarily in the United States and in some European countries, including the United Kingdom, France, Germany, Italy and Spain. If we exercise such option, the costs for co-development and co-commercialization of the chosen Sanofi Collaboration Products would be allocated between the parties. In turn, Sanofi has an option to co-develop and co-commercialize certain mixtures developed by us or with third parties that contain certain amount of the mRNAs of a Sanofi Collaboration Product.

In March 2018, Sanofi selected the first Sanofi Collaboration Product for further development and commercialization and we exercised our option for co-development and co-commercialization of the Sanofi Collaboration Product. Effective as of March 2018, the parties entered into a separate development agreement for the co-development of this Sanofi Collaboration Product.

Under the Sanofi Agreement, Sanofi has paid upfront and near-term milestone payments of approximately €60 million. We are entitled to receive up to approximately €260 million per product upon achievement of certain development, regulatory and commercial milestones. If commercialized successfully, we would also be eligible for mid-single digit to very low double-digit tiered royalties on net sales on a country-by-country and product-by-product basis until the later of (i) expiration of the last relevant patent covering such product in such country, (ii) 10 years following first commercial sale of such product in such country, (iii) expiration of regulatory data exclusivity for such product in such country and (iv) the market entry of a generic biological product with a certain market share in relation to such product in such country.

The Sanofi Agreement will remain effective until the last-to-expire royalty term (or, when a co-development option has been exercised, the completion of all co-development and co-commercialization activities). The parties may terminate the Sanofi Agreement in its entirety or terminate certain co-development activities for convenience, with or without cause.

The Sanofi Agreement provides that we may not engage in certain research and development activities relating to the intratumoral injection of mRNAs.

Genmab—Next-generation Immunomodulator Collaboration

On May 19, 2015, we entered into a License and Collaboration Agreement with Genmab (together with all amendments and side letters thereto, collectively referred to as the Genmab Agreement) to jointly research, develop and commercialize polypeptide-based bispecific antibodies against certain target combinations for the treatment of cancer in humans worldwide, or the Genmab Agreement Field, using certain Genmab technology.

Under the Genmab Agreement, we and Genmab must use commercially reasonable efforts to research and develop clinical candidates, including our next-generation checkpoint immunomodulators, with costs split equally during the research and evaluation phase. Our joint activities in this phase are governed by a research plan, which is subject to annual review and updates, and which specifies the clinical candidates to be developed. This research and evaluation phase is currently set to expire on May 31, 2021, but has in the past been extended.

During the research and evaluation phase, we and Genmab may propose clinical candidates for consideration by a joint research committee for further preclinical and clinical development. If a party, through the joint research committee, indicates that it is not interested in further development and commercialization of any clinical candidate, the other party may continue development and commercialization of such products on a unilateral basis, at its sole expense. The party that continues such development and commercialization is obligated to pay the other party certain development, regulatory and sales milestone payments and royalties on net sales of the applicable Unilateral Products. During either party's development and commercialization of a

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Unilateral Product, the other party must not develop or commercialize any bispecific antibody targeting the same target combination of such Genmab Unilateral Product if such bispecific antibody was generated as part of the collaboration under this agreement.

We and Genmab must use commercially reasonable efforts to develop candidates selected by the joint research committee, or the Genmab Collaboration Products, through preclinical and clinical development. In addition, the joint research committee may select an additional candidate, or the Genmab Back-up Candidate, as a back-up for each Genmab Collaboration Product and may decide at any time to replace the Genmab Collaboration Product with its Genmab Back-up Candidate. The preclinical and clinical development of the Genmab Collaboration Products would be performed pursuant to a development plan to be agreed upon by us and Genmab, with costs to be split equally. The joint steering committee may designate a third party as a manufacturer of a Genmab Collaboration Product or of any of its components.

We and Genmab must use commercially reasonable efforts to jointly commercialize all Genmab Collaboration Products and share equally all expenses and profits arising from such commercialization. We and Genmab, on a product-by-product basis and at least 12 months prior to the anticipated start of a pivotal clinical trial for a Genmab Collaboration Product, will jointly designate between the two of us a lead party responsible for establishing the distribution and marketing operations in each geographical region. Each party would be entitled to equally co-promote the products pursuant to a separately negotiated global commercialization agreement that the parties agree to negotiate.

Unless otherwise agreed by the joint steering committee established under the agreement, Genmab is responsible for all regulatory actions and shall own all regulatory approvals obtained for the Genmab Collaboration Products. Genmab is obligated to provide regular updates to us on regulatory activities.

Each party grants to the other party a worldwide, co-exclusive, sublicensable, royalty-free license under certain of such first party's intellectual property, including certain patents and know-how, to perform the research under this agreement and to research, develop, make, import, use and sell Genmab Collaboration Products in the Genmab Agreement Field pursuant to the terms of the Genmab Agreement. These licenses shall continue on a country-by-country and product-by-product basis for as long as development or commercialization activities are contemplated under the Genmab Agreement.

During the research and evaluation phase prior to the selection of a Genmab Collaboration Product, neither we nor Genmab may engage in any research and development activity in the Genmab Agreement Field relating to the development of any bispecific antibody which targets any combination that is the subject of our joint research plan. During the preclinical and clinical development phase for any Genmab Collaboration Product, engagement in research and development activities in the Genmab Agreement Field unilaterally by a party relating to a Genmab Collaboration Product or its Genmab Back-up Candidate or any bispecific antibody which targets the same target combination for which such Genmab Collaboration Product or Genmab Back-up Candidate has been developed would require the other party's prior written consent.

Each party has the right to discontinue its participation in the further development and commercialization of a Genmab Collaboration Product at two points: (i) when an IND submission package has been agreed upon by the parties and (ii) when the draft clinical trial report from the first Phase 1/2 clinical trial becomes available. The party that wishes to opt out of such further development and commercialization may choose to permit the other party to continue the development and commercialization of the Genmab Collaboration Product or divest its interest in such Genmab Collaboration Product. If the opt-out party permits continued development and commercialization, the other party may elect to pursue development and commercialization of such Genmab Collaboration Product alone as a Unilateral Product, at its sole cost and subject to pre-defined milestone and royalty payments and certain additional pre-defined terms. If the other party wishes to not pursue such continued development and commercialization on such pre-defined payment and additional terms, then the parties will jointly divest their interest in such Genmab Collaboration Product to a third party, and if such divestiture fails,

the parties will cease all development and commercialization of such Genmab Collaboration Product. Alternatively, if the opt-out party seeks to unilaterally divest its interest in the applicable Genmab Collaboration Product, the other party has the right of first exclusive negotiation to obtain exclusive, worldwide rights to develop and commercialize such Genmab Collaboration Product. If such unilateral divestiture fails after the other party's exercise of its right of first exclusive negotiation, the opt-out party may either continue development and commercialization of such Genmab Collaboration Product or offer the other party to continue such development and commercialization on such pre-defined payment and additional terms as set forth above.

The Genmab Agreement will remain in effect until the later of (i) the expiration of the last-to-expire royalty term for any Unilateral Product and (ii) the time when no Genmab Collaboration Products are being developed or commercialized under this agreement. Either party may terminate the agreement in its entirety or on a product-by-product basis with immediate effect upon the other party's uncured material breach or insolvency.

Pfizer—Influenza Collaboration

On July 20, 2018, we and BioNTech RNA entered into a Research Collaboration and License Agreement with Pfizer, or the Pfizer Agreement, for the research, development and Pfizer's commercialization of immunogenic compositions comprising modified RNA and/or replicon technology for prophylaxis against influenza in humans, which we refer to as the Pfizer Agreement Field.

We and Pfizer agreed to collaborate on the research in the Pfizer Agreement Field for an initial period of three years. The details of such research were set forth in a research plan that is governed by a joint steering committee, with Pfizer holding the final decision-making right. Each party will bear its own costs under the research plan. The research term will be extended automatically by a reasonable amount of time if the activities or deliverables under the research plan are delayed due to our material breach of our research obligations under the research plan. In addition, Pfizer may unilaterally extend the research term by up to a year by making an additional payment to us.

After the research term expires, Pfizer has the sole responsibility, authority and control of the development, manufacturing and commercialization of all candidates and products. Pfizer undertakes to use commercially reasonable efforts to seek regulatory approval for one product in the United States and in two countries out of France, Germany, Italy, Spain, the United Kingdom and Japan, and to commercialize such product in such countries where such product has received regulatory approval.

Under the Pfizer Agreement, we grant to Pfizer an exclusive, worldwide, sublicensable license under certain of our intellectual property, including our patents and know-how, relating to replicons and modified RNA in the Pfizer Agreement Field as well as certain intellectual property in-licensed by us from third parties, to use, research, develop, manufacture, commercialize and otherwise exploit candidates and products selected under the Pfizer Agreement. We also grant to Pfizer a non-exclusive, royalty-free, sublicensable license under all intellectual property controlled by us or our affiliates to use, develop, manufacture, commercialize and otherwise exploit candidates and products selected under the Pfizer Agreement in the Pfizer Agreement Field. We undertake to maintain in full effect all intellectual property licenses held by us at the time we entered into the agreement and to not modify or amend any such license in a manner that would adversely affect any of the rights granted to Pfizer under the Pfizer Agreement. We are obligated to notify Pfizer of any breach of our current licenses and may be obligated to take steps to maintain Pfizer's access to any intellectual property licensed under such licenses.

For a limited period of time, we also grant Pfizer an exclusive right of first refusal and a right of first negotiation to acquire an exclusive worldwide license under certain intellectual property controlled by us for Pfizer to develop, manufacture and commercialize immunogenic products comprising RNA for prophylaxis against respiratory syncytial virus or human cytomegalovirus. The right of first refusal expired on July 20, 2019, at which time the right of first negotiation became effective. The right of first negotiation may be exercised until the end of the research term.

In consideration of the rights granted to Pfizer under the agreement, Pfizer subscribed to shares in BioNTech AG under a separate investment agreement. In addition, under the Pfizer Agreement, Pfizer made an upfront payment of \$50 million and agreed to potential payments of up to \$325 million upon the achievement of specified development, regulatory and commercial milestones. Pfizer further agreed to a mid-single digit to very low double-digit tiered royalty on net sales if a product is commercialized. Royalties are subject to stacking provisions. The obligation of Pfizer to pay royalties ends, on a country-by-country and a product-by-product, basis upon the later of (i) the expiration of the last valid licensed patent right covering such product category in such country, (ii) 10 years after the first commercial sale of a product of such product category in such country and (iii) the lapse of regulatory data exclusivity for the first product in such product category in such country. There are only two product categories: one for modified RNA and a second for replicon products.

During the term of the Pfizer Agreement, we have committed not to research, develop, manufacture, commercialize or otherwise exploit immunogenic compositions comprising RNA in the Pfizer Agreement Field other than pursuant to the Pfizer Agreement.

The Pfizer Agreement ends on a country-by-country basis upon expiration of the last royalty term for any product in that country. Thereafter, the licenses granted to Pfizer with respect to such product in such country will convert into a perpetual, exclusive, fully paid-up and royalty-free license. In addition to termination rights granted to each party in the case of the other party's uncured material breach, Pfizer may terminate the agreement, in whole or in part, for convenience and with or without reason at any time upon 60 days' prior written notice. In addition, Pfizer is entitled to terminate the agreement and initiate a technology transfer of certain intellectual property if one of its key competitors acquires control over us.

Genevant—Rare Disease Protein Replacement Therapy Strategic Collaboration

In July 2018, our wholly-owned subsidiary BioNTech RNA Pharmaceuticals GmbH, or BioNTech RNA, entered into a license and co-development agreement with Genevant Sciences GmbH, or Genevant for the joint development of certain pharmaceutical products and the licensing of specified rights to Genevant's lipid nanoparticle delivery technology to BioNTech RNA. We refer to this agreement as the Genevant Agreement.

Under the Genevant Agreement, BioNTech RNA and Genevant have agreed to collaborate to develop pharmaceutical products that contain any of five mRNA payloads created by BioNTech RNA encapsulated within a Genevant (or, if the parties agree, a third party) LNP, or the Co-Development Products, for the treatment, prevention and diagnosis of liver diseases, excluding any oncology diseases, or the Co-Development Field. Each party granted to the other party a worldwide, co-exclusive license or sublicense, with limited sublicensing rights, under certain of its patents and know-how to research, develop, make, have made, use, distribute, sell, offer for sale, have sold, import, export and otherwise commercialize the Co-Development Products in the Co-Development Field as provided in development and commercialization plans approved by a joint steering committee and subject to certain restrictions under the Genevant Agreement.

In addition, BioNTech RNA obtained an exclusive, worldwide, royalty-bearing license or sublicense under Genevant's LNP delivery technology to research, develop, make, have made, use, distribute, sell, offer for sale, have sold, import, export and otherwise commercialize pharmaceutical products containing BioNTech mRNA payloads encapsulated within an LNP, or the BioNTech Products, for the treatment, prevention and diagnosis of illnesses in the field of oncology, or the BioNTech Field.

Each party retained certain rights to practice its intellectual property for all purposes outside of the Co-Development Field or in the Co-Development Field with any product that is not a Co-Development Product, subject to the next sentence as to BioNTech. During the term of the Genevant Agreement for each Co-Development Product or BioNTech Product, BioNTech RNA has agreed not to conduct or enable any clinical development, promotion or commercialization of any product involving the use of LNP with the BioNTech

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mRNA payload contained in the Co-Development Product or BioNTech Product other than in collaboration with Genevant pursuant to the Genevant Agreement. Genevant has also retained rights to practice its intellectual property for all purposes outside the BioNTech Field, or in the BioNTech Field with any product that is not a BioNTech Product.

The parties are jointly responsible for the development of, and must use commercially reasonable efforts to develop, the Co-Development Products in accordance with a development plan approved by a joint steering committee. Genevant is responsible for the preclinical, clinical and commercial manufacture of the Co-Development Products, and BioNTech RNA is obligated to supply the mRNA payloads for use in manufactured Co-Development Products. The parties share equally all costs for the development of Co-Development Products as well as any profits and losses. For each Co-Development Product, one or the other party will take the lead responsibility for commercialization of the Co-Development Product in the Co-Development Field. Each party must use commercially reasonable efforts to perform the commercialization activities allocated to it in a commercialization plan approved by a joint steering committee.

Each party may opt-out of the co-development of any Co-Development Product with 90 days' prior notice at any time after the filing of an IND or equivalent for the Co-Development Product. In such event, the other party may continue the development of the Co-Development Product on its own, at its sole cost and expense apart from specified obligations to support manufacturing and any ongoing clinical studies, but has to pay to the party that opted out pre-defined regulatory and sales milestones for the Co-Development Product of up to a low nine figure U.S. dollar amount in the aggregate and tiered low to mid-single digit percentage royalties on aggregate net sales of the Co-Development Product. In the event that a party opts out of the co-development of any Co-Development Product, the license granted by the party opting out to the other party shall become exclusive licenses, even as to the opting out party.

BioNTech RNA is solely responsible for the development and commercialization of the BioNTech Products, including the performance of preclinical and clinical trials, all regulatory activities, and marketing and sales, and bears all related costs. BioNTech RNA must use commercially reasonable efforts to develop and obtain regulatory approval for BioNTech Products in the BioNTech Field in the United States, Germany, United Kingdom, France, Spain and Italy. Genevant is responsible for the manufacturing of the BioNTech Products, and the details of such manufacturing are to be agreed in a separate manufacturing and supply agreement. BioNTech RNA is obligated to pay regulatory and sales milestone payments on each BioNTech Product, and royalties based on aggregate net sales of all BioNTech Products, to Genevant.

The Genevant Agreement continues until later of (i) the expiration of the last-to-expire royalty term for any BioNTech Product worldwide and (ii) the date on which all Co-Development Products cease being developed or commercialized. BioNTech RNA may terminate the agreement for convenience with respect to one or more BioNTech Products at any time with 90 or 180 days' prior notice, depending on whether regulatory approval has been granted. The Genevant Agreement grants each party termination rights: if the other party challenges the validity, enforceability or scope of any patents licensed to it under the Genevant Agreement; for uncured material breaches of the other party; for the other party's insolvency; or if the other party undergoes a change of control through which it is controlled by a competitor, if specified by the parties at the time of the Genevant Agreement, before the earlier of July 4, 2021 or when the other party undergoes an initial public offering.

Under certain scenarios, if BioNTech RNA terminates the Genevant Agreement with respect to a particular BioNTech Product, before granting a license to a third party for the BioNTech mRNA payload included in the BioNTech Product, Genevant has the right of negotiation with BioNTech. Under certain scenarios, if Genevant terminates the Genevant Agreement, Genevant keeps all licenses and have certain rights, but not the obligation, to continue the development and commercialization of Co-Development Products, and BioNTech RNA has certain obligations to provide assistance, documentation, and certain know-how and inventions to enable Genevant's continued development and commercialization of Co-Development Products.

XV. Government Regulation

Government authorities in the United States, at the federal, state and local levels, and in the European Union and other countries and jurisdictions, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, record-keeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting and import and export of pharmaceutical products, including biological products. In addition, some jurisdictions regulate the pricing of pharmaceutical products. The processes for obtaining marketing approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other requirements of regulatory authorities, require the expenditure of substantial time and financial resources.

Regulation and Procedures Governing Approval of Drug and Biological Products in the United States

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and its implementing regulations and biologics under the FDCA, the Public Health Service Act, or the PHSA, and their implementing regulations. Both drugs and biologics also are subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state and local statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or following approval may subject a sponsor to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, license revocation, clinical hold, untitled or warning letters, voluntary or mandatory product recalls, market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

A sponsor seeking approval to market and distribute a new drug or biological product in the United States generally must satisfactorily complete each of the following steps:

- preclinical laboratory tests, animal studies and formulation studies all performed in accordance with applicable regulations, including the FDA's good laboratory practices, or GLP, regulations;
- submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials may begin;
- approval by the IRB representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials to establish the safety, potency and purity of the product candidate for each proposed indication, in accordance applicable regulations, including with GCP, regulations;
- preparation and submission to the FDA of a NDA for a drug product, or a BLA for a biological product requesting marketing approval for one or more proposed indications, including submission of detailed information on the manufacture and composition of the product in clinical development, evidence of safety, purity and potency from preclinical testing and clinical trials, and proposed labeling;
- review of the product by an FDA advisory committee, if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities, including those of third parties, at which the product, or components thereof, are produced to assess compliance with current GMP requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- satisfactory completion of any FDA audits of the clinical study sites to assure compliance with GCPs, and the integrity of clinical data in support of the NDA or BLA;
- payment of user fees and securing FDA approval of the NDA or BLA; and

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- compliance with any post-approval requirements, including the potential requirement to implement a REMS and to conduct any post-approval studies required by the FDA.

The preclinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our investigational medicines and any future investigational medicines will be granted on a timely basis, or at all.

Preclinical Studies and Investigational New Drug Application

Before testing any drug or biological product candidate in humans, the product candidate must undergo preclinical testing. Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as animal studies to evaluate the potential for activity and toxicity. The conduct of the preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, are submitted to the FDA as part of an IND application. The IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about the product or conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks, and places the trial on a clinical hold. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns before the clinical trial can begin.

As a result, submission of the IND may result in the FDA not allowing the trial to commence or not be conducted on the terms originally specified by the sponsor in the IND. If the FDA raises concerns or questions either during this initial 30-day period, or at any time during the IND process, it may choose to impose a partial or complete clinical hold. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA. A clinical hold issued by the FDA may therefore delay either a proposed clinical study or cause suspension of an ongoing study, until all outstanding concerns have been adequately addressed and the FDA has notified the company that investigation may proceed. This could cause significant difficulties in completing planned clinical trials in a timely manner.

The FDA may impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance.

Human Clinical Trials in Support of an NDA or a BLA

Clinical trials involve the administration of the investigational product candidate to healthy volunteers or patients with the disease to be treated under the supervision of qualified principal investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent for their participation. Clinical trials are conducted under study protocols detailing, among other things, the objectives of the study, inclusion and exclusion criteria, the parameters to be used in monitoring safety, dosing procedures and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND.

A sponsor who wishes to conduct a clinical trial outside the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of the NDA or BLA so long as the clinical trial is well-designed and well-conducted in accordance with GCP, including review and approval by an independent ethics committee, and the FDA is able to validate the study data through an onsite inspection, if necessary.

Further, each clinical trial must be reviewed and approved by an IRB either centrally or individually at each institution at which the clinical trial will be conducted. The IRB will consider, among other things, clinical trial

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design, patient informed consent, ethical factors and the safety of human subjects. An IRB must operate in compliance with FDA regulations. The FDA, IRB, or the clinical trial sponsor may suspend or discontinue a clinical trial at any time for various reasons, including a finding that the clinical trial is not being conducted in accordance with FDA requirements or that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive GCP rules and the requirements for informed consent. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee, or DSMB. This group may recommend continuation of the study as planned, changes in study conduct, or cessation of the study at designated check points based on access to certain data from the study.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Additional studies may be required after approval.

- Phase 1 clinical trials (or Phase 1) are initially conducted in a limited population to test the product candidate for safety, including adverse effects, dose tolerance, absorption, metabolism, distribution, excretion and pharmacodynamics in healthy humans or, on occasion, in patients, such as in the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers.
- Phase 2 clinical trials (or Phase 2) are generally conducted in a limited patient population to identify possible adverse effects and safety risks, preliminarily evaluate the efficacy of the product candidate for specific targeted indications and determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger Phase 3 clinical trials. When a drug is intended to treat life-threatening or severely debilitating illnesses, the FDA may accept well-controlled Phase 2 clinical trials as adequate to provide sufficient data on the drug's safety and effectiveness to support a decision on its approvability for marketing, in which case Phase 3 clinical trials would not be required.
- Phase 3 clinical trials (or Phase 3) proceed if the Phase 2 clinical trials demonstrate that a certain dose or dose range of the product candidate is potentially effective and has an acceptable safety profile. Phase 3 clinical trials are undertaken within an expanded patient population, often at geographically dispersed clinical trial sites, to gather additional information about safety and effectiveness necessary to evaluate the overall benefit-risk relationship of the product and to provide an adequate basis for product labeling.

In some cases, the FDA may approve an NDA or a BLA for a product candidate but require the sponsor to conduct additional clinical trials to further assess the product candidate's safety and effectiveness after approval. Such post-approval trials are typically referred to as Phase 4 clinical trials (or Phase 4). These studies may be used to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of biologics approved under accelerated approval regulations. If the FDA approves a product while a company has ongoing clinical trials that were not necessary for approval, a company may be able to use the data from these clinical trials to meet all or part of any Phase 4 clinical trial requirement or to request a change in the product labeling. Failure to exhibit due diligence with regard to conducting required Phase 4 clinical trials could result in withdrawal of approval for products.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events, any findings from other trials, tests in laboratory animals or *in vitro* testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or

investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. The FDA or the sponsor or its DSMB may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the new drug candidate or biological product candidate has been associated with unexpected serious harm to patients.

There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Sponsors of clinical trials of FDA-regulated products, including biologics, are required to register and disclose certain clinical trial information, which is publicly available at www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved.

Compliance with GMP Requirements

Before approving an NDA or a BLA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in full compliance with GMP requirements and adequate to assure consistent production of the product within required specifications. Among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final drug or biological product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug or biological product does not undergo unacceptable deterioration over its shelf life. In particular, the PHSA emphasizes the importance of manufacturing control for products like biologics whose attributes cannot be precisely defined.

Manufacturers and others involved in the manufacture and distribution of drugs and biological products must also register their establishments with the FDA and certain state agencies. Both domestic and foreign manufacturing establishments must register and provide additional information to the FDA upon their initial participation in the manufacturing process.

The manufacturing facilities may be subject to periodic unannounced inspections by government authorities to ensure compliance with GMPs and other laws. Manufacturers may have to provide, on request, electronic or physical records regarding their establishments. Delaying, denying, limiting or refusing inspection by the FDA may lead to a product being deemed to be adulterated.

Review and Approval of an NDA or a BLA

The results of product candidate development, preclinical testing and clinical trials, including negative or ambiguous results as well as positive findings, are submitted to the FDA as part of an NDA or a BLA requesting a license to market the product. These applications must contain extensive manufacturing information and detailed information on the composition of the product and proposed labeling. The FDA adjusts the Prescription Drug User Fee Act, or PDUFA, user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs or BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA has 60 days after submission of the application to conduct an initial review to determine whether the NDA or BLA is sufficient to accept for filing based on the agency's threshold determination that it is

substantially complete so as to permit substantive review. Once the submission has been accepted for filing, the FDA begins an in-depth review of the application. Under the goals and policies agreed to by the FDA under PDUFA, the FDA aims to complete its initial review of a standard application and respond to the sponsor within ten months of the 60-day filing date, and for a priority review application within six months. The FDA does not always meet its PDUFA goal dates for standard and priority NDA or BLA applications, and its review goals are subject to change from time to time. The review process may often be significantly extended by FDA requests for additional information or clarification. The review process and the PDUFA goal date may also be extended by three months if the FDA requests or if the sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

The FDA reviews NDA and BLA applications to determine, among other things, whether the proposed product is safe and potent, or effective, for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with GMP requirements to assure and preserve the product's identity, safety, strength, quality, potency and purity. On the basis of the FDA's evaluation of the application and accompanying information, including the results of the inspection of the manufacturing facilities and any FDA audits of clinical trial sites to assure compliance with GCPs, the FDA may issue an approval letter, denial letter or complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. Under the FDCA, the FDA may approve an NDA if it determines that the product is safe and effective for its intended use, the benefits of the drug outweigh any risks, and the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality and purity. Under the PHSA, the FDA may approve a BLA if it determines that the product is safe, pure and potent and the facility where the product will be manufactured meets standards designed to ensure that it continues to be safe, pure and potent. If the application is not approved, the FDA may issue a complete response letter, which will contain the conditions that must be met in order to secure final approval of the application, and when possible will outline recommended actions the sponsor might take to obtain approval of the application. If a complete response letter is issued, the sponsor may either resubmit the NDA or BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

Sponsors that receive a complete response letter who elect to address the deficiencies may submit to the FDA information that represents a complete response to the issues identified by the FDA in the response letter. Such resubmissions are classified under PDUFA as either Class 1 or Class 2, based on the information submitted by a sponsor in response to an action letter. Under the goals and policies agreed to by the FDA under PDUFA, the FDA aims to review and act on a Class 1 resubmission with two months of receipt and, with respect to a Class 2 resubmission, within six months of receipt. The FDA will not approve an application until issues identified in the complete response letter have been addressed.

The FDA may also refer the application to an Advisory Committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. In particular, the FDA may refer applications for novel drug or biological products or drug or biological products that present difficult questions of safety or efficacy to an advisory committee. Typically, an Advisory Committee is a panel of independent experts, including clinicians and other scientific experts. The FDA is not bound by the recommendations of an Advisory Committee, but it considers such recommendations carefully when making decisions.

If the FDA approves a new product, it may limit the approved indications for use of the product, or limit the approval to specific dosages. It may also require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may call for post-approval studies, including Phase 4 clinical trials, to further assess the product's safety after approval. The agency may also require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including risk evaluation and mitigation strategies, or REMS, to help ensure that the benefits of the product outweigh the potential risks. REMS can

include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patent registries. If the FDA concludes a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS; the FDA will not approve the NDA or BLA without a REMS, if required. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Fast Track, Breakthrough Therapy and Priority Review Designations

The FDA may designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs include fast track designation, breakthrough therapy designation and priority review designation.

The FDA may designate a product for fast track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug or biologic may request that the FDA designate the drug or biologic as a fast track product at any time during the clinical development of the product. For fast track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a fast track application does not begin until the last section of the application is submitted. Fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

In 2012, Congress enacted the Food and Drug Administration Safety and Innovation Act, or the FDASIA. This law established a new regulatory scheme allowing for expedited review of products designated as "breakthrough therapies." A product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to facilitate the design of clinical trials in an efficient manner.

The FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case-by-case basis, whether the proposed product represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application to six months (compared to 10 months under standard review).

Fast track designation, priority review and breakthrough therapy designation may expedite the development or approval process, but do not change the standards for approval.

Accelerated Approval Pathway

The FDA may grant accelerated approval to a product for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. Products granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a product, such as an effect on IMM. The FDA has stated that although it has limited experience with accelerated approvals based on intermediate clinical endpoints, such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a product.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a product. Thus, accelerated approval has been used extensively in the development and approval of products for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or to confirm a clinical benefit during post-marketing studies, may lead the FDA to withdraw the product from the market. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

Accelerated approval pathways are available for regenerative medicine therapies that meet certain conditions. Regenerative medicine therapies include cell therapies (both allogenic and autologous), therapeutic tissue engineering products, human cell and tissue products, and combination products using any such therapies or products, except those regulated under section 361 of the PHS Act. Human gene therapies, including genetically modified cells, that lead to a sustained effect on cells or tissues, may also meet the definition of a regenerative medicine therapy, as may xenogeneic cell products.

Regenerative medicine therapies designed to treat, modify, reverse or cure serious conditions are eligible for FDA's expedited programs, including fast track designation, breakthrough therapy designation, priority review and accelerated approval, if they meet the criteria for such programs. They may also be eligible for Regenerative Medicine Advanced Therapy Designation, or RMAT designation.

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An investigational drug is eligible for RMAT designation if it meets the definition of regenerative medicine therapy, it is intended to treat, modify, reverse or cure a serious condition, and preliminary clinical evidence indicates that the regenerative medicine therapy has the potential to address unmet medical needs for such condition. An unmet medical need is a condition whose treatment or diagnosis is not addressed adequately by available therapy.

RMAT designation confers all the benefits of the fast track and breakthrough therapy designation programs, including early actions with the FDA. The FDA reviews each application on a case-by-case basis to determine whether the clinical evidence is sufficient to support RMAT designation, considering factors such as the rigor of data collection, the consistency and persuasiveness of the outcomes, the number of patients or subjects, and the severity, rarity or prevalence of the condition, among other factors. The FDA may decline to grant RMAT designation if it finds the clinical evidence insufficient.

RMAT designation may expedite the development or approval process, but it does not change the standards for approval.

Post-Approval Regulation

If regulatory approval for marketing of a product or for a new indication for an existing product is obtained, the sponsor will be required to comply with rigorous and extensive post-approval regulatory requirements as well as any post-approval requirements that the FDA has imposed on the particular product as part of the approval process. The sponsor will be required, among other things, to report certain adverse reactions and production problems to the FDA, provide updated safety and efficacy information and comply with requirements concerning advertising and promotional labeling. Manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including GMP regulations, which impose certain procedural and documentation requirements upon manufacturers. Accordingly, the BLA holder and its third-party manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with GMP regulations and other regulatory requirements. In addition, changes to the manufacturing process or facility generally require prior FDA approval before being implemented, and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market study requirements or clinical trial requirements to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, untitled letters or warning letters or holds on post-approval clinical trials;
- adverse publicity;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions, fines, debarment, disgorgement of profits or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Pharmaceutical products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

Orphan Drug Designation

Orphan drug designation in the United States is designed to encourage sponsors to develop products intended for rare diseases or conditions. In the United States, a rare disease or condition is statutorily defined as a disease or condition that affects fewer than 200,000 individuals in the United States or that affects more than 200,000 individuals in the United States but for which there is no reasonable expectation that the cost of developing and making available the product for the disease or condition will be recovered from sales of the product in the United States.

Orphan drug designation qualifies a company for certain financial incentives, including tax advantages and, if the product receives the first FDA approval for the indication for which it has orphan designation, market exclusivity for seven years following the date of the product's marketing approval. An application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. Once a product receives orphan drug designation from the Office of Orphan Products Development at the FDA, the product must then go through the review and approval process like any other product.

In addition, a sponsor of a product that is otherwise the same product as an already approved orphan drug may seek and obtain orphan drug designation for the subsequent product for the same rare disease or condition if it can present a plausible hypothesis that its product may be clinically superior to the first product. More than one sponsor may receive orphan drug designation for the same product for the same rare disease or condition, but each sponsor seeking orphan drug designation must file a complete request for designation.

The period of exclusivity begins on the date that the marketing application is approved by the FDA and applies only to the indication for which the product has been designated. The FDA may approve a second application for the same product for a different use or a second application for a clinically superior version of the product for the same use. The FDA cannot, however, approve the same product made by another manufacturer for the same indication during the market exclusivity period unless it has the consent of the sponsor, the manufacturer makes a showing of clinical superiority over the product with orphan exclusivity, or the sponsor is unable to provide sufficient quantities.

Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

Pediatric Studies and Exclusivity

Under the Pediatric Research Equity Act of 2003, an NDA or a BLA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. Sponsors who are planning to submit a marketing application for a drug or biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must also submit pediatric study plans prior to the assessment data, and no later than 60 calendar days following an end-of-Phase 2 meeting with the FDA or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 study. Pediatric study plans must contain an outline of the proposed pediatric study or studies the sponsor plans to conduct, including study objectives and design, any deferral or waiver requests and other information required by regulation. The sponsor, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other and agree upon a final plan. The FDA or the sponsor may request an amendment to the plan at any time.

The FDA may, on its own initiative or at the request of the sponsor, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Additional requirements and procedures relating to deferral requests and requests for extension of deferrals are contained in FDASIA. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation.

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent and orphan exclusivity. This six-month exclusivity may be granted if an NDA or a BLA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

Biosimilars and Reference Product Exclusivity

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or the BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. To date, a number of biosimilars have been licensed under the BPCIA, and numerous biosimilars have been approved in Europe.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, recent government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate implementation and impact of the BPCIA is subject to significant uncertainty.

Regulation of Combination Products in the United States

Certain products may be comprised of components that would normally be regulated under different types of regulatory authorities and frequently by different centers at the FDA. These products are known as combination products. Specifically, under regulations issued by the FDA, a combination product may be:

- A product comprised of two or more regulated components that are physically, chemically or otherwise combined or mixed and produced as a single entity;
- Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products;
- A drug, or device or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device or biological product where both are required to achieve the intended use, indication or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, *e.g.*, to reflect a change in intended use, dosage form, strength, route of administration or significant change in dose; or
- Any investigational drug, device or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device or biological product where both are required to achieve the intended use, indication or effect.

Under the FDCA, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. That determination is based on the “primary mode of action” of the combination product. Thus, if the primary mode of action of a device-biologic combination product is attributable to the biological product, the FDA center responsible for premarket review of the biological product would have primary jurisdiction for the combination product. The FDA has also established an Office of Combination Products to address issues surrounding combination products and provide more certainty to the regulatory review process. That office serves as a focal point for combination product issues for agency reviewers and industry. It is also responsible for developing guidance and regulations to clarify the regulation of combination products, and for assignment of the FDA center that has primary jurisdiction for review of combination products where the jurisdiction is unclear or in dispute.

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, an applicant will need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can initiate clinical trials or market and sell the product in those countries or jurisdictions.

Regulation and Procedures Governing Approval of Medicinal Products in the European Union

The process governing approval of medicinal products, including biological medicinal products and advanced therapy medicinal products, or ATMPs, which comprise gene therapy products, somatic cell therapy products and tissue-engineered products, in the European Union generally follows the same lines as in the United States. It entails satisfactory completion of pharmaceutical development, nonclinical and clinical studies to establish the safety and efficacy of the medicinal product for each proposed indication. Moreover, an applicant must also demonstrate the ability to manufacture the product to a suitable quality.

Clinical Trial Approval

Pursuant to the currently applicable Clinical Trials Directive 2001/20/EC and the Directive 2005/28/EC on GCP, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the member states.

Clinical trials must be conducted in accordance with European Union and national regulations and the International Conference on Harmonization, or ICH, guidelines on GCP. Additional GCP guidelines from the European Commission, focusing in particular on traceability, apply to clinical trials of advanced therapy medicinal products. If the sponsor of the clinical trial is not established within the European Union, it must appoint an entity within the European Union to act as its legal representative.

Under this system, a sponsor must obtain approval from the competent national authority of a European Union member state in which the clinical trial is to be conducted or in multiple member states if the clinical trial is to be conducted in a number of member states. Furthermore, the sponsor may only start a clinical trial at a specific study site after the independent ethics committee has issued a favorable opinion. The clinical trial application must be accompanied by a copy of the trial protocol and an investigational medicinal product dossier with supporting information prescribed by Directive 2001/20/EC and Directive 2005/28/EC and corresponding national laws of the member states and further detailed in applicable guidance documents. Moreover, the sponsor must take out a clinical trial insurance policy, and in most European Union countries the sponsor is liable to provide 'no fault' compensation to any study subject injured in the clinical trial.

In April 2014, the European Union adopted a new Clinical Trials Regulation (EU) No 536/2014, which is set to replace the current Clinical Trials Directive 2001/20/EC. It is expected that the new Clinical Trials Regulation will apply at earliest in the second half of 2019. It will overhaul the current system of approvals for clinical trials in the European Union. Specifically, the new regulation, which will be directly applicable in all member states, aims to simplify and streamline the approval of clinical trials in the European Union. For instance, the new Clinical Trials Regulation provides for a streamlined application procedure using a single entry point and strictly defined deadlines for the assessment of clinical trial applications. This means that one national authority takes the lead in reviewing the application and the other national authorities have only a limited involvement. Any substantial changes to the trial protocol or other information submitted with the clinical trial applications must be notified to or approved by the relevant competent authorities and ethics committees.

The sponsor of a clinical trial must register the clinical trial in advance, and information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial will be made public as part of the registration. The results of the clinical trial must be submitted to the competent authorities and, with the exception of non-pediatric Phase 1 trials, will be made public at the latest within 12 months after the end of the trial.

During the development of a medicinal product, the European Medicines Agency, or EMA, and national medicines regulators within the European Union provide the opportunity for dialogue and guidance on the development program. At the EMA level, this is usually done in the form of scientific advice, which is given by the Scientific Advice Working Party of the Committee for Medicinal Products for Human Use, or CHMP. A fee is incurred with each scientific advice procedure. Advice from the EMA is typically provided based on questions concerning, for example, quality (chemistry, manufacturing and controls testing), nonclinical testing and clinical studies, and pharmacovigilance plans and risk-management programs. Advice is not legally binding with regard to any future marketing authorization application of the product concerned.

Marketing Authorization

To obtain a marketing authorization for a product under the European Union regulatory system, a sponsor must submit a marketing authorization application, or MAA, either under a centralized procedure administered by the EMA or one of the procedures administered by competent authorities in European Union member states (decentralized procedure, national procedure or mutual recognition procedure).

All application procedures require an application in the common technical document, or CTD, format, which includes the submission of detailed information about the manufacturing and quality of the product, and nonclinical and clinical trial information. There is an increasing trend in the European Union toward greater

transparency and, while the manufacturing or quality information is currently generally protected as confidential information, the EMA and national regulatory authorities are now liable to disclose much of the nonclinical and clinical information in marketing authorization dossiers, including the full clinical study reports, in response to freedom of information requests after the marketing authorization has been granted. In October 2014, the EMA adopted a policy under which clinical study reports would be posted on the agency's website following the grant, denial or withdrawal of a MAA, subject to procedures for limited redactions and protection against unfair commercial use. A similar requirement is contained in the new Clinical Trials Regulation that is currently expected to take effect at earliest in the second half of 2019.

A marketing authorization may be granted only to a sponsor established in the European Union. Regulation (EC) No. 1901/2006 on medicinal products for pediatric use provides that prior to obtaining a marketing authorization in the European Union in the centralized procedure, a sponsor must demonstrate compliance with all measures included in an EMA-approved Pediatric Investigation Plan covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, class waiver or deferral for one or more of the measures included in the Pediatric Investigation Plan.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all European Union member states. Pursuant to Regulation (EC) No. 726/2004, the centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy medicinal products and products with a new active substance indicated for the treatment of certain diseases, including products for the treatment of cancer. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional.

Under the centralized procedure, the CHMP established at the EMA is responsible for conducting the assessment of a product to define its risk/benefit profile. Under the centralized procedure, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions from the CHMP. Accelerated evaluation may be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health determined by three cumulative criteria: (i) the seriousness of the disease (*e.g.*, heavy disabling or life-threatening diseases) to be treated, (ii) the absence or insufficiency of an appropriate alternative therapeutic approach, and (iii) anticipation of high therapeutic benefit.

If the CHMP accepts such a request, the time limit of 210 days will be reduced to 150 days, but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that it is no longer appropriate to conduct an accelerated assessment.

The Committee for Advanced Therapies, or CAT, is responsible in conjunction with the CHMP for the evaluation of ATMPs. The CAT is primarily responsible for the scientific evaluation of ATMPs and prepares a draft opinion on the quality, safety and efficacy of each ATMP for which a MAA is submitted. The CAT's opinion is then taken into account by the CHMP when giving its final recommendation regarding the authorization of a product in view of the balance of benefits and risks identified. Although the CAT's draft opinion is submitted to the CHMP for final approval, the CHMP may depart from the draft opinion if it provides detailed scientific justification. The CHMP and CAT are also responsible for providing guidelines on ATMPs and have published numerous guidelines, including specific guidelines on gene therapies and cell therapies. These guidelines, which are not legally binding, provide additional guidance on the factors that the EMA will consider in relation to the development and evaluation of ATMPs and include, *inter alia*, the preclinical studies required to characterize ATMPs, the manufacturing and control information that should be submitted in a MAA; and post-approval measures required to monitor patients and evaluate the long term efficacy and potential adverse reactions of ATMPs.

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The European Commission may grant a so-called “marketing authorization under exceptional circumstances.” Such authorization is intended for products for which the applicant can demonstrate that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use, because the indications for which the product in question is intended are encountered so rarely that the applicant cannot reasonably be expected to provide comprehensive evidence, or in the present state of scientific knowledge, comprehensive information cannot be provided, or it would be contrary to generally accepted principles of medical ethics to collect such information. Consequently, marketing authorization under exceptional circumstances may be granted subject to certain specific obligations, which may include the following:

- the applicant must complete an identified program of studies within a time period specified by the competent authority, the results of which form the basis of a reassessment of the benefit/risk profile;
- the medicinal product in question may be supplied on medical prescription only and may in certain cases be administered only under strict medical supervision, possibly in a hospital, and in the case of a radio-pharmaceutical, by an authorized person; and
- the package leaflet and any medical information must draw the attention of the medical practitioner to the fact that the particulars available concerning the medicinal product in question are as yet inadequate in certain specified respects.

A marketing authorization under exceptional circumstances is subject to annual review to reassess the risk-benefit balance in an annual re-assessment procedure. Continuation of the authorization is linked to the annual reassessment and a negative assessment could potentially result in the marketing authorization being suspended or revoked. The renewal of the marketing authorization of a medicinal product under exceptional circumstances follows the same rules as a “normal” marketing authorization. After five years, the marketing authorization will then be renewed under exceptional circumstances for an unlimited period, unless the EMA decides, on justified grounds, to proceed with one additional five-year renewal.

The European Commission may also grant a so-called “conditional marketing authorization” prior to obtaining the comprehensive clinical data required for an application for a full marketing authorization. Such conditional marketing authorizations may be granted for product candidates (including medicines designated as orphan medicinal products) if the CHMP finds that all the following requirements are met:

- the benefit-risk balance of the product is positive;
- it is likely that the applicant will be able to provide comprehensive data;
- unmet medical needs will be fulfilled; and
- the benefit to public health of the medicinal product’s immediate availability on the market outweighs the risks due to need for further data.

A conditional marketing authorization may contain specific obligations to be fulfilled by the marketing authorization holder, including obligations with respect to the completion of ongoing or new studies, and with respect to the collection of pharmacovigilance data. Conditional marketing authorizations are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions and/or specific obligations. The timelines for the centralized procedure described above also apply with respect to the review by the CHMP of applications for a conditional marketing authorization. Once comprehensive data on the medicinal product have been obtained, the marketing authorization may be converted into a standard marketing authorization which is no longer subject to specific obligations. Initially, this is valid for five years, but can be renewed for unlimited validity.

The European Union medicines rules expressly permit the member states to adopt national legislation prohibiting or restricting the sale, supply or use of any medicinal products containing, consisting of or derived from a specific type of human or animal cell, such as embryonic stem cells.

Periods of Authorization and Renewals

A marketing authorization is valid for five years, in principle, and it may be renewed after five years on the basis of a reevaluation of the risk benefit balance by the EMA or by the competent authority of the authorizing Member State. To that end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal period. Any authorization that is not followed by the placement of the product on the European Union market (in the case of the centralized procedure) or on the market of the authorizing Member State within three years after authorization ceases to be valid.

Regulatory Requirements after Marketing Authorization

Following approval, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of the medicinal product. These include compliance with the European Union's stringent pharmacovigilance or safety reporting rules, pursuant to which post-authorization studies and additional monitoring obligations can be imposed. The holder of a marketing authorization must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs. All new MAAs must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the marketing authorization. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies. RMPs and PSURs are routinely available to third parties requesting access, subject to limited redactions.

In addition, the manufacturing of authorized products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the EMA's GMP requirements and comparable requirements of other regulatory bodies in the European Union, which mandate the methods, facilities and controls used in the manufacturing, processing and packing of products to assure their safety and identity. Specifically, medicinal products may only be manufactured in the European Union, or imported into the European Union from another country, by the holder of a manufacturing/import authorization from the competent national authority. The manufacturer or importer must have a qualified person who is responsible for certifying that each batch of product has been manufactured in accordance with European Union standards of good manufacturing practice, or GMP, before releasing the product for commercial distribution in the European Union or for use in a clinical trial. Manufacturing facilities are subject to periodic inspections by the competent authorities for compliance with GMP.

Finally, the marketing and promotion of authorized products, including industry-sponsored continuing medical education and advertising directed toward the prescribers of products and/or the general public, are strictly regulated in the European Union. In principle, all advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the European Union. Although general requirements for advertising and promotion of medicinal products are established under Directive 2001/83/EC, as amended, the details are governed by regulations in each member state and can differ from one country to another.

Human Cells and Tissues

Human cells and tissues that are intended for human applications but that do not fall within the scope of rules governing medicinal products or medical devices are not subject to premarket review and approval, nor do they require extensive preclinical and clinical testing. However, there are European Union rules governing the donation, procurement, testing and storage of human cells and tissues intended for human application, whether or not they are ATMPs. These rules also cover the processing, preservation and distribution of human cell and tissues that are not ATMPs. Establishments that conduct such activities must be licensed and are subject to inspection by regulatory authorities. Such establishments must implement appropriate quality systems and maintain appropriate records to ensure that cells and tissues can be traced from the donor to the recipient and vice versa. There are also requirements to report serious adverse events and reactions linked to the quality and safety of cells and tissues. More detailed rules may exist at the national level.

Named Patient Supplies

The European Union medicines rules allow individual member states to permit the supply of a medicinal product without a marketing authorization to fulfill special needs, where the product is supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of a healthcare professional and for use by an individual patient under his direct personal responsibility. This may in certain countries also apply to products manufactured in a country outside the European Union and imported to treat specific patients or small groups of patients.

Orphan Drug Designation and Exclusivity

Regulation (EC) No. 141/2000 and Regulation (EC) No. 847/2000 provide that a product can be designated as an orphan drug by the European Commission if its sponsor can establish: that the product is intended for the diagnosis, prevention or treatment of (i) a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union when the application is made, or (ii) a life-threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives it is unlikely that the marketing of the product in the European Union would generate sufficient return to justify the necessary investment. For either of these conditions, the sponsor must demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Union or, if such method exists, the product has to be of significant benefit compared to products available for the condition.

An orphan drug designation provides a number of benefits, including fee reductions, regulatory assistance and the possibility to apply for a centralized European Union marketing authorization. Marketing authorization for an orphan drug leads to a 10-year period of market exclusivity. During this market exclusivity period, neither the EMA nor the European Commission or the member states can accept an application or grant a marketing authorization for a “similar medicinal product”. A “similar medicinal product” is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The market exclusivity period for the authorized therapeutic indication may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug designation because, for example, the product is sufficiently profitable not to justify market exclusivity.

European Data Collection and Data Protection Laws

We are required to comply with strict data protection and privacy legislation in the jurisdictions in which we operate, including the General Data Protection Regulation (EU) 2016/679, or GDPR. The GDPR governs our collection and use of personal data in the European Union relating to individuals (e.g., patients). The GDPR imposes several requirements on organizations that process such data, including: to observe core data processing

principles; to comply with various accountability measures; to provide more detailed information to individuals about data processing activities; to establish a legal basis to process personal data (including enhanced consent requirements); to maintain the integrity, security and confidentiality of personal data; and to report personal data breaches. The GDPR also restricts the transfer of personal data outside of the European Economic Area (*e.g.*, to the United States and other countries that are not deemed to provide adequate protection under their domestic laws). The GDPR may impose additional responsibility and liability in relation to personal data that we process, and require us to put in place additional mechanisms ensuring compliance with the new data protection rules. This may be onerous and adversely affect our business, financial condition, results of operations and prospects. Failure to comply with the requirements of the GDPR and related national data protection laws of European Union member states may result in a variety of enforcement measures, including significant fines and other administrative measures. The GDPR has introduced substantial fines for breaches of the data protection rules, increased powers for regulators, enhanced rights for individuals, and new rules on judicial remedies and collective redress. We may be subject to claims by third parties, such as patients or regulatory bodies, that we or our employees or independent contractors inadvertently or otherwise breached GDPR and related data protection rules. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we do not prevail, we could be required to pay substantial fines and/or damages and could suffer significant reputational harm. Even if we are successful, litigation could result in substantial cost and be a distraction to management and other employees.

Regulation of Diagnostic Products in the European Union

In the European Union, *in vitro* diagnostic products are regulated as *in vitro* diagnostic medical devices, or IVDs. The marketing of IVDs is subject to compliance with the In Vitro Diagnostic Medical Devices Directive 98/79/EC (IVD Directive). An IVD may be placed on the market within the European Union only if it conforms to certain “essential requirements” and bears the CE Mark. The most fundamental and essential requirement is that an IVD must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. In addition, the IVD must achieve the performance(s) stated by the manufacturer and be designed and manufactured in a suitable manner.

Manufacturers must demonstrate that their IVDs conform to the relevant essential requirements through a conformity assessment procedure. The nature of the assessment depends upon the classification of the device. For IVDs intended to determine certain conditions or detect certain diseases, conformity assessment procedures involve a notified body. Notified bodies are often private entities and are authorized or licensed to perform such assessments by government authorities. Conformity assessment procedures require an assessment of available clinical evidence, literature data for the product and post-market experience in respect of similar products already marketed. Notified bodies also may review the manufacturer’s quality systems. If satisfied that the product conforms to the relevant essential requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity and application of the CE Mark. For all other IVDs, the manufacturer performs its own conformity assessment procedure and self-declares conformity before applying the CE Mark. Application of the CE Mark allows the general commercializing of an IVD in the European Union. The manufacturer or, if the manufacturer is located outside the European Union, its authorized representative in the European Union must also register with the competent authority in the European Union member state in which it is located.

In May 2017, the European Union adopted a new In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746, or the IVD Regulation, which will apply in the European Union from May 26, 2022. The IVD Regulation does not set out a radically new system, but clearly envisages, among other things, stricter controls of IVDs, including the involvement of notified bodies in conformity assessments of many more categories of IVD and increased expectations as regards clinical data for IVDs. The IVD Regulation also envisages greater control over notified bodies and their standards, increased transparency, more robust device vigilance requirements and clarification of the rules for clinical investigations. Under transitional provisions, IVDs with notified body certificates issued under the IVD Directive prior to May 26, 2022 may continue to be placed on the market for

the remaining validity of the certificate, until May 27, 2024 at the latest. After the expiry of any applicable transitional period, only IVDs that have been CE marked under the IVD Regulation may be placed on the market in the European Union.

Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we may obtain regulatory approval. Even if our product candidates are approved for marketing, sales of such product candidates will depend, in part, on the extent to which third-party payors, including government health programs in the United States (such as Medicare and Medicaid), commercial health insurers and managed care organizations, provide coverage and establish adequate reimbursement levels for such product candidates. In the United States, the member states of the European Union and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Reimbursement rules and levels are not harmonized in the European Union and therefore differ from member state to member state. Patients are unlikely to use any product candidates we may develop unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of such product candidates. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services and imposing controls to manage costs.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, and the cost of these studies would be in addition to the costs required to obtain FDA or other comparable marketing approvals. Even after pharmacoeconomic studies are conducted, product candidates may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover any product candidates we may develop could reduce physician utilization of such product candidates once approved and have a material adverse effect on our sales, results of operations and financial condition. Additionally, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. For example, the payor may require co-payments that patients find unacceptably high. Further, one payor's determination to provide coverage for a product does not assure that such coverage will continue or that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor. Third-party reimbursement and coverage may not be adequate to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. The insurance coverage and reimbursement status of newly approved products for orphan diseases is particularly uncertain, and failure to obtain or maintain adequate coverage and reimbursement for any such product candidates could limit a company's ability to generate revenue.

The containment of healthcare costs also has become a priority of federal, state and foreign governments as well as other third-party payors such as statutory health insurance funds, and the prices of pharmaceuticals have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue from the sale of any approved products. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented or coverage may be ended in the future.

Outside the United States, we will face challenges in ensuring obtaining adequate coverage and payment for any product candidates we may develop. Pricing of prescription pharmaceuticals is subject to governmental

control in many countries, including in particular the member states of the European Union. Pricing negotiations with governmental authorities or other third-party payors such as statutory health insurance funds can extend well beyond the receipt of regulatory marketing approval for a product and may require us to conduct a clinical trial that compares the cost effectiveness of any product candidates we may develop to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in our commercialization efforts.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost effectiveness of a particular product candidate to currently available therapies (so called health technology assessments) in order to obtain reimbursement or pricing approval. Moreover, European Union member states may restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Member states may approve a specific price for a product or may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other member states allow companies to fix their own prices for products, but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the European Union have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the European Union. The downward pressure on health care costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products in the marketplace. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union Member States and parallel trade (arbitrage between low-priced and high-priced member states) can further reduce prices. Special pricing and reimbursement rules may apply to orphan drugs. Inclusion of orphan drugs in reimbursement systems tend to focus on the medical usefulness, need, quality and economic benefits to patients and the healthcare system as for any product. Acceptance of any medicinal product for reimbursement may come with cost, use and often volume restrictions, which again can vary by country. In addition, results based rules of reimbursement may apply. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products, if approved in those countries.

Healthcare Law and Regulation

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of pharmaceutical products that are granted marketing approval. Our current and future arrangements with providers, researchers, consultants, third-party payors and customers are subject to broadly applicable federal and state fraud and abuse, anti-kickback, false claims, transparency and patient privacy laws and regulations and other healthcare laws and regulations that may constrain our business and/or financial arrangements. Restrictions under applicable federal and state healthcare laws and regulations include, without limitation, the following:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in-cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or a specific intent to violate it in order to have committed a violation. Moreover, the government may assert that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false, fictitious, or fraudulent

or knowingly making, using, or causing to be made or used a false record or statement to avoid, decrease, or conceal an obligation to pay money to the federal government;

- HIPAA, which created additional federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or a specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without the appropriate authorization by entities subject to the law, such as healthcare providers, health plans and healthcare clearinghouses and their respective business associates;
- the federal transparency requirements known as the federal Physician Payments Sunshine Act, under the ACA, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services, or CMS, within the U.S. Department of Health and Human Services, information related to payments and other transfers of value made by that entity to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- federal government price reporting laws, which require us to calculate and report complex pricing metrics to government programs and which may be used in the calculation of reimbursement and/or discounts on marketed products;
- the Foreign Corrupt Practices Act, a U.S. law which regulates certain financial relationships with foreign government officials (which could include, for example, certain medical professionals);
- the national anti-bribery laws and laws governing interactions with healthcare professionals of European Union Member States;
- the U.K. Bribery Act 2010; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring pharmaceutical manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures and pricing information. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry.

Violations of these laws can subject us to criminal, civil and administrative sanctions including monetary penalties, damages, fines, disgorgement, individual imprisonment and exclusion from participation in

government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, reputational harm, and we may be required to curtail or restructure our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to similar actions, penalties, and sanctions. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business. Moreover, we expect that there will continue to be federal and state laws and regulations, proposed and implemented, that could impact our future operations and business.

Current and Future Healthcare Reform Legislation

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our investigational medicines, restrict or regulate post-approval activities, and affect our ability to profitably sell any investigational medicines for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any collaborators, may receive for any approved products.

The ACA, for example, contains provisions that subject biological products to potential competition by lower-cost biosimilars and may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid-managed care plans, mandatory discounts for certain Medicare Part D beneficiaries, and annual fees based on pharmaceutical companies' share of sales to federal health care programs. With the current presidential administration and Congress, there may be additional administrative or legislative changes, including modification, repeal or replacement of all, or certain provisions of, the ACA, which may impact reimbursement for drugs and biologics. On January 20, 2017, an Executive Order was signed directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On October 13, 2017, an executive order was signed terminating the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. In addition, CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Further, each chamber of Congress has put forth multiple bills this year designed to repeal or repeal and replace portions of the ACA. While Congress has not passed repeal legislation, the TCJA includes a provision repealing the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Congress may consider other legislation to repeal and replace elements of the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

Additionally, other federal health reform measures have been proposed and adopted in the United States since the ACA was enacted:

- The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2025 unless additional Congressional action is taken.

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- The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.
- The Middle Class Tax Relief and Job Creation Act of 2012 required that CMS reduce the Medicare clinical laboratory fee schedule by 2% in 2013, which served as a base for 2014 and subsequent years. In addition, effective January 1, 2014, CMS also began bundling the Medicare payments for certain laboratory tests ordered while a patient received services in a hospital outpatient setting.

Further, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which have resulted in several recent Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. In addition, the federal government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs, including price-controls, restrictions on reimbursement, and requirements for substitution of generic products for branded prescription drugs to limit the growth of government-paid health care costs. For example, the federal government has passed legislation requiring pharmaceutical manufacturers to provide rebates and discounts to certain entities and governmental payors to participate in federal healthcare programs. Individual states in the United States have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation, from other countries and bulk purchasing.

Packaging and Distribution in the United States

If our products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The failure to comply with any of these laws or regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, exclusion from federal healthcare programs, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, or refusal to allow a firm to enter into supply contracts, including government contracts. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in regulations, statutes, or the interpretation of existing regulations could impact our business in the future by requiring, for example, (i) changes to our manufacturing arrangements, (ii) additions or modifications to product labeling, (iii) the recall or discontinuation of our products or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

Other U.S. Environmental, Health and Safety Laws and Regulations

We may be subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials

and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

We maintain workers' compensation employers' liability insurance to cover us for costs and expenses we may incur due to injuries to our employees, but this insurance may not provide adequate coverage against potential liabilities.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

XVI. Intellectual Property

A. Introduction

We pursue a layered intellectual property strategy to protect our various technology platforms and their application to the treatment of cancer and other serious diseases. One focus of our intellectual property strategy is to provide protection for our platforms and product candidates currently in development. We also pursue intellectual property protection for assets that may be used in future development programs and/or that may be of interest to our collaborators, or otherwise may prove valuable in the field.

Various aspects of our technology platforms and our product candidates are claimed by patent filings. We also pursue other modalities of protection, including trademark and trade secret protection, as appropriate. Many of our intellectual property assets were developed and are owned solely by us, some have been developed via collaboration and are jointly owned, and some have been acquired by acquisition and/or licensed from third parties. We expect that we will continue to make additional patent application filings, and will continue to pursue opportunities to acquire and license additional intellectual property assets, technologies, platforms or product candidates, as developments arise or are identified.

Regardless, given the early stage of development of our product candidates, we cannot be certain that any of the patent filings or other intellectual property rights that we have pursued or obtained will provide protection for any product candidates that may ultimately be commercialized. Our most advanced product candidates are currently in clinical testing, with no certainty that they will be successful, or that significant modification or adjustment may not be required for successful commercialization.

Our future commercial success depends, in part, on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business; defend and enforce our patents and other intellectual property; preserve the confidentiality of our trade secrets; and operate without infringing, misappropriating or violating the valid and enforceable patents and other intellectual property rights of third parties. Our ability to stop third parties from making, using, selling, offering to sell or importing our products may depend on the extent to which we have rights under valid and enforceable patents, trade secrets or other intellectual property rights that cover these activities. With respect to both our owned and licensed intellectual property, we cannot be sure that patents will issue with respect to any of the owned or licensed pending patent applications or with respect to any patent applications that we, our co-owners or our licensors may file in the future, nor can we be sure that any of our owned or licensed patents or any patents that may be issued in the future to us or our licensors will be commercially useful in protecting any products that,

we ultimately attempt to commercialize, or any method of making or using such products. Moreover, we may be unable to obtain patent protection for certain of our product candidates generally as well as with respect to certain indications. See “Risk Factors—Risks Related to our Intellectual Property” for a more comprehensive description of risks related to our intellectual property.

As of July 31, 2019, our overall owned and in-licensed patent portfolio included more than 200 patent families, each of which includes at least one filing in the United States or Europe, and several of which are pending or granted in multiple jurisdictions. The patent families include at least 100 patent families that are solely or jointly owned by BioNTech, including certain families acquired through our acquisitions of antibody assets and infrastructure from MabVax Therapeutics Holdings, Inc., and the rest that we have licensed from a third party.

An issued patent provides its owner (or possibly its licensee) with a right to exclude others from making, using or selling that which is claimed in the patent, for a specified period of time (the “term” of the patent), in the jurisdiction in which the patent is issued. In the United States, and in many other countries, patents have a presumptive term of 20 years from their effective filing date (which is the earliest non-provisional filing date to which the patent claims priority). However, many jurisdictions, including the United States, require the payment of periodic maintenance fees in order for patents to remain in force for the full 20-year term. The United States also has provisions that require a patent term to be shortened if its claims are too similar to another patent owned by the same party that has a shorter term. The United States and certain other jurisdictions also have provisions that permit extension of patent term for patents that claim a drug or drug product, or its approved use, if the patent was issued before clinical trials were completed and certain other requirements were satisfied. In the United States, such extension is called a Patent Term Extension, or PTE, and it is limited to a period of not more than five years, or the total patent term including the PTE cannot exceed 14 years after the date of regulatory approval; only one patent can be extended per product approval. The United States also offers a different form of patent term extension, known as Patent Term Adjustment, or PTA, whereby a particular patent’s term is automatically extended beyond the 20-year date if the United States Patent and Trademark Office, or the USPTO, caused delay during its examination; however, potentially available PTA is reduced by any amount of any delay caused by the patent applicant.

Below, we provide a summary of the contours of our current patent portfolio as it relates to different aspects of relevant technology, including noting ownership and 20-year terms for filings included in the portfolio that are directed to such aspects. Particularly given our pre-commercial state of development, we cannot be certain that any of the patent filings in our portfolio will provide meaningful protection for any product we ultimately attempt to commercialize.

B. Patent Portfolio

The patent portfolios for our most advanced programs as of July 31, 2019 are summarized below. Patent prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the USPTO and its foreign equivalents can be significantly narrowed by the time they issue, if they issue at all. We expect this could be the case with respect to some of our pending patent applications referred to below.

1. mRNA

The patent portfolio for our mRNA therapeutic platforms and product candidates includes patent filings directed to features of therapeutic mRNA structures, some of which are included in current development candidates. Our patent portfolio also includes patent filings directed to mRNA formulations, including the lipoplex formulations currently utilized with our FixVac and iNeST platforms, and the lipid nanoparticles currently utilized with our RiboMab and RiboCytokine platforms, as well as patent filings directed to mRNA manufacturing, and to uses of mRNA therapeutics. We provide more detail below regarding the patent filings directed to these features.

mRNA Structure

Our patent portfolio includes patent filings directed to various features of mRNA structure, which may, for example, contribute to increased immunogenicity (*e.g.*, antigen presentation), translation efficiency, and/or stability of mRNA constructs that include them. Such features include, for example, antigen-MHC fusions, 5' cap structures, 3' UTR structures, polyA tails and reduced-uracil content mRNAs. Filings directed to each of these features, or collectively, the mRNA Structure Filings, have been made in the United States and various foreign jurisdictions. Some such mRNA Structure Filings are owned solely by BioNTech SE or BioNTech RNA which are referred to collectively in this section as BioNTech, some jointly by BioNTech and one or more third parties, and some by BioNTech licensors, such as Louisiana State University, or LSU, and the terms of the applicable agreement with LSU, are further summarized below in “—C. In-Licensing.” Issued existing mRNA Structure Filings have, and pending existing mRNA Structure Filings, if issued, would have, 20-year terms that extend into the mid-2020s to the mid-2030s.

mRNA Formulations

Our patent portfolio includes patent filings directed to various formulations for mRNA delivery, some of which are utilized with current development candidates. For example, our portfolio includes patent filings directed to lipoplex formulations, with 20-year terms that extend into 2038, if issued, or collectively, the mRNA Lipoplex Filings, although none of these filings is currently an issued patent. Such mRNA Lipoplex Filings are solely owned by BioNTech RNA.

In addition, our portfolio includes U.S. and foreign patent filings directed to lipid nanoparticles and polyplex technologies, which are jointly owned by BioNTech RNA and TRON, or collectively, the mRNA Lipid Nanoparticle/Polyplex Filings. Issued mRNA Lipid Nanoparticle/Polyplex Filings have, and pending mRNA Lipid Nanoparticle/Polyplex Filings, if issued, would have, 20 year terms that extend into the mid- to late-2030s. Some such mRNA Lipid Nanoparticle/Polyplex Filings were granted in certain foreign jurisdictions, but do not currently include any U.S. issued patents. The terms of the co-ownership of such patent filings with TRON are summarized below in “—C. In-Licensing.”

mRNA Manufacturing

As discussed below, we utilize trade secret protection for many aspects of our mRNA manufacturing technologies, including as currently utilized for production of certain of our development candidates. In addition, our patent portfolio includes certain patent filings relevant to mRNA manufacturing, or collectively, the mRNA Manufacturing Filings, which we believe may provide commercial value to protect product candidates and/or support collaborations or other licensing arrangements. For example, our mRNA Manufacturing Filings include U.S. and foreign patent filings relating to certain aspects of mRNA purification and production. These mRNA Manufacturing Filings are either solely owned by BioNTech RNA, or jointly owned by BioNTech RNA and TRON and, if issued, would have 20-year terms that would extend into mid to late 2030s, although none is currently an issued patent.

mRNA Product Candidates

Our most advanced mRNA product candidate development programs are in oncology and involve various platforms. Our pipeline also includes mRNA product candidates for treatment of certain infectious diseases and mRNA product candidates for protein replacement therapy in certain rare diseases.

Oncology mRNA Product Candidates

Our current clinical programs are all in oncology. The most advanced involve iNeST immunotherapy product candidates being developed with our collaborator, Genentech. We also have FixVac product candidates in Phase 1 clinical trials, and have recently initiated Phase 1 clinical trials of our mRNA-based intratumoral immunotherapy developed through our collaboration with Sanofi.

FixVac

Our FixVac product candidates share many of the structural elements involved in our iNeST product candidates. Thus, some or all of the mRNA Structure Filings relevant to our iNeST product candidates and discussed above are also relevant to our FixVac product candidates. These patent filings, or the FixVac Platform Filings, include mRNA Structure Filings relating to antigen-MHC fusions, phosphorothioate stabilized 5' cap structures, 3' UTR structures containing a specific sequence element, and interrupted polyA tails, which are solely or jointly owned by BioNTech or BioNTech's licensors. Issued FixVAC Platform Filings have, and pending FixVac Platform Filings, if issued, would have, 20-year terms extending into the mid-2020s to the mid-2030s. While we have pursued or obtained patent protection covering components of FixVac product candidates, manufacturing-related methods and/or formulations, we do not currently have any claims in our owned or in-licensed issued patents that cover the overall construct used in our FixVac product candidates.

Our patent portfolio further includes U.S. and foreign patent filings relating to combined uses of our FixVac and iNeST product candidates. Such issued patent filings have, and such pending patent filings, if issued, would have, 20-year terms that extend into 2033, and are jointly owned by BioNTech RNA and TRON.

Our current Phase 1 clinical trials for FixVac product candidates are studying such product candidates in treatment of advanced melanoma, head and neck cancer, and breast cancer (particularly triple negative breast cancer). While we do not currently have any claims in our owned or in-licensed issued patents that are directed to use of our FixVac product candidates in the indications of these clinical trials, certain FixVac Platform Filings include specific reference to treatment of each of these indications. Additionally, our patent portfolio relevant to FixVac product candidates further includes U.S. and foreign patent filings relating to use of particular tumor antigens for treatment of triple negative breast cancer included in Phase 1 clinical trials, or the Triple Negative Breast Cancer FixVAC Filings. Issued Triple Negative Breast Cancer FixVac Filings have, and pending Triple Negative Breast Cancer FixVac Filings, if issued, would have, 20-year terms that extend into 2034, and are jointly owned by BioNTech SE and TRON.

iNeST

Our patent filings relevant to our iNeST product candidates include mRNA Structure Filings relating to features for increasing antigen presentation (*e.g.*, antigen-MHC fusions) and features for increasing translation efficiency and/or stability of mRNA constructs (*e.g.*, phosphorothioate stabilized 5' cap structures, 3' UTR structures containing a specific sequence element, and polyA tails of a particular length or interrupted polyA tails); mRNA Lipoplex Filings relating to negatively charged lipoplexes (*e.g.*, for spleen targeting); and mRNA Manufacturing Filings, or collectively, the iNeST mRNA Platform Filings. While we have pursued or obtained patent protection covering components of iNeST product candidates, manufacturing-related methods and/or formulations, we do not currently have any claims in our owned or in-licensed issued patents that cover the overall construct used in our iNeST product candidates.

Our patent portfolio further includes U.S. and foreign filings directed to the process of identifying neoantigens in patient samples and/or predicting those that will be immunoreactive in an iNeST immunotherapy product, or collectively, the Neoantigen Filings. Certain issued Neoantigen Filings have, and certain pending Neoantigen Filings, if issued, would have 20-year terms that extend into the mid- to late-2030s, although none is a U.S. issued patent. The Neoantigen Filings are solely owned by BioNTech RNA, or jointly owned by BioNTech RNA and TRON.

We are currently studying our iNeST product candidates for the treatment of metastatic melanoma in Phase 2 clinical trials and those for the treatment of various solid tumors in Phase 1 clinical trials. Certain iNeST mRNA Platform Filings and Neoantigen Filings cover treatment of each of these indications. However, we do not currently have any claims in our owned or in-licensed issued patents that are directed to use of iNeST product candidates in the indications of these clinical trials.

Intratumoral Immunotherapies

Certain of the mRNA Structure Filings (including some that are relevant to iNeST and/or FixVac product candidates, as discussed above) are also directed to one or more features of our intratumoral immunotherapies, including our most advanced intratumoral immunotherapy, which we are developing through our collaboration with Sanofi, and which has recently entered Phase 1 clinical trials. For example, mRNA Structure Filings relating to 3' UTR structures containing a specific sequence element, interrupted polyA tail structures, and reduced-uracil content mRNAs, which, as noted above are solely or jointly owned by BioNTech and, if issued, would have 20-year terms extending into the mid-2030s, provide protection to our current intratumoral immunotherapy development candidate. However, these filings do not currently include any issued patents.

We have also obtained third-party licenses to technologies relating to certain features of the mRNA structure relevant to the intratumoral immunotherapies. These include two non-exclusive sublicenses—one from mRNA RiboTherapeutics, Inc., or MRT, and one from its affiliate CellScript, LLC (these licenses, together, the MRT-CellScript Sublicenses). MRT-CellScript Sublicenses allow us to use, make and/or sell nucleoside-modified mRNA products that are covered by U.S. and European Patent Office patent filings owned by the Trustees of the University of Pennsylvania, or the Penn Modified RNA Patent Rights, which sublicenses are further summarized below in “—C. In-Licensing.”

Additionally, we and Sanofi co-own certain patent filings relating to compositions including mRNAs encoding particular cytokines for treatment of solid tumors, or the mRNA Cytokine Filings. Such mRNA Cytokine Filings, if issued, would have 20-year terms that would extend into 2038. However, these filings do not currently include any issued patents.

RiboMabs and RiboCytokines

We own or license a number of patent filings directed to our RiboMab and RiboCytokine programs. Many are owned solely by us, some are jointly owned, and some have been acquired or licensed.

Patent filings relevant to our RiboMab and RiboCytokine programs include certain mRNA Structure Filings relevant to our iNeST and/or FixVac product candidates, specifically relating to 3' UTR structures containing a specific sequence element, interrupted polyA tail structures, and reduced-uracil content mRNAs; mRNA Lipid Nanoparticle/Polyplex Filings; and patent filings under the MRT-CellScript Sublicenses relating to nucleoside-modified mRNAs.

We have also recently acquired patent assets from MabVax Therapeutics, or the MabVax Filings, that relate to various antibodies, including certain antibodies targeting sialyl Lewis A and ganglioside GD2, as well as nucleic acid encoding them. Issued MabVax Filings have, and the pending MabVax Filings, if issued, would have, 20-year terms that extend into the mid-2030s.

Infectious Diseases

As is discussed elsewhere, we have collaborated with third parties, including Pfizer and Penn, to develop infectious disease mRNA vaccines.

Certain patent filings that might be useful to our infectious disease mRNA vaccines include certain of the mRNA Structure Filings and the mRNA Lipid Nanoparticle/Polyplex Filings.

Rare Diseases

We are developing mRNA-based protein replacement therapy for several rare disease indications through our collaboration with Genevant.

Certain of the mRNA Structure Filings (including some that are relevant to iNeST and/or FixVac product candidates, as discussed above) and patent filings under the CellScript Licenses include patent filings directed to nucleoside-modified mRNAs also provide protection for one or more features of mRNA-based protein replacement product candidates. For example, mRNA Structure Filings include patent filings directed to 3' UTR structures containing a specific sequence element, interrupted poly A tail structures and reduced-uracil content mRNAs, which, as noted above are solely or jointly owned by BioNTech, and, if issued, would have 20-year terms that would extend into the mid-2030s. However, these filings do not currently include any issued patents.

Our patent portfolio relating to our rare disease programs also include certain patent filings that we have licensed from Genevant, or the Genevant Filings. Specifically, the Genevant Filings are owned by Arbutus Biopharma Corporation, which is a Genevant affiliate, and relate primarily to lipid or non-liposomal formulations that might be useful in these programs, and have been filed primarily in the U.S. and Europe, with 20-year terms that extend into mid-2020s to mid-2030s for the issued Genevant Filings and the pending Genevant Filings, if issued.

2. *Engineered Cell Therapy*

Our engineered cell therapy product class features use of chimeric antigen receptor, or CAR-, T cell or individualized T cell receptors for oncology therapy. Our patent filings relevant to these platforms and product candidates, or the CAR T/TCR Filings, are generally co-owned by BioNTech Cell & Gene Therapies GmbH, or BioNTech C>, and TRON. For example, the CAR T/TCR Filings include patent filings directed to various CAR T formats and methods of enhancing CAR-T cells by nucleic acid vaccination, as well as patent filings directed to processes of identifying and/or making individualized T cell receptors. The CAR T/TCR Patent Filings, if issued, would have 20-year terms that would extend into the mid- to late-2030s. However, these filings do not currently include any issued patents.

Certain CAR T programs involve CAR-T cell product candidates that target different members of the claudin family. Our patent portfolio includes certain patent filings specifically relevant to our claudin-specific CAR-T cell product candidates and are jointly owned by BioNTech C>, TRON and Ganymed, or the Claudin-Specific CAR-T Cell Filings. The issued Claudin-Specific CAR-T Cell Filings have, and the pending Claudin-Specific CAR-T Cell Filings, if issued, would have, 20-year terms extending into the mid-2030s. However, these filings do not currently include any U.S. issued patents. The terms of our co-ownership of such patent filings with TRON and Ganymed are summarized below in “—C. In-Licensing.”

3. *Antibodies*

Our antibodies product class features bispecific checkpoint immunomodulators for oncology therapy, which are developed through collaboration with Genmab. Our development candidates include bispecific antibodies that are designed to activate 4-1BB upon simultaneous binding to PD-L1 or CD-40. Our patent portfolio includes certain patent filings relevant to such bispecific antibodies, or the Bispecific Checkpoint Modulator Filings, co-owned by us and Genmab. Such Bispecific Checkpoint Modulator Filings, if issued, would have 20-year terms that would extend into the late-2030s and do not currently include any issued patents.

4. *Small Molecule Immunomodulators*

Our small molecule therapeutics product class features oncology treatment using small molecule product candidates that activate the immune system via TLR7 agonism. Our patent portfolio includes patent filings relevant to these TLR7 agonists, or the TLR7 Agonist Filings. Certain TLR7 Agonist Filings are directed to substituted imidazoquinolines, and, if issued, would have 20-year terms that would extend into the late 2030s. However, these filings do not currently include any issued patents.

C. *In-Licensing*

Some of our intellectual property assets have been acquired by acquisition and/or in-licensing.

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We have pursued a strategy of identifying and in-licensing third-party patents that we believe are complementary to or otherwise interact synergistically with our own intellectual property portfolio. We have entered into material intellectual property licensing or option arrangements with Penn, TRON, Louisiana State University and MRT-CellScript.

The key terms of these arrangements are summarized below.

Penn Agreement

In October 2018, BioNTech RNA entered into a collaboration and license agreement with the Trustees of the University of Pennsylvania regarding the development and commercialization of certain mRNA vaccines and mRNA diagnostics for the diagnosis, detection, evaluation, prophylaxis and treatment of infectious diseases. We refer to this agreement as the Penn Agreement.

Under the Penn Agreement, BioNTech RNA and Penn agree to collaborate with respect to research and development activities and are obligated to use commercially reasonable efforts to develop products that use formulated mRNAs encoding one or more immunogens for 10 disease indications in the field of infectious diseases (each, a Penn Product). Penn is responsible for all research and development work up to completion of studies enabling an IND as well as IND-supporting preclinical work, and BioNTech RNA is responsible for the manufacture of mRNA amounts to support the preclinical and IND-enabling studies. If a Penn Product developed under the research program achieves certain acceptance criteria for a specified indication, BioNTech RNA has the right to obtain an exclusive worldwide license under Penn's patent rights (and a non-exclusive license under Penn's know-how and materials) to research, develop, make, use or commercialize Penn Products in such indication. Under the Penn Agreement, Penn retains certain rights to conduct and authorize non-commercial third-party research, educational and patient care activities under any licensed intellectual property. Moreover, the license granted by Penn is subject to certain rights granted to the U.S. government in connection with government funding provided by the United States, including the requirement that products that result from intellectual property funded by the U.S. government that are sold in the United States be substantially manufactured in the United States.

BioNTech RNA has an obligation to use commercially reasonable efforts to clinically develop, obtain regulatory approval for and commercialize at least one Penn Product for each indication licensed under the Penn Agreement. Moreover, BioNTech RNA is obligated to achieve certain clinical and regulatory milestones within specified time periods, and its failure to do so would provide Penn the right to terminate the Penn Agreement on an indication-by-indication basis.

BioNTech RNA paid to Penn an upfront fee of \$5 million to fund research activities and has agreed to pay Penn additional funds through quarterly payments, not to exceed an aggregate of \$15 million, upon depletion of the previously advanced funds. Under the Penn Agreement, BioNTech RNA also agreed to pay Penn an annual alliance management fee. In addition, if any Penn Product is covered by a Penn patent, BioNTech RNA will pay to Penn development and commercialization milestone payments for each Penn Product licensed under this agreement and royalties on net sales of all Penn Products licensed under the Penn Agreement. Further, Penn will receive a percentage of any income from sublicenses BioNTech RNA grants to third parties, subject to certain caps set forth in the Penn Agreement.

BioNTech RNA has the sole responsibility for and decision-making authority over clinical development and commercialization activities relating to any Penn Product arising from the collaboration. BioNTech RNA is also responsible for the manufacture of mRNA to support clinical development and commercialization efforts.

The Penn Agreement remains in effect until the expiration of the last Penn patent covering any licensed Penn Product or developmental product candidate. BioNTech RNA may terminate the Penn Agreement for convenience in its entirety or on an indication-by-indication basis at any time after October 9, 2019 upon 90

days' prior notice to Penn. The Penn Agreement also grants both parties termination rights for uncured material breaches, including for BioNTech RNA's failure to achieve its obligations to achieve certain diligence milestones, and insolvency.

TRON Agreements

In 2015, we and our subsidiaries BioNTech RNA, BioNTech Diagnostics GmbH, BioNTech Protein Therapeutics GmbH, BioNTech Cell & Gene Therapies GmbH, Eufets GmbH and JPT Peptide Technologies GmbH entered into a Master Agreement for Research Services with TRON. Concurrently with this Master Agreement for Research Services, or the TRON Research Agreement, we entered into a License Agreement with Ganymed, TRON, Johannes Gutenberg-Universität Mainz and Universitätsmedizin der Johannes Gutenberg-Universität Mainz, or the TRON License Agreement. The TRON Research Agreement and TRON License Agreement together replaced and superseded our 2008 Cooperation, Purchase and Licensing Agreement with the University Mainz, or the 2008 Cooperation Agreement.

TRON Research Agreement

Under the TRON Research Agreement, TRON from time to time performs certain services for us under work orders, which may comprise innovative applied research projects, pre-defined research and development or clinical research services. We and TRON meet at regular intervals, but no less than annually, to prepare an overall non-binding project plan, which sets the scope, period and costs for the relevant projects contemplated for that period. Individual work orders set the specific binding terms of each project or service. TRON is obligated to render services in accordance with the scientific standards, all applicable laboratory and legal provisions and with the care customary in the industry.

We are entitled to the exclusive rights to all inventions, methods, specifications, materials, documents, data, know-how and other results (together, the Results) developed or discovered by TRON or by us and TRON jointly under the TRON Research Agreement, except to the extent they constitute improvements of the technologies applied by TRON in the relevant projects. Under the TRON Research Agreement, TRON granted us a non-exclusive, royalty-free license to use TRON Improvements if such TRON Improvements are necessary for the continued development and exploitation of the Results or the manufacture or marketing of products which contain any of the Results and are covered by a patent claiming any of the Results.

Under the TRON Research Agreement, TRON's services rendered in the field of applied research are invoiced at cost. For other services, fixed prices are to be set forth in the individual work orders. TRON invoices us monthly and our payments are due no later than 10 days thereafter. Additionally, we are obligated to pay to TRON low single-digit tiered royalties on net sales of any product developed under the TRON Research Agreement that is covered by a patent claiming any of the Results.

The TRON Research Agreement limits each party's liability to the other to intentional and grossly negligent actions and, in the case of gross negligence, liability for indirect and consequential damages and lost profits is excluded. We are obligated to indemnify TRON for all product liability claims in connection with the products and for third-party claims asserting that the Results violate third-party intellectual property rights.

The TRON Research Agreement has an indefinite term, but may be terminated by either party on six months' notice. If one of our subsidiaries terminates its role in the TRON Research Agreement, the agreement will survive and continue without that subsidiary.

In November 2017, we and TRON entered into an agreement to include certain research and development activities regarding neoepitope RNA immunotherapies as work included in the TRON Research Agreement.

TRON License Agreement

The TRON License Agreement governs the ownership of and licenses under certain patents, inventions, know-how, technologies and other knowledge (together, the Development Results) filed and created before January 1, 2015 in the course of our collaboration with TRON, Johannes Gutenberg-Universität Mainz and Universitätsmedizin der Johannes Gutenberg-Universität Mainz (collectively, the University Parties) and Ganymed pursuant to the 2008 Cooperation Agreement.

The TRON License Agreement sets forth the parties' rights with respect to the Development Results, mainly depending on which parties have contributed to such Development Results. Ownership of the Development Results and any patents and other intellectual property included therein is allocated to either (i) TRON and us as co-owners in equal shares, (ii) TRON and Ganymed as co-owners in equal shares or (iii) TRON, Ganymed and us as co-owners in equal shares. Each party may assign its share in the co-owned Development Results to its affiliates provided that such party provide notice of the transfer and the identity of the new co-owner to the other co-owners. However, in case of an assignment of such share to a third party (except in case of a material asset sale), the assigning party must obligate the assignee to comply with the terms of the TRON License Agreement and the assigning party will remain bound by the obligations of the TRON License Agreement unless the other co-owners have consented to discharge the assigning party from such obligations.

The parties to the TRON License Agreement grant licenses to each other under their shares in the Development Results substantially as follows. Ganymed is exclusively entitled to use the Development Results for certain antibodies, antibody fragments and antibody fusion proteins in terms of recombinant proteins that bind to certain defined targets via an immune globulin domain, nanoparticles combined, fused or otherwise firmly attached to such antibodies, antibody fragments or antibody fusion proteins, related *in vitro* diagnostics as companion diagnostics, as well as products for diagnosing, preventing and treating multiple sclerosis, or the Ganymed Field of Use. We are exclusively entitled to use the Development Results in any other field of use (including immunological therapeutics, small molecule compounds, siRNA-based therapeutics, micro-proteins, antibody based *in vitro* (except for those in the Ganymed Field of Use), diagnostics and therapeutics based on long-chain RNA as well as other cell therapy applications, immune cells transgenized with recombinant directed against certain defined targets or chimeric antigene receptors and RNA-based pharmaceuticals). The University Parties may use the Development Results for internal research purposes only. We and Ganymed have an obligation to use reasonable efforts to develop and commercialize products in our respective fields of use worldwide.

Under the TRON License Agreement, we and Ganymed must agree on which party will have the primary role in filing, prosecuting, maintaining and defending jointly owned patents. We and Ganymed each have the exclusive right to enforce the Development Results in our respective fields of use, subject to certain step-in rights of the other parties.

We are obligated to pay to the University Parties low single-digit tiered royalties on net sales on any product that is covered by certain of the patents including in the Development Results. If licenses are granted to third parties, we are obligated to pay to the University Parties a mid-single-digit share of all upfront payments, milestone payments and other remuneration we receive from such third parties in consideration for the license. Regarding upfront payments only, the University Parties' share will be offset against subsequent license fees on net sales. In addition, we are obligated to pay certain development and regulatory milestones up to a low seven- figure amount to Johannes Gutenberg-Universität Mainz.

The TRON License Agreement contains a limitation on liability as between the parties, wherein the parties will only be liable to each other for intentional and grossly negligent actions, and, in the case of gross negligence, liability for indirect and consequential damages and lost profits is excluded. We are obligated to indemnify the University Parties and Ganymed for third-party claims of product liability or violation of applicable law based on our distribution of our products or if we breach the TRON License Agreement or if we or one of our agents acts culpably.

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The TRON License Agreement will remain in effect as long as there are any obligations on us or Ganymed to pay license fees. After expiry of the TRON License Agreement, each party will have a perpetual, non-exclusive, royalty-free license to use the Developments Results. The TRON License Agreement may be terminated by any party on six months' notice. The licenses granted between the parties will survive such termination. The TRON License Agreement also grants all parties termination rights for uncured material breaches. If only one party terminates its role in the Agreement, the Agreement will survive and continue between the other parties.

LSU License Agreement

In May 2015, we entered into a Patent License Agreement with the Board of Supervisors of Louisiana State University and Agricultural and Mechanical College, or LSU, and the University of Warsaw, or UW. The agreement (which we refer to as the LSU Agreement) replaces and supersedes the earlier license agreement between the parties.

Under the LSU Agreement, UW and LSU granted to us an exclusive royalty-bearing license under certain patent rights relating to mRNA cap analogs and the synthesis and use of anti-reverse phosphorothioate analogs of the mRNA cap in the United States, certain jurisdictions in the European Union and other countries. As consideration for the license granted, we are obligated to pay running royalties in the low single digits on all net sales of products utilizing the licensed patents and to pay annual maintenance fees to LSU.

We are obligated to use commercially reasonable efforts to develop one or more marketable products utilizing the licensed patents, upon which we would owe additional milestone payments to LSU.

The LSU Agreement remains in effect until expiration of the licensed patents. We have the right to terminate the LSU Agreement for convenience with 60 days' prior notice, and LSU and UW may terminate for our uncured material breach.

Cellscript and mRNA Ribotherapeutics License Agreement

BioNTech RNA entered into the two MRT-CellScript Sublicenses discussed above. Together, the MRT-CellScript Sublicenses grant BioNTech RNA worldwide, non-exclusive sublicenses under the Penn Modified mRNA Patent Rights (as defined in the MRT-CellScript Sublicenses) to research, develop, make, import, use and commercialize products for *in vivo* uses in humans and non-human animals, including therapeutic and prophylactic applications, and for certain uses in the diagnostic and prognostic field of use and certain laboratory research or screening uses. Under these sublicenses, BioNTech RNA has the right to grant sublicenses to affiliates and third parties.

BioNTech RNA must use reasonable efforts to develop and commercialize products under the sublicenses. Furthermore, BioNTech RNA is obliged to pay MRT and CellScript development milestone payments of up to approximately \$26 million as well as royalties in the low to mid-single digits on net sales of licensed products, depending on the field of use.

The agreements continue until the expiration or abandonment of the last licensed patent to expire or be abandoned. BioNTech RNA may terminate the agreement for convenience with respect to all or certain patent rights with 60 days' prior written notice. MRT or CellScript may terminate the respective sublicense agreement for payment default, uncured material breach or the bankruptcy of BioNTech RNA.

D. Trademark Portfolio

Certain features of our business and our product candidates are protected by trademarks. Our trademark portfolio includes, but is not limited to, registrations for each of FixVac[®], IVAC[®], MammaTyper[®], RiboCytokine[®] and RiboMab[®].

E. Trade Secret Protection

Certain of our technologies, including in particular certain proprietary manufacturing processes or technologies and/or neoantigen prediction technologies, are protected as trade secrets.

In addition to patent protection, we rely upon unpatented trade secrets and confidential know-how and continuing technological innovation to develop and maintain our competitive position. We protect certain of our technologies, including, in particular, certain proprietary manufacturing processes and technologies and/or neoantigen prediction technologies, as trade secrets. However, trade secrets and confidential know-how are difficult to protect. We seek to protect our proprietary information, in part, by using confidentiality agreements with any future collaborators, scientific advisors, employees and consultants, and invention assignment agreements with our employees. We also have agreements requiring assignment of inventions with selected consultants, scientific advisors and collaborators. These agreements may not provide meaningful protection. These agreements may also be breached, and we may not have an adequate remedy for any such breach. In addition, our trade secrets and/or confidential know-how may become known or be independently developed by a third party, or misused by any collaborator to whom we disclose such information. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our products or to obtain or use information that we regard as proprietary. Although we take steps to protect our proprietary information, third parties may independently develop the same or similar proprietary information or may otherwise gain access to our proprietary information. As a result, we may be unable to meaningfully protect our trade secrets and proprietary information. See “Risk Factors—Risks Related to our Intellectual Property” for a more comprehensive description of risks related to our intellectual property.

XVII. Competition

We compete in an industry characterized by rapidly advancing technologies, intense competition and a complex intellectual property landscape. We face substantial competition from many different sources, including large and specialty pharmaceutical and biotechnology companies, academic research institutions and governmental agencies and public and private research institutions.

Below is a description of competition surrounding each of our technologies.

mRNA Therapies. mRNA therapies are a new medical frontier, and we expect competition in this space to be robust across diverse therapeutic areas. We compete with a number of companies focused on developing mRNA technologies for a wide range of applications, including Moderna, CureVac, eTheRNA immunotherapies, Translate Bio, Arcturus Therapeutics, ethris, Genevant and GlaxoSmithKline.

Oncology. The oncology therapeutics landscape in general is highly competitive and includes large and specialty pharmaceutical and biotechnology companies, academic research institutions and governmental agencies and public and private research institutions. It includes both competition from marketed therapies as well as potential new therapeutics in development. We may compete with products with different mechanisms of action as well as against established standards of care. Companies such as AstraZeneca, Amgen, Bristol-Myers Squibb, Celgene, Eli Lilly, GlaxoSmithKline, Incyte, Janssen Pharmaceuticals, Merck & Co., Novartis, Pfizer, Roche and Sanofi are developing diversified immuno-oncology programs and have substantial resources. We expect our intratumoral immunotherapy candidates for the treatment of solid tumors to face direct competition from companies such as Moderna and CureVac.

We also expect our FixVac and iNeST candidates to face competition from smaller specialized oncology companies such as Agenus, Neon Therapeutics, Gritstone, Moderna in collaboration with Merck & Co., Aduro Biotech, Advaxis Immunotherapies, Achilles Therapeutics, NousCom, ISA Pharmaceuticals, CureVac in collaboration with Eli Lilly, Genocea Biosciences, Vaccibody, PACT Pharma and ZIOPHARM Oncology in the antigen-based therapy space.

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Engineered Cell Therapy Drug Class. We compete with a number of companies focused on adoptive cell therapies, including Novartis Pharmaceuticals, Gilead Sciences, Celgene, Allogene Therapeutics, CRISPR Therapeutics, bluebird bio, Medigene, Adaptimmune Therapeutics, Amgen, Atara Biotherapeutics, Autolus Limited, Cellectis, PACT, Neon, Mustang Bio, Iovance Biotherapeutics, TCR2 Therapeutics, Editas Medicine, Celyad, Celularity, Unum Therapeutics, Intrexon, and Bellicum Pharmaceuticals and Precision Biosciences.

Antibodies Drug Class. We compete with a number of companies with operations focused on checkpoint immunomodulators, including AstraZeneca, Merck, Pfizer, Novartis, Roche and Bristol-Myers Squibb.

Small Molecule Immunomodulator Drug Class. We are aware of a number of other companies developing TLR agonists, including Checkmate Pharmaceuticals, Dynavax Technologies, Exicure, Gilead, GlaxoSmithKline, Hoffmann-La Roche, Mologen and Nektar Therapeutics.

Infectious Diseases. The infectious disease space includes general competition from well-established pharmaceutical companies such as AbbVie, Bayer, Gilead, Janssen Pharmaceuticals, Merck & Co. and Novartis. In addition, Seqirus UK, Sanofi Pasteur, GlaxoSmithKline, Biomedical Corp. of Quebec and AstraZeneca produce influenza vaccines.

Rare Diseases. We compete with a number of companies focused on rare diseases, including Roche, Alexion Pharmaceuticals, Novartis, Bristol-Myers Squibb, Sanofi Novo Nordisk and Pfizer.

Many of our competitors and potential competitors, either alone or with their collaborators, have greater scientific, research and product development capabilities as well as greater financial, marketing, sales and human resources and experience than we do. In addition, smaller or early-stage companies, including immunotherapy-focused therapeutics companies, may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Some of our collaborators, such as Genmab, Pfizer and Sanofi, may also be competitors within the same market or other markets. Accordingly, our competitors may be more successful than us in developing and potentially commercializing technologies and achieving widespread market acceptance. In addition, our competitors may design technologies that are more efficacious, safer or more effectively marketed than ours or have fewer side effects, or may obtain regulatory approvals more quickly than we are able, which could eliminate or reduce our commercial potential. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

We anticipate that the key competitive factors affecting our technologies will be efficacy, safety, cost and convenience, as well as our ability to build a fully-integrated biotechnology company. The availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our products. The timing of market introduction of our products and competitive products will also affect competition among products. We expect the relative speed with which we can develop our products, complete the clinical trials and approval processes, and supply commercial quantities of the products to the market to be important competitive factors. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

XVIII. Employees

As of March 31, 2019, we had 1,032 full-time employees working for BioNTech, of whom 220 hold a doctoral degree or higher. The following tables provide breakdowns of our full-time equivalent employees as of March 31, 2019 by function and by region:

<u>Function</u>	<u>Number</u>
Clinical Research & Development	58
Scientific Research & Development	364
Operations	331
Quality	124
Supporting Functions	118
Commercial & Business Development	37
TOTAL	1,032

<u>Region</u>	<u>Number</u>
Mainz (Headquarters)	727
Munich and Martinsried	21
Idar-Oberstein	194
Berlin & United States	90
TOTAL	1,032

Since 2016, our workforce has grown by 121%, and we have plans to triple the size of our team at our Mainz manufacturing site over the next several years. Within the next several years, two further new production sites are planned to be built in Mainz and Idar-Oberstein.

None of our employees has engaged in any labor strikes. We have no collective bargaining agreements with our employees. We have a workers' council at our Idar-Oberstein site. However, we consider our relationship with our employees to be positive and have not experienced any major labor disputes.

XIX. Properties

Our headquarters are located in Mainz, Germany, where we occupy:

- Approximately 9,416 square meters (equivalent to approximately 101,353 square feet) of laboratory, GMP manufacturing, storage and office space under a lease for the entire building located at An der Goldgrube 12, 55131 Mainz under a lease that has an initial term that expires on October 30, 2027, but which we have the option to extend until April 30, 2039.
- Approximately 1,069 square meters (equivalent to approximately 11,507 square feet) of office and GMP manufacturing space under a lease for part of the building located at Kupferbergterrasse 15, 17019, 44116 Mainz under a lease that expires in March 31, 2022.
- Approximately 4,882 square meters (equivalent to approximately 52,549 square feet) of flexible use space under a lease for the entire building at Adam-Opel-Strasse 10, 55129 Mainz-Hechtsheim that has an initial term that expires on December 31, 2024, but which we have the option to extend until December 31, 2027. If the lease has not been terminated prior to December 31, 2024, and the option has not been exercised prior to this date, the lease will convert to an unlimited period terminable by either party on 12 months' prior written notice.
- Approximately 82,881 square meters (equivalent to approximately 892,124 square feet) of office space and a further area of land associated with this office space of approximately 12,600 square meters (equivalent to approximately 135,625 square feet), which is owned by BioNTech.
- We have entered into an agreement to lease 4,025 square meters (equivalent to 43,324 square feet) of office space under a lease for the entire building at Hechtsheimer Strasse 2, 55131 Mainz-Hechtsheim,

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which commenced on July 1, 2019. The initial term of the lease expires on June 30, 2029, which we have the option to extend until June 30, 2034 and again until June 30, 2039. The grant of the lease is also conditional upon the Company purchasing a 8,753 square meter (equivalent to 94,216 square feet) plot of land at Hechtsheimer Strasse, 55131 Mainz-Hechtsheim, and being entered as the owner of such land in the property register by September 30, 2019.

- We have entered into an agreement to purchase approximately 8,753 square meters (equivalent to 94,216 square feet) of land at Hechtsheimer Strasse, 55131 Mainz. Payment of the purchase price is conditional on a land charge to which the property is subject being removed by the seller. Our registration as owner of such land in the property register has not yet been completed.

In addition, our BioNTech IMFS facility in Idar-Oberstein, Germany, occupies approximately 2,800 square meters (equivalent to approximately 30,140 square feet). This includes 650 square meters (approximately 7,000 square feet) of clean room area, and 700 square meters (approximately 7,500 square feet) of development and quality control laboratories. We occupy approximately 575 square meters (equivalent to approximately 6,200 square feet) of this space, which is used primarily for storage, under a lease that has an initial expiry date of October 1, 2021, but which we have the right to extend by an additional five years. We occupy approximately 100 square meters (equivalent to approximately 1,075 square feet) of this space, which is used primarily for storage, under a lease that can be terminated by either party on six months' written notice (but not earlier than May 1, 2020). We occupy approximately 80 square meters (equivalent to approximately 860 square feet) of this space, which is used as office space, under a lease that can be terminated by either party on three months' written notice. The rest of this facility, including the GMP-certified manufacturing suites, is owned by BioNTech.

At our JPT facility in Berlin, Germany, we occupy approximately 1,755 square meters (equivalent to approximately 18,890 square feet) of office, laboratory and other space. Approximately 250 square meters of that space (equivalent to approximately 2,690 square feet) is occupied under a lease which has an initial expiry date of December 31, 2019 and will continue for further six-month periods, unless terminated by either party on three months' prior written notice. The remaining 1,505 square meters (equivalent to approximately 16,199 square feet) is occupied under a lease for an indeterminate period of time but which may be terminated by either party on 12 months' prior written notice.

In Martinsried, Germany, we occupy approximately 1,681 square meters (equivalent to approximately 18,100 square feet) under a lease that has an initial term that expires on December 31, 2020, but which we have the option to extend until December 31, 2022.

In Neuried, Germany, we occupy approximately 725 square meters (equivalent to approximately 7,800 square feet) of laboratory and office space under a lease that expires on December 31, 2021, but which we have the option to extend until December 31, 2026. If the lease is not terminated before December 31, 2021 (where the option is not exercised) or December 31, 2026 (where the option is exercised) the lease will renew automatically for an additional one-year periods until terminated by either party on 12 months' prior written notice.

In San Diego, we occupy approximately 14,971 square feet of laboratory and office space under a lease to part of a building located at 11535 Sorrento Valley Road, San Diego, California, that expires on February 28, 2022.

We intend to expand our capacity as follows:

- In 2020, we anticipate completing the construction of two new buildings at our BioNTech IMFS facility in Idar-Oberstein, Germany, which we will own, and as a result of which we will occupy an additional 780 square meters (equivalent to approximately 8,395 square feet) of clean room space, 550 square meters (equivalent to approximately 5,900 square feet) of laboratory space, and 650 square meters (equivalent to approximately 7,000 square feet) of office space.
- In 2022, we anticipate completing the construction of a new complex of building for our JPT business in Berlin, Germany, as a result of which we will occupy approximately 2,727 square meters (equivalent

to approximately 29,353 square feet) of laboratory and office space and a total of approximately 5,000 square meters (equivalent to approximately 53,820 square feet) of useable floor space. Upon completion of the construction project we will own this new building.

For additional information on these additions to our facilities, see “—XIII. Manufacturing—Future Manufacturing Outlook.”

XX. Legal Proceedings

From time to time, we may be involved in legal proceedings in the ordinary course of business. We are currently not a party to any material legal or administrative proceedings. In addition, we are not aware of any material legal or administrative proceedings contemplated to be brought against us. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

MANAGEMENT

Management Board and Supervisory Board

Management Board (*Vorstand*)

The following table sets forth the names and functions of the current members of our Management Board, their ages and their terms:

Name	Age	Position
Prof. Ugur Sahin, M.D.	54	Chief Executive Officer
Sean Marett	54	Chief Business Officer and Chief Commercial Officer
Dr. Sierk Poetting, Ph.D.	46	Chief Financial Officer and Chief Operating Officer
Dr. Özlem Türeci, M.D.	52	Chief Medical Officer

The business address of the members of our Management Board is the same as our business address: An der Goldgrube 12, D-55131 Mainz, Germany.

The following is a brief summary of the business experience of the members of our Management Board:

Prof. Ugur Sahin, M.D. co-founded BioNTech in 2008 and has served as our Chief Executive Officer since that time. Prof. Sahin also served as the head of the Scientific Advisory Board and Chief Medical Officer of Ganymed Pharmaceuticals AG from 2008 until the company was acquired by Astellas Pharma Inc., or Astellas, in 2016. In 2010, Prof. Sahin co-founded TRON, and served as a Managing Director from 2010 until 2019. Prof. Sahin has also been a professor (W3) at the Mainz University Medical Center since 2014. Prof. Sahin co-founded the Ci3, the German Cluster Initiative of Individualized ImmunIntervention (Ci3), a non-profit organization. Prof. Sahin earned an M.D. in 1990 from the University of Cologne. Prof. Sahin is married to Dr. Özlem Türeci.

Sean Marett joined BioNTech in 2012. Prior to joining BioNTech, he worked in global strategic and regional marketing and sales roles at GlaxoSmithKline in the United States and Pfizer in Europe before taking business development executive roles at Evotec and Lorantis, the latter of which he helped to successfully sell to Celldex Therapeutics, Inc. He has successfully executed complex licensing transactions with large pharmaceutical companies, negotiated M&A transactions and raised finance from investors. Mr. Marett built and ran a contract clinical manufacturing organization with operations across Europe and the United States for over half a decade for the contract manufacturer, NextPharma. Mr. Marett has been Chairman of PHMR Ltd, a company specializing in market access and pharmaceutical reimbursement, since 2017. He previously held non-executive directorship of KWS BioTest Ltd (successfully sold to Charles River) from 2011 until 2018 and was a member of the investment committee of Mann BioInvest Ltd, a fund dedicated to biotechnology and pharmaceutical company investments from 2013 until 2016. He holds a BSc (Hons) in Biochemistry from Kings College London and an MBA from Manchester Business School.

Dr. Sierk Poetting, Ph.D. is our Chief Financial Officer and Chief Operating Officer. Dr. Poetting joined BioNTech in September 2014 from Novartis International AG, where he served from May 2012 to August 2014 as Vice President and Chief Financial Officer for the Sandoz Division in North America. Dr. Poetting started his career as a consultant with McKinsey & Company. A German citizen, Dr. Poetting holds a Master of Science in Optical Sciences from the University of Arizona and a Ph.D. in Physics from the Ludwig-Maximilians University in Munich.

Dr. Özlem Türeci, M.D. is our Chief Medical Officer. Dr. Türeci joined BioNTech in 2008 as a clinical and scientific advisory board member, before becoming our Chief Medical Officer in 2018. Dr. Türeci co-founded Ganymed Pharmaceuticals, now a subsidiary of Astellas, in 2001 as Chief Scientific Officer and became its Chief Executive Officer in 2008. Dr. Türeci is chairman and co-initiator of Ci3. Dr. Türeci is also an executive board member of the Association for Cancer Immunotherapy (CIMT). Dr. Türeci earned her M.D. from Saarland University Faculty of Medicine, Homburg. Dr. Türeci is married to Prof. Ugur Sahin.

Supervisory Board (*Aufsichtsrat*)

The following table sets forth the names and functions of the current members of our Supervisory Board, their ages, their terms (which expire on the date of the relevant year's general shareholders' meeting) and their principal occupations outside of our Company:

<u>Name</u>	<u>Age</u>	<u>Term Expires</u>	<u>Principal Occupation</u>
Helmut Jeggle	49	2023	Chief Executive Officer and Chief Operating Officer of ATHOS Service GmbH
Michael Motschmann	62	2023	Member of the Board of Management and Head of Equity Investments of MIG Verwaltungs AG
Prof. Christoph Huber, M.D.	75	2023	Chairman Emeritus at the Johannes-Gutenberg University Mainz
Dr. Ulrich Wandschneider	58	2023	Independent consultant to life sciences companies

The business address of the members of our Supervisory Board is the same as our business address: An der Goldgrube 12, D-55131 Mainz, Germany.

The following is a brief summary of the prior business experience of the members of our Supervisory Board:

Helmut Jeggle has served as the Chairman of our Supervisory Board since 2008. Mr. Jeggle has served as the Chief Executive Officer and Chief Operating Officer of ATHOS Service GmbH since 2015. From 2007 until 2015, Mr. Jeggle served as the Head of Direct Investments of ATHOS Service GmbH. From 2002 until 2007, Mr. Jeggle held various positions with Hexal AG, including Head of Business Planning & Analyses. Mr. Jeggle is currently the Chief Executive Officer of each of Salvia GmbH (since 2014), Neula Holding GmbH (since 2010) and AT-Gruppe (since 2008) and a manager of Santo Group (since 2011). Mr. Jeggle is a member of numerous supervisory boards, including 4SC AG. Mr. Jeggle has a degree in business administration from the University of Applied Sciences Neu-Ulm and earned his Master of Business Administration from the Stuttgart Institute of Management and Technology.

Michael Motschmann has served as a member of our Supervisory Board since 2008. Mr. Motschmann co-founded MIG Verwaltungs AG, or MIG, in 2004, where he serves on the Management Board and as Head of Equity Investments. In his role with MIG, Mr. Motschmann currently serves on the supervisory boards of several private portfolio companies.

Prof. Christoph Huber, M.D. is a co-founder of BioNTech and has served as a member of our Supervisory Board since 2008. Prof. Huber has more than 50 years of professional experience in hematology, oncology and translational immunology. Prof. Huber has since 2014 served as Chairman Emeritus of the Department of Hematology and Oncology at the Johannes-Gutenberg University Mainz. Prof. Huber was a co-founder of Ganymed, now a subsidiary of Astellas Pharma Inc. He is President of CIMT and a board member of Ci3. From 2018 to April 2019, Prof. Huber served as a member of the supervisory board of TRON. Prof. Huber earned his M.D. at the University of Innsbruck.

Dr. Ulrich Wandschneider, Ph.D. has served as a member of our Supervisory Board since 2018. Dr. Wandschneider has more than 20 years of experience in the healthcare sector as a manager in the operative business and as a member of boards and committees. From 2011 to 2016 Dr. Wandschneider served as Chief Executive Officer of Asklepios Kliniken GmbH & Co. KGaA. Dr. Wandschneider currently serves on the supervisory board of Mediclin AG.

Two-Tiered Board Structure

We are a European public company with limited liability (*Societas Europaea* or SE) (also referred to as European stock corporation, and in the official terminology of the European legislation referred to as European public limited-liability company), having its seat in Germany. We accordingly are subject to the European legislation on the *Societas Europaea*, namely the Council Regulation (EC) No 2157/2001 of October 8, 2001 on the Statute for a European company, or the SE Regulation; and the German Act on the Implementation of Council Regulation (EC) No 2157/2001 of October 8, 2001 on the Statute for a European company (SE) (*Gesetz zur Ausführung der Verordnung* (EG) NR. 2157/2001 des Rates vom 8. Oktober 2001 über das Statut der Europäischen Gesellschaft (SE) (*SE-Ausführungsgesetz*—SEAG), as well as—insofar as applicable pursuant to the SE Regulation—to the German legislation on stock corporations, most importantly the German Stock Corporation Act (*Aktiengesetz*). In accordance with these statutes, we have chosen to have a two tiered structure. Hence, our corporate bodies are the Management Board (*Vorstand*), the Supervisory Board (*Aufsichtsrat*) and the shareholders' meeting (*Hauptversammlung*). Our Management and Supervisory Boards are entirely separate, and, as a rule, no individual may simultaneously be a member of both boards.

Our Management Board is responsible for the day-to-day management of our business in accordance with applicable laws, our Articles of Association (*Satzung*) and the Management Board's internal rules of procedure (*Geschäftsordnung*). Our Management Board represents us in our dealings with third parties.

The principal function of our Supervisory Board is to supervise our Management Board. The Supervisory Board is also responsible for appointing and removing the members of our Management Board, representing us in connection with transactions between a current or former member of the Management Board and us, and granting approvals for certain significant matters.

Our Management Board and our Supervisory Board are solely responsible for and manage their own areas of competency (*Kompetenztrennung*); therefore, neither board may make decisions that, pursuant to applicable law, our Articles of Association or the internal rules of procedure are the responsibility of the other board. Members of both boards owe a duty of loyalty and care to us. In carrying out their duties, they are required to exercise the standard of care of a prudent and diligent businessperson. If they fail to observe the appropriate standard of care, they may become liable to us.

In carrying out their duties, the members of both boards must take into account a broad range of considerations when making decisions, including our interests and the interests of our shareholders, employees, creditors and, to a limited extent, the general public, while respecting the rights of our shareholders to be treated on equal terms. Additionally, the Management Board is responsible for implementing an internal monitoring system for risk management purposes.

Our Supervisory Board has comprehensive monitoring responsibilities. To ensure that our Supervisory Board can carry out these functions properly, our Management Board must, among other duties, regularly report to our Supervisory Board regarding our current business operations and future business planning (including financial, investment and personnel planning). In addition, our Supervisory Board or any of its members is entitled to request special reports from the Management Board on all matters regarding the Company, our legal and business relations with affiliated companies and any business transactions and matters at such affiliated companies that may have a significant impact on our position at any time.

Under German law, our shareholders have no direct recourse against the members of our Management Board or the members of our Supervisory Board in the event that they are believed to have breached their duty of loyalty and care to us. Apart from insolvency or other special circumstances, only we have the right to claim damages against the members of our two boards.

We may waive these claims to damages or settle these claims only if at least three years have passed since a claim associated with any violation of a duty has arisen and only if our shareholders approve the waiver or

settlement at a shareholders' meeting with a simple majority of the votes cast, provided that no shareholders who in the aggregate hold one-tenth or more of our share capital oppose the waiver or settlement and have their opposition formally recorded in the meeting's minutes maintained by a German civil law notary.

Supervisory Board

German law requires that the Supervisory Board consists of at least three members, while a company's articles of association may stipulate a certain higher number. Our Supervisory Board currently consists of four members.

As we are not subject to co-determination, the members of our Supervisory Board are all elected by the shareholders' meeting in accordance with the provisions of the SE Regulation and the German Stock Corporation Act (*Aktiengesetz*). German law does not require the majority of our Supervisory Board members to be independent and neither our Articles of Association (*Satzung*) nor the rules of procedure for our Supervisory Board provide otherwise. However, the rules of procedure for our Supervisory Board provide that the Supervisory Board shall, taken as a whole, comprise of, in its own estimation, an adequate number of independent members.

Under European law, a member of a supervisory board of an SE may be elected for a maximum term to be specified in the articles of association, which must not exceed six years. Re-election, including repeated re-election, is permissible. The shareholders' meeting may specify a term of office for individual members or all of the members of our Supervisory Board which is shorter than the standard term of office and, subject to statutory limits, may set different start and end dates for the terms of members of our Supervisory Board. Our Articles of Association provide for a term of approximately five years, depending on the date of the annual general shareholders' meeting in the year in which the term of the relevant member is to expire.

The shareholders' meeting may, at the same time as it elects the members of the Supervisory Board, elect one or more substitute members. The substitute members replace members who cease to be members of our Supervisory Board and take their place for the remainder of their respective terms of office. Currently, no substitute members have been elected or have been proposed to be elected.

Members of our Supervisory Board may be dismissed at any time during their term of office by a resolution of the shareholders' meeting adopted by at least a simple majority of the votes cast. In addition, any member of our Supervisory Board may resign at any time by giving one month's written notice—or, in the event of cause, giving written notice with immediate effect—of his or her resignation to the chairperson of our Supervisory Board (in case the chairperson resigns, such notice is to be given to the deputy chairperson) or to the Management Board.

Our Supervisory Board elects a chairperson and a deputy chairperson from its members. The deputy chairperson exercises the chairperson's rights and obligations whenever the chairperson is unable to do so. The members of our Supervisory Board have elected Mr. Helmut Jeggle as chairperson and Dr. Ulrich Wandschneider as deputy chairperson, each for the term of their respective membership on our Supervisory Board.

The Supervisory Board meets at least twice each calendar half-year. Our Articles of Association provide that a quorum of the Supervisory Board members is present if at least three of its members participate in the vote. Members of our Supervisory Board are deemed present if they attend the meeting via telephone or other (electronic) means of communication (including via video conference) or submit their written vote through another member. Additionally, our Articles of Association allow for resolutions to be taken via telephone or other (electronic) means of communications (including via video conference).

Resolutions of our Supervisory Board are passed by the vote of a simple majority of the votes cast unless otherwise required by law, our Articles of Association or the rules of procedure of our Supervisory Board. In the

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event of a tie, the chairperson of the Supervisory Board has the casting vote. Our Supervisory Board is not permitted to make management decisions, but in accordance with European and German law and in addition to its statutory responsibilities, it has determined that certain matters require its prior consent, including:

- conducting an initial public offering;
- entering into certain large transactions;
- creating or holding any interest in businesses (except wholly-owned subsidiaries) or disposing of shares in businesses (except for a sale of JPT);
- issuing shares from authorized capital, unless the shares are issued pursuant to a redemption of stock appreciation rights; and
- acquiring treasury shares in return for valuable consideration.

Supervisory Board Practices

Decisions are generally made by our Supervisory Board as a whole, however decisions on certain matters may be delegated to committees of our Supervisory Board to the extent permitted by law. The chairperson, or if he or she is prevented from doing so, the deputy chairperson, chairs the meetings of the Supervisory Board and determines the order in which the agenda items are discussed, the method and order of voting, as well as any adjournment of the discussion and passing of resolutions on individual agenda items after a due assessment of the circumstances. Our Supervisory Board may designate further types of actions as requiring its approval.

In addition, each member of the Supervisory Board is obliged to carry out his or her duties and responsibilities personally, and such duties and responsibilities cannot be generally and permanently delegated to third parties. However, the Supervisory Board and its committees have the right to appoint independent experts for the review and analysis of specific circumstances in accordance with its control and supervision duties under applicable European and German law. We would bear the costs for any such independent experts that are retained by the Supervisory Board or any of its committees.

Pursuant to Section 107 para. 3 of the German Stock Corporation Act (*Aktiengesetz*), the supervisory board may form committees from among its members and charge them with the performance of specific tasks. The committees' tasks, authorizations and processes are determined by the supervisory board. Where permissible by law, important powers of the supervisory board may also be transferred to committees.

By resolution, the Supervisory Board has established an Audit Committee and a Remuneration, Nominating and Governance Committee. Set forth in the table below are the current members of the Audit Committee and the Remuneration, Nominating and Corporate Governance Committee.

Name of Committee	Current Members
Audit Committee	Dr. Ulrich Wandschneider, Michael Motschmann and Helmut Jeggle
Remuneration, Nominating and Corporate Governance Committee	Michael Motschmann, Prof. Christopher Huber, M.D. and Dr. Ulrich Wandschneider

Audit Committee

Our Audit Committee consists of Dr. Ulrich Wandschneider, Michael Motschmann and Helmut Jeggle. Dr. Ulrich Wandschneider is the chair of the Audit Committee. The Audit Committee assists the Supervisory Board in overseeing the accuracy and integrity of our financial statements, our accounting and financial reporting processes and audits of our financial statements, the effective functioning of our internal control system, our risk management system, our compliance with legal and regulatory requirements, our independent auditor's

qualifications and independence, the performance of the independent auditor and the effective functioning of our internal audit functions, and, subject to certain limitations, to adopt and implement pertinent decisions on behalf of the Supervisory Board. The Audit Committee's duties and responsibilities to carry out its purpose, include, among others:

- considering the commissioning of the audit engagement, as well as the compensation, retention and oversight of the independent auditor;
- evaluating the qualifications, independence and performance of the independent auditor;
- reviewing and pre-approving the audit and non-audit services to be performed by the independent auditor;
- reviewing and discussing with the independent auditor and management the annual audit plan, including critical accounting policies and practices to be used;
- reviewing and discussing with the independent auditor and management the adequacy and effectiveness of our internal accounting controls and critical accounting policies;
- reviewing and discussing with the independent auditor and management the results of our annual audit and the review of our quarterly unaudited financial statements;
- reviewing and discussing with the independent auditor and management any quarterly or annual earnings announcements;
- reviewing and approving, as appropriate, any related party transactions and reviewing and monitoring potential conflict of interest situations on an ongoing basis for compliance with our policies and procedures;
- overseeing procedures for the receipt, retention and treatment of complaints received regarding accounting, internal accounting controls or auditing matters; and
- reviewing and evaluating the performance of the Audit Committee and its members.

Within the limits of applicable European and German law, the Audit Committee shall have the resources and authority appropriate to discharge its duties and responsibilities, including the authority to select, retain, terminate, and approve the fees and other engagement terms of special or independent counsel, accountants or other experts and advisors, as it deems necessary or appropriate for so discharging its duties and responsibilities, without seeking approval of the Management Board or Supervisory Board. The Audit Committee has legal power to enter into the contract on our behalf and we will be bound to these and will be obliged to discharge any obligations as the Audit Committee may incur on our behalf for these purposes.

Each member of the Audit Committee qualifies as an "independent director" as such term is defined in Rule 10A-3 under the Exchange Act and Nasdaq Rule 5605. Additionally, our Supervisory Board has determined that qualifies as an "audit committee financial expert" as that term is defined under the Exchange Act.

Remuneration, Nominating and Corporate Governance Committee

Our Remuneration, Nominating and Corporate Governance Committee consists of Michael Motschmann, Prof. Christopher Huber, M.D. and Dr. Ulrich Wandschneider. Mr. Motschmann is the chair of the committee. The Remuneration, Nominating and Corporate Governance Committee's duties and responsibilities to carry out its purpose include, among others:

- preparing and discussing with management policies relating to the remuneration of the members of our Management Board;
- reviewing and supervising corporate goals and objectives for the remuneration of the members of the Management Board, including evaluation of the performance of the members of the Management Board in light of these goals and proposals to the Supervisory Board for remuneration based on such evaluations;

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- reviewing all equity-based compensation plans and arrangements and making recommendations to the Supervisory Board regarding such plans;
- assisting with identifying and recruiting candidates to fill positions on the Supervisory Board;
- developing, recommending to the Supervisory Board and monitoring compliance with corporate governance policies;
- if delegated to it, overseeing the evaluation of the Supervisory Board and reporting on its performance and effectiveness; and
- reviewing and evaluating the performance of the Remuneration, Nominating and Corporate Governance Committee and its members.

Remuneration of Supervisory Board Members

Our Articles of Association provide for a fixed annual remuneration for each member of the Supervisory Board of €50,000 per year. However, the chairman is entitled to receive €150,000 per year and the vice chairman €75,000 per year. In addition, the chairman of the audit committee is entitled to be paid €20,000 per year. All members of the Supervisory Board are reimbursed for their expenses.

A member of the Supervisory Board who serves for only a portion of a given fiscal year or who holds the position of chairman or vice chairman of the Supervisory Board or of chairman of the Audit Committee for only a portion of a given fiscal year shall only be remunerated pro rata. The same is true if the clause of the Articles of Association regarding the remuneration of the members of the Supervisory Board becomes ineffective (*e.g.*, because it is repealed) during the course of a year.

In case any remuneration or reimbursement of expenses is subject to value added tax, such amount shall be paid additionally by the Company.

Management Board and Senior Management

Pursuant to our Articles of Association (*Satzung*), our Management Board consists of at least two members. Our Supervisory Board determines the exact number of members of our Management Board. The Supervisory Board may also appoint a chairperson and a deputy chairperson of the Management Board. Prof. Ugur Sahin has been appointed chairman of the Management Board.

The members of our Management Board are appointed by our Supervisory Board for a term of up to five years. They are eligible for reappointment or extension, including repeated re-appointment and extension, after the completion of their term in office, in each case again for up to an additional five years. Under certain circumstances, such as a serious breach of duty or a vote of no confidence by the shareholders in a shareholders' meeting, a member of the Management Board may be removed from office by our Supervisory Board prior to the expiration of his or her term.

The members of our Management Board conduct the daily business of our company in accordance with applicable laws, our Articles of Association and the rules of procedure for the Management Board adopted by our Supervisory Board. They are generally responsible for the management of our company and for handling our daily business relations with third parties, the internal organization of our business and communications with our shareholders.

A member of the management board of an SE governed by German law may not deal with or vote on matters relating to proposals, arrangements or contractual agreements between himself or herself and our company, and a member of our Management Board may be liable to us if he or she has a material interest in any contractual agreement between our company and a third party which is not disclosed to and approved by our Supervisory Board.

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The rules of procedure for our Management Board provide that certain matters require a resolution of the entire Management Board, in addition to transactions for which a resolution adopted by the entire Management Board is required by law or required by our Articles of Association. In particular, the entire Management Board shall decide on, among others:

- the budget plan for the following year, which is to be presented by the Management Board to the Supervisory Board by November 15 of each year;
- reporting to the Supervisory Board;
- all measures and transactions that require the Supervisory Board's approval;
- all measures and transactions relating to a business area that is of extraordinary importance to the us or involving an extraordinary economic risk;
- taking on new lines of business or discontinuing existing lines of business;
- investments with a total value above €100,000;
- acquisitions or sales of interests or holdings;
- our initial public offering; and
- certain large transactions.

Remuneration of the Members of Our Management Board

We have entered into agreements with all current members of our Management Board.

We believe that the agreements between us and the members of our Management Board provide for payments and benefits (including upon termination of employment) that are in line with customary market practice.

In the year ended December 31, 2018, the members of our Management Board received aggregate remuneration of €7.2 million.

Employee Stock Ownership Plan

On November 15, 2018, we established a share option program under which we grant selected employees options to receive our shares. The program is designed as an Employee Stock Ownership Plan, or ESOP. We have offered the participants a certain number of rights by explicit acceptance of the participants. The exercise of the option rights in accordance with the agreement gives the participants the right to obtain shares against payment of the exercise price. The option rights vest over four years, can only be exercised if we have executed a public offering in the United States and when meeting the threshold amount. The threshold amount means the exercise price provided increases by eight percentage points on the first and then each subsequent anniversary of the allocation date (September 26, 2018). The option rights can be exercised at the latest eight years after the allocation date. If they have not been exercised by that date, they will forfeit without compensation.

German Corporate Governance Code

The German Corporate Governance Code, or the Corporate Governance Code, was originally published by the German Federal Ministry of Justice (*Bundesministerium der Justiz*) in 2002 and was most recently amended on February 7, 2017 and published in the German Federal Gazette (*Bundesanzeiger*) on April 24, 2017. The Corporate Governance Code contains recommendations (*Empfehlungen*) and suggestions (*Anregungen*) relating to the management and supervision of German companies that are listed on a stock exchange. It follows internationally and nationally recognized standards for good and responsible corporate governance. The purpose

of the Corporate Governance Code is to make the German system of corporate governance transparent for investors. The Corporate Governance Code includes corporate governance recommendations and suggestions with respect to shareholders and shareholders' meetings, the management and supervisory boards, transparency, accounting policies and auditing. While the Corporate Governance Code was originally drafted with only the German stock corporation in mind, it is perceived to be also applicable to the two-tiered *Societas Europaea* and hence to us.

There is no obligation to comply with the recommendations or suggestions of the Corporate Governance Code. The German Stock Corporation Act (*Aktiengesetz*) requires only that the management board and supervisory board of a German company listed on a trading facility (such as a stock exchange) regulated and supervised by government authorities issue an annual declaration that either (i) states that the company has complied with the recommendations of the Corporate Governance Code or (ii) lists the recommendations that the company has not complied with and explains its reasons for deviating from the recommendations of the Corporate Governance Code (*Entsprechenserklärung*). In addition, a listed company is also required to state in this annual declaration whether it intends to comply with the recommendations or list the recommendations it does not plan to comply with in the future. These declarations must be made accessible to shareholders at all times. If the company changes its policy on certain recommendations between such annual declarations, it must disclose this fact and explain its reasons for deviating from the recommendations. Non-compliance with suggestions contained in the Corporate Governance Code need not be disclosed.

While in our opinion it is doubtful whether the above legal requirements and hence the Corporate Governance Code will apply following our listing on the Nasdaq Global Select Market, we intend to issue the annual declaration described above on a voluntary basis. Therefore, our Management Board and Supervisory Board will comply with the Corporate Governance Code except for such provisions which are explicitly listed in the annual declaration and for which they provide an explanation of non-compliance.

We expect to deviate from certain recommendations and suggestions of the Corporate Governance Code. All deviations from the Corporate Governance Code recommendations will be published in the official annual declarations.

Code of Conduct and Conflicts of Interest Policy

We have adopted a Code of Business Conduct & Ethics, or Code of Conduct, which outlines the principles of legal and ethical business conduct under which we do business. The Code of Conduct applies to all of our Supervisory Board members, Management Board members, directors of our subsidiaries and our affiliates and employees. The full text of the Code of Conduct is available on our website at <https://www.biontech.de>. The information and other content appearing on our website are not part of this prospectus and our website address is included in this prospectus as an inactive textual reference only. Any amendments or waivers from the provisions of the Code of Conduct for members of our Supervisory or Management Boards will be made only after approval by our Supervisory Board and will be disclosed on our website promptly following the date of such amendment or waiver.

We have also adopted a Conflicts of Interest Policy which sets forth the procedures by which we manage potential and actual conflicts of interest. Under the Conflicts of Interest Policy, which applies to all of our Supervisory Board Members, Management Board members, directors of our subsidiaries and our affiliates and employees, an actual, potential or perceived conflict of interest must be disclosed as soon as a Board member, director or employee discovers the conflict. If the conflict is transactional in nature and involves a member of the Management Board or the Supervisory Board, the Management or Supervisory Board, as the case may be, with the abstention of the conflicted member, shall decide whether to approve the transaction.

In addition, we have implemented compliance policies that describe the compliance management systems that have been implemented for us and our subsidiaries. Our compliance policies are designed to ensure

compliance with applicable legal requirements, while at the same time implementing high ethical standards that are mandatory for both management and each employee. The overall responsibility for the compliance management system lies with the Management Board. The Audit Committee will receive regular reports on the operation of the compliance management system.

Foreign Private Issuer Exemptions

As a “foreign private issuer,” as defined by the SEC, although we are permitted to follow certain corporate governance practices of the Federal Republic of Germany, instead of those otherwise required under the rules of the Nasdaq Stock Market LLC, or Nasdaq, for domestic issuers, we intend to follow the Nasdaq corporate governance rules applicable to foreign private issuers. While we voluntarily follow most Nasdaq corporate governance rules, we intend to take advantage of the following limited exemptions:

- exemption from filing quarterly reports on Form 10-Q and providing current reports on Form 8-K disclosing significant events within four days of their occurrence (however, we intend to furnish quarterly financial information under cover of Form 6-K);
- exemption from Section 16 rules regarding sales of ordinary shares by insiders, which will provide less data in this regard than the data provided to shareholders of U.S. companies that are subject to the Exchange Act; and
- exemption from the Nasdaq rules applicable to domestic issuers requiring disclosure within four business days of any determination to grant a waiver of the code of business conduct and ethics to directors and officers. Although we will require board approval of any such waiver, we may choose not to disclose the waiver in the manner set forth in the Nasdaq rules, as permitted by the foreign private issuer exemption.

Furthermore, Nasdaq Rule 5615(a)(3) provides that a foreign private issuer, such as we, may rely on home country corporate governance practices in lieu of certain of the rules in the Nasdaq Rule 5600 Series and Rule 5250(d), provided that we nevertheless comply with Nasdaq’s Notification of Noncompliance requirement (Rule 5625) and the Voting Rights requirement (Rule 5640) and that we have an audit committee that satisfies Rule 5605(c)(3), consisting of committee members that meet the independence requirements of Rule 5605(c)(2)(A)(ii). Although we are permitted to follow certain corporate governance rules that conform to German requirements in lieu of many of the Nasdaq corporate governance rules, we intend to comply with the Nasdaq corporate governance rules applicable to foreign private issuers. We may utilize these exemptions for as long as we continue to qualify as a foreign private issuer.

RELATED PARTY TRANSACTIONS**Agreements with TRON**

We have a longstanding relationship with Translational Oncology at the University Medical Center of the Johannes Gutenberg University Mainz (Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH), or TRON. TRON is a non-profit limited liability company engaged in biopharmaceutical research. Prof. Ugur Sahin, our co-founder and Chief Executive Officer, co-founded TRON and serves as Managing Director for Science and Research at TRON. Additionally, Prof. Christoph Huber, a member of our Supervisory Board, served on TRON's supervisory board until his resignation in April 2019.

On January 1, 2015, we and certain of our subsidiaries entered into both a Master Agreement for Research Services and a License Agreement with TRON. During 2017 and 2018, we paid to TRON an aggregate of €17.7 million pursuant to these agreements.

Agreements with Santo Service GmbH

We have several agreements with Santo Service GmbH, or Santo Service, pursuant to which Santo Service provides us with certain real property and custodial services. Santo Service is wholly owned by AT Impf GmbH, our controlling shareholder. During 2017 and 2018, we paid to Santo Service an aggregate of €8.4 million pursuant to these agreements.

Asset Sale and Purchase Agreement

On April 26, 2016, our wholly owned subsidiary, BioNTech Small Molecules GmbH, entered into an asset sale and purchase agreement with 4SC Discovery GmbH. 4SC Discovery GmbH is a wholly owned subsidiary of 4SC AG. Certain of our investors possess a 50% shareholding in 4SC AG. Pursuant to this agreement, BioNTech Small Molecules GmbH acquired the drug discovery business of 4SC Discovery GmbH for €650,000.

February 2018 Financing

In February 2018, we issued and sold an aggregate of 1,254,884 of our ordinary shares to certain new and existing shareholders at a price of \$215.87 per share for aggregate proceeds of \$270.9 million. The following table sets forth the aggregate number of ordinary shares that we issued and sold in this transaction to our related parties and the aggregate purchase price for such shares:

PARTICIPANTS	ORDINARY SHARES (#)	AGGREGATE PURCHASE PRICE (\$)
AT Impf GmbH(1)	277,934	59,997,612.58

(1) See "Principal Shareholders" for additional information about shares held by this entity.

June-July 2019 Financing

In June and July 2019, we issued and sold an aggregate of 666,123 of our ordinary shares to certain new and existing shareholders at a price of \$325.82 per share for aggregate proceeds of \$217 million. The following table sets forth the aggregate number of ordinary shares that we issued and sold in this transaction to our related parties and the aggregate purchase price for such shares:

PARTICIPANTS	ORDINARY SHARES (#)	AGGREGATE PURCHASE PRICE (\$)
AT Impf GmbH(1)	274,848	89,550,975.36

(1) See "Principal Shareholders" for additional information about shares held by this entity.

PRINCIPAL SHAREHOLDERS

The following table presents information, as of June 14, 2019, regarding the beneficial ownership of our ordinary shares (i) prior to the consummation of this offering and (ii) as adjusted to reflect the sale of our ADSs in this offering, for:

- each person, or group of affiliated persons, known by us to own beneficially 5% or more of our outstanding ordinary shares;
- each member of our Supervisory Board;
- each member of our Management Board; and
- all members of our Supervisory Board and Management Board as a group.

The number of ordinary shares beneficially owned by each entity, person, and member of our Supervisory Board and our Management Board is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any ordinary shares over which the individual has sole or shared voting power or investment power as well as any ordinary shares that the individual has the right to acquire within 60 days of June 14, 2019 through the exercise of any option, warrant or other right. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all ordinary shares held by that person.

The percentage of outstanding ordinary shares before this offering is computed on the basis of 11,129,000 ordinary shares outstanding as of June 14, 2019. The percentage of shares beneficially owned on an adjusted basis after this offering is based on shares to be outstanding after this offering after giving effect to the completion of this offering, assuming no exercise of the underwriters' option to purchase additional ADSs from us, and shares to be outstanding after this offering after giving effect to the completion of this offering and assuming full exercise of the underwriters' option to purchase additional ADSs from us. Ordinary shares that a person has the right to acquire within 60 days of June 14, 2019 are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person, except with respect to the percentage ownership of all members of our Supervisory Board and our Management Board as a group. Unless otherwise indicated, the address for each beneficial owner is An der Goldgrube 12, D-55131 Mainz, Germany.

Shareholder	Shares Beneficially Owned before This Offering		Shares Beneficially Owned after This Offering		Percent of Shares Beneficially Owned Assuming Full Exercise of Underwriters' Option to Purchase Additional Shares
	Number	Percent	Number	Percent	
5% Shareholders					
AT Impf GmbH ⁽¹⁾	6,093,566	54.75%			
Medine GmbH ⁽²⁾	2,316,165	20.81%			
Entities affiliated with MIG GmbH & Co. ⁽³⁾	753,117	6.77%			
Members of the Supervisory Board and the Management Board					
Prof. Ugur Sahin, M.D. ⁽⁴⁾	2,316,165	20.81%			
Sean Marett	60,639	0.54%			
Dr. Sierk Poetting, Ph.D.	39,546	0.36%			
Dr. Özlem Türeçci, M.D.	—	*			
Helmut Jeggle ⁽⁵⁾	6,112,028	54.92%			
Michael Motschmann ⁽⁶⁾	753,117	6.77%			

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Shareholder	Shares Beneficially Owned before This Offering		Shares Beneficially Owned after This Offering		Percent of Shares Beneficially Owned Assuming Full Exercise of Underwriters' Option to Purchase Additional Shares
	Number	Percent	Number	Percent	
	Prof. Christoph Huber, M.D.	141,780	1.27%		
Dr. Ulrich Wandschneider	—	*			
All members of our Supervisory Board and Management Board, as a group	9,423,275	84.67%			

- (1) Consists of 6,093,566 ordinary shares held by AT Impf GmbH as of June 14, 2019. Members of the Strüngmann family wholly own AT Impf GmbH. Dr. Andreas Strüngmann and Dr. Thomas Strüngmann may be deemed to beneficially own any or all of these shares.
- (2) Consists of 2,316,165 ordinary shares held by Medine GmbH as of June 14, 2019.
- (3) Consists of (a) 305,286 ordinary shares held by MIG GmbH & Co. Fonds 7 KG, Munich, (b) 98,889 ordinary shares held by MIG GmbH & Co. Fonds 8 KG, Munich and (c) 348,942 ordinary shares held by MIG GmbH & Co. Fonds 9 KG, Munich.
- (4) Consists of the shares described in note 2 above. Prof. Sahin is the sole shareholder of Medine GmbH.
- (5) Consists of (a) the shares described in note 1 above and (b) 18,462 ordinary shares held directly by Mr. Jeggler. Mr. Jeggler has no voting or dispositive power with regard to such shares described in note 1 above and disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein.
- (6) Consists of the shares described in note 3 above. Mr. Motschmann has no voting or dispositive power with regard to such shares and disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein.

Holdings by U.S. Shareholders

As of June 14, 2019, there were no issued and outstanding ordinary shares held by U.S. record holders.

DESCRIPTION OF SHARE CAPITAL AND ARTICLES OF ASSOCIATION (SATZUNG)

General

We were incorporated as a German stock corporation (*Aktiengesellschaft*) with the legal name Petersberg 91. V V AG under the laws of the Federal Republic of Germany on June 2, 2008. We changed our name to BioNTech AG on December 11, 2008. Effective as of March 8, 2019, the date on which the change of legal form and company was registered with the commercial register (*Handelsregister*) of the local court (*Amtsgericht*) of Mainz, Germany, we converted to a *Societas Europaea* with the legal name BioNTech SE. The principal legislation under which we operate and our shares are issued are the Council Regulation (EC) No 2157/2001 of October 8, 2001 on the Statute for a European company (SE), the German Law on the Implementation of Council Regulation (EC) No 2157/2001 of October 8, 2001 on the Statute for a European company (SE) (*Gesetz zur Ausführung der Verordnung (EG) NR. 2157/2001 des Rates vom 8. Oktober 2001 über das Statut der Europäischen Gesellschaft (SE) (SE-Ausführungsgesetz—SEAG)*) and the German Stock Corporation Act (*Aktiengesetz*), in each case as amended.

We are registered with the commercial register (*Handelsregister*) of the local court (*Amtsgericht*) in Mainz, Germany, under number HRB 48720. Our statutory seat is in Mainz, Germany, and our registered office is An der Goldgrube 12, 55131 Mainz, Germany. Copies of our Articles of Association will be publicly available from the commercial register (*Handelsregister*) at the local court of Mainz, Germany, electronically at www.unternehmensregister.de and as an exhibit to the registration statement of which this prospectus forms a part.

Share Capital

As of June 13, 2019, we have share capital registered in the commercial register (*Handelsregister*) in the amount of €11,153,243, which is divided into 11,153,243 registered shares (*Namensaktien*). All shares are shares with no par value (*Stückaktien ohne Nennbetrag*) with a notional amount attributable to each ordinary share of €1. Each issued ordinary share is fully paid.

Form, Certification and Transferability of Shares

The form and contents of our share certificates, collective share certificates and global share certificates are determined by our Management Board with the approval of our Supervisory Board. A shareholder's right to certification of its shares is excluded, to the extent permitted by law and to the extent that certification is not required by the stock exchange on which the shares are admitted to trading. We are permitted to issue collective share certificates and global share certificates that represent multiple or all of our shares.

Our shares are freely transferable under German law.

Changes in Our Share Capital During the Last Three Fiscal Years

As of June 13, 2019, our share capital as registered with the commercial register amounted to 11,153,243. Since January 1, 2016, our share capital has changed as follows:

- On September 14, 2017, our share capital as registered with the commercial register was increased by issuing 9,083,000 shares;
- On February 1, 2018, our share capital as registered with the commercial register was increased by issuing 1,254,884 shares;
- On September 12, 2018, our share capital as registered with the commercial register was increased by issuing 32,373 shares;

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- On October 18, 2018, our share capital as registered with the commercial register was increased by issuing 186,715 shares;
- On January 29, 2019, our share capital as registered with the commercial register was increased by issuing 282,678 shares;
- On April 24, 2019, our share capital as registered with the commercial register was increased by issuing 131,933 shares against contributions in kind (swap of shares in our company against shares in one of our subsidiary companies).

Anti-takeover Provisions of Our Charter Documents

Our Articles of Association do not include any provisions that would have a direct effect of delaying, deferring or preventing a change of control. However, in the event of a hostile takeover, we could use our authorized capital to increase our share capital to issue new shares to an investor at a premium. An increase in the number of shares outstanding could have a negative effect on a party's ability to carry out a hostile takeover. The provisions of German law relating to public bids and takeovers that require any such bids to be carried out in a manner designed to safeguard equal and fair treatment to all shareholders and give them a right to be bought out at an adequate compensation where a party acquires "control" (as such term is defined in such provisions) over the relevant company do not apply.

Future Changes to the Share Capital

Authorized Capital

Under the relevant law, the general meeting of a European stock corporation (*Societas Europaea*) governed by German law can authorize the management board to, with the consent of the supervisory board, issue shares in a specified aggregate nominal amount of up to 50% of the issued share capital of such company at the time the resolution becomes effective. The shareholders' authorization becomes effective upon registration in the commercial register (*Handelsregister*) and may extend for a period of no more than five years thereafter. As of June 13, 2019, under § 4(6) of our Articles of Association (*Satzung*), the Management Board is authorized to increase our share capital, on one or more occasions, by a total of up to €5,228,861 by issuing, on one or more occasions, up to 5,228,861 new, registered shares with no par value (*Genehmigtes Kapital*), in each case with consent of the Supervisory Board. This authorization expires on August 15, 2024.

Any new shares issued from the authorized capital will participate in the profits starting with the fiscal year in which they are issued. Further details of a capital increase from the authorized capital may be specified by the Management Board.

Conditional Capital

Pursuant to § 4(7) of our Articles of Association, our share capital as of the date hereof is conditionally increased by up to €1,207,399 through issuance of new, registered shares with no par value (*Bedingtes Kapital*). The conditional capital may only be used to issue shares to the holders of option rights granted under our ESOP to members of our management board and to certain of our employees.

The conditional capital increase will only be implemented to the extent that stock options under our ESOP are exercised and said stock options are not satisfied by our providing treasury shares or through cash payments. Any new shares issued under the conditional capital will participate in our profits starting with (i) the fiscal year preceding the fiscal year in which they are issued in case they are issued before annual general meeting of the fiscal year in which they are issued or else (ii) the fiscal year in which they are issued.

Preemptive Rights

German law generally provides shareholders with preemptive rights when new shares are issued. This requirement, however, may also be satisfied by way of a credit institution subscribing for the shares and then offering them to the shareholders for purchase (*mittelbares Bezugsrecht*).

Further, it is possible for a shareholder resolution approved by three-quarters of the share capital voting on the resolution to exclude preemptive rights both where the general meeting itself resolves that the new shares to be issued and in relation to the authorized capital, *i.e.*, an authorization to the management board to, with the consent of the supervisory board, resolve on the issuance of new shares; provided, however, that in each case the exclusion or the authorization to so exclude preemptive rights, respectively, must be justified by specific facts, in accordance with established case law of the German Federal Court of Justice (*BGH*). The German Federal Court of Justice (*BGH*) considers the exclusion of subscription rights justified if it (i) serves a purpose in the company's interests, (ii) is suitable for attaining such purpose, and (iii) is necessary and appropriate. Additionally, the management board must submit a written report to the shareholders' meeting in which it presents the reasons for the exclusion of the subscription rights.

Accordingly, under our Articles of Association, the Management Board may, with the consent of the Supervisory Board, exclude such preemptive rights in a capital increase from the authorized capital in the following circumstances:

- to balance out fractional amounts;
- in the case of a cash capital increase only if the issue price of the new shares is not substantially lower than the market price of our shares already listed on a stock exchange at the time the issue price is determined; however, this authorization is subject to the proviso that the total amount of shares issued under this authorization to exclude preemptive rights—including such shares previously issued thereunder—may not exceed 10% of our share capital, neither at the time of issuance nor at the time the authorization to exclude preemptive rights became effective. For the purpose of calculating whether or not such threshold of 10% is exceeded, all shares will be considered that (i) potentially are to be issued where such issuance would occur to satisfy conversion or option rights attaching to bonds which during the current term of the authorization to exclude preemptive rights have been issued in analogous application of sec. 186 para. 3 sentence 4 of the German Stock Corporation Act (*Aktiengesetz*) or (ii) that are treasury shares sold in (analogous) application of sec. 186 para. 3 sentence 4 of the German Stock Corporation Act (*Aktiengesetz*);
- in case of a capital increase against contributions in kind, especially to offer the new shares to third parties in relation to the acquisition of businesses, parts of businesses or equity interests in businesses or in relation to the acquisition of licenses or property rights;
- to the extent necessary to issue shares to holders of conversion or option rights on the basis of bonds issued by us or our domestic or foreign subsidiary companies in order to award such holders subscription rights in the same amount as they would be entitled to had they already exercised such conversion or option rights.

Corporate Purpose of our Company

Our business objective, as described in § 2 of our articles of association, is the research and development of immunological drugs and test methods for the diagnosis, prevention and treatment of cancers and infectious diseases.

Shareholders' Meetings and Voting Rights

Pursuant to our Articles of Association, shareholders' meetings may be held at our seat or in any municipality in Germany with more than 500,000 inhabitants. Generally, shareholders' meetings are convened by

our Management Board or our Supervisory Board. Shareholders representing in the aggregate at least five percent of our ordinary shares may, subject to certain formal prerequisites, request that a shareholders' meeting be convened. Shareholders representing in the aggregate at least five percent of our ordinary shares or owning shares with an aggregate nominal value of at least €500,000 may request the addition of one or several items to the agenda of any shareholders' meeting.

Invitations to shareholders' meetings must be published in the German Federal Gazette (*Bundesanzeiger*) at least 36 days before the meeting.

Shareholders may participate in and vote in the shareholders' meeting if they are registered as a shareholder with the Company's share register. A shareholder who wishes to attend the shareholders' meeting—either in person or by proxy, which may also be appointed by us (*Stimmrechtsvertreter*)—must register for the meeting, which registration must occur no later than six days before the meeting (or at a later date, if so determined by our Management Board).

Each share carries one vote at a shareholders' meeting. Resolutions are, in accordance with our Articles of Association, generally taken by simple majority of the votes cast. However, under applicable German and European law, a number of resolutions must be passed by either a three-quarter majority of the votes cast or a three-quarter majority of the share capital represented at the meeting. The fact that in these cases the quorum is determined in relation to the share capital or shares present (as opposed to, for example, all shares eligible to vote) means that holders of a minority of our shares could potentially control the outcome of resolutions.

Claims against Directors and Shareholders' Derivative Actions

Under German law, generally, the company, rather than its shareholders, is the proper claimant in an action with respect to a wrong committed against the company, or in cases where there is an irregularity in the company's internal management or supervision. Therefore, such claims may only be raised by the company represented by its management board, or, in the case of a wrong committed by a member of the management board, by the supervisory board. This concerns, in particular, claims against members of the management board or the supervisory board.

However, pursuant to German case law, the supervisory board is obliged to pursue the company's claims against the management board, unless the interest of the company keeps them from doing so. Further, the management board, or, if a claim is against a member of the management board, the supervisory board, is obliged to pursue the company's claims against the designated individuals if so resolved by a simple majority of votes cast during a shareholders' meeting. With a simple majority of votes, shareholders can also request that a representative pursue the claim on behalf of the company. The court may appoint such a representative upon the request of shareholders holding at least 10% of the company's share capital or a participation of at least €1,000,000 in the share capital.

If the company is unable to fulfill its third-party obligations, the company's creditors may pursue the company's damage claims against members of the management board for certain wrongdoings.

Under certain circumstances, shareholders can bring forward damage claims of the company against its management on their own behalf. In order to bring forward such a claim one shareholder alone or together with other shareholders needs to hold at least 1% of the company's share capital or a participation of €100,000 in the share capital. Additionally, the claimant(s) must comply with special claim approval procedures conducted before a competent court which will allow the pertinent request only if there are circumstances justifying the assumption that damage has been afflicted on the company by improper conduct or a gross breach of the law or the articles of association.

Dividend Rights

Under German law, distributions of dividends on shares for a given fiscal year are generally determined by a process in which the management board and supervisory board submit a proposal to the company's annual general shareholders' meeting held in the subsequent fiscal year and such annual general shareholders' meeting adopts a resolution.

German law provides that a resolution concerning dividends and distribution thereof may be adopted only if the company's unconsolidated financial statements prepared in accordance with German law show net retained profits. In determining the profit available for distribution, the result for the relevant year must be adjusted for profits and losses brought forward from the previous year and for withdrawals from or transfers to reserves. Certain reserves are required by law and must be deducted when calculating the profit available for distribution.

Shareholders generally participate in profit distributions in proportion to the number of shares they hold. Dividends on shares resolved by the general shareholders' meeting are paid annually, shortly after the general shareholders' meeting, in compliance with the rules of the respective clearing system. Dividend payment claims are subject to a three-year statute of limitation in the company's favor.

Squeeze-Out of Minority Shareholders

Under German law, the shareholders' meeting of a stock corporation may resolve, upon request of a shareholder that holds at least 95% of the share capital, that the shares held by any remaining minority shareholders be transferred to the majority shareholder against payment of "adequate cash compensation" (*Ausschluss von Minderheitsaktionären*). This amount must take into account the full value of the company at the time of the resolution, which is generally determined using the future earnings value method (*Ertragswertmethode*).

A squeeze-out in the context of a merger (*umwandlungsrechtlicher Squeeze-Out*) only requires a majority shareholder to hold at least 90% of the share capital.

Liquidation Rights

Apart from liquidation as a result of insolvency proceedings, we may be liquidated with a vote of the holders of at least three-quarters of the share capital represented at the shareholders' meeting at which such a vote is taken. If we are liquidated, any assets remaining after all of our liabilities have been paid off would be distributed among our shareholders in proportion to their holdings in accordance with German statutory law. The German Stock Corporation Act provides certain protections for creditors which must be observed in the event of liquidation.

Differences in Corporate Law

The applicable provisions of the SE Regulation in conjunction with the German Stock Corporation Act as applied to a European stock corporation that has its legal seat in Germany differ from laws applicable to U.S. corporations and their shareholders. Set forth below is a summary of certain differences between the provisions of the SE Regulation in conjunction with the German Stock Corporation Act applicable to us and the General Corporation Law of the State of Delaware relating to shareholders' rights and protections. This summary is not intended to be a complete discussion of the respective rights and it is qualified in its entirety by reference to Delaware law and European and German law.

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Board System

A European stock corporation may choose to have a two-tier board structure composed of the management board (*Vorstand*) and the supervisory board (*Aufsichtsrat*). We have chosen this structure.

Under Delaware law, a corporation has a unitary board structure, and it is the responsibility of the board of directors to appoint and oversee the management of the corporation on behalf of and in the best interests of the stockholders of the corporation.

The management board is responsible for running the company's affairs and representing the company in dealings with third parties.

Management is responsible for running the corporation and overseeing its day-to-day operations.

The supervisory board of a European stock corporation under German law has a control and supervisory function. The supervisory board does not actively manage the company but certain management board actions require the approval of the supervisory board.

Appointment and
Number of Directors

Under applicable European and German law, a European stock corporation governed by German law with a share capital of at least €3 million must have at least two members on its management board and the number of members shall be determined by or in the manner provided in the company's articles of association.

Under Delaware law, a corporation must have at least one director and the number of directors shall be fixed by or in the manner provided in the bylaws.

The supervisory board must consist of at least three but—depending on the share capital—no more than 21 supervisory board members, whereby the number of supervisory board members must be divisible by three if this is necessary for the fulfilment of co-determination requirements. The articles of association of the company must specify if the supervisory board has more than three members.

Supervisory board members are either appointed by the shareholders' meeting or delegated by one or more individual shareholders if so provided for in the company's articles of association. If the supervisory board consists of fewer members than is required to meet the quorum for resolutions (either statutory or pursuant to the company's articles of association), a competent court may appoint additional members as needed to

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meet the quorum. The provisions of German law in relation to employees' co-determination do not apply to the Company.

Removal of Directors

Members of the management board of a European stock corporation are appointed by the supervisory board for a maximum period of six years with an opportunity to be reelected. The articles of association may provide for a shorter term, which in our case is up to five years. The members of the management board may be reelected, even repeatedly. The supervisory board may remove a member of the management board prior to the expiration of his or her term only for cause, such as gross breach of duties (*grobe Pflichtverletzung*), the inability to manage the business properly (*Unfähigkeit zur ordnungsgemäßen Pflichtausübung*) or a vote of no-confidence during the shareholders' meeting (*Vertrauensentzug*). The shareholders themselves are not entitled to appoint or dismiss the members of the management board.

Under European law, a member of the supervisory board of a company may be elected for a term of up to six years. The articles of association may provide for a shorter term. Our Supervisory Board members are, if the general meeting does not resolve on a shorter term, elected for a period up to the end of the general meeting deciding on the discharge for the fourth financial year after the election. Reelection, including repeated reelection, is permissible. Members of the supervisory board may be removed with or without cause by way of a general meeting resolution, with the applicable majority requirement depending on the relevant company's articles of association.

Vacancies on the Board of Directors

Under the law, vacant positions on the management board are filled by the supervisory board in accordance with the general rules of appointment, which provide that vacancies are filled by the

Under Delaware law, any director or the entire board of directors may be removed, with or without cause, by the holders of a majority of the shares then entitled to vote at an election of directors, except (i) unless the certificate of incorporation provides otherwise, in the case of a corporation whose board of directors is classified, stockholders may effect such removal only for cause; or (ii) in the case of a corporation having cumulative voting, if less than the entire board of directors is to be removed, no director may be removed without cause if the votes cast against his removal would be sufficient to elect him if then cumulatively voted at an election of the entire board of directors, or, if there are classes of directors, at an election of the class of directors of which he is a part.

Under Delaware law, vacancies and newly created directorships may be filled by a majority of the directors then in office (even though less than a quorum) or by a sole remaining director unless (i)

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simple majority of votes of supervisory board members present or represented by proxy at the vote (with, under certain circumstances, the chairman having a casting vote), unless otherwise provided by the company's articles of association. In case of emergencies, a vacant position on the management board may be filled by an individual appointed by the court.

Vacant positions on the supervisory board are filled in accordance with the general rules of appointment.

otherwise provided in the certificate of incorporation or by-laws of the corporation or (ii) the certificate of incorporation directs that a particular class of stock is to elect such director, in which case a majority of the other directors elected by such class, or a sole remaining director elected by such class, will fill such vacancy.

Annual General Meeting

A European stock corporation which is governed by German law must hold an annual shareholders' meeting within six months of the end of its fiscal year. The annual shareholders' meeting must be held at a location determined by the articles of association. If the articles of association do not provide for a specific location, the shareholders' meeting shall be held at the company's seat or, if applicable, at the venue (in Germany) where its shares are listed.

Under Delaware law, the annual meeting of stockholders shall be held at such place, on such date and at such time as may be designated from time to time by the board of directors or as provided in the certificate of incorporation or by the bylaws.

General Meeting

Under the law, extraordinary shareholders' meetings, in addition to the annual shareholders' meetings, may be called by either the management board, or by the supervisory board. Shareholders holding at least 5% of the company's share capital are entitled to request that an extraordinary shareholders' meeting be convened. In the event that the meeting is not then so convened, the court may order that the meeting be convened or authorize the shareholders or their representative to convene the meeting themselves.

Under Delaware law, special meetings of the stockholders may be called by the board of directors or by such person or persons as may be authorized by the certificate of incorporation or by the bylaws.

Notice of General Meetings

Under applicable European and German law, unless a longer period is otherwise provided for in the articles of association or applies because of registration requirements stipulated in the articles of association, the shareholders must be given at least 30 days' advance notice of the shareholders' meeting. Such notices must at least specify the name of the company, the statutory seat of the company, and the location, date and time

Under Delaware law, unless otherwise provided in the certificate of incorporation or bylaws, written notice of any meeting of the stockholders must be given to each stockholder entitled to vote at the meeting not less than ten nor more than 60 days before the date of the meeting and shall specify the place, date, hour, and purpose or purposes of the meeting.

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of the shareholders' meeting. In addition, the invitation must contain the agenda items as well as the management board's and the supervisory board's voting proposal for each agenda item and, depending on the circumstances, certain further information.

If all shareholders entitled to attend the shareholders' meeting are present or represented and do not object to the meeting being held, the formalities of calling and holding of a shareholders' meeting do not apply.

Proxy

A shareholder may designate another person to attend, speak and vote at a shareholders' meeting of the company on such shareholder's behalf by proxy.

With respect to management board meetings, a management board member may transmit its (written or verbal) vote via another management board member.

With respect to supervisory board meetings, a supervisory board member may participate in voting by issuing a written vote to another supervisory board member or any third party entitled to attend the supervisory board meeting.

Preemptive Rights

Under the law applicable to European stock corporations governed by German law, existing shareholders have a statutory subscription right for any additional issue of shares or any security convertible into shares pro rata to the nominal value of their respective holdings in the company, unless (i) shareholders representing three-quarters of the registered share capital present at the shareholders' meeting have resolved upon the whole or partial exclusion of the subscription right and (ii) there exists good and objective cause for such exclusion. No separate resolution on the exclusion of subscription rights is required if all shareholders waive their statutory subscription rights.

Under Delaware law, at any meeting of stockholders, a stockholder may designate another person to act for such stockholder by proxy, but no such proxy shall be voted or acted upon after three years from its date, unless the proxy provides for a longer period. A director of a Delaware corporation may not issue a proxy representing the director's voting rights as a director.

Under Delaware law, stockholders have no preemptive rights to subscribe to additional issues of stock or to any security convertible into such stock unless, and except to the extent that, such rights are expressly provided for in the certificate of incorporation.

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Authority to Allot

Under applicable European and German law, the management board may not allot shares, grant rights to subscribe for or to convert any security into shares unless a shareholder resolution to that effect has been passed at the company's shareholders' meeting granting the management board with such authority—subject to the approval of the supervisory board—in each case in accordance with the provisions of the German Stock Corporation Act.

Under Delaware law, if the corporation's certificate of incorporation so provides, the board of directors has the power to authorize the issuance of stock. It may authorize capital stock to be issued for consideration consisting of cash, any tangible or intangible property or any benefit to the corporation or any combination thereof. It may determine the amount of such consideration by approving a formula. In the absence of actual fraud in the transaction, the judgment of the directors as to the value of such consideration is conclusive.

Liability of Directors and Officers

Under German law, any provision, whether contained in the company's articles of association or any contract or otherwise, that purports to exempt a management or supervisory board member from any liability that would otherwise attach to such board member in connection with any negligence, default, breach of duty or breach of trust in relation to the company is void.

Under German law, members of both the management board and members of the supervisory board are liable to the company, and in certain cases to third parties or shareholders, for any damage caused to them due to a breach of such member's duty of care. Apart from insolvency or special circumstances, only the company has the right to claim damages from members of either board. The company may waive claims for damages against a negligent management or supervisory board member only after the expiry of three years.

Under Delaware law, a corporation's certificate of incorporation may include a provision eliminating or limiting the personal liability of a director to the corporation and its stockholders for damages arising from a breach of fiduciary duty as a director. However, no provision can limit the liability of a director for:

- any breach of the director's duty of loyalty to the corporation or its stockholders;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- intentional or negligent payment of unlawful dividends or stock purchases or redemptions; or
- any transaction from which the director derives an improper personal benefit.

Voting Rights

Under the relevant European and German law, each share, except for statutory non-voting preferred shares (*nicht stimmberechtigte Vorzugsaktien*), entitles its holder to vote at the shareholders' meeting with, in the case of no-par value shares, each share conferring one vote. While German law does not provide for a minimum attendance quorum for

Delaware law provides that, unless otherwise provided in the certificate of incorporation, each stockholder is entitled to one vote for each share of capital stock held by such stockholder.

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shareholders' meetings, the company's articles of association may so provide. In general, resolutions adopted at a shareholders' meeting may be passed by a simple majority of votes cast, unless a higher majority is required by law or under the company's articles of association.

Shareholder Vote on Certain Transactions

Under applicable European and German law, certain shareholders' resolutions of fundamental importance require the vote of at least three-quarters of the share capital present or represented in the voting at the time of adoption of the resolution. Resolutions of fundamental importance include, in particular, capital increases with exclusion of subscription rights, capital decreases, the creation of authorized or conditional share capital, the dissolution of a company, a merger into or with another company, split-offs and split-ups, the conclusion of inter-company agreements (*Unternehmensverträge*), in particular domination agreements (*Beherrschungsverträge*) and profit and loss transfer agreements (*Ergebnisabführungsverträge*).

Generally, under Delaware law, unless the certificate of incorporation provides for the vote of a larger portion of the stock, completion of a merger, consolidation, sale, lease or exchange of all or substantially all of a corporation's assets or dissolution requires:

- the approval of the board of directors; and
- approval by the vote of the holders of a majority of the outstanding stock or, if the certificate of incorporation provides for more or less than one vote per share, a majority of the votes of the outstanding stock of a corporation entitled to vote on the matter.

Standard of Conduct for Directors

Under applicable European and German law, both management and supervisory board members must conduct their affairs with "the care and diligence of a prudent business man" and act in the best interest of the company. The scope of the fiduciary duties of management and supervisory board members is generally determined by European and German legislation and by the courts.

Delaware law does not contain specific provisions setting forth the standard of conduct of a director. The scope of the fiduciary duties of directors is generally determined by the courts of the State of Delaware. In general, directors have a duty to act without self-interest, on a well-informed basis and in a manner they reasonably believe to be in the best interest of the stockholders.

Statutory and fiduciary duties of members of the management board to the company include, among others:

- to act in accordance with the law, the company's articles of association and the rules of procedure for the management board, if any;
- to report to the supervisory board on a regular basis as well

Directors of a Delaware corporation owe fiduciary duties of care and loyalty to the corporation and to its stockholders. The duty of care generally requires that a director act in good faith, with the care that an ordinarily prudent person would exercise under similar circumstances. Under this duty, a director must inform himself of all material information reasonably available regarding a significant transaction. The duty of loyalty

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	<p>as on certain important occasions;</p> <ul style="list-style-type: none">• to exercise reasonable care, skill and diligence;• to maintain a proper accounting system;• to not compete, directly or indirectly, with the company without permission by the supervisory board; and• to secure that no further transactions are made in case of insolvency.	<p>requires that a director act in a manner he reasonably believes to be in the best interests of the corporation. He must not use his corporate position for personal gain or advantage. In general, but subject to certain exceptions, actions of a director are presumed to have been made on an informed basis, in good faith and in the honest belief that the action taken was in the best interests of the corporation. However, this presumption may be rebutted by evidence of a breach of one of the fiduciary duties. Delaware courts have also imposed a heightened standard of conduct upon directors of a Delaware corporation who take any action designed to defeat a threatened change in control of the corporation.</p>
	<p>Statutory and fiduciary duties of members of the supervisory board to the company include, among others:</p> <ul style="list-style-type: none">• to effectively supervise the management board's handling of the company's affairs;• to evaluate and issue a resolution on certain transactions which can only be conducted by the management board after approval of the supervisory board;• to approve the company's financial statements;• to appoint the management board members and to represent the company in transactions between the company and members of the management board; and• to approve service contracts between individual members of the supervisory board and the company.	<p>In addition, under Delaware law, when the board of directors of a Delaware corporation approves the sale or break-up of a corporation, the board of directors may, in certain circumstances, have a duty to obtain the highest value reasonably available to the stockholders.</p>
Stockholder Actions	<p>Under German law, generally, the company, rather than its shareholders, is the proper claimant in an action with respect to a wrong committed against the company, or in cases where there is an irregularity in the company's internal management or supervision. Therefore,</p>	<p>Under Delaware law, a stockholder may initiate a derivative action to enforce a right of a corporation if the corporation fails to enforce the right itself. The complaint must:</p> <ul style="list-style-type: none">• state that the plaintiff was a stockholder at the time of the

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such claims may only be raised by the company represented by its management board, or, in the case of a wrong committed by a member of the management board, by the supervisory board.

Additionally, pursuant to German case law, the supervisory board is obliged to pursue the company's claims against the management board, unless the interest of the company keeps them from doing so.

The management board, or, if a claim is against a member of the management board, the supervisory board, is obliged to pursue the company's claims against the designated individuals if so resolved by a simple majority of votes cast during a shareholders' meeting. With a simple majority of votes, shareholders can request that a representative pursues the claim on behalf of the company.

If the company is unable to fulfill its third-party obligations, the company's creditors may pursue the company's damage claims against members of the management board for certain wrongdoings.

Under certain circumstances, shareholders can bring forward damage claims of the company against its management on their own behalf. In order to bring forward such a claim one shareholder alone or together with other shareholders needs to hold at least one percent of the company's share capital or a participation of €100,000 in the share capital. Additionally, the claimant(s) need(s) to pass through special claim approval procedures.

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transaction of which the plaintiff complains or that the plaintiff's shares thereafter devolved on the plaintiff by operation of law; and

- either (i) allege with particularity the efforts made by the plaintiff to obtain the action the plaintiff desires from the directors and the reasons for the plaintiff's failure to obtain the action, or (ii) or state the reasons for not making the effort.

Additionally, the plaintiff must remain a stockholder through the duration of the derivative suit. The action will not be dismissed or compromised without the approval of the Delaware Court of Chancery.

Stock Exchange Listing

We have applied to list the ADSs representing our ordinary shares on the Nasdaq Global Select Market under the symbol "BNTX."

DESCRIPTION OF AMERICAN DEPOSITARY SHARES

American Depositary Shares

The Bank of New York Mellon, as depositary, will register and deliver the American Depositary Shares, or the ADSs. Each ADS will represent _____ shares (or a right to receive _____ shares) deposited with _____, as custodian for the depositary in _____. Each ADS will also represent any other securities, cash or other property which may be held by the depositary. The deposited shares together with any other securities, cash or other property held by the depositary are referred to as the deposited securities. The depositary's office at which the ADSs will be administered and its principal executive office are located at 240 Greenwich Street, New York, New York 10286.

You may hold ADSs either (i) directly (a) by having an American Depositary Receipt, or an ADR, which is a certificate evidencing a specific number of ADSs registered in your name, or (b) by having uncertificated ADSs registered in your name, or (ii) indirectly by holding a security entitlement in ADSs through your broker or other financial institution that is a direct or indirect participant in The Depository Trust Company, or DTC. If you hold ADSs directly, you are a registered ADS holder, or an ADS holder. This description assumes you are an ADS holder. If you hold the ADSs indirectly, you must rely on the procedures of your broker or other financial institution to assert the rights of ADS holders described in this section. You should consult with your broker or financial institution to find out what those procedures are.

Registered holders of uncertificated ADSs will receive statements from the depositary confirming their holdings.

As an ADS holder, we will not treat you as one of our shareholders and you will not have shareholder rights. European and German law governs shareholder rights. The depositary will be the holder of the shares underlying your ADSs. As a registered holder of ADSs, you will have ADS holder rights. A deposit agreement among us, the depositary, ADS holders and all other persons indirectly or beneficially holding ADSs sets out ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs.

The following is a summary of the material provisions of the deposit agreement. For more complete information, you should read the entire deposit agreement and the form of ADR. Those documents are filed as exhibits to the registration statement of which this prospectus forms a part.

Dividends and Other Distributions

How will ADS holders receive dividends and other distributions on the shares?

The depositary has agreed to pay or distribute to ADS holders the cash dividends or other distributions it or the custodian receives on shares or other deposited securities, upon payment or deduction of its fees and expenses. You will receive these distributions in proportion to the number of shares your ADSs represent.

Cash. The depositary will convert any cash dividend or other cash distribution we pay on the shares into U.S. dollars, if it can do so on a reasonable basis and can transfer the U.S. dollars to the United States. If that is not possible or if any government approval is needed and cannot be obtained, the deposit agreement allows the depositary to distribute the foreign currency only to those ADS holders to whom it is possible to do so. It will hold the foreign currency it cannot convert for the account of the ADS holders who have not been paid. It will not invest the foreign currency and it will not be liable for any interest.

Before making a distribution, any withholding taxes, or other governmental charges that must be paid will be deducted. See "Taxation" included elsewhere in this prospectus. The depositary will distribute only whole U.S. dollars and cents and will round fractional cents to the nearest whole cent. *If the exchange rates fluctuate during a time when the depositary cannot convert the foreign currency, you may lose some of the value of the distribution.*

Shares. The depositary may distribute additional ADSs representing any shares we distribute as a dividend or free distribution. The depositary will only distribute whole ADSs. It will sell shares which would require it to deliver a fraction of an ADS (or ADSs representing those shares) and distribute the net proceeds in the same way as it does with cash. If the depositary does not distribute additional ADSs, the outstanding ADSs will also represent the new shares. The depositary may sell a portion of the distributed shares (or ADSs representing those shares) sufficient to pay its fees and expenses in connection with that distribution.

Rights to purchase additional shares. If we offer holders of our securities any rights to subscribe for additional shares or any other rights, the depositary may (i) exercise those rights on behalf of ADS holders, (ii) distribute those rights to ADS holders or (iii) sell those rights and distribute the net proceeds to ADS holders, in each case after deduction or upon payment of its fees and expenses. To the extent the depositary does not do any of those things, it will allow the rights to lapse. **In that case, you will receive no value for them.** The depositary will exercise or distribute rights only if we ask it to and provide satisfactory assurances to the depositary that it is legal to do so. If the depositary will exercise rights, it will purchase the securities to which the rights relate and distribute those securities or, in the case of shares, new ADSs representing the new shares, to subscribing ADS holders, but only if ADS holders have paid the exercise price to the depositary. U.S. securities laws may restrict the ability of the depositary to distribute rights or ADSs or other securities issued on exercise of rights to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer.

Other Distributions. The depositary will send to ADS holders anything else we distribute on deposited securities by any means it thinks is legal, fair and practical. If it cannot make the distribution in that way, the depositary has a choice. It may decide to sell what we distributed and distribute the net proceeds, in the same way as it does with cash. Or, it may decide to hold what we distributed, in which case ADSs will also represent the newly distributed property. However, the depositary is not required to distribute any securities (other than ADSs) to ADS holders unless it receives satisfactory evidence from us that it is legal to make that distribution. The depositary may sell a portion of the distributed securities or property sufficient to pay its fees and expenses in connection with that distribution. U.S. securities laws may restrict the ability of the depositary to distribute securities to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer.

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADS holders. We have no obligation to register ADSs, shares, rights or other securities under the Securities Act. We also have no obligation to take any other action to permit the distribution of ADSs, shares, rights or anything else to ADS holders. **This means that you may not receive the distributions we make on our shares or any value for them if it is illegal or impractical for us to make them available to you.**

Deposit, Withdrawal and Cancellation

How are ADSs issued?

The depositary will deliver ADSs if you or your broker deposits shares or evidence of rights to receive shares with the custodian. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will register the appropriate number of ADSs in the names you request and will deliver the ADSs to or upon the order of the person or persons that made the deposit.

How can ADS holders withdraw the deposited securities?

You may surrender your ADSs to the depositary for the purpose of withdrawal. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will deliver the shares and any other deposited securities underlying the ADSs to the ADS holder or a person the ADS holder designates at the office of the custodian. Or, at your request, risk and expense, the depositary will deliver the deposited securities at its office, if feasible. However, the depositary is not required to accept surrender of ADSs to the extent it would require delivery of a fraction of a deposited share or other security. The depositary may charge you a fee and its expenses for instructing the custodian regarding delivery of deposited securities.

How do ADS holders interchange between certificated ADSs and uncertificated ADSs?

You may surrender your ADR to the depository for the purpose of exchanging your ADR for uncertificated ADSs. The depository will cancel that ADR and will send to the ADS holder a statement confirming that the ADS holder is the registered holder of uncertificated ADSs. Upon receipt by the depository of a proper instruction from a registered holder of uncertificated ADSs requesting the exchange of uncertificated ADSs for certificated ADSs, the depository will execute and deliver to the ADS holder an ADR evidencing those ADSs.

Voting Rights

How do ADS holders vote?

ADS holders may instruct the depository how to vote the number of deposited shares their ADSs represent. If we request the depository to solicit your voting instructions (and we are not required to do so), the depository will notify you of a shareholders' meeting and send or make voting materials available to you. Those materials will describe the matters to be voted on and explain how ADS holders may instruct the depository how to vote. For instructions to be valid, they must reach the depository by a date set by the depository. The depository will try, as far as practical, subject to the laws of the State of New York and the provisions of our articles of association or similar documents, to vote or to have its agents vote the shares or other deposited securities as instructed by ADS holders. If we do not request the depository to solicit your voting instructions, you can still send voting instructions, and, in that case, the depository may try to vote as you instruct, but it is not required to do so.

Except by instructing the depository as described above, you won't be able to exercise voting rights unless you surrender your ADSs and withdraw the shares. However, you may not know about the meeting enough in advance to withdraw the shares. In any event, the depository will not exercise any discretion in voting deposited securities and it will only vote or attempt to vote as instructed.

We cannot assure you that you will receive the voting materials in time to ensure that you can instruct the depository to vote your shares. In addition, the depository and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. **This means that you may not be able to exercise voting rights and there may be nothing you can do if your shares are not voted as you requested.**

In order to give you a reasonable opportunity to instruct the depository as to the exercise of voting rights relating to deposited securities, if we request the depository to act, we agree to give the depository notice of any such meeting and details concerning the matters to be voted upon at least 45 days in advance of the meeting date.

Fees and Expenses

<i>Persons depositing or withdrawing shares or ADS holders must pay:</i>	<i>For:</i>
\$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)	Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property
	Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates
\$.05 (or less) per ADS	Any cash distribution to ADS holders
A fee equivalent to the fee that would be payable if securities distributed to you had been shares and the shares had been deposited for issuance of ADSs	Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depository to ADS holders
\$.05 (or less) per ADS per calendar year	Depository services

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Persons depositing or withdrawing shares or ADS holders must pay:

For:

Registration or transfer fees	Transfer and registration of shares on our share register to or from the name of the depositary or its agent when you deposit or withdraw shares
Expenses of the depositary	Cable and facsimile transmissions (when expressly provided in the deposit agreement) Converting foreign currency to U.S. dollars
Taxes and other governmental charges the depositary or the custodian has to pay on any ADSs or shares underlying ADSs, such as stock transfer taxes, stamp duty or withholding taxes	As necessary
Any charges incurred by the depositary or its agents for servicing the deposited securities	As necessary

The depositary collects its fees for delivery and surrender of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depositary may collect any of its fees by deduction from any cash distribution payable (or by selling a portion of securities or other property distributable) to ADS holders that are obligated to pay those fees. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the depositary may make payments to us to reimburse us for costs and expenses generally arising out of establishment and maintenance of the ADS program, waive fees and expenses for services provided to us by the depositary or share revenue from the fees collected from ADS holders. In performing its duties under the deposit agreement, the depositary may use brokers, dealers, foreign currency dealers or other service providers that are owned by or affiliated with the depositary and that may earn or share fees, spreads or commissions.

The depositary may convert currency itself or through any of its affiliates and, in those cases, acts as principal for its own account and not as agent, advisor, broker or fiduciary on behalf of any other person and earns revenue, including, without limitation, transaction spreads, that it will retain for its own account. The revenue is based on, among other things, the difference between the exchange rate assigned to the currency conversion made under the deposit agreement and the rate that the depositary or its affiliate receives when buying or selling foreign currency for its own account. The depositary makes no representation that the exchange rate used or obtained in any currency conversion under the deposit agreement will be the most favorable rate that could be obtained at the time or that the method by which that rate will be determined will be the most favorable to ADS holders, subject to the depositary's obligations under the deposit agreement. The methodology used to determine exchange rates used in currency conversions is available upon request.

Payment of Taxes

You will be responsible for any taxes or other governmental charges payable on your ADSs or on the deposited securities represented by any of your ADSs. The depositary may refuse to register any transfer of your ADSs or allow you to withdraw the deposited securities represented by your ADSs until those taxes or other

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charges are paid. It may apply payments owed to you or sell deposited securities represented by your ADSs to pay any taxes owed and you will remain liable for any deficiency. If the depositary sells deposited securities, it will, if appropriate, reduce the number of ADSs to reflect the sale and pay to ADS holders any proceeds, or send to ADS holders any property, remaining after it has paid the taxes.

Tender and Exchange Offers; Redemption, Replacement or Cancellation of Deposited Securities

The depositary will not tender deposited securities in any voluntary tender or exchange offer unless instructed to do by an ADS holder surrendering ADSs and subject to any conditions or procedures the depositary may establish.

If deposited securities are redeemed for cash in a transaction that is mandatory for the depositary as a holder of deposited securities, the depositary will call for surrender of a corresponding number of ADSs and distribute the net redemption money to the holders of called ADSs upon surrender of those ADSs.

If there is any change in the deposited securities such as a sub-division, combination or other reclassification, or any merger, consolidation, recapitalization or reorganization affecting the issuer of deposited securities in which the depositary receives new securities in exchange for or in lieu of the old deposited securities, the depositary will hold those replacement securities as deposited securities under the deposit agreement. However, if the depositary decides it would not be lawful and practical to hold the replacement securities because those securities could not be distributed to ADS holders or for any other reason, the depositary may instead sell the replacement securities and distribute the net proceeds upon surrender of the ADSs.

If there is a replacement of the deposited securities and the depositary will continue to hold the replacement securities, the depositary may distribute new ADSs representing the new deposited securities or ask you to surrender your outstanding ADRs in exchange for new ADRs identifying the new deposited securities.

If there are no deposited securities underlying ADSs, including if the deposited securities are cancelled, or if the deposited securities underlying ADSs have become apparently worthless, the depositary may call for surrender of those ADSs or cancel those ADSs upon notice to the ADS holders.

Amendment and Termination

How may the deposit agreement be amended?

We may agree with the depositary to amend the deposit agreement and the ADRs without your consent for any reason. If an amendment adds or increases fees or charges, except for taxes and other governmental charges or expenses of the depositary for registration fees, facsimile costs, delivery charges or similar items, or prejudices a substantial right of ADS holders, it will not become effective for outstanding ADSs until 30 days after the depositary notifies ADS holders of the amendment. **At the time an amendment becomes effective, you are considered, by continuing to hold your ADSs, to agree to the amendment and to be bound by the ADRs and the deposit agreement as amended.**

How may the deposit agreement be terminated?

The depositary will initiate termination of the deposit agreement if we instruct it to do so. The depositary may initiate termination of the deposit agreement if:

- 60 days have passed since the depositary told us it wants to resign but a successor depositary has not been appointed and accepted its appointment;
- we delist the ADSs from an exchange in the United States on which they were listed and do not list the ADSs on another exchange in the United States or make arrangements for trading of ADSs on the U.S. over-the-counter market;

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- we delist our ordinary shares from an exchange outside the United States on which they were listed and do not list the shares on another exchange outside the United States;
- the depositary has reason to believe the ADSs have become, or will become, ineligible for registration on Form F-6 under the Securities Act of 1933;
- we appear to be insolvent or enter insolvency proceedings
- all or substantially all the value of the deposited securities has been distributed either in cash or in the form of securities;
- there are no deposited securities underlying the ADSs or the underlying deposited securities have become apparently worthless; or
- there has been a replacement of deposited securities.

If the deposit agreement will terminate, the depositary will notify ADS holders at least 90 days before the termination date. At any time after the termination date, the depositary may sell the deposited securities. After that, the depositary will hold the money it received on the sale, as well as any other cash it is holding under the deposit agreement, unsegregated and without liability for interest, for the pro rata benefit of the ADS holders that have not surrendered their ADSs. Normally, the depositary will sell as soon as practicable after the termination date.

After the termination date and before the depositary sells, ADS holders can still surrender their ADSs and receive delivery of deposited securities, except that the depositary may refuse to accept a surrender for the purpose of withdrawing deposited securities or reverse previously accepted surrenders of that kind that have not settled if it would interfere with the selling process. The depositary may refuse to accept a surrender for the purpose of withdrawing sale proceeds until all the deposited securities have been sold. The depositary will continue to collect distributions on deposited securities, but, after the termination date, the depositary is not required to register any transfer of ADSs or distribute any dividends or other distributions on deposited securities to the ADSs holder (until they surrender their ADSs) or give any notices or perform any other duties under the deposit agreement except as described in this paragraph.

Limitations on Obligations and Liability

Limits on our Obligations and the Obligations of the Depositary; Limits on Liability to Holders of ADSs

The deposit agreement expressly limits our obligations and the obligations of the depositary. It also limits our liability and the liability of the depositary. We and the depositary:

- are only obligated to take the actions specifically set forth in the deposit agreement without negligence or bad faith, and the depositary will not be a fiduciary or have any fiduciary duty to holders of ADSs;
- are not liable if we are or it is prevented or delayed by law or by events or circumstances beyond our or its control from performing our or its obligations under the deposit agreement;
- are not liable if we or it exercises discretion permitted under the deposit agreement;
- are not liable for the inability of any holder of ADSs to benefit from any distribution on deposited securities that is not made available to holders of ADSs under the terms of the deposit agreement, or for any special, consequential or punitive damages for any breach of the terms of the deposit agreement;
- have no obligation to become involved in a lawsuit or other proceeding related to the ADSs or the deposit agreement on your behalf or on behalf of any other person;
- may rely upon any documents we believe or it believes in good faith to be genuine and to have been signed or presented by the proper person;.

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- are not liable for the acts or omissions of any securities depository, clearing agency or settlement system; and
- the depository has no duty to make any determination or provide any information as to our tax status, or any liability for any tax consequences that may be incurred by ADS holders as a result of owning or holding ADSs or be liable for the inability or failure of an ADS holder to obtain the benefit of a foreign tax credit, reduced rate of withholding or refund of amounts withheld in respect of tax or any other tax benefit.

In the deposit agreement, we and the depository agree to indemnify each other under certain circumstances.

Requirements for Depository Actions

Before the depository will deliver or register a transfer of ADSs, make a distribution on ADSs, or permit withdrawal of shares, the depository may require:

- payment of stock transfer or other taxes or other governmental charges and transfer or registration fees charged by third parties for the transfer of any shares or other deposited securities;
- satisfactory proof of the identity and genuineness of any signature or other information it deems necessary; and
- compliance with regulations it may establish, from time to time, consistent with the deposit agreement, including presentation of transfer documents.

The depository may refuse to deliver ADSs or register transfers of ADSs when the transfer books of the depository or our transfer books are closed or at any time if the depository or we think it advisable to do so.

Your Right to Receive the Shares Underlying your ADSs

ADS holders have the right to cancel their ADSs and withdraw the underlying shares at any time except:

- when temporary delays arise because (i) the depository has closed its transfer books or we have closed our transfer books, (ii) the transfer of shares is blocked to permit voting at a shareholders' meeting or (iii) we are paying a dividend on our shares;
- when you owe money to pay fees, taxes and similar charges; or
- when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of shares or other deposited securities.

This right of withdrawal may not be limited by any other provision of the deposit agreement.

Direct Registration System

In the deposit agreement, all parties to the deposit agreement acknowledge that the Direct Registration System, or DRS, and Profile Modification System, or Profile, will apply to the ADSs. DRS is a system administered by DTC that facilitates interchange between registered holding of uncertificated ADSs and holding of security entitlements in ADSs through DTC and a DTC participant. Profile is a feature of DRS that allows a DTC participant, claiming to act on behalf of a registered holder of uncertificated ADSs, to direct the depository to register a transfer of those ADSs to DTC or its nominee and to deliver those ADSs to the DTC account of that DTC participant without receipt by the depository of prior authorization from the ADS holder to register that transfer.

In connection with and in accordance with the arrangements and procedures relating to DRS/Profile, the parties to the deposit agreement understand that the depository will not determine whether the DTC participant

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that is claiming to be acting on behalf of an ADS holder in requesting registration of transfer and delivery as described in the paragraph above has the actual authority to act on behalf of the ADS holder (notwithstanding any requirements under the Uniform Commercial Code). In the deposit agreement, the parties agree that the depositary's reliance on and compliance with instructions received by the depositary through the DRS/Profile system and in accordance with the deposit agreement will not constitute negligence or bad faith on the part of the depositary.

Shareholder Communications; Inspection of Register of Holders of ADSs

The depositary will make available for your inspection at its office all communications that it receives from us as a holder of deposited securities that we make generally available to holders of deposited securities. The depositary will send you copies of those communications or otherwise make those communications available to you if we ask it to. You have a right to inspect the register of holders of ADSs, but not for the purpose of contacting those holders about a matter unrelated to our business or the ADSs.

Jury Trial Waiver

The deposit agreement provides that, to the extent permitted by law, ADS holders waive the right to a jury trial of any claim they may have against us or the depositary arising out of or relating to our shares, the ADSs or the deposit agreement, including any claim under the U.S. federal securities laws. If we or the depositary opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable in the facts and circumstances of that case in accordance with applicable case law.

You will not, by agreeing to the terms of the deposit agreement, be deemed to have waived our or the depositary's compliance with U.S. federal securities laws and the rules and regulations promulgated thereunder.

SHARES AND ADSs ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no market for our ordinary shares or ADSs. Future sales of substantial amounts of our ordinary shares or ADSs in the public market, or the perception that such sales may occur, could adversely affect prevailing market prices of our ordinary shares or ADSs.

Based on the _____ ordinary shares that were outstanding on _____, upon the closing of this offering, _____ ordinary shares, and _____ ADSs representing _____ ordinary shares, will be outstanding, assuming no exercise of the underwriters' option to purchase additional ADSs. The _____ ADSs sold in this offering will be freely tradable without restriction or further registration under the Securities Act of 1933, as amended, or the Securities Act, except for any ADSs purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act, or Rule 144, whose sales would be subject to the Rule 144 resale restrictions described below. The remaining _____ ordinary shares will be held by our existing shareholders and will be deemed to be "restricted securities" under Rule 144, and we expect that substantially all of these restricted securities will be subject to the 180-day lock-up period under the lock-up agreements as described below. These restricted securities may only be sold in the public market upon release or waiver of any applicable lock-up agreements and only if registered or pursuant to an exemption from registration, such as Rule 144 or Rule 701 under the Securities Act, or Rule 701.

Rule 144

In general, under Rule 144, beginning 90 days after the date of this prospectus, a person who is not an affiliate of ours and has held their ordinary shares for at least six months, including the holding period of any prior owner other than one of our affiliates, may sell those shares without restriction, subject to the availability of current public information about us. In addition, under Rule 144, any person who is not an affiliate of ours and has not been an affiliate of ours at any time during the preceding three months and has held their ordinary shares for at least one year, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell an unlimited number of shares immediately upon the closing of this offering without regard to whether current public information about us is available.

Beginning 90 days after the date of this prospectus, a person who is an affiliate of ours or who was an affiliate of ours at any time during the preceding three months and who has beneficially owned restricted securities for at least six months, including the holding period of any prior owner other than one of our affiliates, is entitled to sell within any three-month period only a number of securities that does not exceed the greater of either of:

- 1% of the number of our ordinary shares then outstanding, including ordinary shares represented by ADSs, which will equal approximately _____ ordinary shares immediately after this offering, assuming no exercise of the underwriters' option to purchase additional ADSs; and
- the average weekly trading volume of the ADSs on the Nasdaq Global Select Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Such sales both by affiliates and by non-affiliates must also comply with the manner-of-sale, current public information and notice provisions of Rule 144, to the extent applicable. Rule 144 also requires that affiliates relying on Rule 144 to sell securities that are not restricted securities must nonetheless comply with the same restrictions applicable to restricted securities, other than the holding period requirement.

Regulation S

Regulation S under the Securities Act provides that ordinary shares or ADSs owned by any person may be sold without registration in the United States, provided that the sale is effected in an offshore transaction and no directed selling efforts are made in the United States (as these terms are defined in Regulation S), subject to certain other conditions. In general, this means that our shares or ADSs may be sold outside the United States without registration in the United States being required.

Rule 701

In general, under Rule 701, any of our employees, board members, executive management, consultants or advisors who purchased ordinary shares from us in connection with a compensatory share or option plan or other written agreement before the closing of this offering is entitled to resell such shares.

The SEC has indicated that Rule 701 will apply to typical share options granted by an issuer before it becomes subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, along with the shares acquired upon exercise of such options, including exercises after the date of this prospectus. Securities issued in reliance on Rule 701 are restricted securities and, subject to the lock-up restrictions described below, may be sold beginning 90 days after the date of this prospectus in reliance on Rule 144 by:

- persons other than affiliates, without restriction, subject only to the manner-of-sale provisions of Rule 144; and
- affiliates, subject to the manner-of-sale, current public information and filing requirements of Rule 144, in each case, without compliance with the six-month holding period requirement of Rule 144.

Lock-up Agreements

For a description of the lock-up arrangements that we, members of our Supervisory Board and Management Board and substantially all of our shareholders have entered into in connection with this offering, see “Underwriting.”

Options and Form S-8 Registration Statement

As of December 31, 2018, options to purchase a total of 658,109 ordinary shares were issued and outstanding. Of the total number of issued and outstanding options, will be vested upon the closing of this offering. All of our ordinary shares issuable under these options are subject to contractual lock-up agreements with us or the underwriters.

Following the completion of this offering, we intend to file a registration statement on Form S-8 under the Securities Act to register up to ordinary shares, in the aggregate, issued or reserved for issuance under the ESOP. The registration statement on Form S-8 will become effective automatically upon filing. Ordinary shares issued upon exercise of a share option and registered pursuant to the Form S-8 registration statement will, subject to vesting provisions and Rule 144 volume limitations applicable to our affiliates, be available for sale in the open market immediately unless they are subject to the 180-day lock-up period.

EXCHANGE CONTROLS AND LIMITATIONS AFFECTING SHAREHOLDERS

There are currently no legal restrictions in the Federal Republic of Germany on international capital movements and foreign exchange transactions, except in limited embargo circumstances (*Teilembargo*) relating to certain areas, entities or persons as a result of applicable resolutions adopted by the United Nations and the European Union. Restrictions currently exist with respect to, among others, Belarus, Congo, Egypt, Eritrea, Guinea, Guinea-Bissau, Iran, Iraq, Lebanon, Libya, North Korea, Somalia, South Sudan, Sudan, Syria, Tunisia and Zimbabwe.

For statistical purposes, there are, however, limited notification requirements regarding transactions involving cross-border monetary transfers. With some exceptions, every corporation or individual residing in the Federal Republic of Germany must report to the German Central Bank (*Deutsche Bundesbank*) (i) any payment received from, or made to, a non-resident corporation or individual that exceeds €12,500 (or the equivalent in a foreign currency) and (ii) in case the sum of claims against, or liabilities payable to, non-residents or corporations exceeds €5,000,000 (or the equivalent in a foreign currency) at the end of any calendar month. Payments include cash payments made by means of direct debit, checks and bills, remittances denominated in euros and other currencies made through financial institutions, as well as netting and clearing arrangements.

TAXATION

German Taxation

The following discussion addresses certain German tax consequences of acquiring, owning or disposing of the ADSs. With the exception of “—Taxation of Holders Tax Resident in Germany” below, which provides an overview of dividend taxation and of capital gains taxation with respect to holders that are residents of Germany, this discussion applies only to U.S. treaty beneficiaries (defined below) that acquire ADSs in the offering.

This discussion is based on domestic German tax laws, including, but not limited to, circulars issued by German tax authorities, which are not binding on the German courts, and the Treaty (defined below). It is based upon tax laws in effect at the time of filing of this prospectus. These laws are subject to change, possibly with retroactive effect. For example, certain member states of the European Union are considering introducing a financial transaction tax (*Finanztransaktionssteuer*) which, if and when introduced, may also be applicable on sales and/or transfer of ADSs. In addition, in Germany, for example, there are currently ongoing discussions on the raise of the top tax rate, which may also have an effect on the German tax consequences of acquiring, owning and disposing of the ADSs. There is no assurance that German tax authorities will not challenge one or more of the tax consequences described in this discussion.

In addition, this discussion is based upon the assumption that each obligation in the deposit agreement and any related agreement will be performed in accordance with its terms. It does not purport to be a comprehensive or exhaustive description of all German tax considerations that may be of relevance in the context of acquiring, owning and disposing of ADSs.

The tax information presented in this prospectus is not a substitute for tax advice. Prospective holders of ADSs should consult their own tax advisors regarding the German tax consequences of the purchase, ownership, disposition, donation or inheritance of ADSs in light of their particular circumstances, including the effect of any state, local, or other foreign or domestic laws or changes in tax law or interpretation. The same applies with respect to the rules governing the refund of any German dividend withholding tax (*Kapitalertragsteuer*) withheld. Only an individual tax consultation can appropriately account for the particular tax situation of each investor.

General

Based on the circular issued by the German Federal Ministry of Finance (*BMF-Schreiben*), dated May 24, 2013, reference number IV C 1-S2204/12/10003, in respect of the taxation of American Depositary Receipts, or ADRs, on domestic shares, or the ADR Tax Circular, for German tax purposes, the ADSs represent a beneficial ownership interest in the underlying shares of BioNTech and qualify as ADRs for the purpose of the ADR Tax Circular. If the ADSs qualify as ADRs under the ADR Tax Circular, dividends would accordingly be attributable to holders of the ADSs for German tax purposes, and not to the legal owner of the ordinary shares (*i.e.*, the financial institution on behalf of which the ordinary shares are stored at a domestic depository for the ADS holders). Furthermore, holders of the ADSs should be treated as beneficial owners of the capital of BioNTech with respect to capital gains (see below in section “—German Taxation of Capital Gains of the U.S. Treaty Beneficiaries of the ADSs”). However, investors should note that circulars published by the German tax authorities (including the ADR Tax Circular) are not binding on German courts, including German tax courts, and it is unclear whether a German court would follow the ADR Tax Circular in determining the German tax treatment of the ADSs. For the purpose of this German tax section, it is assumed that the ADSs qualify as ADRs within the meaning of the ADR Tax Circular.

Taxation of Holders Not Tax Resident in Germany

The following discussion describes the material German tax consequences for a holder that is a U.S. treaty beneficiary of acquiring, owning and disposing of the ADSs. For purposes of this discussion, a “U.S. treaty

beneficiary” is a resident of the United States for purposes of the Agreement between the Federal Republic of Germany and United States of America for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income and on Capital as of June 4, 2008 (*Abkommen zwischen der Bundesrepublik Deutschland und den Vereinigten Staaten von Amerika zur Vermeidung der Doppelbesteuerung und zur Verhinderung der Steuerverkürzung auf dem Gebiet der Steuern vom Einkommen und vom Vermögen und einiger anderer Steuern in der Fassung vom 4. Juni 2008*), hereinafter referred to as the “Treaty,” who is fully eligible for benefits under the Treaty.

A holder will be a U.S. treaty beneficiary entitled to full Treaty benefits in respect of the ADSs if it is, inter alia:

- the beneficial owner of the ADSs (and the dividends paid with respect thereto);
- a U.S. holder;
- not also a resident of Germany for German tax purposes; and
- not subject to the limitation on benefits (*i.e.*, anti-treaty shopping) article of the Treaty that applies in limited circumstances.

Special rules apply to pension funds and certain other tax-exempt investors.

This discussion does not address the treatment of ADSs that are (i) held in connection with a permanent establishment or fixed base through which a U.S. treaty beneficiary carries on business or performs personal services in Germany or (ii) part of business assets for which a permanent representative in Germany has been appointed.

General Rules for the Taxation of Holders Not Tax Resident in Germany

Non-German resident holders of ADSs are subject to German taxation with respect to German source income (*beschränkte Steuerpflicht*). According to the ADR Tax Circular, income from the shares should be attributed to the holder of the ADSs for German tax purposes. As a consequence, income from the ADSs should be treated as German source income.

German Withholding Taxation of Dividends of the U.S. Treaty Beneficiaries of the ADSs

Generally, the full amount of a dividend distributed by BioNTech to a non-German resident holder which does not maintain a permanent establishment or other taxable presence in Germany is subject to (final) German withholding tax at an aggregate rate of 26.375%. German withholding tax is withheld and remitted to the German tax authorities by (i) the disbursing agent (*i.e.*, the German credit institution, financial services institution, securities trading enterprise or securities trading bank (each as defined in the German Banking Act (*Kreditwesengesetz*) and in each case including a German branch of a foreign enterprise, but excluding a foreign branch of a German enterprise)) that holds or administers the underlying shares in custody and (a) disburses or credits the dividend income from the underlying shares, (b) disburses or credits the dividend income from the underlying shares on delivery of the dividend coupons or (c) disburses such dividend income to a foreign agent; or (ii) the central securities depository (*Wertpapiersammelbank*) in terms of the German Depository Act (*Depotgesetz*) holding the underlying shares in a collective deposit, if such central securities depository disburses the dividend income from the underlying shares to a foreign agent, regardless of whether a holder must report the dividend for tax purposes and regardless of whether or not a holder is a resident of Germany (each such institution, a Withholding Agent). Dividend payments, to the extent funded from BioNTech’s tax-recognized contribution account (*steuerliches Einlagekonto*), do not, subject to certain prerequisites, form part of the taxable dividend income but lower the holder’s acquisition costs for the ADSs.

Pursuant to the Treaty, the German withholding tax may generally not exceed (i) 15% of the gross amount of the dividends received by a U.S. treaty beneficiary other than a company holding ADSs which represent 10%

or more of the voting shares in BioNTech, and (ii) 5% of the gross amount of the dividends received by a U.S. treaty beneficiary that is a company holding ADSs which represent 10% or more of the voting shares in BioNTech. The excess of the total withholding tax, including the solidarity surcharge, over the maximum rate of withholding tax permitted by the Treaty is refunded to U.S. treaty beneficiaries upon application. For example, for a declared dividend of 100, a U.S. treaty beneficiary initially receives 73.625 (100 minus the 26.375% withholding tax including solidarity surcharge). The U.S. treaty beneficiary is entitled to a partial refund from the German tax authorities in the amount of 11.375% of the gross dividend (of 100). As a result, the U.S. treaty beneficiary ultimately receives a total of 85 (85% of the declared dividend) following the refund of the excess withholding. However, investors should note that it is unclear how the German tax authorities will apply the refund process to dividends on the ADSs with respect to non-German resident holders of the ADSs. Further, such refund is subject to the German anti-avoidance treaty shopping rule (as described below in “—Withholding Tax Refund for U.S. Treaty Beneficiaries”).

German Withholding Taxation of Capital Gains of the U.S. Treaty Beneficiaries of the ADSs

The capital gains from the disposition of the ADSs realized by a non-German resident holder which does not maintain a permanent establishment or other taxable presence in Germany would be treated as German source income and be subject to German tax if the ADSs qualify as a Qualified Participation. A Qualified Participation is given if a holder at any time during the five years preceding the disposition, directly or indirectly, owned 1% or more of BioNTech’s share capital, irrespective of whether through the ADSs or shares of BioNTech. If such holder had acquired the ADSs without consideration, the previous owner’s holding period and quota would be taken into account.

Pursuant to the Treaty, capital gains from the disposition of a Qualified Participation realized by a U.S. treaty beneficiary are, however, generally exempt from German taxation. Pursuant to the Treaty, U.S. treaty beneficiaries are not subject to German tax in relation to capital gains from the disposition of a Qualified Participation even under the circumstances described in the preceding paragraph and therefore should not be subject to German taxation on capital gains from the disposition of the ADSs.

German statutory law requires the Withholding Agent to levy withholding tax on capital gains from the sale of ADSs or other securities held in a custodial account in Germany. The German statutory law does not explicitly condition the obligation to withhold taxes on capital gains being subject to taxation in Germany under German statutory law or on an applicable income tax treaty permitting Germany to tax such capital gains.

However, a circular issued by the German Federal Ministry of Finance, dated January 18, 2016, reference number IV C 1-S2252/08/10004 :017, provides that taxes need not be withheld when the holder of the custody account is not a resident of Germany for tax purposes and the income is not subject to German taxation. The circular further states that there is no obligation to withhold such tax even if the non-resident holder owns 1% or more of the share capital of a German company. While circulars issued by the German Federal Ministry of Finance are only binding on the German tax authorities but not on the German courts, in practice, the disbursing agents nevertheless typically rely on guidance contained in such circulars. Therefore, a disbursing agent would only withhold tax at 26.375% on capital gains derived by a U.S. treaty beneficiary from the sale of ADSs held in a custodial account in Germany in the event that the disbursing agent did not follow the abovementioned guidance. In this case, the U.S. treaty beneficiary may be entitled to claim a refund of the withholding tax from the German tax authorities under the Treaty, as described below in “—Withholding Tax Refund for U.S. Treaty Beneficiaries.” A refund of taxes withheld on capital gains from the disposition of the ADSs which do not qualify as Qualified Participations may also be claimed based on German statutory domestic law.

Withholding Tax Refund for U.S. Treaty Beneficiaries

U.S. treaty beneficiaries are generally eligible for treaty benefits under the Treaty, as described above in “—Taxation of Holders Not Tax Resident in Germany.” Accordingly, U.S. treaty beneficiaries are in general

entitled to claim a refund of (i) the portion of the otherwise applicable 26.375% German withholding tax (*Kapitalertragsteuer*) on dividends that exceeds the applicable Treaty rate and (ii) the full amount of German withholding tax (*Kapitalertragsteuer*) on capital gains from the disposition of ADSs. The application for such claim is generally to be filed with the Federal Central Office of Taxation (*Bundeszentralamt für Steuern*).

However, in respect of dividends, the refund described in the preceding paragraph is only possible if, due to special rules on the restriction of withholding tax credit, the following three cumulative requirements are met: (i) the holder must qualify as beneficial owner of the ADSs for an uninterrupted minimum holding period of 45 days within a period starting 45 days prior to and ending 45 days after the due date of the dividends, (ii) the holder has to bear at least 70% of the change in value risk related to the ADSs during the minimum holding period as described under (i) of this paragraph and has not entered into (acting by itself or through a related party) hedging transactions which lower the change in value risk by more than 30%, and (iii) the holder must not be obliged to fully or largely compensate directly or indirectly the dividends to third parties. If these requirements are not met, then for a holder not being tax-resident in Germany who applied for a full or partial refund of the withholding tax pursuant to a double taxation treaty, no refund is available. This restriction generally does only apply if (a) the tax underlying the refund application is below a tax rate of 15% based on the gross amount of the dividends and (b) the holder does not directly own 10% or more of the shares of BioNTech and is subject to income taxes in its state of residence, without being tax-exempt.

In general, as previously discussed, investors should note that it is unclear how the German tax administration will apply the refund process to dividends on the ADSs. Further, such refund is subject to the German anti-avoidance treaty shopping rule. Generally, this rule requires that the U.S. treaty beneficiary (in case it is a non-German resident company) maintains its own administrative substance and conducts its own business activities. In particular, a foreign company has no right to a full or partial refund to the extent persons holding ownership interests in BioNTech would not be entitled to the refund if they derived the income directly and the gross income realized by the foreign company is not caused by the business activities of the foreign company, and there are either no economic or other considerable reasons for the interposition of the foreign company, or the foreign company does not participate in general commerce by means of a business organization with resources appropriate to its business purpose. However, this shall not apply if the foreign company's principal class of stock is regularly traded in substantial volume on a recognized stock exchange, or if the foreign company is subject to the provisions of the German Investment Tax Act (*Investmentsteuergesetz*). Whether or not and to which extent the anti-avoidance treaty shopping rule applies to the ADSs has to be analyzed on a case by case basis taking into account all relevant tests. In addition, the interpretation of these tests is disputed and to date no published decisions of the German Federal Finance Court exist in this regard.

Due to the legal structure of the ADSs, only limited guidance of the German tax authorities exists on the practical application of this procedure with respect to the ADSs.

Taxation of Holders Tax Resident in Germany

This subsection provides an overview of dividend taxation and of capital gains taxation with regard to the general principles applicable to ADS's holders that are tax resident in Germany. A holder is a German tax resident if, in case of an individual, he or she maintains a domicile (*Wohnsitz*) or a usual residence (*gewöhnlicher Aufenthalt*) in Germany or if, in case of a corporation, it has its place of management (*Geschäftsleitung*) or registered office (*Sitz*) in Germany.

The German dividend and capital gains taxation rules applicable to German tax residents require a distinction between ADSs held as private assets (*Privatvermögen*) and ADSs held as business assets (*Betriebsvermögen*).

ADSs as Private Assets (Privatvermögen)

If the ADSs are held as private assets by a German tax resident, dividends and capital gains (other than capital gains from the disposition of a Qualified Participation) are taxed as investment income and are principally

subject to 25% German flat income tax on capital income (*Abgeltungsteuer*) (plus a 5.5% solidarity surcharge (*Solidaritätszuschlag*) thereon, resulting in an aggregate rate of 26.375%), which is levied in the form of withholding tax (*Kapitalertragsteuer*). In other words, once deducted, the holder's income tax liability on the dividends will be settled. Dividend payments to the extent funded from BioNTech's tax-recognized contribution account (*steuerliches Einlagekonto*), do not, subject to certain prerequisites, form part of the taxable dividend income but lower the holder's acquisition costs for the ADSs.

Holders of ADSs may apply to have their capital investment income assessed in accordance with the general rules and with an individual's personal income tax rate if this would result in a lower tax burden in which case actually incurred expenses are not deductible. The holder would be taxed on gross personal investment income (including dividends or gains with respect to ADSs), less the saver's allowance of €801 for an individual or €1,602 for a married couple and a registered civil union (*eingetragene Lebenspartnerschaft*) filing taxes jointly. The deduction of expenses related to the investment income (including dividends or gains with respect to ADSs) is generally not possible for private investors.

Losses resulting from the disposal of ADSs can only be offset against capital gains from the sale of any shares (*Aktien*) and other ADSs. If, however, a holder holds a Qualifying Participation, 60% of any capital gains resulting from the sale and transfer are taxable at the holder's personal income tax rate (plus 5.5% solidarity surcharge thereon). Conversely, 60% of any capital losses are recognized for tax purposes.

Church tax generally has to be withheld, if applicable, based on an automatic data access procedure, unless the holder of ADSs has filed a blocking notice (*Sperrvermerk*) with the Federal Central Tax Office. Where church tax is not levied by way of withholding, it is determined by means of income tax assessment.

ADSs as Business Assets (*Betriebsvermögen*)

In case the ADSs are held as business assets, the taxation depends on the legal form of the holder (*i.e.*, whether the holder is a corporation or an individual).

Irrespective of the legal form of the holder, dividends are subject to the aggregate withholding tax rate of 26.375%. The withholding tax is generally creditable against the respective holder's corporate income tax or income tax liability. Due to special rules on the restriction of withholding tax credits in respect of dividends, a full withholding tax credit requires that the following three cumulative requirements are met: (i) the holder must qualify as beneficial owner of the ADSs for an uninterrupted minimum holding period of 45 days occurring within a period starting 45 days prior to and ending 45 days after the due date of the dividends, (ii) the holder has to bear at least 70% of the change in value risk related to the ADSs during the minimum holding period as described under (i) of this paragraph and has not entered into (acting by itself or through a related party) hedging transactions which lower the change in value risk for more than 30%, and (iii) the holder must not be obliged to fully or largely compensate directly or indirectly the dividends to third parties. If these requirements are not met, three-fifths of the withholding tax imposed on the dividends must not be credited against the holder's corporate income tax or income tax liability, but may, upon application, be deducted from the holder's tax base for the relevant tax assessment period. A holder that is generally subject to German income tax or corporate income tax and that has received gross dividends without any deduction of withholding tax due to a tax exemption without qualifying for a full tax credit under the aforementioned requirements has to notify the competent local tax office accordingly and has to make a payment in the amount of the omitted withholding tax deduction. The special rules on the restriction of withholding tax credit do not apply to a holder whose overall dividend earnings within an assessment period do not exceed €20,000 or that has been the beneficial owner of the ADSs for at least one uninterrupted year upon receipt of the dividends.

To the extent the amount withheld exceeds the income tax liability, the withholding tax will be refunded, provided that certain requirements are met (including the aforementioned requirements).

Special rules apply to credit institutions (*Kreditinstitute*), financial services institutions (*Finanzdienstleistungsinstitute*), financial enterprises (*Finanzunternehmen*), life insurance and health insurance companies, and pension funds.

With regard to holders in the legal form of a corporation, capital gains are in general effectively 95% tax exempt from corporate income tax (including solidarity surcharge). Dividends are also generally 95% tax exempt from corporate income tax (including solidarity surcharge), inter alia, if the holder held at least 10% of the registered share capital (*Grundkapital oder Stammkapital*) of BioNTech at the beginning of the calendar year (“Qualifying Dividends”). Five percent of the capital gains and five percent of the Qualifying Dividends are treated as non-deductible business expenses, respectively, and, as such, are subject to corporate income tax (including solidarity surcharge); actual business expenses incurred to generate dividends may be deducted. The acquisition of a participation of at least 10% in the course of a calendar year is deemed to have occurred at the beginning of such calendar year for the determination of whether a dividend is a Qualifying Dividend. Participations in the share capital of BioNTech held through a partnership, including co-entrepreneurships (*Mitunternehmerschaften*), are attributable to the respective partner only on a pro rata basis at the ratio of its entitlement to the profits of the partnership.

Further, capital gains and dividend income of a German tax resident corporation are generally subject to German trade tax. The aforementioned 95% exemption for capital gains generally applies also for trade tax purposes.

However, the amount of any dividends after deducting business expenses related to the dividends is not subject to trade tax if the corporation held at least 15% of BioNTech’s registered share capital at the beginning of the relevant tax assessment period. In the latter case, the aforementioned exemption of 95% of the dividend income also applies for trade tax purposes. Losses from the sale of ADSs are generally not tax deductible for corporate income tax and trade tax purposes.

With regard to individuals holding ADSs as business assets, 60% of dividends and capital gains are taxed at the individual’s personal income tax rate (plus 5.5% solidarity surcharge thereon). Correspondingly, only 60% of business expenses related to the dividends and capital gains as well as losses from the sale of ADSs are principally deductible for income tax purposes. The dividend income and 60% of the capital gains are generally subject to trade tax, which is fully or partly creditable against the individual’s personal income tax by a lump-sum method. Dividends (after deduction of business expenses economically related thereto) are exempt from trade tax if the holder held at least 15% of BioNTech’s registered share capital at the beginning of the relevant tax assessment period.

German Inheritance and Gift Tax (Erbschaft- und Schenkungsteuer)

The transfer of ADSs to another person by inheritance or gift should be generally subject to German inheritance and gift tax only if:

- (i) the decedent or donor or heir, beneficiary or other transferee (a) maintained his or her domicile or a usual residence in Germany, (b) had its place of management or registered office in Germany at the time of the transfer, (c) is a German citizen who has spent no more than five consecutive years outside of Germany without maintaining a domicile in Germany or (d) is a German citizen who serves for a German entity established under public law and is remunerated for his or her service from German public funds (including family members who form part of such person’s household, if they are German citizens) and is only subject to estate or inheritance tax in his or her country of domicile or usual residence with respect to assets located in such country (special rules apply to certain former German citizens who neither maintain a domicile nor have their usual residence in Germany);
- (ii) at the time of the transfer, the ADSs are held by the decedent or donor as business assets forming part of a permanent establishment in Germany or for which a permanent representative in Germany has been appointed; or

- (iii) the ADSs subject to such transfer form part of a portfolio that represents at the time of the transfer 10% or more of the registered share capital of BioNTech and that has been held directly or indirectly by the decedent or donor, either alone or together with related persons.

The Agreement between the Federal Republic of Germany and the United States of America for the avoidance of double taxation with respect to taxes on inheritances and gifts as of December 21, 2000 (*Abkommen zwischen der Bundesrepublik Deutschland und den Vereinigten Staaten von Amerika zur Vermeidung der Doppelbesteuerung auf dem Gebiet der Nachlass-, Erbschaft- und Schenkungssteuern in der Fassung vom 21. Dezember 2000*), hereinafter referred to as the “United States-Germany Inheritance and Gifts Tax Treaty,” provides that the German inheritance tax or gift tax can, with certain restrictions, only be levied in the cases of (i) and (ii) above. Special provisions apply to certain German citizens living outside of Germany and former German citizens.

Other Taxes

No German transfer tax, value-added tax, stamp duty or similar taxes are assessed on the purchase, sale or other transfer of ADSs. Provided that certain requirements are met, an entrepreneur may, however, opt for the payment of value-added tax on transactions that are otherwise tax-exempt. Net wealth tax (*Vermögensteuer*) is currently not imposed in Germany. Certain member states of the European Union and also Germany on a standalone basis are considering introducing a financial transaction tax (*Finanztransaktionssteuer*) which, if and when introduced, may also be applicable on sales and/or transfer of ADSs.

Material United States Federal Income Tax Considerations

The following discussion describes material U.S. federal income tax considerations relating to the acquisition, ownership and disposition of ADSs by a U.S. Holder (as defined below) that acquires our ADSs and holds them as a capital asset. This discussion is based on the tax laws of the United States, including the Internal Revenue Code of 1986, as amended, or the Code, Treasury regulations promulgated or proposed thereunder, and administrative and judicial interpretations thereof, all as in effect on the date hereof. These tax laws are subject to change, possibly with retroactive effect, and subject to differing interpretations that could affect the tax consequences described herein. This section does not address the treatment of a non-U.S. holder, nor does it address the tax treatment under the laws of any state, local or foreign taxing jurisdiction.

For purposes of this discussion, a “U.S. Holder” is a beneficial owner of our ADSs that, for U.S. federal income tax purposes, is:

- an individual who is a citizen or resident of the United States;
- a domestic corporation (or other entity taxable as a corporation);
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust if (i) a court within the United States is able to exercise primary supervision over the trust’s administration and one or more U.S. persons have the authority to control all substantial decisions of the trust or (ii) a valid election under the Treasury regulations is in effect for the trust to be treated as a U.S. person.

This discussion does not address all aspects of U.S. federal income taxation that may be applicable to U.S. Holders in light of their particular circumstances or status (including, for example, banks and other financial institutions, insurance companies, broker and dealers in securities or currencies, traders that have elected to mark securities to market, regulated investment companies, real estate investment trusts, partnerships or other pass-through entities, corporations that accumulate earnings to avoid U.S. federal income tax, tax-exempt organizations, pension plans, persons that hold our shares as part of a straddle, hedge or other integrated investment, persons subject to alternative minimum tax or whose “functional currency” is not the U.S. dollar).

If a partnership (including any entity or arrangement treated as a partnership for U.S. federal income tax purposes) holds our ADSs, the tax treatment of a person treated as a partner in the partnership for U.S. federal income tax purposes generally will depend on the status of the partner and the activities of the partnership. Partnerships (and other entities or arrangements so treated for U.S. federal income tax purposes) and their partners should consult their own tax advisors.

In general, and taking into account the earlier assumptions, for U.S. federal income and German tax purposes, a holder of ADSs will be treated as the owner of the shares represented by those ADSs. Exchanges of shares for ADSs, and ADSs for shares, generally will not be subject to U.S. federal income or to German tax.

This discussion addresses only U.S. Holders and does not discuss any tax considerations other than U.S. federal income tax considerations. Prospective investors are urged to consult their own tax advisors regarding the U.S. federal, state and local, and foreign tax consequences of the purchase, ownership, and disposition of ADSs.

Dividends

Under the U.S. federal income tax laws, and subject to the passive foreign investment company, or PFIC, rules discussed below, the gross amount of any dividend we pay out of our current or accumulated earnings and profits (as determined for U.S. federal income tax purposes) is includible in income for a U.S. Holder and subject to U.S. federal income taxation. Dividends paid to a noncorporate U.S. Holder that constitute qualified dividend income will be taxable at a preferential tax rate applicable to long-term capital gains, provided that the U.S. Holder holds the ADSs for more than 90 days during the 121-day period beginning 60 days before the ex-dividend date and meets other holding period requirements. Dividends we pay with respect to the ADSs generally will be qualified dividend income.

A U.S. Holder must include any German tax withheld from the dividend payment, as described above under “—German Taxation—General Rules for the Taxation of Holders Not Tax Resident in Germany,” in the gross amount of dividend paid even though the holder does not in fact receive it. The dividend is taxable to the holder when the depository receives the dividend, actually or constructively. Because we are not a U.S. corporation, the dividend will not be eligible for the dividends-received deduction generally allowed to U.S. corporations in respect of dividends received from other U.S. corporations. The amount of the dividend distribution includible in U.S. Holder’s income will be the U.S. dollar value of the Euro payments made, determined at the spot Euro/U.S. dollar rate on the date the dividend distribution is includible in income, regardless of whether the payment is in fact converted into U.S. dollars. Generally, any gain or loss resulting from currency exchange fluctuations during the period from the date the dividend payment is included in income to the date the payment is converted into U.S. dollars will be treated as ordinary income or loss and will not be eligible for the special tax rate applicable to qualified dividend income. The gain or loss generally will be income or loss from sources within the United States for foreign tax credit limitation purposes.

To the extent a distribution with respect to ADSs exceeds our current or accumulated earnings and profits, as determined under U.S. federal income tax principles, the distribution will be treated, first, as a tax-free return of the U.S. Holder’s investment, up to the holder’s adjusted tax basis in its ADSs, and, thereafter, as capital gain, which is subject to the tax treatment described below in “—Gain on Sale, Exchange or Other Taxable Disposition.”

Subject to certain limitations, the German tax withheld in accordance with the Treaty and paid over to the German taxing authority will be creditable or deductible against a U.S. Holder’s U.S. federal income tax liability. To the extent a refund of the tax withheld is available to a U.S. Holder under German law or under the Treaty, the amount of tax withheld that is refundable will not be eligible for credit against a U.S. Holder’s U.S. federal income tax liability. See “—German Taxation—Withholding Tax Refund for U.S. Treaty Beneficiaries” above for the procedures for obtaining a tax refund.

Gain On Sale, Exchange or Other Taxable Disposition

Subject to the PFIC rules described below under “—Passive Foreign Investment Company Considerations”, a U.S. Holder that sells, exchanges or otherwise disposes of ADSs in a taxable disposition generally will recognize capital gain or loss for U.S. federal income tax purposes equal to the difference between the U.S. dollar value of the amount realized and the holder’s tax basis, determined in U.S. dollars, in the ADSs. Gain or loss recognized on such a sale, exchange or other disposition of ADSs generally will be long-term capital gain if the U.S. Holder’s holding period in the ADSs exceeds one year. Long-term capital gains of non-corporate U.S. Holders are generally taxed at preferential rates. The gain or loss generally will be income or loss from sources within the United States for foreign tax credit limitation purposes. A U.S. Holder’s ability to deduct capital losses is subject to limitations.

Passive Foreign Investment Company Considerations

We do not believe that we should be treated as, and do not expect to become, a PFIC. Because the determination of our PFIC status is made annually based on the factual tests described below, however, we cannot provide any assurances regarding our PFIC status for the current or future taxable years or that the IRS will agree with our conclusion regarding our PFIC status.

If we were classified as a PFIC in any taxable year, a U.S. Holder would be subject to special rules with respect to distributions on and sales, exchanges and other dispositions of the ADSs. We will be treated as a PFIC for any taxable year in which at least 75 percent of our gross income is “passive income” or at least 50 percent of our gross assets during the taxable year (based on the average of the fair market values of the assets determined at the end of each quarterly period) are assets that produce or are held for the production of passive income. Passive income for this purpose generally includes, among other things, dividends, interest, rents, royalties, gains from commodities and securities transactions, and gains from assets that produce passive income. However, rents and royalties received from unrelated parties in connection with the active conduct of a trade or business are not considered passive income for purposes of the PFIC test. In determining whether we are a PFIC, a pro rata portion of the income and assets of each corporation in which we own, directly or indirectly, at least a 25% interest (by value) is taken into account.

If we were a PFIC with respect to a U.S. Holder, then unless such U.S. Holder makes one of the elections described below, a special tax regime would apply to the U.S. Holder with respect to (i) any “excess distribution” (generally, aggregate distributions in any year that are greater than 125% of the average annual distribution received by the holder in the shorter of the three preceding years or the holder’s holding period for the ADSs) and (ii) any gain realized on the sale or other disposition of the ADSs. Under this regime, any excess distribution and realized gain will be treated as ordinary income and will be subject to tax as if (a) the excess distribution or gain had been realized ratably over the U.S. Holder’s holding period, (b) the amount deemed realized in each year had been subject to tax in each year of that holding period at the highest marginal rate for such year (other than income allocated to the current period or any taxable period before we became a PFIC, which would be subject to tax at the U.S. Holder’s regular ordinary income rate for the current year and would not be subject to the interest charge discussed below), and (c) the interest charge generally applicable to underpayments of tax had been imposed on the taxes deemed to have been payable in those years. If we were determined to be a PFIC, this tax treatment for U.S. Holders would apply also to indirect distributions and gains deemed realized by U.S. Holders in respect of stock of any of our subsidiaries determined to be PFICs. In addition, dividend distributions would not qualify for the lower rates of taxation applicable to long-term capital gains discussed above under “—Taxation of Dividends.”

A U.S. Holder that holds the ADSs at any time during a taxable year in which we are classified as a PFIC generally will continue to treat such ADSs as ADSs in a PFIC, even if we no longer satisfy the income and asset tests described above, unless the U.S. Holder elects to recognize gain, which will be taxed under the excess distribution rules as if such ADSs had been sold on the last day of the last taxable year for which we were a PFIC.

Certain elections by a U.S. Holder would alleviate some of the adverse consequences of PFIC status and would result in an alternative treatment of the ADSs, as described below.

If we were a PFIC, the rules above would not apply to a U.S. Holder that makes an election to treat ADSs as stock of a “qualified electing fund” or QEF. However, we do not expect that a U.S. Holder would be able to make this election because we do not intend to provide to U.S. Holders the required information to make a valid QEF election.

If we were a PFIC, the rules above also would not apply to a U.S. Holder that makes a “mark-to-market” election with respect to the ADSs, but this election will be available with respect to the ADSs only if they meet certain minimum trading requirements to be considered “marketable stock” for purposes of the PFIC rules. Generally, shares of ADSs will be treated as marketable stock if they are “regularly traded” on a “qualified exchange” within the meaning of applicable U.S. Treasury Regulations. ADSs generally will be considered regularly traded during any calendar year during which they are traded, other than in *de minimis* quantities, on at least 15 days during each calendar quarter. Any trades that have as their principal purpose meeting this requirement will be disregarded. Our ADSs will be marketable stock as long as they remain listed on the Nasdaq Global Select Market and are regularly traded.

A U.S. Holder that makes a valid mark-to-market election for the first tax year in which the holder holds (or is deemed to hold) ADSs and for which we are a PFIC will be required to include each year an amount equal to the excess, if any, of the fair market value of such ADSs the holder owns as of the close of the taxable year over the holder’s adjusted tax basis in such ADSs. The U.S. Holder will be entitled to a deduction for the excess, if any, of the holder’s adjusted tax basis in the ADSs over the fair market value of such ADSs as of the close of the taxable year, but only to the extent of any net mark-to-market gains with respect to such ADSs included by the U.S. Holder under the election for prior taxable years. The U.S. Holder’s basis in such ADSs will be adjusted to reflect the amounts included or deducted pursuant to the election. Amounts included in income pursuant to a mark-to-market election, as well as gain on the sale, exchange or other taxable disposition of such ADSs, will be treated as ordinary income. The deductible portion of any mark-to-market loss, as well as loss on a sale, exchange or other disposition of ADSs to the extent that the amount of such loss does not exceed net mark-to-market gains previously included in income, will be treated as ordinary loss.

The mark-to-market election applies to the taxable year for which the election is made and all subsequent taxable years, unless the shares cease to be treated as marketable stock for purposes of the PFIC rules or the IRS consents to its revocation. The excess distribution rules described above generally will not apply to a U.S. Holder for tax years for which a mark-to-market election is in effect. However, if we were a PFIC for any year in which the U.S. Holder owns the ADSs but before a mark-to-market election is made, the interest charge rules described above would apply to any mark-to-market gain recognized in the year the election is made.

A U.S. Holder of PFIC shares must generally file an annual information return on IRS Form 8621 (Information Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund). The failure to file IRS Form 8621 could result in the imposition of penalties and the extension of the statute of limitations with respect to U.S. federal income tax.

U.S. Holders are urged to consult their tax advisors as to our status as a PFIC, and the tax consequences to them if we were a PFIC, including the reporting requirements and the desirability of making, and the availability of, a QEF election or a mark-to-market election with respect to the ADSs.

Medicare Tax

Non-corporate U.S. Holders that are individuals, estates or trusts and whose income exceeds certain thresholds generally are subject to a 3.8% tax on all or a portion of their net investment income, which may include their gross dividend income and net gains from the disposition of ADSs. A U.S. person that is an individual, estate or trust is encouraged to consult its tax advisors regarding the applicability of this Medicare tax to its income and gains in respect of any investment in ADSs.

Information Reporting with Respect to Foreign Financial Assets

Individual U.S. Holders may be subject to certain reporting obligations on IRS Form 8938 (Statement of Specified Foreign Financial Assets) with respect to the ADSs for any taxable year during which the U.S. Holder's aggregate value of these and certain other "specified foreign financial assets" exceed a threshold amount that varies with the filing status of the individual. This reporting obligation also applies to domestic entities formed or availed of to hold, directly or indirectly, specified foreign financial assets, including the ADSs. Significant penalties can apply if U.S. Holders are required to make this disclosure and fail to do so.

U.S. Holders who acquire ADSs for cash may be required to file IRS Form 926 (Return by a U.S. Transferor of Property to a Foreign Corporation) with the IRS and to supply certain additional information to the IRS if (i) immediately after the transfer, the U.S. Holder owns directly or indirectly (or by attribution) at least 10% of our total voting power or value or (ii) the amount of cash transferred to us in exchange for ADSs, when aggregated with all related transfers under applicable regulations, exceeds \$100,000. Substantial penalties may be imposed on a U.S. Holder that fails to comply with this reporting requirement.

Information Reporting and Backup Withholding

In general, information reporting, on IRS Form 1099, will apply to dividends in respect of ADSs and the proceeds from the sale, exchange or redemption of ADSs that are paid to a holder of ADSs within the United States (and in certain cases, outside the United States), unless such holder is an exempt recipient such as a corporation. Backup withholding (currently at a 24% rate) may apply to such payments if a holder of ADSs fails to provide a taxpayer identification number (generally on an IRS Form W-9) or certification of other exempt status or fails to report in full dividend and interest income.

Backup withholding is not an additional tax. A U.S. Holder generally may obtain a refund of any amounts withheld under the backup withholding rules that exceed the U.S. Holder's income tax liability by filing a refund claim with the IRS.

UNDERWRITING

We are offering ordinary shares represented by ADSs described in this prospectus through a number of underwriters. J.P. Morgan Securities LLC, BofA Securities, Inc., UBS Securities LLC and SVB Leerink LLC are acting as representatives of the underwriters. We have entered into an underwriting agreement with the underwriters. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase, at the public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, the number of ADSs listed next to its name in the following table:

<u>Name</u>	<u>Number of ADSs</u>
J.P. Morgan Securities LLC	
BofA Securities, Inc.	
UBS Securities LLC	
SVB Leerink LLC	
Canaccord Genuity LLC	
Bryan, Garnier & Co. Limited	
Berenberg Capital Markets LLC	
WR Securities, LLC	
Kempen & Co U.S.A., Inc.	
Mirae Asset Securities (HK) Limited	
Total	

The underwriters are committed to purchase all the ADSs offered by us if they purchase any ADSs. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may also be increased or the offering may be terminated.

The underwriters propose to offer the ADSs directly to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of \$ per ADS. Any such dealers may resell ADSs to certain other brokers or dealers at a discount of up to \$ per ADS from the initial public offering price. After the initial offering of the ADSs to the public, if all of the ADSs are not sold at the initial public offering price, the underwriters may change the offering price and the other selling terms. Sales of ADSs made outside of the United States may be made by affiliates of the underwriters.

The underwriters have an option to buy up to additional ADSs from us to cover sales of ADSs by the underwriters which exceed the number of ADSs specified in the table above. The underwriters have 30 days from the date of this prospectus to exercise this option to purchase additional ADSs. If any ADSs are purchased with this option to purchase additional ADSs, the underwriters will purchase ADSs in approximately the same proportion as shown in the table above. If any additional ADSs are purchased, the underwriters will offer the additional ADSs on the same terms as those on which the ADSs are being offered.

For reasons of German law, will initially subscribe for all of the new ordinary shares represented by the ADSs on behalf of the underwriters, at an issue price of € per share. This issue price will be credited against the amount due from the underwriters at closing. If the underwriters exercise their option to purchase additional ADSs, will initially subscribe for the new ordinary shares representing such additional ADSs at an issue price equal to the price to the public less underwriting discounts and commissions.

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The underwriting fee is equal to the public offering price per ADS less the amount paid by the underwriters to us per ADS. The underwriting fee is \$ per ADS. The following table shows the per ADS and total underwriting discounts and commissions to be paid to the underwriters assuming both no exercise and full exercise of the underwriters' option to purchase additional ADSs.

	Without exercise of option to purchase additional ADSs	With full exercise of option to purchase additional ADSs
Per ADS	\$	\$
Total	\$	\$

We estimate that the total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding the underwriting discounts and commissions, will be approximately \$. We have also agreed to reimburse the underwriters for certain of their expenses in an amount of up to \$.

A prospectus in electronic format may be made available on the web sites maintained by one or more underwriters, or selling group members, if any, participating in the offering. The underwriters may agree to allocate a number of ADSs to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters and selling group members that may make Internet distributions on the same basis as other allocations.

We have agreed that we will not (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, or submit to or file with the SEC a registration statement under the Securities Act relating to, any ordinary shares or ADSs or securities convertible into or exchangeable or exercisable for any of our ordinary shares or ADSs, or publicly disclose the intention to undertake any of the foregoing, or (ii) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of any ADSs, ordinary shares or any such other securities (regardless of whether any of the transactions described in clause (i) or (ii) above is to be settled by the delivery of ADSs, ordinary shares or such other securities, in cash or otherwise), without the prior written consent of J.P. Morgan Securities LLC and BofA Securities Inc. for a period of 180 days after the date of this prospectus, other than the ADSs to be sold hereunder and any of our ordinary shares or ADSs issued upon the exercise of options granted under our existing share-based compensation plans.

Our directors and executive officers, and substantially all of our shareholders, have entered into lock-up agreements with the underwriters prior to the commencement of this offering pursuant to which each of these persons or entities, with limited exceptions, for a period of 180 days after the date of this prospectus, may not, without the prior written consent of J.P. Morgan Securities LLC and BofA Securities, Inc., (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any of our ordinary shares or ADSs or any securities convertible into or exercisable or exchangeable for our ordinary shares (including, without limitation, ordinary shares, ADSs, restricted shares, share options or such other securities which may be deemed to be beneficially owned by such directors, executive officers, and shareholders in accordance with the rules and regulations of the SEC and securities which may be issued upon exercise of a stock option or warrant), or publicly disclose the intention to undertake any of the foregoing, (2) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the ADSs, ordinary shares or such other securities, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of ADSs, ordinary shares or such other securities, in cash or otherwise, or (3) make any demand for or exercise any right with respect to the registration of any of our ordinary shares or ADSs or any security convertible into or exercisable or exchangeable for ADSs or ordinary shares.

Notwithstanding the foregoing, the terms of the lock-up agreements do not apply to or prohibit, among others, the items described below:

- transactions relating to our ordinary shares or ADSs acquired in this initial public offering or open market transactions on or after the date of this prospectus, provided that no filing by any party (donor, donee, transferor or transferee) under the Exchange Act (or the equivalent thereof in non-U.S. jurisdictions) (other than a filing on a Schedule 13F or 13G) or other public announcement shall be required or shall be made voluntarily;
- the exercise of a warrant or the exercise of a stock option granted under an existing or future stock incentive plan for our ordinary shares or ADSs through a “cashless” exercise;
- transfers or dispositions of our ordinary shares or ADSs in connection with the conversion of any security convertible or exercisable into securities in accordance with their terms (including the settlement of restricted stock units), provided that any such ordinary shares or ADSs received by such party shall be subject to the lock-up restrictions, and provided, further, that no public announcement or voluntary filing shall be made and if a filing by any party (donor, donee, transferor or transferee) under the Exchange Act (or the equivalent thereof in non-U.S. jurisdictions) is required to be made, such filing shall indicate that any disposition of ordinary shares or ADSs was made solely to us in connection with a conversion;
- transfers or dispositions of our ordinary shares or ADSs pursuant to (i) any outstanding equity award or any current or future employee benefit plan or (ii) any contractual arrangement that provides for the repurchase of the party subject to the lock-up restrictions or a right of first refusal with respect to transfers of such ordinary shares or ADSs, provided that no public announcement or voluntary filing shall be made and if a filing by any party (donor, donee, transferor or transferee) under the Exchange Act (or the equivalent thereof in non-U.S. jurisdictions) is required to be made, such filing shall indicate that any disposition of ordinary shares or ADSs was made solely to us;
- the establishment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of our ordinary shares or ADSs, provided that (i) such plan does not provide for the transfer of our ordinary shares and ADSs during the lock-up period and (ii) the entry into such plan is not publicly disclosed, included in any filings under the Exchange Act (or the equivalent thereof in non-U.S. jurisdictions) or otherwise, during the lock-up period; and
- pursuant to a bona fide third-party tender offer for all our outstanding ordinary shares or ADSs, merger, consolidation or other similar transaction approved by our Supervisory Board and made to all holders of our ordinary shares or ADSs involving a change of control (including, without limitation, the entering into of any lock-up, voting or similar agreement pursuant to which the party subject to the lock-up restrictions may agree to transfer, sell, tender or otherwise dispose of our ordinary shares or ADSs in connection with such transaction, or vote any ordinary shares or ADSs in favor of any such transaction), provided that in the event that such tender offer, merger, consolidation or other such transaction is not completed, such ordinary shares or ADSs shall remain subject to the lock-up restrictions.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act of 1933.

We have applied to have ADSs representing our ordinary shares approved for listing/quotation on the Nasdaq Global Select Market under the symbol “BNTX.”

In connection with this offering, the underwriters may engage in stabilizing transactions, which involves making bids for, purchasing and selling ADSs in the open market for the purpose of preventing or retarding a decline in the market price of the ADSs while this offering is in progress. These stabilizing transactions may include making short sales of the ADSs, which involves the sale by the underwriters of a greater number of ADSs than they are required to purchase in this offering, and purchasing ADSs on the open market to cover

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positions created by short sales. Short sales may be “covered” shorts, which are short positions in an amount not greater than the underwriters’ option to purchase additional ADSs referred to above, or may be “naked” shorts, which are short positions in excess of that amount. The underwriters may close out any covered short position either by exercising their option to purchase additional ADSs, in whole or in part, or by purchasing ADSs in the open market. In making this determination, the underwriters will consider, among other things, the price of ADSs available for purchase in the open market compared to the price at which the underwriters may purchase ADSs through the option to purchase additional ADSs. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the ADSs in the open market that could adversely affect investors who purchase in this offering. To the extent that the underwriters create a naked short position, they will purchase ADSs in the open market to cover the position.

The underwriters have advised us that, pursuant to Regulation M of the Securities Act of 1933, they may also engage in other activities that stabilize, maintain or otherwise affect the price of the ADSs, including the imposition of penalty bids. This means that if the representatives of the underwriters purchase ADSs in the open market in stabilizing transactions or to cover short sales, the representatives can require the underwriters that sold those shares as part of this offering to repay the underwriting discount received by them.

These activities may have the effect of raising or maintaining the market price of the ADSs or preventing or retarding a decline in the market price of the ADSs, and, as a result, the price of the ADSs may be higher than the price that otherwise might exist in the open market. If the underwriters commence these activities, they may discontinue them at any time. The underwriters may carry out these transactions on the Nasdaq Global Select Market, in the over-the-counter market or otherwise.

Prior to this offering, there has been no public market for the ADSs or our ordinary shares. The initial public offering price will be determined by negotiations between us and the representatives of the underwriters. In determining the initial public offering price, we and the representatives of the underwriters expect to consider a number of factors including:

- the information set forth in this prospectus and otherwise available to the representatives;
- our prospects and the history and prospects for the industry in which we compete;
- an assessment of our management;
- our prospects for future earnings;
- the general condition of the securities markets at the time of this offering;
- the recent market prices of, and demand for, publicly traded common stock of generally comparable companies; and
- other factors deemed relevant by the underwriters and us.

Neither we nor the underwriters can assure investors that an active trading market will develop in the United States for the ADSs, or that the ADSs will trade in the public market at or above the initial public offering price.

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Certain of the underwriters and their affiliates have provided in the past to us and our affiliates and may provide from time to time in the future certain commercial banking, financial advisory, investment banking and other services for us and such affiliates in the ordinary course of their business, for which they have received and may continue to receive customary fees and commissions. In addition, from time to time, certain of the underwriters and their affiliates may effect transactions for their own account or the account of customers, and hold on behalf of themselves or their customers, long or short positions in our debt or equity securities or loans, and may do so in the future.

Notice to Prospective Investors in the European Economic Area

No offer of ordinary shares or ADSs may be made to the public in any member state of the European Economic Area, or an EEA Member State, other than:

- A. to any legal entity which is a qualified investor as defined in the Regulation (EU) 2017/1129 on the prospectus to be published when securities are offered to the public or admitted to trading on a regulated market and repealing Directive 2003/71/EC, or the Prospectus Regulation;
- B. to fewer than 150 natural or legal persons per EEA Member State (other than qualified investors as defined in the Prospectus Regulation), as permitted under the Prospectus Regulation, subject to obtaining the prior consent of the representatives of the underwriters for any such offer; or
- C. in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of ordinary shares or ADSs shall require the Company or the representatives to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

Each person in an EEA Member State who initially acquires any ADSs or to whom any offer is made will be deemed to have represented, acknowledged and agreed that it is a “qualified investor” as defined in Article 2(e) of the Prospectus Regulation. In the case of any ADSs being offered to a financial intermediary as that term is used in Article 5 of the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the ADSs acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any ADSs to the public other than their offer or resale in an EEA Member State to qualified investors as so defined or in circumstances in which the prior consent of the representatives has been obtained to each such proposed offer or resale.

This prospectus has been prepared on the basis that any offer of ordinary shares or ADSs in any EEA Member State will be made pursuant to an exemption under the Prospectus Regulation from the requirement to publish a prospectus for offers of securities. Accordingly any person making or intending to make an offer in an EEA Member State of ADSs which are the subject of the offering contemplated in this prospectus may only do so in circumstances in which no obligation arises for the Company or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Regulation in relation to such offer. Neither the Company nor the underwriters have authorized, nor do they authorize, the making of any offer of ordinary shares or ADSs in circumstances in which an obligation arises for the Company or the underwriters to publish a prospectus for such offer.

For the purpose of the above provisions, the expression “an offer to the public” in relation to any ordinary shares or ADSs in any EEA Member State means a communication to persons in any form and by any means, presenting sufficient information on the terms of the offer and the ordinary shares or ADSs to be offered, including any placing of ordinary shares or ADSs through financial intermediaries.

Notice to Prospective Investors in the United Kingdom

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are “qualified investors” (as defined in the

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Prospectus Directive) (i) who have professional experience in matters relating to investments falling within Article 19 (5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the “Order”) and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as “relevant persons”).

Any person in the United Kingdom that is not a relevant person should not act or rely on the information included in this document or use it as basis for taking any action. In the United Kingdom, any investment or investment activity that this document relates to may be made or taken exclusively by relevant persons. Any person in the United Kingdom that is not a relevant person should not act or rely on this document or any of its contents.

Notice to Prospective Investors in Canada

The ADSs may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the ADSs must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser’s province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser’s province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Notice to Prospective Investors in Switzerland

The ADSs may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document, nor any other offering or marketing material relating to the ADSs or this offering, may be publicly distributed or otherwise made publicly available in Switzerland. Neither this document nor any other offering or marketing material relating to this offering, the Company or the ADSs has been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of the ADSs will not be supervised by, the Swiss Financial Market Supervisory Authority, or FINMA, and the offer of the ADSs has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of ADSs.

Notice to Prospective Investors in Hong Kong

The ADSs may not be offered or sold by means of any document other than (i) in circumstances that do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong),

(ii) to “professional investors” within the meaning of the Securities and Futures Ordinance (Cap.571, Laws of Hong Kong) and any rules made thereunder, or (iii) in other circumstances that do not result in the document being a “prospectus” within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong), and no advertisement, invitation or document relating to the ADSs may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to ADSs that are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder.

Notice to Prospective Investors in Japan

The securities have not been and will not be registered under the Financial Instruments and Exchange Law of Japan, or the Financial Instruments and Exchange Law, and each underwriter has agreed that it will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term, as used in this prospectus means any person resident in Japan, including any corporation or other entity organized under the laws of Japan) or to others for re-offering or resale, directly or indirectly, in Japan or to a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Law and any other applicable laws, regulations and ministerial guidelines of Japan.

Notice to Prospective Investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of ADSs may not be circulated or distributed, nor may the ADSs be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the “SFA”), (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the ADSs are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries’ rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the ADSs pursuant to an offer made under Section 275 of the SFA except:

- to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- where no consideration is or will be given for the transfer;
- where the transfer is by operation of law;
- as specified in Section 276(7) of the SFA; or
- as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

Notice to Prospective Investors in the United Arab Emirates

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority, or DFSA. This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for this prospectus. The ADSs to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the ADSs offered should conduct their own due diligence on the ADSs. If you do not understand the contents of this prospectus, you should consult an authorized financial advisor.

Notice to Prospective Investors in Israel

This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968, and has not been filed with or approved by the Israel Securities Authority. In Israel, this prospectus is being distributed only to, and is directed only at, and any offer of the ADSs is directed only at (i) a limited number of persons in accordance with the Israeli Securities Law and (ii) investors listed in the first addendum, or the Addendum, to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and “qualified individuals,” each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case, purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors are required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

EXPENSES OF THE OFFERING

The following table sets forth the total costs and expenses, other than underwriting discounts and commissions, that we expect to incur in connection with the offer and sale of our ADSs. With the exception of the SEC registration fee, the Nasdaq listing fee and the FINRA filing fee, all of these amounts are estimates:

<u>Expenses</u>	<u>Amount</u>
Securities and Exchange Commission registration fee	*
Nasdaq listing fee	*
FINRA filing fee	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Miscellaneous costs	*
Total	\$ *

* To be provided by amendment.

LEGAL MATTERS

The validity of the ADSs and certain other matters of German law will be passed upon for us by Freshfields Bruckhaus Deringer LLP, Hamburg, Germany. Certain matters of U.S. law will be passed upon for us by Covington & Burling LLP, New York, New York. Legal counsel to the underwriters in connection with the offering are Skadden, Arps, Slate, Meagher & Flom LLP, Frankfurt, Germany with respect to German law and Davis Polk & Wardwell LLP, New York, New York with respect to U.S. law.

CHANGE IN ACCOUNTANTS

In 2018, we dismissed Baker Tilly GmbH & Co. KG Wirtschaftsprüfungsgesellschaft, or Baker Tilly, as our independent auditors and retained Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft, or EY, as our independent public accounting firm. Our Supervisory Board approved the decision to change independent auditors. We had no disagreements with Baker Tilly on any matter of accounting principles or practices, financial statements disclosure, or auditing scope of procedures during our two most recent fiscal years prior to our change in independent auditors, which, if not resolved to the satisfaction of Baker Tilly, would have caused them to make reference to the matter in their report.

EXPERTS

The consolidated financial statements of BioNTech SE as of December 31, 2018 and 2017 and for each of the years in the two-year period ended December 31, 2018 have been included herein in reliance upon the report of Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft, independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of said firm as experts in accounting and auditing. The registered business address of Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft is Börsenplatz 1, 50667 Cologne, Germany.

SERVICE OF PROCESS AND ENFORCEMENT OF LIABILITIES

We are incorporated and currently existing under European laws and the laws of the Federal Republic of Germany. In addition, all of our directors and officers reside outside of the United States and our assets and those of our non-U.S. subsidiaries are located outside of the United States. As a result, it may not be possible for investors to effect service of process on us or those persons in the United States or to enforce in the United States judgments obtained in U.S. courts against us or those persons based on the civil liability or other provisions of the U.S. securities laws or other laws.

Awards of punitive damages in actions brought in the United States or elsewhere may be unenforceable in Germany. In addition, actions brought in a German court against BioNTech or the members of our supervisory board and management board, our senior management and the experts named herein to enforce liabilities based on U.S. federal securities laws may be subject to certain restrictions; in particular, German courts generally do not award punitive damages. An award for monetary damages under the U.S. securities laws would be considered punitive if it does not seek to compensate the claimant for loss or damage suffered and is intended to punish the defendant. The enforceability of any judgment in Germany will depend on the particular facts of the case as well as the laws and treaties in effect at the time.

Litigation in the Federal Republic of Germany is also subject to rules of procedure that differ from the U.S. rules, including with respect to the taking and admissibility of evidence, the conduct of the proceedings and the allocation of costs. Proceedings in Germany would have to be conducted in the German language, and all documents submitted to the court would, in principle, have to be translated into German. For these reasons, it

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may be difficult for a U.S. investor to bring an original action in a German court predicated upon the civil liability provisions of the U.S. federal securities laws against us, certain members of our management and supervisory boards and senior management and the experts named in this prospectus. The United States and Germany do not currently have a treaty providing for recognition and enforcement of judgments (other than arbitration awards) in civil and commercial matters, though recognition and enforcement of foreign judgments in Germany is possible in accordance with applicable German laws. Even if a judgment against our company, the members of our management board, supervisory board, senior management or the experts named in this prospectus based on the civil liability provisions of the U.S. federal securities laws is obtained, a U.S. investor may not be able to enforce it in U.S. or German courts.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form F-1 under the Securities Act relating to this offering of our ADSs. This prospectus, which constitutes part of the registration statement, does not include all of the information contained in the registration statement and the exhibits, schedules and amendments to the registration statement. For further information with respect to us and our ordinary shares and ADSs, we refer you to the registration statement and the exhibits and schedules to the registration statement. Statements made in this prospectus concerning the contents of any contract, agreement or other document are summaries of all material information about the documents summarized, but are not complete descriptions of all terms of these documents. If we file any of these documents as an exhibit to the registration statement, we refer you to the copy of the document that has been filed for a complete description of its terms. Each statement in this prospectus relating to a document filed as an exhibit is qualified in all respects by the filed exhibit.

Upon completion of this offering, we will become subject to the information reporting requirements of the Exchange Act that are applicable to foreign private issuers. Accordingly, we will be required to file reports and other information with the SEC, including annual reports on Form 20-F and reports on Form 6-K. Our filings with the SEC are available to the public through the SEC's website at <http://www.sec.gov>.

As a foreign private issuer, we are exempt under the Exchange Act from, among other things, the rules prescribing the furnishing and content of proxy statements, and our board members, executive officers and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we will not be required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act.

We will send our transfer agent a copy of all notices of our general meetings of shareholders and other reports, communications and information that are made generally available to shareholders. The transfer agent has agreed to mail to all shareholders a notice containing the information (or a summary of the information) contained in any notice of a meeting of our shareholders received by the transfer agent and will make available to all shareholders such notices and all such other reports and communications received by the transfer agent.

We maintain a corporate website at <https://www.biontech.de>. Information contained on, or that can be accessed through, our website does not constitute a part of this prospectus and our website address is included in this prospectus as an inactive textual reference only.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Management and the Board of Directors of BioNTech SE (formerly BioNTech AG)

Opinion on the Financial Statements

We have audited the accompanying consolidated statements of financial position of BioNTech AG (the Company) as of December 31, 2018 and 2017 and as of January 1, 2017, the related consolidated statements of operations, comprehensive income (loss), changes in equity and cash flows for each of the two years in the period ended December 31, 2018, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017 and as of January 1, 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2018, in conformity with International Financial Reporting Standards as issued by the International Accounting Standard Board.

Basis for Opinion

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Titus Zwirner
Wirtschaftsprüfer
(German Public Auditor)

/s/ Oliver Conrad
Wirtschaftsprüfer
(German Public Auditor)

Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft

We have served as the Company’s auditor since 2018.

Cologne, Germany
June 18, 2019

[Table of Contents](#)**BioNTech AG****Consolidated Statements of Operations**

(in thousands, except share and per share data)

	Note	Year ended December 31,	
		2018	2017
Revenues from contracts with customers	4	€ 127,575	€ 61,598
Cost of sales	6.1	(13,690)	(9,318)
Gross profit		113,885	52,280
Research and development expenses	6.2	(143,040)	(85,496)
Sales and marketing expenses	6.3	(3,041)	(6,603)
General and administrative expenses	6.4	(26,334)	(23,520)
Other operating income	6.5	5,396	2,349
Other operating expenses	6.6	(720)	(288)
Operating loss		(53,854)	(61,277)
Finance income	6.7	8,046	2,133
Finance expense	6.8	(48)	(26,007)
Interest expense related to lease liability	19	(1,721)	(676)
Share of loss of equity method investees	5	(84)	(78)
Loss before tax		(47,662)	(85,905)
Income taxes	7	(600)	(45)
Loss for the year		€ (48,262)	€ (85,950)
Attributable to:			
Equity holders of the parent		(48,019)	(85,653)
Non-controlling interests		(243)	(297)
		€ (48,262)	€ (85,950)
Earnings per share			
Basic & diluted, loss for the year attributable to ordinary equity holders of the parent	8	€ (4.53)	€ (9.28)

The accompanying notes form an integral part of these financial statements.

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BioNTech AG
Consolidated statements of comprehensive income (loss)
(in thousands)

	Note	Year ended December 31,	
		2018	2017
Loss for the year		€(48,262)	€(85,950)
Other comprehensive income			
<i>Other comprehensive income that may be reclassified to profit or loss in subsequent periods (net of tax)</i>			
Exchange differences on translation of foreign operations		10	(23)
Net other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods		10	(23)
Other comprehensive income/(loss) for the year, net of tax		10	(23)
Comprehensive loss for the year, net of tax		(48,252)	(85,973)
Attributable to:			
Equity holders of the parent		(48,009)	(85,677)
Non-controlling interests		(243)	(297)
Comprehensive loss for the year, net of tax		€(48,252)	€(85,973)

The accompanying notes form an integral part of these financial statements.

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BioNTech AG
Consolidated statements of financial position
(in thousands)

<u>Assets</u>	<u>Note</u>	<u>As at December 31, 2018</u>	<u>As at December 31, 2017</u>	<u>As at January 1, 2017</u>
Non-current assets				
Intangible assets	10	€ 88,042	€ 83,537	€ 11,184
Property, plant and equipment	9, 18	115,966	101,521	60,506
Other assets		—	—	78
Other financial assets		18	19	66
Total non-current assets		€ 204,025	€ 185,076	€ 71,834
Current assets				
Inventories	12	5,789	3,876	3,266
Trade receivables	13	18,938	4,575	3,161
Contract assets	4	—	—	637
Other financial assets	11	336	246	1,528
Other assets	14	9,164	6,227	4,699
Income tax assets	7	891	687	2
Deferred expense		2,348	1,872	1,153
Cash and cash equivalents	11	411,495	172,106	303,680
Total current assets		448,961	189,637	318,125
Total assets		€ 652,986	€ 374,713	€ 389,959
Equity and liabilities				
Equity				
Share capital	15	€ 10,739	€ 9,265	€ 182
Capital reserve		526,672	166,421	175,504
Accumulated losses		(245,771)	(197,753)	(112,100)
Other reserves		(25,487)	(27,229)	(33,115)
Equity attributable to equity holders of the parent		€ 266,153	€ (49,296)	€ 30,471
Non-controlling interest		847	1,090	1,387
Total equity		€ 267,000	€ (48,206)	€ 31,858
Non-current liabilities				
Financial liabilities	11	54,218	50,349	26,669
Other liabilities	17	—	—	1,383
Contract liabilities	4	205,647	214,026	273,414
Total non-current liabilities		€ 259,865	€ 264,375	€ 301,466
Current liabilities				
Tax provisions		297	—	—
Provisions		710	118	120
Trade payables	17	41,721	52,538	6,218
Contract liabilities	4	66,027	77,346	33,466
Other financial liabilities	11	8,266	3,771	12,765
Other liabilities	17	9,100	24,771	4,067
Total current liabilities		€ 126,121	€ 158,544	€ 56,636
Total liabilities		€ 385,986	€ 422,920	€ 358,102
Total equity and liabilities		€ 652,986	€ 374,713	€ 389,959

The accompanying notes form an integral part of these financial statements.

BioNTech AG
Consolidated statements of changes in equity
(in thousands)

	Note	Attributable to the equity holders of the parent				Foreign currency translation reserve	Total	Non-controlling interests	Total equity
		Issued capital	Capital reserve	Accumulated losses	Other reserves				
As at January 1, 2018		€ 9,265	166,421	(197,753)	(27,206)	(23)	(49,296)	1,090	(48,206)
Loss for the year		—	—	(48,019)	—	—	(48,019)	(243)	(48,262)
Other comprehensive income		—	—	—	—	10	10	—	10
Total comprehensive income		—	—	(48,019)	—	10	(48,009)	(243)	(48,252)
Issuance of share capital	15	1,442	354,374	—	—	—	355,816	—	355,816
Share-based payments	16	—	—	—	7,641	—	7,641	—	7,641
Settlement of share-based payment plan		32	5,877	—	(5,909)	—	—	—	—
At December 31, 2018		€10,739	526,672	(245,771)	(25,474)	(13)	266,153	847	270,000

	Notes	Attributable to the equity holders of the parent				Foreign currency translation reserve	Total	Non-controlling interests	Total equity
		Issued capital	Capital reserve	Accumulated losses	Other reserves				
As at January 1, 2017		€ 182	175,504	(112,100)	(33,115)	—	30,471	1,387	31,858
Loss for the year		—	—	(85,653)	—	—	(85,653)	(297)	(85,950)
Other comprehensive income		—	—	—	—	(23)	(23)	—	(23)
Total comprehensive income		—	—	(85,653)	—	(23)	(85,676)	(297)	(85,973)
Issuance of share capital	15	9,083	(9,083)	—	—	—	—	—	—
Share-based payments	16	—	—	—	5,909	—	5,909	—	5,909
At December 31, 2017		€9,265	166,421	(197,753)	(27,206)	(23)	(49,296)	1,090	(48,206)

The accompanying notes form an integral part of these financial statements.

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BioNTech AG
Consolidated statements of cash flows
(in thousands)

	Year ended December 31,	
	2018	2017
Operating activities		
Loss for the year	€ (48,262)	€ (85,950)
Income taxes	600	45
Loss before tax	€ (47,662)	€ (85,905)
Adjustments to reconcile loss before tax to net cash flows:		
Depreciation and amortization of property, plant and equipment and intangible assets	21,984	10,529
Share-based payment expense	7,641	5,909
Net foreign exchange differences	459	24,820
Gain/(Loss) on disposal of property, plant and equipment	(14)	15
Finance income	(1,996)	(2,133)
Interest on lease liability	1,721	676
Finance expense	48	53
Share of loss of an associate and a joint venture	84	78
Movements in provisions	592	(2)
Working capital adjustments:		
Decrease/(Increase) in trade receivable and contract assets	(18,732)	(2,816)
Decrease/(Increase) in inventories	(1,253)	(574)
(Decrease)/Increase in trade and other payables, contract liabilities and refund liabilities	(20,976)	(4,572)
Interest received	1,996	2,133
Interest paid	(1,769)	(729)
Income tax paid	(304)	(45)
Net cash flows used in operating activities	€ (58,180)	€ (52,562)
Investing activities		
Purchase of property, plant and equipment	(30,598)	(24,320)
Proceeds from sale of property, plant and equipment	705	5,193
Purchase of intangible assets	(37,256)	(33,422)
Net cash flows used in investing activities	€ (67,148)	€ (52,549)
Financing activities		
Proceeds from issuance of share capital	361,725	—
Proceeds from loans and borrowings	5,600	—
Payment of finance lease liabilities	(2,148)	(1,643)
Net cash flows from/(used in) financing activities	€ 365,177	€ (1,643)
Net increase/(decrease) in cash and cash equivalents	239,848	(106,753)
Change in cash resulting from exchange rate differences	(459)	(24,820)
Cash and cash equivalents at 1 January	172,106	303,680
Cash and cash equivalents at 31 December	€ 411,495	€ 172,106

The accompanying notes form an integral part of these financial statements.

BioNTech AG

Notes to the financial statements

1 Corporate Information

BioNTech AG is a limited company incorporated and domiciled in Germany. Its shares are not publicly traded. The registered office is located in Mainz, An der Goldgrube 12, 55131 Germany. The accompanying International Financial Reporting Standards (IFRS) consolidated financial statements present the financial position and the results of operation of BioNTech AG and its subsidiaries, hereinafter also referred to as “BioNTech” or the “Group”. Effective March 8, 2019, BioNTech AG changed its name and legal form to BioNTech SE. The Group is principally engaged in developing innovative immunotherapies for the individualized treatment of cancer and other infectious diseases.

Information on the Group’s structure is provided in Note 5. Information on other related party relationships of the Group is provided in Note 26.

The consolidated financial statements of the Group for the year ended December 31, 2018 were authorized for issue in accordance with a resolution of the directors on June 18, 2019.

BioNTech prepares and publishes its consolidated financial statements in Euros. Unless otherwise stated, the numbers are rounded to thousands of Euros.

2 Significant accounting policies

2.1 Basis of preparation

The consolidated financial statements have been prepared on a going concern basis in accordance with the IFRS as issued by the International Accounting Standards Board (IASB).

BioNTech adopted IFRS for the first time on January 1, 2017 and therefore, an additional statement of financial position as of January 1, 2017 is presented in these consolidated financial statements due to the first-time adoption of IFRS.

2.2 Basis of consolidation

The consolidated financial statements comprise the financial statements of the Company and its controlled investees (subsidiaries) as at December 31, 2018.

The Group controls an investee if, and only if, the Group has

- power over the investee (*i.e.*, existing rights that give it the current ability to direct the relevant activities of the investee);
- exposure, or rights, to variable returns from its involvement with the investee; and
- the ability to use its power over the investee to affect its returns.

Generally, there is a presumption that a majority of voting rights results in control.

The Group re-assesses whether it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control. Consolidation of a subsidiary begins when the Group obtains control over the subsidiary and ceases when the Group loses control of the subsidiary. Assets, liabilities, income and expenses of a subsidiary acquired or disposed of during the year are included in the consolidated financial statements from the date the Group gains control of the subsidiary until the date the Group ceases to control the subsidiary.

The statement of profit or loss and each component of other comprehensive income are attributed to the equity holders of the parent of the Group and to the non-controlling interests, even if this results in the non-controlling interests having a deficit balance. When necessary, adjustments are made to the financial statements of subsidiaries to bring their accounting policies in line with the Group's accounting policies. All intra-group assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated in full on consolidation.

A change in the ownership interest of a subsidiary, without a loss of control, is accounted for as an equity transaction.

If the Group loses control over a subsidiary, it derecognizes the related assets (including goodwill), liabilities, non-controlling interests and other components of equity, while any resultant gain or loss is recognized in the statement of profit or loss. Any investment retained is recognized at fair value.

2.3 Summary of significant accounting policies

2.3.1 Business combinations and goodwill

Business combinations are accounted for using the acquisition method. The cost of an acquisition is measured as the aggregate of the consideration transferred, which is measured at acquisition date fair value, and the amount of any non-controlling interests in the acquiree.

Goodwill is initially measured at cost as the excess of the aggregate of the consideration transferred and the amount recognized for non-controlling interests and any previous interest held over the net identifiable assets acquired and liabilities assumed.

After initial recognition, goodwill is tested at least annually or when there is an indication for impairment. See Note 2.3.13.

2.3.2 Current versus non-current classifications

The Group presents assets and liabilities in the consolidated statements of financial position based on current or non-current classification. An asset is current when it is either: (i) expected to be realized within 12 months after the reporting period or (ii) cash or cash equivalents, unless it is restricted from being exchanged or used to settle a liability for at least 12 months after the reporting period. All other assets are classified as non-current. A liability is current when it is due to be settled within 12 months after the reporting period. The Group classifies all other liabilities as non-current.

Deferred tax assets and liabilities are classified as non-current assets and liabilities, respectively.

2.3.3 Fair value measurement

Fair value is a market-based measurement. For some assets and liabilities, observable market transactions or market information is available. For other assets and liabilities, observable market transactions or market information might not be available. When a price for an identical asset or liability is not observable, another valuation technique is used. To increase consistency and comparability in fair value measurements, there are three levels of the fair value hierarchy:

- Level 1 contains the use of quoted prices in active markets for identical assets or liabilities.
- Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability either directly or indirectly.
- Level 3 inputs are unobservable.

Within this hierarchy, estimated values are made by management based on reasonable assumptions, including other fair value methods.

For assets and liabilities that are recognized in the financial statements at fair value on a recurring basis, the Group determines whether transfers have occurred between levels in the fair value hierarchy by re-assessing categorization (based on the lowest level input that is significant to the fair value measurement as a whole) at the end of each reporting period.

For the purpose of fair value disclosures, the Group has determined classes of assets and liabilities on the basis of the nature, characteristics and risks of the asset or liability and the level of the fair value hierarchy, as explained above.

2.3.4 Revenue from contracts with customers

Adoption of IFRS 15

In applying IFRS 15 effective January 1, 2017, the Group has used the following practical expedients permitted by the standard:

- for completed contracts that have variable consideration, the transaction price at the date the contract was completed was used rather than estimating variable consideration amounts; and
- for contracts that were modified before the beginning of the earliest period presented, the aggregate effect of all of the modifications that occurred before the beginning of the earliest period presented were reflected.

Revenue recognition

Revenue from contracts with customers is recognized when control of the goods or services are transferred to the customer at an amount that reflects the consideration to which BioNTech expects to be entitled in exchange for those goods or services. If a contract with a customer contains more than one performance obligation, the transaction price is allocated to each performance obligation on a relative-stand-alone selling price basis. BioNTech has generally concluded that it acts as the principal in its revenue arrangements because it typically controls the goods or services before transferring them to the customer. The following is a description of these activities.

Revenue from collaboration and license agreements

BioNTech generates revenues from collaboration and license agreements under which BioNTech grants licenses to use, research, develop, manufacture and commercialize product candidates and products. If the grant of a license is bundled together with the rendering of services, it is assessed whether these agreements are comprised of more than one performance obligation. A performance obligation is only accounted for as the grant of a license if the grant of a license is the sole or the predominant promise of the performance obligation. For each promise to grant a license that is a separate performance obligation, it is considered whether control is transferred to a licensee either at a point in time or over time. Under the terms of its licensing arrangements, BioNTech provides the licensee with a right to access BioNTech's intellectual property as it exists throughout the license period (as BioNTech's intellectual property is still subject to further research). Therefore, the promise to grant a license is accounted for as a performance obligation satisfied over time, as the licensee simultaneously receives and consumes the benefits of BioNTech's performance.

If the consideration in an agreement includes a variable amount, BioNTech estimates the amount of consideration to which BioNTech will be entitled in exchange for transferring the goods to the customer. At contract inception, the variable consideration is estimated based on the most likely amount of consideration

expected from the transaction and constrained until it is highly probable that a significant revenue reversal in the amount of cumulative revenue recognized will not occur when the associated uncertainty with respect the variable consideration is subsequently resolved. The estimated deferred revenue is updated at each reporting date to reflect the current facts and circumstances.

Rendering of services

BioNTech provides development and manufacturing services to customers and recognizes revenue over time using an input-based method to measure progress toward complete satisfaction of the services because the customer simultaneously receives and consumes the benefits provided by BioNTech. If BioNTech has a right to consideration from a customer in the amount that corresponds directly with the value to the customer of BioNTech's performance completed to date (for example, service contracts in which BioNTech bills a fixed amount for each hour or day of service provided), BioNTech recognizes revenue in the amount for which BioNTech has a right to invoice the customer.

Sale of products

Revenue from the sale of medical products (*e.g.*, peptides and retroviral vectors for clinical supply) is recognized when BioNTech transfers control of the product to the customer. Control of the product normally transfers when the customer gains physical possession and BioNTech has not retained any significant risks of ownership or future obligations with respect to the product. A receivable is recognized, as the consideration is unconditional and only the passage of time is required before payment is due. The transaction price is quoted in the relevant price lists in force at the date of customer placing the respective order for such products. Payments from customers are due within 20 days (Europe) or 30 days (non-Europe) after invoice.

Contract balances

Contract assets

A contract asset is the right to consideration in exchange for goods or services transferred to the customer. If BioNTech performs by transferring goods or services to a customer before the customer pays consideration or before payment is due, a contract asset is recognized for the earned consideration that is conditional.

Trade receivables

A receivable represents BioNTech's right to an amount of consideration that is unconditional (*i.e.*, only the passage of time is required before payment of the consideration is due).

Contract liabilities

A contract liability is the obligation to transfer goods or services to a customer for which BioNTech has received consideration (or an amount of consideration is due) from the customer. If a customer pays consideration before BioNTech transfers goods or services to the customer, a contract liability is recognized when the payment is made or when the payment is due (whichever is earlier). Contract liabilities are recognized as revenue when BioNTech performs under the contract.

2.3.5 Government grants

Government grants are recognized where there is reasonable assurance that the grant will be received and all attached conditions will be complied with. When the grant relates to an expense item, it is recognized as income on a systematic basis over the periods that the related costs, for which the grant is intended to compensate, are expensed. When the grant relates to an asset, it is recognized as deduction in calculating the carrying amount of the asset and thus in the statement of profit or loss over the life of the depreciable asset as a reduced depreciation expense.

2.3.6 Taxes

Current income tax

Current income tax assets and liabilities are measured at the amount expected to be recovered from or paid to the taxation authorities. The tax rates and tax laws used to compute the amount are those that are enacted or substantively enacted at the reporting date in the countries where the Group operates and generates taxable income.

Management periodically evaluates positions taken in the tax returns with respect to situations in which applicable tax regulations are subject to interpretation and establishes provisions where appropriate.

Deferred tax

Deferred tax is provided using the liability method on temporary differences between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes at the reporting date.

Deferred tax liabilities are recognized for all taxable temporary differences, except:

- when the deferred tax liability arises from the initial recognition of goodwill or an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss; or
- in respect of taxable temporary differences associated with investments in subsidiaries, associates and interests in joint arrangements, when the timing of the reversal of the temporary differences can be controlled and it is probable that the temporary differences will not reverse in the foreseeable future.

Deferred tax assets are recognized for all deductible temporary differences, the carry forward of unused tax credits and any unused tax losses. Deferred tax assets are recognized to the extent that it is probable that taxable profit will be available against which the deductible temporary differences, the carry forward of unused tax credits and unused tax losses can be utilized, except:

- when the deferred tax asset relating to the deductible temporary difference arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss; or
- in respect of deductible temporary differences associated with investments in subsidiaries, associates and interests in joint arrangements, deferred tax assets are recognized only to the extent that it is probable that the temporary differences will reverse in the foreseeable future and taxable profit will be available against which the temporary differences can be utilized.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply in the year in which the asset is realized, or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted at the reporting date.

Deferred tax items are recognized in relation to the underlying transaction either in other comprehensive income or directly in equity.

The Group offsets deferred tax assets and deferred tax liabilities only if it has a legally enforceable right to set off current tax assets and current tax liabilities and the deferred tax assets and deferred tax liabilities relate to income taxes levied by the same taxation authority on either (i) the same taxable entity or (ii) different taxable entities which intend either to settle current tax liabilities and assets on a net basis, or to realize the assets and settle the liabilities simultaneously, in each future period in which significant amounts of deferred tax liabilities or assets are expected to be settled or recovered.

Sales tax

Expenses and assets are recognized net of sales tax, except when the sales tax incurred on a purchase of assets or services is not recoverable from the taxation authority.

The net amount of sales tax recoverable from, or payable to, the taxation authority is included as part of receivables or payables in the statement of financial position.

2.3.7 Foreign currencies

The Group's consolidated financial statements are presented in Euros, which is also the parent company's functional currency. For each entity, the Group determines the functional currency, and items included in the financial statements of such entity are measured using that functional currency. The Group uses the direct method of consolidation and on disposal of a foreign operation, the gain or loss that is reclassified to the statement of profit or loss reflects the amount that arises from using this method.

Transactions and balances

Transactions in foreign currencies are initially recorded by the Group's entities at their respective functional currency spot rates at the date the transaction first qualifies for recognition.

Monetary assets and liabilities denominated in foreign currencies are translated at the functional currency spot rates of exchange at the reporting date.

Non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rates at the dates of the initial transactions.

In determining the spot exchange rate to use on initial recognition of the related asset, expense or income (or part of it) on the derecognition of a non-monetary asset or non-monetary liability relating to advance consideration, the date of the transaction is the date on which the Group initially recognizes the non-monetary asset or non-monetary liability arising from the advance consideration. If there are multiple payments or receipts in advance, the Group determines the transaction date for each payment or receipt of advance consideration.

Foreign currency translation

On consolidation, the assets and liabilities of foreign operations are translated into Euros at the rate of exchange prevailing at the reporting date and their statements of profit or loss are translated at exchange rates prevailing at the dates of the transactions.

The exchange differences arising on translation for consolidation are recognized in other comprehensive income. On disposal of a foreign operation, the component of other comprehensive income relating to that particular foreign operation is reclassified to profit or loss.

Any goodwill arising on the acquisition of a foreign operation and any fair value adjustments to the carrying amounts of assets and liabilities arising upon the acquisition are treated as assets and liabilities of the foreign operation and translated at the spot rate of exchange at the reporting date.

2.3.8 Property, plant and equipment

Construction in progress is stated at cost, net of accumulated impairment losses, if any. Property, plant and equipment are stated at cost, net of accumulated depreciation and accumulated impairment losses, if any. Such cost includes the cost of replacing part of the property, plant and equipment if the recognition criteria are met. All other repair and maintenance costs are expensed as incurred.

Depreciation is calculated on a straight-line basis over the estimated useful lives of the assets, as follows:

<u>Property, plant and equipment</u>	<u>Useful life (years)</u>
Buildings	7-33
Equipment, tools and installations	3-15

An item of property, plant and equipment initially recognized is derecognized upon disposal (*i.e.*, at the date the recipient obtains control) or when no future economic benefits are expected from its use or disposal. Any gain or loss arising on derecognition of the asset (calculated as the difference between the net disposal proceeds and the carrying amount of the asset) is included in the statement of profit or loss when the asset is derecognized.

The residual values, useful lives and methods of depreciation of property, plant and equipment are reviewed at each financial year end and adjusted prospectively, if appropriate.

2.3.9 Leases

The Group adopted IFRS 16 Leases for annual periods beginning on January 1, 2017.

At the inception of a contract, the Group assesses whether the contract is, or contains, a lease. A contract is, or contains, a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. To assess whether a contract conveys the right to control the use of an identified asset, the Group assesses whether:

- the contract involves the use of an identified asset—this may be specified explicitly or implicitly and should be physically distinct or represent substantially all of the capacity of a physically distinct asset. If the supplier has a substantive substitution right, then the asset is not identified;
- the Group has the right to obtain substantially all of the economic benefits from use of the asset throughout the period of use; and
- the Group has the right to direct the use of the asset. The Group has this right when it has the decision-making rights that are most relevant to changing how and for what purpose the asset is used. In rare cases where the decision about how and for what purpose the asset is used is predetermined, the Group has the right to direct the use of the asset if either:
 - the Group has the right to operate the asset; or
 - the Group designed the asset in a way that predetermines how and for what purpose it will be used.

At inception or on reassessment of a contract that contains a lease component, the Group allocates the consideration in the contract to each lease component on the basis of their relative stand-alone prices. However, for the leases of land and buildings in which it is a lessee, the Group has elected not to separate non-lease components, and instead accounts for the lease and non-lease components as a single lease component.

The Group recognizes a right-of-use asset and a lease liability at the lease commencement date. The right-of-use asset is initially measured at cost, which comprises the initial amount of the lease liability adjusted for any lease payments made at or before the commencement date, plus any initial direct costs incurred and an estimate of the costs to dismantle and remove the underlying asset or to restore the underlying asset or the site on which it is located, less any lease incentives received by the Group.

The right-of-use asset is subsequently depreciated using the straight-line method from the commencement date to the earlier of the end of the useful life of the right-of-use asset and the end of the lease term. The estimated useful lives of right-of-use assets are determined on the same basis as those of property and equipment. In addition, the right-of-use asset is periodically reduced by impairment losses, if any, and adjusted for certain remeasurements of the lease liability.

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The lease liability is initially measured at the present value of the lease payments that are not paid at the commencement date, discounted using the interest rate implicit in the lease or, if that rate cannot be readily determined, the Group's incremental borrowing rate. Generally, the Group uses its incremental borrowing rate as the discount rate.

Lease payments included in the measurement of the lease liability comprise the following:

- fixed payments, including in-substance fixed payments;
- variable lease payments that depend on an index or a rate, initially measured using the index or rate as of the commencement date;
- amounts expected to be payable under a residual value guarantee; and
- the exercise price under a purchase option that the Group is reasonably certain to exercise, lease payments in an optional renewal period if the Group is reasonably certain to exercise an extension option, and penalties for early termination of a lease unless the Group is reasonably certain not to terminate early.

The lease liability is measured at amortized cost using the effective interest method. It is remeasured when there is a change in future lease payments arising from a change in an index or rate, if there is a change in the Group's estimate of the amount expected to be payable under a residual value guarantee, or if the Group changes its assessment of whether it will exercise a purchase, extension or termination option. When the lease liability is remeasured, a corresponding adjustment is made to the carrying amount of the right-of-use asset or is recorded in the statement of profit or loss if the carrying amount of the right-of-use asset has been reduced to zero.

The Group presents right-of-use assets in 'property, plant and equipment' and lease liabilities in 'financial liabilities' in the statement of financial position.

Depreciation is calculated on a straight-line basis over the estimated useful lives of the assets or shorter lease term, as follows:

<u>Right-of-use assets</u>	<u>Useful life (Years)</u>
Buildings	1-25
Equipment, tools and installations	2-5
Automobiles	3-4

Short-term leases and leases of low-value assets

The Group has elected not to recognize right-of-use assets and lease liabilities for short-term leases of machinery that have a lease term of 12 months or less or leases of low-value assets. The Group recognizes the lease payments associated with these leases as an expense in the statement of profit or loss on a straight-line basis over the lease term.

Adoption of IFRS 16

The right-of-use assets are measured at the amount equal to the lease liability, adjusted by the amount of any prepaid or accrued lease payments relating to that lease.

In applying IFRS 16 for the first time on January 1, 2017, the Group has used the following practical expedients permitted by the standard:

- the use of a single discount rate for a portfolio of leases with reasonably similar characteristics;

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- the accounting for operating leases with a remaining lease term of less than 12 months as at January 1, 2017 as short-term leases;
- the exclusion of initial direct costs for the measurement of the right-of-use asset at the date of initial application; and
- the use of hindsight in determining the lease term where the contract contains options to extend or terminate the lease.

2.3.10 Intangible assets

Intangible assets acquired separately are measured on initial recognition at cost. The cost of intangible assets acquired in a business combination is their fair value at the date of acquisition. Following initial recognition, intangible assets are carried at cost less any accumulated amortization and accumulated impairment losses.

The useful lives of intangible assets are assessed as either finite or indefinite.

Intangible assets with finite lives are amortized generally on a straight-line basis over the useful economic life and assessed for impairment whenever there is an indication that the intangible asset may be impaired. The amortization period and the amortization method for an intangible asset with a finite useful life are at least reviewed at the end of each reporting period. The amortization expense on intangible assets with finite lives is recognized in the statement of profit or loss in the expense category that is consistent with the function of the intangible assets.

A summary of the useful lives applied to the Group's intangible assets is as follows:

<u>Intangible assets</u>	<u>Useful life (years)</u>
Industrial property rights	10-20
Licenses	3-20

Intangible assets with indefinite useful lives are not amortized, but are tested for impairment annually, either individually or at the level of a cash-generating unit. The assessment of indefinite life is reviewed annually to determine whether the indefinite life continues to be supportable. If not, the change in useful life from indefinite to finite is made on a prospective basis.

The group has classified advanced payments on intangible assets as intangible assets with an indefinite useful life. Advanced payments on intangible assets are tested for impairment on an annual basis.

An intangible asset is derecognized upon disposal (*i.e.*, at the date the recipient obtains control) or when no future economic benefits are expected from its use or disposal. Any gain or loss arising upon derecognition of the asset (calculated as the difference between the net disposal proceeds and the carrying amount of the asset) is included in the statement of profit or loss.

Research and development costs

Research costs are expensed as incurred. Development expenditures on an individual project are recognized as an intangible asset when the Group can demonstrate:

- the technical feasibility of completing the intangible asset so that the asset will be available for use or sale;
- its intention to complete and its ability and intention to use or sell the asset;
- how the asset will generate future economic benefits;

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- the availability of resources to complete the asset; and
- the ability to reliably measure the expenditure during development.

The Group has not capitalized any development expenditures. The related expenditure is reflected in the statement of profit or loss in the period in which the expenditure is incurred.

2.3.11 Financial instruments – initial recognition and subsequent measurement

A financial instrument is any contract that gives rise to a financial asset of one entity and a financial liability or equity instrument of another entity.

i) Financial assets

Initial recognition and measurement

Financial assets are initially measured at fair value, after the initial measurement the financial assets are subsequently classified as either measured at amortized cost, fair value through other comprehensive income, or fair value through profit or loss.

The classification of financial assets at initial recognition depends on the financial asset's contractual cash flow characteristics and the Group's business model for managing them. With the exception of trade receivables that do not contain a significant financing component or for which the Group has applied the practical expedient, the Group initially measures a financial asset at its fair value plus, in the case of a financial asset not at fair value through profit or loss, transaction costs. Trade receivables that do not contain a significant financing component or for which the Group has applied the practical expedient are measured at the transaction price determined under IFRS 15. Refer to the accounting policies in Note 2.3.4.

In order for a financial asset to be classified and measured at amortized cost or fair value through OCI, it needs to give rise to cash flows that are 'solely payments of principal and interest (SPPI)' on the principal amount outstanding. This assessment is referred to as the SPPI test and is performed at an instrument level.

Subsequent measurement

For purposes of subsequent measurement, financial assets are classified into four categories:

- financial assets at amortized cost (debt instruments);
- financial assets at fair value through other comprehensive income with recycling of cumulative gains and losses (debt instruments);
- financial assets designated at fair value through other comprehensive income with no recycling of cumulative gains and losses upon derecognition (equity instruments); or
- financial assets at fair value through profit or loss.

Financial assets at amortized cost (debt instruments)

The Group measures financial assets at amortized cost if both of the following conditions are met:

- the financial asset is held within a business model with the objective to hold financial assets in order to collect contractual cash flows; and
- the contractual terms of the financial asset give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding.

Financial assets at amortized cost are subsequently measured using the effective interest (EIR) method, and are subject to impairment. Gains and losses are recognized in the statement of profit or loss when the asset is derecognized, modified or impaired.

Derecognition

A financial asset (or, where applicable, a part of a financial asset or part of a group of similar financial assets) is primarily derecognized (*i.e.*, removed from the Group's consolidated statement of financial position) when:

- the rights to receive cash flows from the asset have expired; or
- the Group has transferred its rights to receive cash flows from the asset or has assumed an obligation to pay the received cash flows in full without material delay to a third party under a 'pass-through' arrangement; and either (i) the Group has transferred substantially all the risks and rewards of the asset, or (ii) the Group has neither transferred nor retained substantially all the risks and rewards of the asset, but has transferred control of the asset.

When the Group has transferred its rights to receive cash flows from an asset it evaluates if, and to what extent, it has retained the risks and rewards of ownership. When it has neither transferred nor retained substantially all of the risks and rewards of the asset, nor transferred control of the asset, the Group continues to recognize the transferred asset to the extent of its continuing involvement. In that case, the Group also recognizes an associated liability. The transferred asset and the associated liability are measured on a basis that reflects the rights and obligations that the Group has retained.

Continuing involvement that takes the form of a guarantee over the transferred asset is measured at the lower of the original carrying amount of the asset and the maximum amount of consideration that the Group could be required to repay.

Impairment of financial assets

An allowance for expected credit losses (ECLs) should be recognized for all debt instruments not held at fair value through profit or loss. ECLs are based on the difference between the contractual cash flows due in accordance with the contract and all of the cash flows that the Group expects to receive, discounted at an approximation of the original effective interest rate. The expected cash flows will include cash flows from the sale of collateral held or other credit enhancements that are integral to the contractual terms.

For credit exposures for which there has not been a significant increase in credit risk since initial recognition, ECLs are provided for credit losses that result from default events that are possible within the next 12-months (a 12-month ECL). For those credit exposures for which there has been a significant increase in credit risk since initial recognition, a loss allowance is required for credit losses expected over the remaining life of the exposure, irrespective of the timing of the default (a lifetime ECL).

For trade receivables and contract assets, the Group applies a simplified approach in calculating ECLs. Therefore, the Group does not track changes in credit risk, but instead recognizes a loss allowance based on lifetime ECLs at each reporting date. The Group has established a provision matrix that is based on its historical credit loss experience, adjusted for forward-looking factors specific to the debtors and the economic environment.

The Group considers a financial asset in default when contractual payments are 180 days past due. However, in certain cases, the Group may also consider a financial asset to be in default when internal or external information indicates that the Group is unlikely to receive the outstanding contractual amounts in full before taking into account any credit enhancements held by the Group. A financial asset is written off when there is no reasonable expectation of recovering the contractual cash flows.

ii) Financial liabilities

Initial recognition and measurement

Financial liabilities are classified, at initial recognition, as financial liabilities at fair value through profit or loss, loans and borrowings or as payables.

All financial liabilities are recognized initially at fair value and, in the case of loans and borrowings and payables, net of directly attributable transaction costs.

The Group's financial liabilities include trade payables and other financial liabilities.

Subsequent measurement

The measurement of financial liabilities depends on their classification, as described below.

Financial liabilities at fair value through profit or loss

The Group has no financial liabilities measured at fair value through profit or loss.

Loans, borrowings, trade payables and other financial liabilities

After initial recognition, interest-bearing loans and borrowings, trade payables and other financial liabilities are subsequently measured at amortized cost using the EIR method. Gains and losses are recognized in the statement of profit or loss when the liabilities are derecognized as well as through the EIR amortization process.

Amortized cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the EIR. The EIR amortization is included as finance costs in the statement of profit or loss.

This category generally applies to interest-bearing loans and borrowings.

Derecognition

A financial liability is derecognized when the obligation under the liability is discharged or cancelled or expires. When an existing financial liability is replaced by another from the same lender on substantially different terms, or the terms of an existing liability are substantially modified, such an exchange or modification is treated as the derecognition of the original liability and the recognition of a new liability. The difference in the respective carrying amounts is recognized in the statement of profit or loss.

2.3.12 Inventories

Inventories are valued at the lower of cost and net realizable value.

Costs incurred in bringing each product to its present location and condition are accounted for as follows:

- raw materials and supplies: purchase cost on a first-in/first-out basis; or
- unfinished goods and services and finished goods and services: cost of direct materials and labor and a proportion of manufacturing overheads based on the normal operating capacity, but excluding borrowing costs.

Net realizable value is the estimated selling price in the ordinary course of business, less estimated costs of completion and the estimated costs necessary to make the sale.

2.3.13 Impairment of non-financial assets

The Group assesses, at each reporting date, whether there is an indication that an asset may be impaired. If any indication exists, or when annual impairment testing for an asset is required, the Group estimates the asset's recoverable amount. An asset's recoverable amount is the higher of an asset's or cash generating unit's (CGU) fair value less costs of disposal and its value in use. The recoverable amount is determined for an individual asset, unless the asset does not generate cash inflows that are largely independent of those from other assets or groups of assets. When the carrying amount of an asset or cash generating unit exceeds its recoverable amount, the asset is considered impaired and is written down to its recoverable amount.

In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset. In determining fair value less costs of disposal, recent market transactions are taken into account. If no such transactions can be identified, an appropriate valuation model is used. These calculations are corroborated by valuation multiples, quoted share prices for publicly traded companies or other available fair value indicators.

The Group bases its impairment calculation on detailed budgets and forecast calculations, which are prepared separately for each of the Group's cash generating units to which the individual assets are allocated. These budgets and forecast calculations generally cover a period of five years. A long-term growth rate is calculated and applied to project future cash flows after the fifth year.

Impairment losses of continuing operations are recognized in the statement of profit or loss in expense categories consistent with the function of the impaired asset.

For assets excluding goodwill, an assessment is made at each reporting date to determine whether there is an indication that previously recognized impairment losses no longer exist or have decreased. If such indication exists, the Group estimates the asset's or cash generating unit's recoverable amount. A previously recognized impairment loss is reversed only if there has been a change in the assumptions used to determine the asset's recoverable amount since the last impairment loss was recognized. The reversal is limited so that the carrying amount of the asset does not exceed its recoverable amount, nor exceed the carrying amount that would have been determined, net of depreciation, had no impairment loss been recognized for the asset in prior years. Such reversal is recognized in the statement of profit or loss unless the asset is carried at a revalued amount, in which case, the reversal is treated as a revaluation increase.

2.3.14 Cash and cash equivalents

Cash and cash equivalents comprise cash in banks and on hand and short-term deposits with an original maturity of three months or less, which are subject to an insignificant risk of changes in value.

2.3.15 Provisions

General

Provisions are recognized when the Group has a present obligation (legal or constructive) as a result of a past event, it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation and a reliable estimate can be made of the amount of the obligation. When the Group expects some or all of a provision to be reimbursed, for example, under an insurance contract, the reimbursement is recognized as a separate asset, but only when the reimbursement is virtually certain. The expense relating to a provision is presented in the statement of profit or loss net of any reimbursement.

2.3.16 Share-based payments

Employees (and others providing similar services) receive remuneration in the form of share-based payments. Furthermore, employees and others providing similar services to the group are granted share appreciation rights, which are settled in equity instruments (equity-settled transactions).

Equity-settled transactions

The cost of equity-settled transactions is determined by the fair value at the date when the grant is made using an appropriate valuation model, further details of which are given in Note 16.

These costs are recognized in Research and development expenses, Sales and marketing expenses or General and administrative expenses, together with a corresponding increase in equity (other capital reserves), over the period in which the service is provided (the vesting period). The cumulative expense recognized for equity-settled transactions at each reporting date until the vesting date reflects the extent to which the vesting period has expired and the Group's best estimate of the number of equity instruments that will ultimately vest.

2.4 First-time adoption of IFRS

These financial statements, for the year ended December 31, 2018, are the first the Group has prepared in accordance with IFRS. For periods up to and including the year ended December 31, 2017, the Group prepared its financial statements in accordance with German GAAP as local generally accepted accounting principles.

Accordingly, the Group has prepared financial statements that comply with IFRS applicable as at December 31, 2018 and the early adoption of IFRS 16 Leases, together with the comparative period data for the year ended December 31, 2017, as described in the summary of significant accounting policies. In preparing the financial statements, the Group's opening statement of financial position was prepared as at 1 January 2017, the Group's date of transition to IFRS. The principal adjustments made by the Group in restating its German GAAP financial statements, including the statement of financial position as at 1 January 2017 and the financial statements for the year ended December 31, 2017 as described below.

Exemptions applied

IFRS 1 allows first-time adopters certain exemptions from the retrospective application of certain requirements under IFRS.

The Group has applied the following exemptions:

- IFRS 3 Business Combinations has not been applied to either acquisitions of subsidiaries that are considered businesses under IFRS, or acquisitions of interests in associates and joint ventures that occurred before January 1, 2017. Use of this exemption means that the German GAAP carrying amounts of assets and liabilities, which are required to be recognized under IFRS, is their deemed cost at the date of the acquisition. After the date of the acquisition, measurement is in accordance with IFRS. Assets and liabilities that do not qualify for recognition under IFRS are excluded from the opening IFRS statement of financial position. The Group did not recognize or exclude any previously recognized amounts as a result of IFRS recognition requirements.
- IFRS 1 also requires that the German GAAP carrying amount of goodwill is used in the opening IFRS statement of financial position (apart from adjustments for goodwill impairment and recognition or derecognition of intangible assets). In accordance with IFRS 1, the Group has tested goodwill for impairment at the date of transition to IFRS. No goodwill impairment was deemed necessary at January 1, 2017.
- BioNTech measures the lease liability under IFRS 16 for all leases at the date of transition to IFRS. The lease liability is measured at the present value of the remaining lease payments, discounted using BioNTech's incremental borrowing rate at the date of transition to IFRS. The right-of-use asset is measured at cost, which consists of the present value of the unpaid lease payments, adjusted for any initial direct costs, prepaid payments or dismantling costs. The Group applies a single discount rate to a portfolio of leases with reasonably similar characteristics. The Group elects not to apply the requirements for lease liabilities and right-of-use assets as described above to leases for which the lease term ends within 12 months of the transition to IFRSs, and BioNTech elects to exclude initial direct costs from measurement of the right-of-use asset at the date of transition to IFRSs and the use of hindsight, in determining the lease term if the contract contains options to extend or terminate the lease.

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- Cumulative currency translation differences for all foreign operations are deemed to be zero as at January 1, 2017.

Estimates

The estimates at January 1, 2017 and at December 31, 2017 are consistent with those made for the same dates in accordance with German GAAP (after adjustments to reflect any differences in accounting policies).

The differences between German GAAP and IFRS as of January 1, 2017 were as follows:

Consolidated statement of operations

(in thousands)

	Note	German GAAP Year ended December 31, 2017	Adjustment	IFRS Year ended December 31, 2017
Revenues from contracts with customers	G, F	€ 87,741	€ (26,143)	€ 61,598
Cost of sales	I	(11,472)	2,154	(9,318)
Gross profit		76,269	(23,989)	52,280
Research and development expenses	J	(91,342)	5,847	(85,496)
Sales and marketing expenses	B, K	(12,355)	5,752	(6,603)
General and administrative expenses	B, K	(18,176)	(5,344)	(23,520)
Other operating income	H, L	4,508	(2,160)	2,349
Other operating expenses	L	(26,384)	26,096	(288)
Operating loss		(67,479)	6,202	(61,277)
Finance income		2,133	—	2,133
Finance expense	L	(53)	(25,954)	(26,007)
Interest expense related to lease liability	B	—	(676)	(676)
Share of profit of equity method investees		(78)	—	(78)
Loss before tax		(65,477)	(20,428)	(85,905)
Income taxes		(24)	(21)	(45)
Loss for the year		€ (65,501)	€ (20,449)	€ (85,950)
Attributable to:				
Equity holders of the parent		(65,204)	(20,449)	(85,653)
Non-controlling interests		(297)	—	(297)
		(65,501)	(20,449)	(85,950)

[Table of Contents](#)**Consolidated statement of comprehensive income (loss)**

(in thousands)

	Note	German GAAP Year ended December 31, 2017	Adjustment	IFRS Year ended December 31, 2017
Loss for the year		€ (65,501)	€ (20,449)	€ (85,950)
Other comprehensive income				
<i>Other comprehensive income that may be reclassified to profit or loss in subsequent periods (net of tax)</i>				
Exchange differences on translation of foreign operations		—	(23)	(23)
Net other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods		—	(23)	(23)
Other comprehensive income/(loss) for the year, net of tax		—	(23)	(23)
Comprehensive loss for the year, net of tax		(65,501)	(20,473)	(85,973)
Attributable to:				
Equity holders of the parent		(65,204)	(20,473)	(85,677)
Non-controlling interests		(297)	—	(297)
Comprehensive loss for the year, net of tax		(65,501)	(20,473)	(85,973)

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Consolidated statement of financial position

(in thousands)

Assets	Notes	German GAAP as at January 1, 2017	Adjustment	IFRS as at January 1, 2017
Non-current assets				
Intangible assets	C, D	€ 11,098	€ 86	€ 11,184
Property, plant and equipment	A, B	31,118	29,388	60,506
Other assets		78	—	78
Other financial assets	B	78	(12)	66
Total non-current assets		42,372	29,462	71,834
Current assets				
Inventories	E	€ 6,928	€ (3,662)	€ 3,266
Trade receivables		3,161	—	3,161
Contract assets	G	—	637	637
Other financial assets	B, C	137	1,391	1,528
Other assets		3,855	844	4,699
Income tax assets		2	—	2
Deferred expense	G	8,910	(7,758)	1,153
Cash and cash equivalents		303,680	—	303,680
Total current assets		€ 326,672	€ (8,547)	€ 318,125
Total assets		€ 369,044	€ 20,915	€ 389,959
Equity and liabilities				
Equity				
Share capital		€ 182	€ —	€ 182
Capital reserve		175,504	—	175,504
Accumulated losses		(112,100)	—	(112,100)
Other reserves	N	30	(33,145)	(33,115)
Equity attributable to equity holders of the parent		€ 63,616	€ (33,145)	€ 30,471
Non-controlling interest		1,387	—	1,387
Total equity		€ 65,002	€ (33,145)	€ 31,858
Non-current liabilities				
Financial liabilities	E	—	26,669	26,669
Other liabilities	F	1,956	(573)	1,383
Contract liabilities	G	—	273,414	273,414
Total non-current liabilities		€ 1,956	€ 299,509	€ 301,466
Current liabilities				
Provisions	F	13,790	(13,671)	120
Trade payables		6,218	—	6,218
Contract liabilities	G	—	33,466	33,466
Other financial liabilities	E, F	87	14,256	14,344
Other liabilities	H	38,394	(35,906)	2,488
Deferred income and accrued expenses		243,595	(243,595)	—
Total current liabilities		€ 302,085	€ (245,450)	€ 56,636
Total liabilities		€ 304,042	€ 54,060	€ 358,102
Total equity and liabilities		€ 369,044	€ 20,915	€ 389,959

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Consolidated statement of financial position

(in thousands)

Assets	Notes	German GAAP as at December 31, 2017	Adjustment	IFRS as at December 31, 2017
Non-current assets				
Intangible assets	C	€ 81,691	€ 1,845	€ 83,537
Property, plant and equipment	A, B	44,313	57,208	101,521
Other financial assets	B	31	(13)	19
Total non-current assets		€ 126,036	€ 59,040	€ 185,076
Current assets				
Inventories	E	€ 5,248	€ (557)	€ 4,691
Trade receivables		4,575	—	4,575
Other financial assets	B, C	202	44	246
Other assets		5,462	—	5,462
Income tax assets		687	—	687
Deferred expense	G	9,090	(7,218)	1,872
Cash and cash equivalents		172,106	—	172,106
Total current assets		€ 197,368	€ (7,730)	€ 189,637
Total assets		€ 323,403	€ 51,310	€ 374,713
Equity and liabilities				
Equity				
Share capital		€ 9,265	€ —	€ 9,265
Capital reserve		166,421	—	166,421
Accumulated losses		(177,325)	(20,427)	(197,753)
Other reserves		7	(27,236)	(27,229)
Equity attributable to equity holders of the parent		€ (1,633)	€ (47,663)	€ (49,296)
Non-controlling interest		1,090	—	1,090
Total equity		€ (543)	€ (47,663)	€ (48,206)
Non-current liabilities				
Financial liabilities	E	€ 41,634	€ 8,715	€ 50,349
Contract liabilities	G	—	214,026	214,026
Total non-current liabilities		€ 41,634	€ 222,741	€ 264,375
Current liabilities				
Provisions	F	€ 7,059	€ (6,941)	€ 118
Trade payables		12,460	—	12,460
Contract liabilities	G	—	77,346	77,346
Other financial liabilities	E, F	7,968	45,484	53,452
Other liabilities	H	12,923	2,245	15,168
Deferred income and accrued expenses	F, G	241,902	(241,902)	—
Total current liabilities		€ 282,312	€(123,768)	€ 158,544
Total liabilities		€ 323,946	€ 98,973	€ 422,920
Total equity and liabilities		€ 323,403	€ 51,310	€ 374,714

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Consolidated statement of cash flows

(in thousands)

	<i>Note</i>	German GAAP Year ended December 31, 2017	Adjustment	IFRS Year ended December 31, 2017
Operating activities				
Loss for the year		€ (65,522)	€ (20,428)	€ (85,950)
Income taxes		24	21	45
Loss before tax		<u>€ (65,498)</u>	<u>€ (20,407)</u>	<u>€ (85,905)</u>
Adjustments to reconcile loss before tax to net cash flows:				
Depreciation of property, plant and equipment and intangible assets	B	10,298	231	10,529
Share-based payment expense	K	—	5,909	5,909
Net foreign exchange differences		24,707	113	24,820
Loss on disposal of property, plant and equipment		15	—	15
Finance income		(2,133)	—	(2,133)
Interest on lease liability	B	—	676	676
Finance expense		53	—	53
Share of loss of an associate and a joint venture		78	—	78
Movements in provisions		(6,731)	6,729	(2)
Working capital adjustments:				
Decrease/(Increase) in trade receivable, contract assets and further positions		(1,012)	(1,804)	(2,816)
Decrease/(Increase) in inventories		(1,211)	637	(574)
(Decrease)/Increase in trade and other payables, contract liabilities and refund liabilities		26,633	(31,205)	(4,572)
Interest received		2,133	—	2,133
Interest paid	B	(53)	(676)	(729)
Income tax paid		(24)	(21)	(45)
Net cash flows from operating activities		<u>€ (12,745)</u>	<u>€ (39,818)</u>	<u>€ (52,562)</u>
Investing activities				
Purchase of property, plant and equipment		(24,320)		(24,320)
Proceeds from sale of property, plant and equipment		5,193	—	5,193
Purchase of intangibles	M	(74,882)	41,460	(33,422)
Net cash flows used in investing activities		<u>€ (94,009)</u>	<u>€ 41,460</u>	<u>€ (52,549)</u>
Financing activities				
Payment of finance lease liabilities	B	—	(1,643)	(1,643)
Net cash flows from/(used in) financing activities		<u>€ —</u>	<u>€(1,642,634)</u>	<u>€ (1,643)</u>
Net increase/(decrease) in cash and cash equivalents		(106,754)	—	(106,754)
Change in cash resulting from exchange rate differences		(24,820)	—	(24,820)
Cash and cash equivalents at 1 January		303,680	—	303,680
Cash and cash equivalents at 31 December		<u>€ 172,106</u>	<u>€ —</u>	<u>€ 172,106</u>

Notes to the reconciliation of equity as at 1 January 2017 and December 2017, total comprehensive income and cash flow for the year ended December 31, 2017

A. Property, Plant and Equipment

Under IFRS, carrying amounts of Property, plant and equipment have been determined based on the useful lives listed in Note 2.3.8. The useful lives under IFRS reflect the economic lives of the respective assets appropriately and differ from those according to German GAAP. According to IFRS the carrying amounts of Property, Plant and Equipment as of January 1, 2017 are k€1,256 higher compared to HGB (December 31, 2017: k€5,293 higher).

B. Leasing

Under German GAAP, all leases have been classified as operating leases and no assets or liabilities have been capitalized for the Group's leases.

Under IFRS, all leases except short-term leases and leases of low-value assets have been capitalized, which leads to right-of-use assets and corresponding lease liabilities in the balance sheet. According to IFRS the Right-of-use assets as of 1 January 2017 amount to k€28,132 (December 31, 2017: k€51,915), while the corresponding lease liabilities as of 1 January 2017 are k€28,132 (December 31, 2017: k€52,182).

In the statement of operations the finance costs have increased as a result from interest expenses, resulting from the lease liabilities.

In the statement of cash flows the Group reported cash payments for the reduction of the outstanding liability relating to leases under financing activities for the purposes of IFRS and the interest on the lease liability is reported in the cash flows from operating activities.

C. Other Intangible Assets

Carrying amounts of Intangible Assets have been determined based on the useful lives listed in note 2.3.10. The useful lives in the IFRS financial statements reflect the consumption of use of the respective assets appropriately. According to IFRS, the carrying amounts of Other Intangible Assets as of 1 January 2017 are k€86 higher compared to German GAAP (December 31, 2017: k€1,512 higher).

D. Goodwill

According to German GAAP, goodwill is amortized on a straight-line basis over a period of five years. Under IFRS goodwill is tested annually for impairment (see Note 2.3.1).

E. Inventories

Under German GAAP, inventories comprise amongst other items capitalized cost for products in the process of production for customer orders. Under IFRS, these customer orders are contracts with customers including performance obligations satisfied over time. Therefore, capitalized costs have to be expensed and revenue has to be recognized dependent on the measure of progress. As BioNTech does not have an unconditional right to consideration for goods and services transferred at this moment, BioNTech presents a contract asset or a contract liability for each contract with a customer depending on the proportion of goods and services transferred and consideration received.

F. Deferred income and accrued expenses

Under German GAAP, expenses from license payments were capitalized as prepaid expenses and released over the term of the license to the statement of operations. Under IFRS, these costs are inputs to the satisfaction of performance obligation and have to be expensed as incurred.

G. Deferred income and revenues

Under German GAAP, upfront and advance payments received are presented as deferred income. Under IFRS, if a payment from a contract with a customer is received or due (whichever is earlier) before BioNTech transfers a good or service to the customer or these payments exceed the goods and services transferred to a customer so far, a contract liability shall be presented. The contract liability is presented as current and non-current.

Furthermore, under German GAAP, revenues from advance payments received were partly recognized on a straight-line basis and additional milestone payments were recognized as revenue when the milestone payments were due. Under IFRS, the timing of revenue recognition of milestone payments as a variable consideration depends on the satisfaction of the performance obligation to which the variable consideration is allocated. Therefore, under IFRS, revenue from performance obligations satisfied over time is only recognized by measuring the progress toward complete satisfaction of the respective performance obligation. Additionally, under IFRS, reimbursed costs were presented net instead of gross presentation under German GAAP.

H. Other current liabilities and other operating income

Under German GAAP, other current liabilities are presented for a grant received from a customer related to the acquisition of property, plant and equipment and intangibles. Under IFRS, these payments received are treated as part of the transaction price and therefore presented as contract liability.

Under German GAAP, other operating income was presented for a partial release of the grant received from the customer related to amortization and depreciation of acquired assets attributable to the customer. Under IFRS, revenue has only to be recognized depending on the measure of progress of the related performance obligation.

I. Cost of sales

Under German GAAP, expenses from license payments were capitalized as prepaid expenses and released over the term of the license (see D. Accrued expenses). According to IFRS, these expenses are expensed as incurred as at January 1, 2017 as these expenses were costs of a performance obligation.

J. Research and development expenses

Under German GAAP, reimbursements of research and development costs were presented as revenue. Under IFRS, reimbursed costs are presented net instead of a presentation as revenues.

K. Share-based payments

Under German GAAP, the Group recognized only the costs for the equity-settled share-based payment plan as expenses. IFRS requires the fair value of the equity-settled share-based payment plan to be determined using an appropriate valuation model. Costs were recognized in fiscal year 2017 because the plan vested immediately. An additional expense of k€5,291 was recognized in the statement of operations for the year ended December 31, 2017. Please refer to Note 16 for further information on the share-based payment plan.

L. Other operating expenses/Finance cost

Under German GAAP, foreign exchange gains and losses are shown in other operating expenses and other operating income. Under IFRS, net foreign exchange losses of k€25,954 are reclassified and shown as finance cost within finance result.

M. Cash flow from investing activities

Under German GAAP, the Group presented the acquisition of an intangible asset (*e.g.*, patent) in the cash flow from investing activities with a corresponding increase in trade and other payables (k€41,460 were payable as of December 31, 2017).

Under IFRS, the Group only reports the cash payments made during fiscal year 2017 to acquire the intangible asset in the cash flows arising from investing activities. Please refer to Note 10 for further information on such intangible assets.

N. Equity

The change in the opening equity balance is the net accumulation of all IFRS opening balance adjustments.

2.5 Standards issued but not yet effective

The new and amended standards and interpretations that are issued, but not yet effective, up to the date of issuance of the Group's financial statements and that might have an impact on the Group's financial statements are disclosed below. The Group intends to adopt these new and amended standards and interpretations, if applicable, when they become effective.

	<u>Standards/Interpretation</u>	<u>Date of application</u>
IFRIC 23	Uncertainty over income tax treatment	January 1, 2019
Amendments to IFRS 9	Prepayment Features with Negative Compensation	January 1, 2019
Amendments to IAS 19	Plan Amendment, Curtailment or Settlement	January 1, 2019
Amendments to IAS 28	Long-term interests in associates and joint ventures	January 1, 2019
Annual improvements 2015-2017 Cycle	Annual improvement cycle to IFRS 2015-2017	January 1, 2019

The Group does not expect a significant impact of the application of these standards.

3 Significant accounting judgments, estimates and assumptions continued

The preparation of the Group's consolidated financial statements requires management to make judgements, estimates and assumptions that affect the reported amounts of revenues, expenses, assets and liabilities, the accompanying disclosures, and the disclosure of contingent liabilities. Uncertainty about these assumptions and estimates could result in outcomes that require a material adjustment to the carrying amount of assets or liabilities affected in future periods.

Judgments

In the process of applying the Group's accounting policies, management has made the following judgments, which have the most significant effect on the amounts recognized in the consolidated financial statements:

Revenue from contracts with customers

BioNTech applied the following judgements that significantly affect the determination of the amount and timing of revenue from contracts with customers:

- Identification and determination of the nature of performance obligations in collaboration and license agreements.

BioNTech generates revenues from collaboration and license agreements under which BioNTech grants licenses to use, research, develop, manufacture and commercialize candidates and products. As these agreements

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comprise several promises, it must be assessed whether these promises are capable of being distinct within the context of the contract. If these promises are not distinct, they have to be combined until the bundle of promised goods and services is distinct. For some agreements, this results in BioNTech accounting for all goods and services promised in a collaboration and license agreement as a single performance obligation with a single measure of progress.

For these combined performance obligations, it must be assessed which of these promises is the predominant promise to determine the nature of the performance obligation. BioNTech determined that the grant of the license is the predominant promise within the (combined) performance obligation to grant a license to the customers. It was assessed that BioNTech grants their customers a right to access or a right to use BioNTech's intellectual property due to the collaboration and license agreements.

Consequently, the promise to grant a license is accounted for as a performance obligation satisfied over time as BioNTech's customer simultaneously receive and consumes the benefits from BioNTech's performance.

- Estimation of variable consideration and assessment of the constraint when determining the deferred revenue.

BioNTech's collaboration and license agreements comprise variable considerations which are contingent on the occurrence or non-occurrence of a future event (*i.e.*, reaching a certain milestone). When determining the deferred revenue of a collaboration and license agreement, BioNTech is required to estimate the amount of consideration to which it will be entitled in exchange for transferring the promised goods or services to the customer.

As there are usually only two possible outcomes (*i.e.*, milestone is reached or not), BioNTech has assessed that the method of the most likely amount is the best method to predict the amount of consideration to which BioNTech will be entitled.

The most likely amount of these milestone payments (*i.e.*, the full milestone payment) is only included in the transaction price if the occurrence of reaching future milestone is highly probable. BioNTech has assessed that the likelihood of achieving the respective milestone decreases depending on how far the expected date of achieving the milestone lies in the future.

BioNTech has concluded that future milestone payments are fully constrained at the end of the current fiscal year.

Future milestone payments would become unconstrained at the satisfaction of the milestone event, specifically a development event, a regulatory approval or achievement of a sales milestone.

Estimates and assumptions

The key assumptions concerning the future and other key sources of estimation uncertainty at the reporting date that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year are described below. The Group based its assumptions and estimates on parameters available when the consolidated financial statements were prepared. Existing circumstances and assumptions about future developments, however, may change due to market changes or circumstances arising that are beyond the control of the Group. Such changes are reflected in the assumptions when they occur.

For the carrying amounts of the revenue recognition-related contract balances, see Note 4.

Share-based payments

Determining the fair value of share-based payment transactions requires the most appropriate valuation for the specific program, which depends on the underlying terms and conditions.

This estimate also requires the determination of the most appropriate inputs to the valuation model, including the fair value of the share option.

Due to the lack of quoted market prices, the Group has used an external appraisal for the measurement of the cash- and equity-settled transactions' fair value at the grant date considering certain assumption relating to, *e.g.*, the volatility of stock price, the determination of an appropriate risk-free interest rate, expected dividends and the probability of reaching a minimum hurdle to exercise the relevant options.

Leases

Right-of-use assets are measured at the amount equal to the lease liability, adjusted by the amount of any prepaid or accrued lease payments relating to that lease.

Significant accounting judgments are required for the determination of the appropriate incremental borrowing rate, which is to be used in the calculation of the asset and liability that are recognized in the financial statements regarding the lease contracts.

For the carrying amounts of right-of-use assets and the related lease liability, see Note 18.

Taxes

Deferred tax assets are recognized for unused tax losses only to the extent that it is probable that taxable profit will be available against which the losses can be utilized. Significant management judgement is required to determine the amount of deferred tax assets that can be recognized, based upon the likely timing and the level of future taxable profits, together with future tax planning strategies.

The Group has tax losses carried forward and these losses relate to subsidiaries that have a history of losses. The subsidiaries neither have any taxable temporary difference nor any tax planning opportunities available that could partly support the recognition of these losses as deferred tax assets.

On this basis, the Group has determined that it cannot recognize deferred tax assets on the tax losses carried forward.

4 Revenue from contracts with customers

4.1 Disaggregated revenue information

Set out below is the disaggregation of the Group's revenue from contracts with customers:

(in thousands)	Year ended	
	2018	2017
Revenues resulting from collaboration and license agreements	€101,837	€42,333
Eli Lilly and Company	676	2,074
Genentech Inc.	49,536	27,829
Genmab A/S	2,740	6,765
Pfizer Inc.	7,174	—
Sanofi S.A.	41,712	5,665
Revenues from other sales transactions	25,738	19,265
Sum	€127,575	€61,598

Through December 31, 2018, BioNTech received k€279,542 in upfront fees from Genentech under the Genentech Collaboration Agreement. Such amounts are initially deferred and subsequently recognized as revenue as the Company performs under the agreement and measured based on the costs incurred under the respective research programs. Of these upfront fees, k€49,536 was recognized as revenue in the year ended 2018 (k€27,829 in 2017). As of December 31, 2018, k€195,582 of upfront fees is recognized as deferred revenue within Contract liabilities in the statement of financial position.

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Through December 31, 2018 BioNTech received k€52,200 in upfront fees from Sanofi under the Sanofi Agreement. Such amounts are initially deferred and subsequently recognized as revenue as BioNTech performs under the agreement and measured based on the costs incurred under the respective research programs. Of these upfront fees, k€8,535 was recognized as revenue in the year ended 2018 (k€5,665 in 2017). As of December 31, 2018, k€38,716 of upfront fees is recognized as deferred revenue within Contract liabilities in the statement of financial position.

Revenue from BioNTech's collaborators that exceeds 10% of BioNTech's total revenue is included in the segments Clinical, Manufacturing and Technology Platform. Of the revenue from other sales transactions, k€10,748 in 2018 (k€10,652 in 2017) apply to product sales.

4.2 Contract balances

<u>(in thousands)</u>	<u>December 31,</u> <u>2018</u>	<u>December 31,</u> <u>2017</u>	<u>January 1,</u> <u>2017</u>
Trade receivables	€ 18,938	€ 4,575	€ 3,161
Contract assets	—	—	637
Contract liabilities	€ 271,674	€ 291,372	€306,880

Trade receivables are non-interest bearing and are generally settled within 20 to 30 days.

Contract assets are recognized for revenue earned from BioNTech's performance of creating customer-specific cell and gene therapies. Upon completion of the produced product or upon reaching a contracted progress payment, the amounts recognized as contract assets are reclassified to trade receivables. As the customers' advance payments exceeded BioNTech's transferred goods and services for which a conditional right to consideration exists in all contracts in 2017 and 2018, only contract liabilities are presented.

Additionally, contract liabilities include long-term advances received from BioNTech's major collaboration and license agreements. The outstanding balances of these accounts decreased in 2018 and 2017 as revenues resulting from these agreements exceeded further payments received from the collaborators due to the achievement of milestones. BioNTech received payments or an unconditional right of consideration of k€71,761 in 2018 (2017: k€26,552) from the collaboration and license agreements and recognized revenues resulting from collaboration and license agreements of k€101,837 in 2018 (2017: k€42,333), which reduced the contract liabilities.

Set out below is the amount of revenue recognized from:

<u>(in thousands)</u>	<u>2018</u>	<u>2017</u>
Amounts included in contract liabilities at the beginning of the year	€65,068	€40,428

4.3 Performance obligations

Information about BioNTech's performance obligations is summarized below:

Collaboration and license agreements

BioNTech accounts for its promises to grant licenses as performance obligations satisfied over time as the customers simultaneously receive and consume the benefit of BioNTech's performance of providing access to its intellectual property as the performance occurs. BioNTech recognizes revenue over time by measuring the progress toward complete satisfaction of that performance obligation according to the method that demonstrates BioNTech's performance towards complete satisfaction. In contracts in which the costs vary based on the stage of research, an input-based measure considering cost incurred depicts most reliably the progress of the related

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research activities. In other contracts, revenue recognition on a straight-line basis most reliably depicts BioNTech's performance toward complete satisfaction.

The deferred revenue allocated to the remaining performance obligations (unsatisfied or partially unsatisfied) as at year-end are as follows:

(in thousands)	2018	2017
Within one year	€ 64,522	€ 76,582
More than one year	€205,647	€214,026
Sum	€270,169	€290,608

The deferred revenue allocated to the remaining performance obligations does not contain deferred revenues of performance obligations which are part of contracts that have an original expected duration of one year or less or of performance obligations for which the consideration from the customer corresponds directly to the value to the customer of BioNTech's performance to date.

5 Group information

Information about subsidiaries

The consolidated financial statements of the Group include the following subsidiaries:

Name	Country of incorporation	Headquarter	% equity interest		
			2018	2017	As at January, 2017
BioNTech RNA Pharmaceuticals GmbH	Germany	Mainz	100%	100%	100%
BioNTech Protein Therapeutics GmbH	Germany	Mainz	100%	100%	100%
BioNTech Diagnostics GmbH	Germany	Mainz	100%	100%	100%
BioNTech Small Molecules GmbH	Germany	Mainz	100%	100%	100%
BioNTech Business Services GmbH	Germany	Mainz	100%	100%	—
BioNTech Austria Beteiligungen GmbH	Austria	Wien	100%	100%	100%
BioNTech Innovative Manufacturing Services GmbH (Frühere Eufets GmbH)	Germany	Idar-Oberstein	100%	100%	100%
JPT Peptide Technologies GmbH	Germany	Berlin	100%	100%	100%
TheraCode JPT Inc.	United States	Acton	100%	100%	100%
BioNTech Cell & Gene Therapies GmbH	Germany	Mainz	94.50%	94.50%	94.50%
Apta IT GmbH	Germany	Munich	100%	49.99%	49.99%
BioNTech Real Estate Verwaltungs GmbH	Germany	Holzkirchen	100%	—	—
BioNTech Real Estate GmbH & Co. KG	Germany	Holzkirchen	100%	—	—

BioNTech Real Estate Verwaltungs GmbH and BioNTech Real Estate GmbH & Co. KG were established during 2018.

Parent company

AT Impf GmbH, Munich, owns 54.16% (December 31, 2017 and January 1, 2017: 62.77%) of the ordinary shares in BioNTech and is the parent company of the Group.

Entity with significant influence over the Group

Medine GmbH, Mainz, owns 21.57% (December 31, 2017: 25%; January 1, 2017: 25.99%) of the ordinary shares in BioNTech and has significant influence over the Group.

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6 Income and expenses

6.1 Costs of sales (in thousands)

	Year ended December 31,	
	2018	2017
Wages and social security expenses	€ 6,726	€6,105
Laboratory supplies	1,368	2,849
Purchased Services	2,514	—
Depreciation	1,367	—
Other	1,715	364
Total	€13,690	€9,318

6.2 Research and development expenses (in thousands)

	Year ended December 31,	
	2018	2017
Wages and social security expenses	€ 45,668	€31,970
Purchased services	42,079	22,686
Lab supplies	22,921	15,762
Depreciation	18,312	9,859
Lease and lease related cost	882	2,745
Other	13,178	2,474
Total	€ 143,040	€85,496

Other expenses were mainly comprised of clinical studies (2018: k€3,500; 2017: k€887), travel costs (2018: k€1,281; 2017: k€776) and incidental rental costs (2018: k€1,523; 2017: k€730).

6.3 Sales and marketing expenses (in thousands)

	Year ended December 31,	
	2018	2017
Wages and social security expenses	€1,728	€1,631
Purchased services	794	2,771
Travel costs	267	260
Other	252	1,940
Total	€3,041	€6,603

In 2018, the other costs were mainly comprised of transport costs (k€119) and depreciation (k€21). In 2017, the other costs were mainly comprised of distribution costs of the entity TheraCode JPT Inc. (k€441) and transport costs (k€146).

6.4 General and administrative expenses
(in thousands)

	<u>2018</u>	<u>2017</u>
Wages and social security expenses	€ 8,582	€ 9,861
Purchased services	5,177	3,544
IT and office equipment	3,774	2,706
Depreciation	2,284	630
Office costs	608	1,611
Other	5,908	5,167
Total	<u>€26,334</u>	<u>€ 23,520</u>

In 2018, the other expenses were mainly comprised of travel costs (k€1,043), job advertisement expenses (k€861) and contract staffing (k€781). In the prior year, the other expenses were mainly comprised of job advertisement expenses (k€719), travel costs (k€247), training expenses (k€210) and incidental rental costs (k€182).

6.5 Other operating income
(in thousands)

	<u>2018</u>	<u>2017</u>
Government grants	€4,228	€2,266
Other	1,168	83
Total other operating income	<u>€5,396</u>	<u>€2,349</u>

6.6 Other operating expenses
(in thousands)

	<u>2018</u>	<u>2017</u>
Impairment intangible assets	€ 0	€281
Other	720	7
Total other operating expenses	<u>€720</u>	<u>€288</u>

In 2017, the impairment loss of k€281 represented the write-down of a software program as it was no longer usable.

6.7 Finance income
(in thousands)

	<u>2018</u>	<u>2017</u>
Finance income		
Interest income on cash	€1,996	€2,133
Foreign exchange gains (net)	6,050	—
Finance income	<u>€8,046</u>	<u>€2,133</u>

Finance income results from BioNTech's interests on short-term deposits.

[Table of Contents](#)**6.8 Finance expense**
(in thousands)

	<u>2018</u>	<u>2017</u>
Finance expense		
Financial instruments measured at amortised cost	€ 48	€ 53
Foreign exchange losses (net)	—	25,955
Finance expense	<u>€ 48</u>	<u>€26,007</u>

Foreign exchange losses are a result from the Group's unhedged USD cash accounts.

7 Income tax

Tax expense for the years ended December 31, 2018 and 2017 are comprised of current income taxes.

Reconciliation of tax expense to the estimated tax rate for the years ended 2017 and 2018 is as follows (in thousands):

	<u>Year ended</u> <u>December 31,</u>	
	<u>2018</u>	<u>2017</u>
Loss before tax	<u>€(47,662)</u>	<u>€(85,950)</u>
Expected tax benefit (based on BioNTech's statutory tax rate of 30.99%; prior year: 30.86%)	14,776	26,517
<i>Effects</i>		
Government grants exempted from taxes	28	17
Non deductible tax-expenses	(114)	(92)
Utilization of tax losses	1,165	—
Non-recognition of deferred taxes on tax losses and temporary differences	(13,634)	(26,015)
Other effects	(2,821)	(472)
Income tax expense	<u>€ (600)</u>	<u>€ (45)</u>

Deferred taxes

Deferred taxes relate to the following (in thousands):

<u>2018</u>	At January 1, 2018	Recognized in P&L	At December 31, 2018
Fixed Assets	€ (877)	€ 787	€ (90)
Inventories	83	(83)	—
Leases	83	223	306
Revenues	16,631	11,810	28,441
Accruals	73	61	134
Other	684	(523)	161
Deferred Tax Assets Net (before valuation)	16,676	12,275	28,951
Valuation Adjustment	€ (16,676)	€ (12,275)	€ (28,951)
Deferred Tax Assets Net (after valuation)	—	—	—
<u>2017</u>	At January 1, 2017	Recognized in P&L	At December 31, 2017
Fixed Assets	€ (454)	€ (423)	€ (877)
Inventories	83	—	83
Leases	—	83	83
Revenues	10,560	6,071	16,631
Bank accounts	(2,467)	3,122	655
Liabilities (currency losses)	—	28	28
Accruals	29	44	73
Deferred Tax Assets (before valuation)	7,751	8,925	16,676
Valuation Adjustment	€ (7,751)	€ (8,925)	€ (16,676)
Deferred Tax Assets (after valuation)	—	—	—

Accumulated tax losses of the Group amount to the following:

<u>(in thousands)</u>	Year ended December 31,		January 1,
	2018	2017	2017
Corporate Tax	€179,264	€178,491	€124,401
Trade Tax	176,425	176,024	122,904

Deferred tax assets on tax losses have not been capitalized as there is no sufficient probability in terms of IAS 12 that there will be future taxable profits available against which the unused tax losses can be utilized. The accumulated tax losses relate entirely to Germany. There is no expiration date for any for the accumulated tax losses under German law.

8 Earnings per share

Basic earnings per share (EPS) is calculated by dividing the loss for the year attributable to ordinary equity holders of the parent by the weighted average number of ordinary shares outstanding during the year.

Diluted EPS is calculated by dividing the profit attributable to ordinary equity holders of the parent by the weighted average number of ordinary shares outstanding during the year plus the weighted average number of ordinary shares that would be issued on conversion of all the dilutive potential ordinary shares into ordinary shares.

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The following table reflects the income and share data used in the basic and diluted EPS calculations:

(in thousands)	Year ended December 31,	
	2018	2017
Loss attributable to ordinary equity holders of the parent for basic earnings	€(48,018)	€(85,653)
Weighted average number of ordinary shares for basic EPS*	10,595	9,265
Effects of dilution from share options	—	—
Weighted average number of ordinary shares adjusted for the effect of dilution*	10,595	9,265

* The weighted average number of shares takes into account the weighted average effect of changes in shares during the year.

There have been no other transactions involving ordinary shares or potential ordinary shares between the reporting date and the date of authorization of these financial statements. Stock options were not included in the calculation of diluted EPS because they are antidilutive for the periods presented.

9 **Property, plant and equipment**

<i>(in thousands)</i>	Land and buildings	Equipment, tools and installations	Construction in progress and advance payments	Total
Acquisition and production costs				
As of January 1, 2017	€ 11,126	€ 39,944	€ 3,613	€ 54,683
Additions	1,951	23,233	2,636	27,820
Disposals		(5,193)	—	(5,193)
Reclassifications		96	(96)	—
As of December 31, 2017	€ 13,077	€ 58,080	€ 6,153	€ 77,310
As of January 1, 2018	€ 13,077	€ 58,080	€ 6,153	€ 77,310
Additions	8,925	11,322	6,154	26,401
Disposals	—	(858)	—	(858)
Reclassifications	145	5,069	(5,216)	—
As of December 31, 2018	€ 22,147	€ 73,613	€ 7,091	€ 102,853
Cumulative depreciation and impairment charges				
As of January 1, 2017	€ 5,232	€ 17,076	€ —	€ 22,308
Depreciation	458	4,937	—	5,395
As of December 31, 2017	€ 5,690	€ 22,013	€ —	€ 27,703
As of January 1, 2018	€ 5,690	€ 22,013	€ —	€ 27,703
Depreciation	782	8,349	—	9,131
Reclassifications	—	(182)	—	(182)
As of December 31, 2018	€ 6,472	€ 30,180	€ —	€ 36,652
Carrying amount				
As of January 1, 2017	€ 5,894	€ 22,868	€ 3,613	€ 32,374
As of December 31, 2017	7,387	36,067	6,153	49,606
As of December 31, 2018	€ 15,675	€ 43,433	€ 7,091	€ 66,199

Assets under construction

Assets under construction for buildings included in property, plant and equipment amounted to k€5,725 as of December 31, 2018 (December 31, 2017: k€1,327; January 1, 2017: nil).

10 Intangible assets

(in thousands)	<u>Goodwill</u>	<u>Concessions, licenses and similar rights</u>	<u>Advance payments</u>	<u>Total</u>
Acquisition costs				
As of January 1, 2017	€ 534	€ 9,421	€ 3,839	€ 13,793
Additions	—	74,500	1,077	75,577
Reclassifications	—	1,351	(1,351)	—
As at December 31, 2017	€ 534	€ 85,271	€ 3,565	€ 89,370
As of January 1, 2018	€ 534	€ 85,271	€ 3,565	€ 89,370
Additions	—	12,150	3,128	15,278
Disposals	—	—	(765)	(765)
Reclassifications	—	4,431	(4,431)	—
As at December 31, 2018	€ 534	€ 101,853	€ 1,497	€ 103,883
Cumulative amortization and impairment charges				
As of January 1, 2017	€ —	€ 2,609	€ —	€ 2,609
Amortization	—	2,943	—	2,943
Impairment loss	—	281	—	281
As at December 31, 2017	€ —	€ 5,833	€ —	€ 5,833
As of January 1, 2018	€ —	€ 5,833	€ —	€ 5,833
Amortization	—	10,009	—	10,009
As at December 31, 2018	€ —	€ 15,842	€ —	€ 15,842
Carrying amount				
As January 1, 2017	€ 534	€ 6,812	€ 3,839	€ 11,185
As of December 31, 2017	534	79,438	3,565	83,537
As of December 31, 2018	€ 534	€ 86,011	€ 1,497	€ 88,042

Intangible assets comprise a license with a carrying amount of k€55,420 (December 31, 2017: k€61,876; January 1, 2017: nil) and a useful lifetime of 10 years.

Impairments

In 2017, an impairment loss of k€281 was recorded for a software program. The impairment loss was recognized under other operating expenses.

Contractual commitments

Contractual commitments for the acquisition of intangible assets amounts to k€19,482 (2017: k€40,078; January 1, 2017: nil).

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Goodwill

For impairment testing, goodwill acquired through business combinations and intangible assets not yet in use have been allocated to the respective cash-generating units.

CGUs are based on the level of legal entities. Therefore, the goodwill has been allocated to the CGU JPT.

(in thousands)	JPT		
	December 31, 2018	December 31, 2017	January 1, 2017
Goodwill	€ 534	534	534

The Group performed its annual goodwill impairment for the balance sheet dates January 1, 2017, December 31, 2017 and December 31, 2018.

The recoverable amount was determined on a value in use calculation using cash flow projections from budgets approved by senior management covering a five-year period.

Management concluded that no reasonable possible change of key assumptions on which the calculation of the recoverable amount is based would cause the carrying amount of the CGU to exceed its recoverable amount.

The pre-tax discount rate applied to cash flow projections for the year ended 2018 is 12.2% (December 31, 2017: 12.3%; January 1, 2017: 12.3%) and cash flows beyond the five-year period are extrapolated using a 1.0% growth rate (2017: 1.0%; 2016: 1.0%).

As the recoverable amount exceeded the carrying amount of the CGU for every balance sheet date, no impairment charge was required.

Intangible assets not yet available for use

In 2018, there were no intangible assets not yet available that were not recognized.

In 2017, the Group performed an impairment test for intangible assets not yet in use, which had carrying amounts of k€1,190 (January 1, 2017: nil).

The recoverable amount was determined on a value in use calculation. Intangible assets of k€1,190 were available for use as planned during the current period.

Management concluded that no reasonable possible change of key assumptions on which the calculation of the recoverable amount is based would cause the carrying amount of the CGU to exceed its recoverable amount.

11 Financial assets and financial liabilities

11.1 Capital risk management

The objective of the capital management of BioNTech is primarily designed to finance the Group's growth strategy.

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The Group's controlling committee reviews the total amount of cash of the Group on a weekly basis. As part of this review, the committee considers the total cash and cash equivalents, the cash outflow, currency translation differences and refinancing activities. The Group monitors cash using a burn rate. The cash burn rate is defined as the average monthly net cash flow from operating and investing activities during a financial year.

(in thousands)	December 31,		As at 1 January
	2018	2017	2017
Cash and cash equivalents	€411,495	€172,106	€ 303,680
Total	€411,495	€172,106	€ 303,680

In meeting its financing objectives, the Group negotiates and enters into research cooperation agreements. In general, the aim is to maximize the financial resources available for further research and development projects.

BioNTech is not subject to externally imposed capital requirements. The objectives of BioNTech's capital management were achieved in the reporting year.

No changes were made in the objectives, policies or processes for managing cash during the years ended December 31, 2018 and 2017.

11.2 Categories of financial instruments

Financial assets at amortised cost

(in thousands)	2018	2017	As at 1
			January 2017
Trade receivables	€18,938	€4,575	€ 3,161
Receivables from co-operation agreements	—	—	1,373
Other financial assets and receivables	354	264	221
Total	€19,292	€4,839	€ 4,755
Total current	19,273	4,820	4,689
Total non-current	18	19	66

Financial liabilities: Interest-bearing loans and borrowings

(in thousands)	Maturity	2018	2017	As at 1
				January 2017
2.15% €10,000,000 secured bank loan	12/30/2027	€4,000	—	—
2.08% €9,450,000 secured bank loan	09/30/2028	1,600	—	—
Total		€5,600	—	—
Total current		—	—	—
Total non-current		5,600	—	—

Other financial liabilities at amortised cost, other than interest-bearing loans and borrowings

(in thousands)	2018	2017	As at 1 January 2017
Trade and other payables	€41,721	€ 52,538	€ 6,218
Lease liabilities	50,752	52,182	28,132
Liabilities from license agreements	—	—	8,889
Other payables	6,132	1,938	2,412
Total	€98,605	€106,658	€ 45,651
Total current	49,987	56,309	18,983
Total non-current	48,618	50,349	26,669

2.15% secured loan

The loan is secured by a lien over land and buildings with a carrying value of k€10,000 (2017: nil). Additionally, the loan is secured by a permanent guarantee (*Höchstbetragsbürgschaft*) of the Company to the bank to the amount of k€10,000. The loan is repayable in equal quarterly instalments of k€312.5 commencing on March 31, 2020. As at December 31, 2018, the undrawn available amount is k€6,000.

2.08% bank loan

The loan is secured by a lien over land and buildings to the amount of k€9,450. Additionally, the loan is secured by a permanent guarantee (*Höchstbetragbürgschaft*) of the Company to the bank to the amount of k€9,450 (2017: nil). The loan is repayable by quarterly instalments of k€286.4 commencing on September 30, 2020. As at December 31, 2018, the available undrawn amount of k€7,850 will be drawn on predetermined dates. The loan will be fully drawn at January 15, 2020.

11.3 Fair values

Fair values of cash and cash equivalents, trade receivables, trade payables and other current liabilities approximate their carrying amounts largely due to the short-term maturities of these instruments.

The liabilities include two fixed-interest rate loans. The fair value of the two fixed-interest rate loans is calculated based on significant observable inputs (Level 2). As of December 31, 2018, the carrying value approximates their fair values as they were agreed only recently and there have been no significant changes in relevant interest rates.

11.4 Financial instruments risk management objectives and policies

The Group's financial liabilities comprise of bank loans, lease liabilities, trade and other payables. The main purpose of these financial liabilities is to enable the Group's operations. The Group's principal financial assets include mainly cash and trade receivables that derive directly from its operations.

The Group is exposed to market risk, credit risk and liquidity risk. The Group's senior management oversees the management of these risks.

The controlling committee provides assurance to the Group's senior management that the Group's financial risk activities are governed by appropriate policies and procedures and that financial risks are identified, measured and managed in accordance with the Group's policies and risk objectives. The Board of Directors reviews and agrees policies for managing each of these risks, which are summarized below.

11.5 Market risk

Market risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate due to changes in market prices. Market risk comprises of three types of risk: interest risk, foreign currency risk and other price risk. Financial instruments affected by market risk include cash and cash equivalents. Interest risk is not a risk for the Group.

The sensitivity analysis in the following sections relate to the position as at December 31, 2018 and 2017.

There were no material changes in the Group's market risk exposures or changes in the way risk was managed and valued during the periods.

11.5.1 Foreign currency risk

Foreign currency risk is the risk that the fair value or future cash flows of an exposure will fluctuate because of changes in foreign exchange rates. The Group's exposure to the risk of changes in foreign currency rates relates primarily to the Group's operating activities (when revenue or expense is denominated in a foreign currency).

In order to reduce exchange rate risk, BioNTech makes every effort to generate expenses and income in the same functional currency. The Group does not hedge exchange rate risks.

The carrying amount of the monetary assets (the Group's cash and cash equivalents) of BioNTech denominated in foreign currencies at the reporting date are as follows:

(in thousands)	As at December 31,	
	2018	2017
USD Bank accounts	€176,376	€140,822

The following tables demonstrate the sensitivity to a reasonably possible change in USD exchange rates, with all other variables held constant. The impact on the Group's profit before tax is due to changes in the fair value of monetary assets. The Group's exposure to foreign currency changes for all other currencies is not material.

Currency	1 € = Country	Closing rate		As at January 1, 2017	Average rate	
		2018	2017		2018	2017
USD	United States	1.1450	1.1993	1.1194	1.1810	1.1297
		Change in USD rate	Effect on loss before tax		Effect on pre-tax equity	
		+5 %	(8,399)		(8,399)	
2018		-5%	9,283		9,283	
		+5 %	(6,706)		(6,706)	
2017		-5%	7,412		7,412	

11.6 Credit risk management

Credit risk is the risk that a counterparty will not meet its obligations under a financial instrument or customer contract, leading to a financial loss. The Group is exposed to credit risk from its operating activities, including deposits with banks and financial institutions, foreign exchange transactions and trade accounts receivable.

Trade receivables and contract assets

The Group's exposure to credit risk of trade receivables and contract assets is primarily on transactions with corporate customers in the biopharma/biotech industry that operate in Germany or in the United States. The Group evaluates this risk through detailed aging analysis and also detailed analysis of the creditworthiness of the customers at each reporting date. The Group follows risk control procedures to assess the credit quality of the customers taking into account their financial position, past experience and other factors. The compliance with credit limits by corporate customers is regularly monitored by management.

The credit risk on trade receivables and contract assets is very low as the customer portfolio of BioNTech mainly consists of medical universities, other public institutions and peers in the biopharma industry, which all have a very high credit rating and the group has not incurred bad debt expense. BioNTech does not expect that its customer portfolio will change.

Generally, trade receivables are written off if past due for more than one year and are not subject to enforcement activity. The maximum exposure to credit risk at the reporting date is the carrying value of each class of financial assets disclosed in Note 11.2. The Group does not hold collateral as security.

The credit risk exposure on the Group's trade receivables and contract assets is as follows:

Year ended December 31, 2018

<u>(in thousands)</u>	<u>Contract assets</u>	<u>Trade receivables</u>
Expected credit loss rate	— %	— %
Estimated total gross carrying amount at default	€ —	€ 18,938
Expected credit loss	€ —	€ —

Year ended December 31, 2017

<u>(in thousands)</u>	<u>Contract assets</u>	<u>Trade receivables</u>
Expected credit loss rate	— %	— %
Estimated total gross carrying amount at default	€ —	€ 4,575
Expected credit loss	€ —	€ —

As at January 1, 2017

<u>(in thousands)</u>	<u>Contract assets</u>	<u>Trade receivables</u>
Expected credit loss rate	— %	— %
Estimated total gross carrying amount at default	€ 637	€ 3,161
Expected credit loss	€ —	€ —

Cash deposits

Credit risk from balances with banks and financial institutions is managed by the Group's controlling department in accordance with the Group's policy. Investments of surplus funds are made only with banks.

Credit risk stemming from cash and deposits is very low.

The Group's maximum exposure to credit risk for the components of the statements of financial position at December 31, 2018 and 2017 are the carrying amounts as illustrated in Note 11.1.

11.7 Liquidity risk

Historically, BioNTech has relied on the financing from shareholders and collaborators in order to ensure sufficient liquidity. Lack of external financial support could pose a risk of going concern. The liquidity management of BioNTech ensures the availability of cash and cash equivalents for operational activities and further investments through appropriate budget planning. In addition, a sufficient level of cash and cash equivalents, which is managed centrally, is always maintained to finance the operational activities.

The Group monitors liquidity risks using a liquidity planning tool.

Ultimately, the responsibility for liquidity risk management lies with the management, which has established an appropriate approach to managing short-, medium- and long-term financing and liquidity requirements. BioNTech manages liquidity risks by holding appropriate reserves, as well as by monitoring forecasted and actual cash flows and reconciling the maturity profiles of financial assets and liabilities.

Risk concentration

Concentrations arise when a number of counterparties are engaged in similar business activities, or activities in the same geographical region, or have economic features that would cause their ability to meet contractual obligations to be similarly affected by changes in economic, political or other conditions. Concentrations indicate the relative sensitivity of the Group's performance to developments affecting a particular industry.

In order to avoid concentrations of risk, the Group's policies and procedures include specific guidelines to focus on the maintenance of an effective diversification in the sources of funding and distribution of cash deposits. Identified concentrations of credit risks are controlled and managed accordingly.

The maturity profile of the Group's financial liabilities based on contractual undiscounted payments is summarized as follows:

Year ended December 31, 2018 (in thousands)	Less than 1 year	1 to 5 years	> 5 years	Total
Interest bearing loans and borrowings	—	5,600	—	€ 5,600
Trade payables	41,721	—	—	41,721
Lease liability	3,822	13,346	56,524	73,692
Other financial liabilities	6,132	—	—	6,132
Total	€51,675	€ 13,346	€56,524	€127,145

Year ended December 31, 2017 (in thousands)	Less than 1 year	1 to 5 years	> 5 years	Total
Trade payables	52,538	—	—	€ 52,538
Lease liability	3,552	13,743	59,263	76,558
Other financial liabilities	1,939	—	—	1,939
Total	€58,029	€ 13,743	€59,263	€131,035

As at January 1, 2017 (in thousands)	Less than 1 year	1 to 5 years	> 5 years	Total
Trade payables	6,218	—	—	€ 6,218
Lease liability	2,392	8,193	32,606	43,191
Other financial liabilities	11,301	—	—	11,301
Total	€19,911	€ 8,193	€32,606	€60,701

11.8 Changes in liabilities arising from financing activities

BioNTech uses leases to acquire the right to use assets for a specified amount of time. Due to the first-time adoption of IFRS 16, lease liabilities at an amount of k€28,132 were recognized as of January 1, 2017. The liability arising from leases amounts to k€52,182 as of December 31, 2017 and 50,775 as of December 31, 2018.

Year ended December 31, 2018 (in thousands)	January 1, 2018	Cash flows	New Leases	Reclassification	December 31, 2018
Current obligations under lease contracts	€ 1,832	(2,126)	296	2,132	2,134
Non-current obligations under lease contracts	€ 50,349	—	401	(2,132)	48,618
Interest-bearing loans and borrowings	—	5,600	—	—	5,600
Total	€ 52,182	3,474	€ 697	€ —	€ 56,352

Year ended December 31, 2017 (in thousands)	January 1, 2017	Cash flows	New Leases	Reclassification	December 31, 2017
Current obligations under lease contracts	1,464	(2,319)	—	2,687	1,832
Non-current obligations under lease contracts	26,669	676	25,692	(2,687)	50,349
Total	€ 28,132	€(1,643)	€25,692	€ —	€ 52,182

12 Inventories

(in thousands)	December 31, 2018	December 31, 2017	January 1, 2017
Raw materials and supplies	€ 4,475	€ 2,874	€ 2,702
Unfinished goods and services	80	95	10
Finished goods and services	1,234	907	554
Total inventories	€ 5,789	€ 3,876	€ 3,266

During 2018, inventories of k€5,382 (2017: k€7,448) were recognized as an expense and recognized in cost of sales.

BioNTech has not pledged any inventories as securities for liabilities.

13 Trade receivables

(in thousands)	December 31, 2018	December 31, 2017	January 1, 2017
Trade Receivables	18,938	4,575	3,161
Total	€ 18,938	€ 4,575	€ 3,161

Trade receivables are non-interest bearing and are generally due on terms of 20 to 30 days. As described in Note 11.6, expected credit loss for trade receivables is immaterial.

14 Other assets

(in thousands)	December 31,		As of 1 January
	2018	2017	2017
Sales tax receivable	€8,611	€3,832	€ 2,172
Prepayments on inventories	155	815	851
Other assets	397	1,630	1,676
Total	€9,164	€6,227	€ 4,699

Other assets were mainly comprised of interest income of k€270 (2017 other assets were mainly comprised of receivables due to grants of k€1,356).

15 Issued capital and reserves

Issued capital:

Authorized shares

(in thousands)	December 31,		As of 1 January
	2018	2017	2017
Ordinary shares	9,297	9,265	182
Series A shares	1,255	—	—
Qualifying shares	187	—	—
Total	€10,739	€9,265	€ 182

During the fiscal year 2018, the issued capital of BioNTech was increased by €1.5 million (2017: €9.1 million) to €10.7 million (2017: €9.3 million) in conjunction with a cash investment of €355.8 million. The capital increase in 2017 is due to a conversion of capital reserves into share capital. There were no cash proceeds in this transaction. Each share has a par value of €1.

16 Share-based payments

16.1 Description of share-based payments

At December 31, 2018 and 2017, the Group had the following share-based arrangements.

16.1.1 Employee Stock Ownership Plan (equity-settled)

On November 15, 2018, the Group established a share option program that grants selected employees options to receive shares in the company. The program is designed as an Employee Stock Ownership Plan (ESOP). The Group has offered the participants a certain number of rights (Option Rights) by explicit acceptance of the participants. The exercise of the Option Rights in accordance with the terms of the ESOP, gives the participants the right to obtain shares against payment of the exercise price. The Option Rights vest over four years, can only be exercised if the company has executed a public offering in the United States (IPO) and when meeting the Threshold Amount. Threshold Amount means the exercise price provided increases by eight percentage points on the first and then each subsequent anniversary of the Allocation Date (September 26, 2018). The Option Rights can be exercised at the latest eight years after the Allocation Date. If they have not been exercised by that date, they will forfeit without compensation.

16.1.2 Share appreciation rights (equity-settled)

On December 1, 2017, the Group granted 32,373 shares to selected employees under the share appreciation rights (SAR) program. The shares vested immediately at the grant date (December 2017) as there were no vesting conditions.

There were no other SARs granted.

16.2 Measurement of fair values

16.2.1 Equity-settled share-based payment arrangement

The fair value of the employee share options has been measured using a binomial model. Service conditions attached to the arrangement were not taken into account in measuring the fair value.

The share options can only be exercised by the grantee if the price of the share is equal or greater to the Threshold Amount as defined in the arrangement. Moreover, the option rights can only be exercised if the IPO has occurred. Both conditions have been incorporated into the fair value at grant date.

The inputs used in the measurement of the fair values at grant date of the equity-settled share-based payment plan was as follows:

	Grant date 15 November 2018
Fair value at grant date	€ 133.40
Share price at grant date	€ 259.28
Exercise price	€ 182.53
Expected volatility (%)	46.0%
Expected life (years)	5.84
Expected dividends	0.0%
Risk-free interest rate (%)	0.05%

Expected volatility has been based on an evaluation of the historical and the implied volatilities of comparable companies over the historical period commensurate with the expected term. The expected term has been based on general option holder behavior for employee options.

16.2.2 Share appreciation rights

The fair value of the SARs has been determined using a discounted cash flow (DCF) model as of December 2017.

The inputs used in the measurement of the fair values at grant date of the SARs were as follows.

	Grant date 1 December 2017
Fair value	€ 182.33
WACC	8.2%
Tax rate	31.2%
Debt free net working capital (in % of sales)	5.5%
Risk-free interest rate (%)	1.2%
Long-term growth rate (%)	1.8%

Growth rate estimates are based on epidemiology data for different indications in focus geographies. The average market growth rates per indication and stage have been extrapolated with data derived from published industry research.

The expected life of the SARs is based on historical data and current expectations and is not necessarily indicative of exercise patterns that may occur.

Expected dividends were not incorporated into the measurement of fair value.

16.3 Reconciliation of outstanding share-options

The number and weighted-average exercise prices of share options under the ESOP were as follows:

Reconciliation of outstanding share options

	Number of options	Weighted average exercise price
Outstanding at 1 January 2018	—	—
Granted during the year	658,109	€ 182.53
Outstanding at 31 December 2018	658,109	€ 182.53
Exercisable at 31 December 2018	—	—

The options outstanding at December 31, 2018 have a weighted-average contractual life of 7.75 years.

16.4 Expense recognized in the statement of operations

The expense recognized for employee services received during the year is shown in the following table:

<u>(in thousands)</u>	<u>2018</u>	<u>2017</u>
Expense arising from equity-settled share-based payment transactions	€7,641	€5,909
Total	€7,641	€5,909

The expenses were recognized in the statement of operations as follows:

<u>(in thousands)</u>	<u>2018</u>	<u>2017</u>
Cost of sales	€ 114	€ —
Research and development expenses	6,786	3,620
Sales and marketing expenses	14	14
Administrative expenses	728	2,275
Total	€7,641	€5,909

There were no cancellations or modifications to the awards in 2018 or 2017.

16.5 Net settlement feature for withholding tax obligation

Under the agreement, BioNTech must withhold an amount for an employee's tax obligation associated with the share-based payment and transfer that amount in cash to the tax authority on the employee's behalf. BioNTech does not withhold shares in order to settle the employee's tax obligations. The Group withheld an amount of k€7,761 that was paid to the taxation authority in relation to the SARs in 2018.

17 Other liabilities

<u>(in thousands)</u>	<u>2018</u>	<u>2017</u>	<u>As at 1 January 2017</u>
Liabilities employees	€5,236	€19,277	€2,919
Other	3,864	5,494	1,148
Total	€9,100	€24,771	€4,067

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Other liabilities comprise accruals for outstanding invoices in the amount of k€3,739 (2017: k€1,383) and several other non-material positions.

18 Leases

18.1 Amounts recognized in the balance sheet

The following amounts relate to leases and are included in Property, plant and equipment.

Right-of-use assets

(in thousands)	2018	2017	1 January 2017
Buildings	€49,718	€51,772	€ 27,870
Equipment	21	81	192
Cars	27	62	71
Total	€49,766	€51,915	€ 28,132

The following amounts are included in other financial liabilities.

Lease liability

(in thousands)	2018	2017	1 January 2017
Current	€ 2,134	€ 1,832	€ 1,464
Non-current	48,618	50,349	26,669
Total	€50,752	€52,182	€ 28,132

Additions to the right-of-use assets during 2018 were k€723 (2017: k€25,662; as of January 1, 2017: k€28,132).

18.2 Amounts recognized in the statement of operations

Depreciation charge of right-of-use assets

(in thousands)	2018	2017
Buildings	€2,751	€1,759
Equipment	60	111
Cars	35	39
Total depreciation charge	€2,846	€1,909
Interest on lease liabilities	1,721	676
Expense related to short-term leases (included in other expenses)	431	442
Expense relating to leases of low-value assets that are not short-term leases (included in other expenses)	90	95
Total amounts recognised in statement of operations	€5,088	€3,121

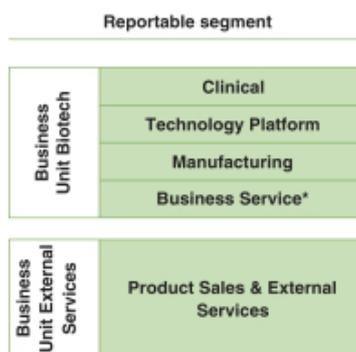
The total cash outflow for leases in 2018 amounted to k€3,847 (2017: k€2,319).

19 Segment information

BioNTech develops individualized treatments for cancer patients and improved therapeutics to treat infectious and rare diseases. This activity, together with research and development activities, forms the core of the company. External services provide the interface where medical products are sold to third parties.

BioNTech’s business is managed in two business units, the biotech business unit and the external services business unit. The biotech business unit is comprised of three operation segments, which are individually monitored by the Chief Operating Decision Maker (CODM). Four operating segments have been identified in accordance with IFRS 8. No aggregation of operating segments was performed.

Resource allocation and performance assessment is performed at the level of the Management Board. The Management Board members are jointly responsible for the management and strategic decision making. Consequently, the Management Board has been identified as the CODM. BioNTech’s business consist of the following reportable segments:



* Business Service bundles the Group’s central functions. In line with IFRS 8.6, Business Services is not an operating segment but the information is separately disclosed

Research and Development activities form the Biotech Business Unit and are divided in the segments Clinical, Technology Platform and Manufacturing.

The **Clinical** segment subsumes all development activities relating to clinical programs. Clinical studies include testing the product candidates on humans. Clinical trials are an essential part of the development and licensing of the medicinal products and are performed before the respective product can be placed on the market. BioNTech is actively engaged in many collaborations and licensing deals with reputable pharmaceutical companies and academic partners.

Technology Platform contains all development activities relating to preclinical programs. Preclinical development is the stage of research that begins before clinical trials. It is performed to determine the desired pharmacological effects and to identify any unwanted effects that may cause adverse reactions during human exposure.

Manufacturing is an essential part of the research and development process as it comprises the manufacturing unit of mRNA and engineered cell therapies. All the medical substances and tools that form the basis for the research studies performed at BioNTech are manufactured in this segment, (i.e., the Manufacturing segment contains only internally produced substances and tools).

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Product Sales & External Services comprises the legal entities JPT Peptide Technology GmbH and Innovative Manufacturing Services GmbH (IMFS), which form the interface to third parties. External services and medicinal products (*e.g.*, peptides and retroviral vectors) that are in the areas of molecular immunotherapies and biomarker-based diagnostic approaches for individualized treatment of cancer and other infectious diseases are sold to customers worldwide.

Business Service contains the Group's central administrative functions (*e.g.*, Finance, Procurement, Human Resources, Legal and Intellectual Property) and overarching projects. Business Service does not fulfil the requirements for an operating segment according to IFRS 8, as it will never generate more than incidental revenues. However, financial information about Business Service is disclosed, as it contributes to the understanding of the company.

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The table below reconciles segment figures to Group figures.

(in thousands)	Biotech Business Unit				External Services Business Unit	Total	Adjustments	Group
	Clinical	Technology Platform	Manufacturing	Business Service	External Services			
Year ended December 31, 2018								
Revenues								
Collaboration Revenue	€ 36,750	€ 39,452	€ 25,635	€ —	€ —	€ 101,837		€ 101,837
Revenues from other sales transactions	—	6,783	—	42	18,914	25,738		25,738
Cost of sales	—	—	—	(40)	(13,358)	(13,398)	(292)	(13,690)
Gross Profit	€ 36,750	€ 46,235	€ 25,635	€ 2	€ 5,556	€ 114,177	€ (292)	€ 113,885
Research and development expenses	(48,641)	(60,320)	(31,508)	(1,979)	(884)	(143,332)	292	(143,040)
Sales and marketing expenses	—	—	—	(2,106)	(935)	(3,041)		(3,041)
General and administrative expenses	—	—	(2,558)	(21,233)	(2,542)	(26,334)		(26,334)
Other result	3,772	178	30	85	559	4,624	52	4,676
Segment operating profit/loss	€ (8,119)	€ (13,908)	€ (8,401)	€ (25,231)	€ 1,753	€ (53,906)	€ 52	€ (53,854)

	Biotech Business Unit				External Services Business Unit	Total	Adjustments	Group
	Clinical	Technology Platform	Manufacturing	Business Service	External Services			
Year ended December 31, 2017								
Revenues								
Collaboration Revenue	€ 25,721	€ 14,504	€ 2,108			€ 42,333		€ 42,333
Revenues from other sales transactions		324			18,941	19,265		19,265
Cost of sales					(9,318)	(9,318)		(9,318)
Gross Profit	€ 25,721	€ 14,828	€ 2,108	€ 0	€ 9,623	€ 52,280	€ —	€ 52,280
Research and development expenses	(25,099)	(37,019)	(14,764)	(6,701)	(1,912)	(85,496)	—	(85,496)
Sales and marketing expenses				(4,904)	(1,698)	(6,603)	—	(6,603)
General and administrative expenses			(785)	(20,309)	(2,427)	(23,520)	—	(23,520)
Other result		777		820	463	2,061	—	2,061
Segment operating profit/loss	€ 623	€ (21,414)	€ (13,441)	€ (31,094)	€ 4,049	€ (61,277)	€ —	€ (61,277)

The segments are managed based on external sales and operating profit/loss, which represents the operating profit earned by each segment. Segment figures are reported consolidated, which reflects the way management steers the business.

BioNTech's internal reporting is generally set up in accordance with IFRS and in line with the Group's accounting policies, except for minor deviations in classification between cost of sales and research and development cost. Whenever revenues are attributable to different segments, these revenues are split based on the incurred cost. Internal overhead costs are allocated to segments based on revenues when they are directly attributable to a service rendered. Sales and marketing expenses, general and administrative expenses and the other result that are not directly attributable to one of the segments are allocated to Business Service.

To reconcile the segment figures to the Group's financial statements in 2018, the presentation of k€292 of research and development cost was adjusted.

Revenue at BioNTech can be differentiated between revenues resulting from collaboration and license agreements and revenues from other sales. The Company collaborates with reputable pharmaceutical and healthcare companies and several global academic collaborators. Revenues from other sales result from the sale of medical products (e.g., peptides and retroviral vectors) for clinical supply. Research and development activities are managed on a worldwide basis but the operative manufacturing facilities and sales offices are located and managed in Germany. External sales are originated in Germany.

20 Related party disclosures

20.1 Parent and ultimate controlling party

Members of the Strüngmann family wholly own AT Impf GmbH. Dr. Andreas Strüngmann and Dr. Thomas Strüngmann may be deemed to beneficially own any or all of these shares.

20.2 Transactions with key management personnel

Key management personnel compensation

Key management personnel at BioNTech has been defined as the members of the Management Board and of the Supervisory Board. Key management personnel compensation is comprised of the following:

Compensation of key management personnel (in thousands)	2018	2017
Short-term employee benefits	€1,161	€ 880
Share-based compensation	6,163	1,855
Total compensation paid to key management personnel	€7,324	€2,735

Executive officers also participate in the Group's ESOP and SAR program (see Note 16).

Key management personnel transactions

A number of key management personnel, or their related parties, hold positions in other companies that results in them having control or significant influence over these companies. A number of these companies have had transactions with the Group during the year.

The Group purchases various goods and services from research institutes where a director of BioNTech holds a key management position.

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The aggregate value of transactions related to key management personnel were as follows:

Transaction

(in thousands)	2018	2017	As of 1 January 2017
Consulting services	€ 25	€ 25	€ 30
Purchases of various goods and services from TRON	€ 11,160	€ 6,553	€ 5,801

20.3 Other related party transactions

The total amount of transactions with AT Impf GmbH or entities controlled by them was as follows:.

(in thousands)	Transaction values for the year ended		
	2018	2017	As of 1 January 2017
Purchases of various goods and services from entities controlled by AT Impf GmbH	€ 2,431	€ 1,240	€ 1,050
Purchases of property and other assets from entities controlled by AT Impf GmbH	€ 4,748	€ —	€ —
Total	€ 7,179	€ 1,240	€ 1,050

None of the balances are secured and no bad debt expense has been recognized in respect of amounts owed by related parties.

21 Events after the reporting period

In January 2019, BioNTech entered into an agreement to acquire MAB Discovery GmbH's operational antibody generation unit based near Munich, Germany for a total consideration of €9 million. The acquisition was completed on April 1, 2019.

In January 2019, BioNTech AG increased its Share Capital by k€283 in conjunction with a receipt of a cash investment of k€80,000.

In March 2019, BioNTech AG changed its legal form to a European company (*Societas Europaea* or "SE"). As an SE, BioNTech will be a public limited company under EU law. The supranational aspect of this legal form represents an international focus with Europe as the company's base, and is the next logical step in the development of BioNTech's worldwide operations.

In March 2019, BioNTech AG increased its share capital by k€132. In this transaction, an investor exchanged its shares in a subsidiary for shares of the parent company.

In May 2019, BioNTech entered into an agreement to purchase the assets of MabVax Therapeutics, Inc. The acquisition was completed on May 8, 2019. The total purchase price was \$5 million.

In June 2019, BioNTech SE increased its share capital by k€666 in conjunction with the Series B financing.

American Depositary Shares



Representing Ordinary Shares

PRELIMINARY PROSPECTUS

J.P. Morgan	BofA Merrill Lynch	UBS Investment Bank	SVB Leerink
Canaccord Genuity	Bryan, Garnier & Co.	Berenberg	
Wolfe Capital Markets and Advisory	Kempen	Mirae	

, 2019

Through and including _____, 2019 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

PART II

INFORMATION NOT REQUIRED IN THE PROSPECTUS

Item 6. Indemnification of Directors and Officers

As a German European public company with limited liability, we are—insofar as applicable pursuant to the SE Regulation and the German law on the implementation of the SE (SEAG)—subject to the German Stock Corporation Act (*Aktiengesetz*), as amended. Under German law, we may not indemnify members of our Management Board and Supervisory Board to the extent the relevant claim or loss has arisen as a result of the breach by the member of his or her duties owed to us. Otherwise we are required under the law to indemnify our Management Board and Supervisory Board members from and against any liabilities arising out of or in connection with their services to us.

We provide directors' and officers' liability insurance for the members of our Management and Supervisory Boards against civil liabilities, which they may incur in connection with their activities on behalf of our company.

In the underwriting agreement, the form of which is filed as Exhibit 1.1 to this Registration Statement, the underwriters will agree to indemnify, under certain conditions, us, the members of our Supervisory Board, Management Board and persons who control our company within the meaning of the Securities Act, against certain liabilities, but only to the extent that such liabilities are caused by information relating to the underwriters furnished to us in writing expressly for use in this registration statement and certain other disclosure documents.

Insofar as indemnification of liabilities arising under the Securities Act may be permitted to our board, executive officers, or persons controlling us pursuant to the foregoing provisions, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Item 7. Recent Sales of Unregistered Securities

Set forth below is information regarding all securities issued by us without registration under the Securities Act since January 1, 2016. We believe that each of such issuances was exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act or Rule 506 promulgated thereunder as transactions by an issuer not involving a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was either an accredited investor within the meaning of Rule 501 of Regulation D under the Securities Act or was our employee, director or consultant and received the securities under our equity incentive plans. None of these transactions involved any underwriters, underwriting discounts or commissions or any public offering. All recipients had adequate access, through their relationships with us to information about us. The sales of these securities were made without any general solicitation or advertising.

- In February 2018 we issued 1,254,884 ordinary shares in private placements to a group of existing and new investors for aggregate proceeds received of \$270.9 million, which we refer to as our Series A financing.
- In September 2018 we issued 32,373 ordinary shares as part of our Stock Appreciation Rights program for aggregate consideration of \$6.8 million.
- In October 2018 we issued 186,715 ordinary shares in private placements to Pfizer, Fidelity and an existing investor for aggregate proceeds received of \$55.0 million.
- In January 2019 we issued 282,678 ordinary shares in private placements to Sanofi and an existing investor for aggregate proceeds received of \$92.1 million.

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- In April 2019 we issued 131,933 ordinary shares in a private placement to Eli Lilly. The shares were subscribed for by Eli Lilly against contribution in kind of shares in BioNTech Cell & Gene Therapies GmbH, which were valued at \$43.0 million.
- In June and July 2019 we issued an aggregate of 666,123 ordinary shares in private placements to a group of existing and new investors for aggregate proceeds received of \$217 million, which we refer to as our Series B financing. An additional 333,310 ordinary shares have been sold as part of the Series B financing and will be issued to certain shareholders following registration in the commercial register (*Handelsregister*) for aggregate proceeds received of \$108.6 million.

Item 8. Exhibits

(a) The following documents are filed as part of this registration statement:

<u>Exhibit No.</u>	<u>Exhibit</u>
1.1*	Form of Underwriting Agreement
3.1*	Articles of Association of the Registrant
3.2*	Articles of Association of the Registrant, as effective immediately prior to this offering
4.1*	Form of Specimen American Depositary Receipt (included in Exhibit 4.3)
4.2*	Registrant's Specimen Certificate for Ordinary Shares
4.3*	Form of Deposit Agreement among the Registrant, the depositary and holders and beneficial owners of the American Depositary Shares
5.1*	Opinion of Freshfields Bruckhaus Deringer LLP regarding the validity of the Ordinary Shares being registered
10.1*†	Master Agreement for Research Services by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH, BioNTech Diagnostics GmbH, BioNTech Protein Therapeutics GmbH, BioNTech Cell & Gene Therapies GmbH, Eufets GmbH, JPT Peptide Technologies GmbH and TRON-Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH, dated January 1, 2015
10.2*†	Confirmation Letter by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH and TRON-Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH dated September 15, 2016
10.3*†	Supplementary Agreement for IVAC Developments to the Master Agreement for Research Services by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH, BioNTech Diagnostics GmbH, BioNTech Protein Therapeutics GmbH, BioNTech Cell & Gene Therapies GmbH, BioNTech Innovative Manufacturing Services GmbH (f/k/a Eufets GmbH), JPT Peptide Technologies GmbH and TRON-Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH, dated November 28, 2017
10.4*†	License Agreement by and among the Registrant, TRON-Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH, Johannes Gutenberg-Universität Mainz, Universitätsmedizin der Johannes Gutenberg-Universität and Ganymed Pharmaceuticals AG, dated January 1, 2015
10.5†	Amended Patent License Agreement by and among the Registrant, the Board of Supervisors of Louisiana State University and Agricultural and Mechanical College and Uniwersytet Warszawski, dated May 12, 2015
10.6†	License and Collaboration Agreement by and between the Registrant and Genmab A/S, dated May 19, 2015
10.7†	Amendment No. 1 to License and Collaboration Agreement by and between the Registrant and Genmab A/S, dated May 18, 2017
10.8†	Amendment No. 2 to License and Collaboration Agreement by and between the Registrant and Genmab A/S, dated August 4, 2017

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<u>Exhibit No.</u>	<u>Exhibit</u>
10.9†	Amendment No. 3 to License and Collaboration Agreement by and between the Registrant and Genmab A/S, dated May 18, 2018
10.10†	Collaboration and License Agreement by and between Sanofi S.A. and BioNTech RNA Pharmaceuticals GmbH, dated November 2, 2015
10.11†	Amendment to Collaboration and License Agreement by and between Sanofi S.A. and BioNTech RNA Pharmaceuticals GmbH, dated December 22, 2018
10.12†	Development Agreement by and between Sanofi S.A. and BioNTech RNA Pharmaceuticals GmbH, dated March 29, 2018
10.13†	Collaboration Agreement by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH, Genentech, Inc. and F. Hoffman-La Roche Ltd, dated September 20, 2016
10.14†	Patent Sublicense Agreement by and between Cellscript, LLC and BioNTech RNA Pharmaceuticals GmbH, dated July 19, 2017
10.15†	Patent Sublicense Agreement by and between mRNA RiboTherapeutics, Inc. and BioNTech RNA Pharmaceuticals GmbH, dated July 19, 2017
10.16†	License and Co-Development Agreement by and between Genevant Sciences GmbH and BioNTech RNA Pharmaceuticals GmbH, dated July 4, 2018
10.17†	Research Collaboration and License Agreement by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH and Pfizer, Inc., dated July 20, 2018
10.18†	Collaboration and License Agreement by and between the Trustees of the University of Pennsylvania and BioNTech RNA Pharmaceuticals GmbH, dated October 9, 2018
10.19*†	BioNTech Shareholders' Agreement by and among the Spring 2019 Parties listed therein, dated May 31, 2019
10.20†	Lease Agreement by and among the Registrant and Universitätsmedizin der Johannes Gutenberg-Universität Mainz, dated January 14, 2013
10.21†	Amendment to Lease Agreement by and among the Registrant and Universitätsmedizin der Johannes Gutenberg-Universität Mainz, dated July 5, 2014
10.22†	Amendment to Lease Agreement by and among the Registrant and Universitätsmedizin der Johannes Gutenberg-Universität Mainz, dated June 8, 2015
10.23†	Amendment to Lease Agreement by and among the Registrant and Universitätsmedizin der Johannes Gutenberg-Universität Mainz, dated October 18, 2017
10.24†	Lease Agreement by and among the Registrant and Wolfram Richter, dated August 17, 2011
10.25†	Amendment No. 1 to Lease Agreement by and among the Registrant and Wolfram Richter, dated February 17, 2012
10.26†	Amendment No. 2 to Lease Agreement by and among the Registrant and Wolfram Richter, dated February 1, 2013
10.27†	Amendment No. 3 to Lease Agreement by and among the Registrant and Wolfram Richter, dated March 6, 2013
10.28†	Amendment No. 4 to Lease Agreement by and among the Registrant and Wolfram Richter, dated December 10, 2013
10.29†	Amendment No. 5 to Lease Agreement by and among the Registrant and Wolfram Richter, dated March 29, 2016

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<u>Exhibit No.</u>	<u>Exhibit</u>
10.30†	Amendment No. 6 to Lease Agreement by and among the Registrant and Wolfram Richter, dated June 10, 2017
10.31†	Lease Agreement by and among the Registrant and Wista-Management GmbH, dated April 12, 2005
10.32†	Amendment to Lease Agreement by and among the Registrant and Wista-Management GmbH, dated January 11, 2019
10.33†	Loan Agreement by and between BioNTech Innovative Manufacturing Services GmbH and Deutsche Bank AG dated November 21, 2017
10.34†	Loan Agreement by and between JPT Peptides Technologies GmbH and Deutsche Bank AG dated July 18, 2018
16.1*	Letter from Baker Tilly GmbH & Co. KG Wirtschaftsprüfungsgesellschaft
21.1*	List of Subsidiaries of the Registrant
23.1*	Consent of Ernst & Young GmbH, Independent Registered Public Accounting Firm
23.2*	Consent of Freshfields Bruckhaus Deringer LLP (included in Exhibit 5.1)
24.1*	Powers of Attorney (included on signature page)

* To be filed by amendment.

† Certain information has been excluded from the exhibit because it both (i) is not material and (ii) would likely cause competitive harm to the Registrant if publicly disclosed.

Item 9. Undertakings

The undersigned hereby undertakes:

(a) The undersigned registrant hereby undertakes to provide to the underwriter at the closing specified in the underwriting agreements certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

(b) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

(c) The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form F-1 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Mainz, Germany on _____, 2019.

BIONTECH SE

By: _____

Name: Prof. Ugur Sahin, M.D.

Title: Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Prof. Ugur Sahin, M.D., Dr. Özlem Türeci, Sean Marett and Dr. Sierk Poetting and each of them, individually, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead in any and all capacities, in connection with this registration statement, including to sign in the name and on behalf of the undersigned, this registration statement and any and all amendments thereto, including post-effective amendments and registrations filed pursuant to Rule 462 under the Securities Act of 1933, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto such attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or his substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons on _____, 2019 in the capacities indicated:

<u>Name</u>	<u>Title</u>	<u>Date</u>
_____ Prof. Ugur Sahin, M.D.	Chief Executive Officer (principal executive officer)	
_____ Dr. Sierk Poetting, Ph.D.	Chief Financial Officer (principal accounting officer)	
_____ Helmut Jeggle	Chair of the Supervisory Board	
_____ Michael Motschmann	Director	
_____ Prof. Christoph Huber, M.D.	Director	
_____ Dr. Ulrich Wandschneider	Director	

SIGNATURE OF AUTHORIZED U.S. REPRESENTATIVE OF REGISTRANT

Pursuant to the requirements of the Securities Act of 1933, as amended, the undersigned, the duly authorized representative in the United States of BioNTech SE has signed this registration statement on _____, 2019.

Name:
Title:

THE SYMBOL “[*]” DENOTES PLACES WHERE CERTAIN IDENTIFIED
INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i)
NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE
COMPANY IF PUBLICLY DISCLOSED**

**AMENDED PATENT LICENSE AGREEMENT
LSU FILE LSUHSC-S- 07-006 and LSUHSC-S-09-015**

This Agreement is effective as of the 12th day of May, 2015 (the “Effective Date”), between BioNTech AG, a corporation incorporated in Germany, with offices located at An der Goldgrube 12, D-55131 Mainz, Germany (“LICENSEE”); the Board of Supervisors of Louisiana State University and Agricultural and Mechanical College, a public constitutional corporation, organized and existing under the laws of the State of Louisiana (“LSU”); and Uniwersytet Warszawski (the University of Warsaw), a Polish nonprofit corporation (“UW”); LSU and UW sometimes to be referred to, collectively, individually or independently, as “LICENSOR” or “LICENSORS.”

UW and LICENSEE have entered on the 15th day of November 2010 into a separate Research Cooperation Agreement [***] (“RESEARCH COOPERATION AGREEMENT”). Therein UW and LICENSEE agreed to cooperate in the synthesis and characterization of chemically modified cap analogs and their evaluation on the efficacy of RNA-based immunotherapies in pre-clinical and clinical studies (“COOPERATION”) and UW granted LICENSEE certain rights in patent applications already filed as well as in future sole inventions of UW and joint inventions of UW and LICENSEE resulting from the COOPERATION. UW and LICENSEE agreed that any remuneration for the rights granted is already covered by the considerations as set out in clause 2 of this agreement.

This agreement replaces the “Patent License Agreement LSU FILE LSUHSC-S- 07-006 and LSUHSC-S-09-015” of BioNTech AG (LICENSEE), Uniwersytet Warszawski (UW) and Louisiana State University (LSU) made of 15th day of March, 2011, effective on 16th day of December. This agreement also replaces the “Amendment NO. 1 to Patent License Agreement” referring to said “Patent License Agreement LSU FILE LSUHSC-S- 07-006 and LSUHSC-S-09-015” effective on 1st day of January, 2013. This named two agreements are herein after referred to as “PRIOR AGREEMENTS” [***].

ARTICLE 1 – DEFINITIONS

1.1 “AFFILIATE” of LICENSEE shall mean a company or other person controlling, controlled by, or under common control with LICENSEE, where “control” shall mean the direct or indirect control by ownership or otherwise of more than fifty percent (50%) of the outstanding voting shares or voting rights, or other similar measure of control.

1.2 “FIELD OF USE” means all fields of use.

1.3 “FIRST COMMERCIAL SALE” means the first sale of any LICENSED PRODUCT or the first commercial use of any LICENSED PROCESS by LICENSEE or a SUBLICENSEE, other than a sale of a LICENSED PRODUCT or the use of a LICENSED PROCESS for use in trials, such as field trials or clinical trials, being conducted to obtain FDA or other governmental approvals to market LICENSED PRODUCTS or otherwise commercially use LICENSED PROCESSES.

1.4 “COOPERATION PATENT RIGHTS” shall mean UWs legal rights under the patent laws of the United States or relevant foreign countries for all of the following:

- (a) the United States and foreign patents and/or patent applications which will be or have been filed for sole or joint inventions resulting from the COOPERATION and/or for inventions from previous research projects between UW and LICENSEE as set out in Section 8.6 of the RESEARCH COOPERATION AGREEMENT (“COOPERATION INVENTIONS”); non-provisional applications claiming priority under 35 U.S.C. § 119(e) from any provisional applications filed for COOPERATION INVENTIONS, continuations, and continuations-in-part of any of the above applications; the United States and foreign patents and/or patent applications filed for COOPERATION INVENTIONS; non-provisional applications claiming priority under 35 U.S.C. § 119(e) from any provisional applications filed for COOPERATION INVENTIONS; divisionals, continuations, and continuations-in-part of any of the above applications
- (b) United States and foreign patents issued from the applications described above in part (a) as well as utility models, extensions or supplemental protection certificates (SPCs) thereof or equivalent patent term extensions;
- (c) claims in all foreign patent applications, and in resulting patents, that are directed to subject matter specifically described in the United States patents and/or patent applications described in (a) and/or (b) above;
- (d) any reissued or reexamined patents based upon the United States patents described in (a) and/or (b).

1.5 “LICENSED PRODUCT(S)” means a product or part of a product in the licensed FIELD OF USE:

- (a) for which, absent this Agreement, the making, using, importing or selling, would infringe, induce infringement, or contribute to infringement of an issued or unexpired claim contained in the PATENT RIGHTS in the country in which any such product or product part is made, used, imported, offered for sale or sold; or
- (b) that is manufactured using a LICENSED PROCESS or is employed to practice a LICENSED PROCESS.

1.6 “LICENSED PROCESS(ES)” means any process or method that is covered in whole or in part by an issued or unexpired claim contained in the PATENT RIGHTS.

1.7 MARKET EXCLUSIVITY means that there is no product equivalent to the LICENSED PRODUCT on the market, serving for the same purpose or addressing the same needs of the same customer target group.

1.8 “NET SALES” means the amount billed or invoiced on sales, rental, lease, or use, however characterized, by LICENSEE and SUBLICENSEES for LICENSED PRODUCTS and LICENSED PROCESSES, less

- (a) discounts allowed in amounts customary in the trade;
- (b) sales tax, tariffs, duties and use tax included in bills or invoices with reference to particular sales and actually paid by LICENSEE to a governmental unit;
- (c) outbound transportation prepaid or allowed; or
- (d) amounts refunded or credited on returns.

No deductions shall be made for the cost of collections or for commissions, whether paid to independent sales agents or employees of LICENSEE.

Whenever the term “LICENSED PRODUCT” may apply to a product during various stages of manufacture, use, sale, or other transfer, NET SALES shall be based on the amount derived from the sale, distribution or use of such LICENSED PRODUCT at the stage of its highest billed or invoiced value to an arms-length third party.

If a potential SUBLICENSEE does not agree with the above NET SALES definition, LICENSEE and LSU shall mutually discuss and put forth good faith efforts to agree upon an amendment of the above NET SALES definition, in so far as LSU is able taking into account United States Federal definitions of NET SALES. A consent to reasonable amendments shall not unreasonably be withheld or delayed.

1.9 “PATENT RIGHTS” means LICENSORS’ legal rights under the patent laws of the United States or relevant foreign countries for all of the following:

- (a) the United States and foreign patents and/or patent applications listed in Appendix A; non-provisional applications claiming priority under 35 U.S.C. § 119(e) from any provisional applications listed in Appendix B; divisionals, continuations, and continuations-in-part of any of the above applications;

- (b) United States and foreign patents issued from the applications described above in part (a) as well as utility models, extensions or supplemental protection certificates (SPCs) thereof or equivalent patent term extensions;
- (c) claims in all foreign patent applications, and in resulting patents, that are directed to subject matter specifically described in the United States patents and/or patent applications described in (a) and/or (b) above;
- (d) claims in all patent applications, and in the resulting patents, that are directed to subject matter specifically described as of the 16th day of December 2010 in the LSU Office of Technology Transfer files listed in Appendix B; and
- (e) any reissued or reexamined patents based upon the United States patents described in (a), (b), and/or (d) above.

1.10 "ROYALTY PERIOD(S)" means the twelve-month periods ending on the last day of December.

1.11 "SUBLICENSEE(S)" means any person or entity sublicensed by LICENSEE under this Agreement.

1.12 "TERRITORY" means all countries in which patent applications or patents within the PATENT RIGHTS are pending or issued.

1.13 "VALID CLAIM" means a claim of an issued patent in the TERRITORY, which is not expired, not withdrawn nor invalidated by final judgment. In case of pending applications a valid claim exists for the period of [***] years from the priority date of the respective patent, if no request for examination has been filed, but longest for a period of [***] years from the priority date of the respective patent.

ARTICLE 2 - GRANT OF LICENSE

2.1 Subject to the terms and conditions of this Agreement, LICENSORS hereby grant to LICENSEE an exclusive royalty-bearing license under the PATENT RIGHTS, with the right to assign, sublicense, otherwise transfer rights pursuant to this Agreement, in the FIELD OF USE in the TERRITORY to make, have made, import, use, offer for sale and sell LICENSED PRODUCTS and LICENSED PROCESSES.

2.2 The license granted to LICENSEE shall extend to an AFFILIATE of LICENSEE as well, provided that LICENSORS first receive written notice, signed on behalf of both LICENSEE and the AFFILIATE: (1) stating that the AFFILIATE intends to exercise such rights, and (2) agreeing that the AFFILIATE and LICENSEE shall be solidarily liable for all obligations to LICENSORS under the Agreement arising from the activities of that AFFILIATE. The activities of the AFFILIATE under the Agreement shall then be deemed to be the activities of LICENSEE. The rights of an AFFILIATE under the Agreement shall terminate if LICENSEE's rights under the Agreement terminate. An AFFILIATE has the right to sublicense, assign, or otherwise transfer rights under the Agreement, if AFFILATE agrees to submit to the same obligations as LICENSEE as set out in Section 6 of this Agreement.

2.3 LICENSORS retain the right, on behalf of themselves and all other non-profit academic research institutions to practice the PATENT RIGHTS for any non-profit purpose, including sponsored research and collaborations.

2.4 This Agreement shall extend until expiration of the last-to-expire of the licensed PATENT RIGHTS or COOPERATION PATENT RIGHTS, unless sooner terminated as provided in another specific article of this Agreement.

2.5 Nothing in the Agreement shall be construed as granting by implication, estoppel, or otherwise any licenses or rights under any patents, patent applications, or know how other than the license under the PATENT RIGHTS granted in Article 2.1 or as already granted under the RESEARCH COOPERATION AGREEMENT.

2.6 LSU further reserves to the United States Government all rights that may be required by research funding agreements between LSU and the United States Government pursuant to 35 U.S.C. §200 *et seq.* and applicable implementing regulations.

2.7 LICENSEE agrees that LICENSED PRODUCTS used, leased or sold in the United States shall be manufactured in compliance with 35 U.S.C. §204, and any applicable implementing regulations. LICENSOR and LICENSEE agree to jointly petition the NIH for a waiver of the manufacturing requirement but LICENSEE understands that the decision for such a waiver will be that of the NIH.

ARTICLE 3 - CONSIDERATION

3.1.1 LICENSEE shall pay running royalties and fees to LICENSORS until the expiration date of the last to expire of PATENT RIGHTS or COOPERATION PATENT RIGHTS or until this Agreement is otherwise terminated. All payments under this Agreement shall be made to LSU. LSU will make payments to University of Warsaw in accordance with Inter-Institutional Agreements executed by LICENSORS. The University of Warsaw shall not have any claims against LICENSEE if LSU defaults in its obligation to University of Warsaw under the Inter-Institutional Agreement.

Running royalties and fees shall include:

- (a) License Issue Fee of [***]. Such License Issue Fee shall be nonrefundable and is due by January 31, 2011.
- (b) License Amendment Fee of [***]. Such License Amendment Fee shall be non-refundable and is due within [***] business days after the Effective Date of this Patent License Agreement.
- (c) Running royalties equal to [***] of NET SALES for all LICENSED PRODUCTS that are used, sold, offered for sale, or imported anywhere in the TERRITORY, regardless of whether other acts concerning specific LICENSED PRODUCTS occur outside the TERRITORY. If LICENSEE makes any sales to any party affiliated with LICENSEE, or in any way directly or indirectly related to or under the common control with LICENSEE, at a price less than the regular price charged to arm's length third parties, the running royalties payable to LSU shall be computed on imputed NET SALES equal to the regular price charged to arm's-length third parties;
- (d) Running royalties equal to [***] of NET SALES earned outside the TERRITORY for all LICENSED PRODUCTS that are made anywhere in the TERRITORY and used, sold, offered for sale, or imported outside the TERRITORY, provided that there is MARKET EXCLUSIVITY for the respective LICENSED PRODUCT outside the TERRITORY. If LICENSEE makes any sales to any party affiliated with LICENSEE, or in any way directly or indirectly related to or under the common control with LICENSEE, at a price less than the regular price charged to arm's length third parties, the running royalties payable to LSU shall be computed on imputed NET SALES equal to the regular price charged to arm's-length third parties under this section (c);
- (e) [***] of any consideration that is not based on NET SALES (e.g., sublicense issue fees, sublicense maintenance fees, etc.) that LICENSEE receives from SUBLICENSEES or assignees in consideration for rights to practice under the PATENT RIGHTS or COOPERATION PATENT RIGHTS, excepting only research and development funding. If a sublicense agreement concluded by LICENSEE does not solely relate to the PATENT RIGHTS and/or COOPERATION PATENT RIGHTS but also includes additional intellectual property or know-how, then and only then shall the above [***] royalty be reduced to reflect the relative value of the sublicensed PATENT RIGHTS or COOPERATION PATENT RIGHTS taking into account said number of the other intellectual property and know-how licensed under the relevant sublicensing agreement. The consideration to be paid to LSU shall be determined according to the following payment table:

LICENSEE shall report to LSU any other intellectual property (technology claimed in intellectual property or know-how) having relevance for each LICENSED PRODUCT, whereas in case of intellectual property "having relevance" shall mean that any manufacture, use, sale, offer for sale or importation of LICENSED PRODUCT would infringe at the time point of conclusion of a sublicense agreement at least one VALID CLAIM of the intellectual property considered for calculation of the consideration payable to LSU. For the avoidance of doubt, an individual intellectual property, in regard to the counting required by the preceding table, comprises all patent rights or know-how which relate to the same independent (provide a benefit for the product of its own) technical feature, especially all members of patent families claiming the same priority date.

- (f) Reimbursement of LICENSORS' reasonable past and future out-of-pocket patenting costs related to the PATENT RIGHTS including reasonable attorneys' fees, but not including salaries of LICENSORS employees. Such reimbursement is nonrefundable and is due by January 31, 2011.

3.1.2 LICENSEE shall pay to LICENSORS an annual license maintenance fee ("Annual Fee"). This Annual Fee shall be due on the last day of June of the years specified below. LICENSEE may credit each Annual Fee in full against all running royalties otherwise due LICENSORS for the same calendar year for which the specific Annual Fee is due. This credit may not otherwise be carried forward or carried back for any other ROYALTY PERIOD.

The Annual Fees are:

[***]

- (1) [***]
- (2) [***]
- (3) [***]

(4) In 2015 and in each year thereafter during the term of this Agreement: [***]

3.2 LICENSEE shall be responsible for the payment of all taxes, duties, levies, and other charges, subject to the deduction from NET SALES allowed by Paragraph 1.7(b).

3.3. LICENSORS shall be responsible for the payment of all taxes, duties, levies and other charges due to LICENSORS' receipt of royalties and fess pursuant to Article 3.1.1.

3.4 LICENSEE is not obligated to pay multiple running royalties to LICENSORS if any LICENSED PRODUCT or LICENSED PROCESS is covered by more than one claim of PATENT RIGHTS, or by more than one patent application or patent within PATENT RIGHTS.

3.5 Payments due to LICENSORS are exclusive of value added tax, which shall, if applicable, be invoiced separately. Payments due to LICENSORS shall be paid to the "Louisiana State University" in United States dollars in Baton Rouge, Louisiana, sent as provided in article 14 or at such other place as LSU may reasonably designate consistent with the laws and regulations controlling in any country. At LSU's request, LICENSEE shall remit payments either by wire transfer or by check drawn upon a United States bank.

3.6 In computing running royalties, LICENSEE shall convert any revenues it receives in foreign currency into its equivalent in United States dollars at the exchange rate LICENSEE, using its standard accounting procedures, uses to make reports to relevant regulatory and taxing authorities, as long as such accounting procedures are consistent with fair business practices and generally accepted accounting principles.

3.7 Running royalty payments shall be made on a [***] basis with submission of the reports required by Article 4. All amounts due under this Agreement, including amounts due for the payment of patent expenses, shall, if overdue, bear interest until payment at a per annum rate [***] percent ([***]%) above the prime rate in effect at the JP Morgan Chase Bank or its successor on the due date, or at the highest allowed rate if a lower rate is required by law. The payment of such interest shall not foreclose LICENSORS from exercising any other rights it may have resulting from any late payment.

3.8 All amounts paid to LICENSORS by LICENSEE under this Agreement shall be non-refundable.

3.9 If LICENSORS and LICENSEE disagree in good faith as to whether certain payments are due to LICENSORS, then the procedures of this Section 3.9 shall be followed to place the disputed amounts into escrow. If these procedures are followed, then LICENSEE shall not be deemed to be in default for failure to make the disputed payments timely. If these procedures are not followed, however, then LICENSEE shall be deemed to be in default for failure to make payments timely under the Agreement, regardless of whether or not it is ultimately determined that the disputed amounts were actually due under the Agreement.

3.9.1 All undisputed amounts shall be paid to LICENSORS as otherwise provided.

3.9.2 All disputed amounts shall be paid to an escrow agent mutually acceptable to LSU and LICENSEE. Disputed amounts that are past due shall be paid to the escrow agent within [***] days after the establishment of an escrow account with a mutually acceptable escrow agent. Disputed amounts that are not yet due but that become due during pendency of the dispute shall be paid to the escrow agent on or before the dates those amounts are otherwise due under the Agreement. LSU shall be given prompt confirmation of the date and amount of any such payments made.

3.9.3 The escrow agent shall place the funds in a safe, interest-bearing instrument or account jointly approved by LSU and LICENSEE; or if LSU and LICENSEE are unable thus to agree, in a safe, interest-bearing instrument or account chosen by the escrow agent. Any interest thus received shall ultimately be distributed by the escrow agent in the same proportions as the distribution of the principal amount. A reasonable fee for the escrow agent's services may first be deducted from the interest.

3.9.4 The escrow agent shall release the funds in escrow only in accordance with the joint, written instructions of both LSU and LICENSEE; or in accordance with an order of the court or an award of the arbitrator under Section 16.2.

ARTICLE 4 - REPORTS

4.1 LICENSEE shall provide to LICENSORS a written annual report within [***] days after each ROYALTY PERIOD closes or within [***] days after termination of this agreement. The annual report shall include: reports of progress and of the amount of capital expended on research and development, regulatory approvals, manufacturing, sublicensing, marketing and sales during the preceding [***] months, and plans for the coming year. Each annual report shall include confirmation of existing insurances in compliance with Paragraph 11.3.

4.2 After the FIRST COMMERCIAL SALE, the annual report of LICENSEE according to 4.1 shall further include for that ROYALTY PERIOD:

- (a) number of LICENSED PRODUCTS manufactured and sold by LICENSEE and all SUBLICENSEES;
- (b) total billings for LICENSED PRODUCTS sold by LICENSEE and all SUBLICENSEES;

- (c) accounting for all LICENSED PROCESSES used or sold by LICENSEE and all SUBLICENSEES;
- (d) deductions applicable as provided in the definition for NET SALES in Paragraph 1.8; and
- (e) any consideration due on additional payments from SUBLICENSEES under Paragraph 3.1(c).

LICENSEE shall include the amount of all payments due, and the various calculations used to arrive at those amounts, including the quantity, description (nomenclature and type designation as described in Paragraph 4.3 below), country of manufacture and country of sale of LICENSED PRODUCTS. If no payment is due, LICENSEE shall so report. LICENSEE shall direct its authorized representative to certify that each report is correct to the best of LICENSEE's knowledge and information. Failure to provide reports as required under this Article shall be a material breach of this Agreement.

4.3 LICENSEE covenants that it will promptly establish and consistently employ a system of specific nomenclature and type designations for LICENSED PRODUCTS and LICENSED PROCESSES to permit identification and segregation of various types where necessary. LICENSEE shall consistently employ, and shall require SUBLICENSEES to consistently employ, the system when rendering invoices thereon. On request, LICENSEE shall promptly explain to LSU, or its auditors, all details reasonably necessary to understand such nomenclature system, all additions thereto and changes therein.

4.4 LICENSEE shall keep, and shall require all SUBLICENSEES to keep, true and accurate records containing data reasonably required for the computation and verification of payments due under this Agreement. LICENSEE shall, and it shall require all SUBLICENSEES to:

- (1) open such records for inspection upon prior written, reasonable notice during business hours by either LSU auditor(s) or an independent certified accountant selected by LSU, for the purpose of verifying the amount of payments due with such inspection not occurring more than once per [***] unless required by the State of Louisiana or United States federal agencies; and
- (2) Wherever practical combine an inspection by LSU with a Licensee inspection of said records
- (3) retain such records for [***] years from date of origination.

The terms of this Article shall survive any termination of this Agreement. LSU is responsible for all expenses of such inspection, except that if any inspection reveals an underpayment greater than [***] percent ([***]%) of the amounts due LSU for any ROYALTY PERIOD, then LICENSEE shall pay all expenses of that inspection and the amount of the underpayment and interest to LSU within [***] days of written notice thereof. LICENSEE shall also reimburse LSU for reasonable expenses required to collect any amount underpaid.

ARTICLE 5 - DILIGENCE

5.1 LICENSEE has the responsibility to develop LICENSED PRODUCTS into marketable products.

5.2 LICENSEE shall use commercially reasonable efforts (including, without limitation, commitment of funding and personnel) comparable to the standards of other biotechnology companies to bring one or more LICENSED PRODUCTS to market or one or more LICENSED PROCESSES to commercial use through a thorough, vigorous and diligent program for exploiting the PATENT RIGHTS; and to continue active, diligent marketing efforts for one or more LICENSED PRODUCTS or LICENSED PROCESSES throughout the life of this Agreement.

5.3 As part of the diligence required by Paragraph 5.2, LICENSEE agrees to use best efforts to reach the following commercialization and research and development milestones anywhere in the TERRITORY for the LICENSED PRODUCTS and LICENSED PROCESSES resulting from PATENT RIGHTS (together the "MILESTONES") by the following dates:

[***]

For clarity: The lack of commercialization of LICENSED PRODUCTS in the U.S. shall not be considered a lack of effort of LICENSEE to commercialize LICENSED PRODUCTS under Sections 5.2 and 5.3.

5.4. LICENSEE shall inform LICENSORS in writing, on or before the deadline for meeting any MILESTONE, whether such MILESTONE has been met.

5.5 If LICENSEE fails to meet any MILESTONE within [***] days after the date specified in Paragraph 5.3, LICENSORS may notify LICENSEE of this material breach. If LICENSEE does not achieve the MILESTONE within [***] days of receipt of this notice, LICENSORS may terminate this Agreement.

ARTICLE 6 - SUBLICENSING

6.1 LICENSEE shall notify LICENSORS in writing and shall send LICENSORS a copy of every sublicense agreement and each amendment thereto within [***] days after their execution. LICENSEE shall be entitled to redact those parts of the sublicense agreement which are not relevant for LSU's rights or obligations hereunder in relation to such sublicense agreement,

including LSU's royalty rights under Section 3.1.1 (c) to (e) above and the sublicensing restrictions set forth in this Article 6. LSU may, upon written reasonable notice, during business hours enlist an independent third party individual under a duty of obligation of confidentiality with LICENSEE and LICENSOR, to review said sublicense agreement for compliance with terms of this Amended Patent License Agreement.

6.2 LICENSEE shall contemporaneously certify to LICENSORS in writing that each sublicense:

- (1) is consistent with the terms and conditions of this Agreement;
- (2) contains the SUBLICENSEE'S acknowledgment of the disclaimer of warranty and limitation on LICENSORS' liability, as provided by Article 11 below; and
- (3) contains provisions under which the SUBLICENSEE accepts duties at least equivalent to those accepted by the LICENSEE in the following Articles:

4.4 duty to keep records

10.4 duty to avoid improper representations or responsibilities

11.1 duty to defend, hold harmless, and indemnify LICENSORS

11.3 duty to obtain and maintain insurance

15.4 duty to properly mark LICENSED PRODUCTS with patent notices

15.6 duty to refrain from the use of LICENSORS' names

15.7 duty to control exports and comply with applicable laws

6.3 If LICENSEE receives from a SUBLICENSEE anything in value other than cash payments in consideration for any sublicense under this Agreement, the notification pursuant to Paragraph 6.1 will include the assumed fair market value of such consideration and a basis for that assumed value. Unless LICENSORS jointly but not solely disagree with the assumed fair market value within [***] days of such notification, the assumed fair market value is used for the purpose of calculating running royalties due to LICENSORS pursuant to Paragraph 3.1.1 (c). In case of disagreement the parties will settle the dispute as provided in Paragraph 15.1. Both LICENSORS and LICENSEE will bear its own costs of such dispute resolution and each party an equal part of the costs of the arbitration.

6.4 Each sublicense granted by LICENSEE under this Agreement shall provide for its termination upon termination of this Agreement. Each sublicense shall terminate upon termination of this Agreement unless LICENSEE has previously assigned its rights under the sublicense to LICENSORS and LICENSORS have agreed at LICENSORS' sole discretion in writing to such assignment.

6.5 LICENSEE shall cause every sublicense to provide LICENSEE the right to assign its rights under the sublicense to LICENSORS. Any such assignment is subject to the limitations of Article 15.11 herein and, to be effective, LICENSORS must first accept at their sole discretion such assignment in writing.

6.6 No SUBLICENSEE shall have the right to grant further sublicenses without the express written permission of LICENSORS.

6.7 Failure of LICENSEE to meet any of the obligations in this Article 6 shall be considered a material breach or default of this Agreement under Paragraph 12.4.

ARTICLE 7 - PATENT PROSECUTION AND MAINTENANCE

7.1 LICENSORS have the right to control all aspects of drafting, filing, prosecuting, and maintaining all patents and patent applications within the PATENT RIGHTS, including foreign filings and Patent Cooperation Treaty filings. LICENSEE shall, at its own expense, perform all actions and execute or cause to be executed all documents necessary to support such filing, prosecution, or maintenance.

7.2 LICENSORS shall notify LICENSEE of all official communications received by LICENSORS relating to the filing, prosecution and maintenance of the patents and patent applications within the PATENT RIGHTS, including any lapse, revocation, surrender, invalidation, interference, opposition or abandonment of any of the patents or patent applications which form the basis for the PATENT RIGHTS, and shall allow LICENSEE to review and comment upon such communications and will make efforts to follow any suggestions and fulfill reasonable requests of LICENSEE on the drafting, filing, prosecution, and maintaining all PATENT RIGHTS.

7.3 LICENSEE shall reimburse LICENSORS for all reasonable past and future legal fees relating to the filing, prosecution, interference proceedings and maintenance of the PATENT RIGHTS including reasonable attorneys' fees, but not including salaries of LICENSORS' employees, except as specifically provided in Paragraph 7.4. Such reimbursement shall be made for each calendar quarter, and shall be paid within [***] days of receipt of LICENSORS' invoice and shall bear interest, if overdue, at the rate specified in Paragraph 3.7 above.

7.4 LICENSEE may elect to not reimburse LICENSORS for fees and costs related to a particular patent application or patent within PATENT RIGHTS in a particular country, subject to the terms of this Paragraph 7.4. LICENSORS will provide LICENSEE with reasonable advance notice to allow LICENSEE to consider the action to be taken for a particular patent application or patent within PATENT RIGHTS to make such an election. If LICENSEE makes such an election, LICENSEE shall provide reasonable notice to LICENSORS in writing. LICENSORS may then elect to continue the prosecution or maintenance of such application or patent at LICENSORS' sole expense, provided that such patent applications and issued patents thereafter shall be excluded from the definition of PATENT RIGHTS.

7.5 LICENSORS shall be responsible for any remuneration of inventors of the PATENT RIGHTS that are due the inventors pursuant to a contract of employment or otherwise and shall keep LICENSEE harmless of any such claim.

7.6 On a case-by-case basis, the parties may agree in writing (which includes electronic mail) that LICENSEE shall manage the prosecution and maintenance of specifically-identified patents and patent applications within the PATENT RIGHTS in specifically-identified countries, at LICENSEE's sole expense. In such a case LICENSORS shall provide reasonable assistance to LICENSEE's efforts in this regard, at no out-of-pocket expense to the LICENSORS. The provisions of Paragraph 7.2 shall apply in such a case, with the roles of LICENSORS and LICENSEE reversed, *mutatis mutandis*. The provisions of Paragraph 7.4 shall apply in such a case, *mutatis mutandis*, in the event LICENSEE elects to discontinue prosecution, to discontinue maintenance, or otherwise to abandon any affected patent or patent application.

ARTICLE 8 - ENFORCEMENT

8.1 Each party shall promptly advise the other in writing of any known acts of potential infringement of the PATENT RIGHTS by a third party. LICENSEE and LICENSORS shall mutually agree on an adequate strategy, whereas LICENSEE has the first option to police the PATENT RIGHTS against infringement by third parties within the TERRITORY in the FIELD OF USE, but LICENSEE shall notify LICENSORS in writing [***] days before filing any suit. This right to police includes defending any action for declaratory judgment of noninfringement or invalidity; and prosecuting, defending or settling all infringement and declaratory judgment actions at LICENSEE's expense and through counsel of LICENSEE's selection, except that LICENSEE shall make any such settlement only with the advice and consent of LICENSORS, which will not be unreasonably withheld. LICENSORS shall provide reasonable assistance to LICENSEE with respect to such actions, but only if LICENSEE reimburses LICENSORS for out-of-pocket expenses incurred in connection with any such assistance rendered at LICENSEE'S request. LICENSORS retain the right to participate, with counsel of their own choosing and at their own expense, in any action under this Article 8.1. LICENSEE shall defend, indemnify and hold harmless LICENSORS with respect to any claims or counterclaims asserted by an alleged infringer reasonably related to the enforcement of the PATENT RIGHTS, under this Paragraph 8.1, including but not limited to antitrust claims or counterclaims unless such claims or counterclaims are due to LICENSORS participation in any action under this Paragraph 8.1.

8.2 If LICENSEE undertakes to enforce or defend the PATENT RIGHTS by litigation in any country, LICENSEE may withhold up to [***] percent ([***]%) of running royalties (as described in Paragraph 3.1.1(b)) due to LICENSORS for sales in such country in which the litigation is pending to reimburse LICENSEE's out-of-pocket litigation expenses, including reasonable attorneys' fees, but not including salaries of LICENSEE's employees. Such pending litigation does not affect any other payment due to LICENSORS under this Agreement. If LICENSEE recovers damages in the patent litigation, the award shall be applied first to satisfy LICENSEE'S unreimbursed expenses and legal fees for the litigation, next to reimburse LICENSORS for any payments under Article 3 which are past due, and then to reimburse LICENSORS for any other unreimbursed expenses and legal fees for the litigation under Paragraph 8.1. LICENSEE shall pay ten percent (10%) of the remaining balance to LICENSORS. If LICENSEE does not recover any damages the withheld running royalties shall be applied to satisfy LICENSEE'S unreimbursed expenses and legal fees for the litigation. Withheld running royalties beyond that required to reimburse LICENSEE'S out-of-pocket litigation expenses as described above shall be paid to LICENSORS.

8.3 If LICENSEE declines its option to take action to abate an alleged infringement of a patent within the PATENT RIGHTS within [***] days of a request by a LICENSOR to do so (or within a shorter period if required to preserve the legal rights of LICENSORS under applicable law), then LICENSORS have the right to take such action (including prosecution of a suit) at LICENSORS expense. LICENSEE shall use reasonable efforts to cooperate in such action, and LICENSORS will reimburse LICENSEE for out-of-pocket expenses incurred in connection with any such assistance rendered at LICENSORS' request. LICENSORS have full authority to settle on such terms as LICENSORS determine, except that LICENSORS shall not reach any settlement whereby it provides a license for future activities to a third party under the PATENT RIGHTS in the TERRITORY in the FIELD OF USE without the consent of LICENSEE, which consent shall not be unreasonably withheld by LICENSEE. LICENSOR retains one hundred percent (100%) of any recovery or settlement under this Paragraph 8.3 after reimbursement of any of LICENSEE's out-of-pocket expenses.

ARTICLE 9 - CONFIDENTIAL INFORMATION

9.1 All Confidential Information disclosed, revealed or otherwise made available by one Party ("**Disclosing Party**") to the other Party ("**Receiving Party**") under, or as a result of, this Agreement is furnished to the Receiving Party solely to permit the Receiving Party to exercise its rights, and perform its obligations, under this Agreement. The Receiving Party shall not use any of the Disclosing Party's Confidential Information for any other purpose, and shall not disclose, reveal or otherwise make any of the Disclosing Party's Confidential Information available to any other person, firm, corporation or other entity, without the prior written authorization of the Disclosing Party.

9.2 In furtherance of the Receiving Party's obligations under Paragraph 9.1 hereof, the Receiving Party shall take all appropriate steps, and shall implement all appropriate and reasonable safeguards, to prevent the unauthorized use or disclosure of any of the Disclosing Party's Confidential Information. Without limiting the generality of this Paragraph 9.2, the Receiving Party shall disclose any of the Disclosing Party's Confidential Information only to those of its officers, employees, advisors, representatives, licensees, sublicensees, potential sublicensees and financial investors that have a need to know the Disclosing Party's Confidential Information, in order for the Receiving Party to exercise its rights and perform its obligations under this Agreement, and only if such officers, employees, advisors, representatives, licensees, sublicensees, potential sublicensees and financial investors are notified of the terms regarding confidentiality as those set out in this Agreement or are otherwise bound by obligations of confidentiality effectively prohibiting the unauthorized use or disclosure of the Disclosing Party's Confidential Information. The Receiving Party shall furnish the Disclosing Party with immediate written notice of any unauthorized use or disclosure of any of the Disclosing Party's Confidential Information by any officer, employee, advisor, representative, licensee or sublicensee of the Receiving Party, and shall take all actions that the Disclosing Party reasonably requests in order to prevent any further unauthorized use or disclosure of the Disclosing Party's Confidential Information.

9.3 The Receiving Party's obligations under Paragraphs 9.1 and 9.2 hereof shall not apply to the extent that the Receiving Party can prove by written or equivalent evidence that any of the Disclosing Party's Confidential Information:

- (1) passed into the public domain, or became generally available to the public through no fault of the Receiving Party;
- (2) was known to the Receiving Party prior to disclosure hereunder by the Disclosing Party;
- (3) was disclosed, revealed or otherwise made available to the Receiving Party by a Third Party that is under no obligation of non-disclosure and/or non-use to the Disclosing Party; or
- (4) is required to be disclosed under applicable law, or in connection with any application by the Receiving Party for any Regulatory Approvals; provided, however, that the Receiving Party shall furnish the Disclosing Party's with as much prior written notice of such disclosure requirement as reasonably practicable, so as to permit the Disclosing Party, in its sole discretion, to take appropriate action, including seeking a protective order, in order to prevent the Disclosing Party's Confidential Information from passing into the public domain or becoming generally available to the public.

ARTICLE 10 - NO WARRANTIES; LIMITATION ON LICENSORS' LIABILITY

10.1 LSU and University of Warsaw, their board members, officers, employees and agents make no representations or warranties that PATENT RIGHTS are or will be held valid or enforceable, nor that the manufacture, importation, use, offer for sale, sale or other distribution of any LICENSED PRODUCTS or the use of LICENSED PROCESSES will be free from infringement of third party patent rights or other third party rights; nor respecting the scope of any of the PATENT RIGHTS.

10.2 LSU AND UNIVERSITY OF WARSAW, THEIR BOARD MEMBERS, OFFICERS, EMPLOYEES AND AGENTS MAKE NO REPRESENTATIONS, AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, AND ASSUME NO RESPONSIBILITIES WHATEVER WITH RESPECT TO DESIGN, DEVELOPMENT, MANUFACTURE, USE, SALE OR OTHER DISPOSITION BY LICENSEE OR SUBLICENSEES OF LICENSED PRODUCTS OR LICENSED PROCESSES.

10.3 LICENSEE AND SUBLICENSEES ASSUME THE ENTIRE RISK AS TO PERFORMANCE OF LICENSED PRODUCTS AND LICENSED PROCESSES. In no event shall LSU or University of Warsaw, including their board members, officers, employees and agents, be responsible or liable for any direct, indirect, special, incidental, or consequential damages or lost profits or other economic loss or damage with respect to LICENSED PRODUCTS or LICENSED PROCESSES, to LICENSEE, SUBLICENSEES or any other person or entity regardless of legal theory. The above limitations on liability apply even though LICENSORS, their board members, officers, employees or agents may have been advised of the possibility of such damage.

10.4 LICENSEE shall not, and shall require that its SUBLICENSEES do not, make any statements, representations or warranties whatsoever to any person or entity, or accept any liabilities or responsibilities whatsoever from any person or entity that are inconsistent with this Article 10.

ARTICLE 11 - INDEMNITY; INSURANCE

11.1 LICENSEE shall defend, indemnify and hold harmless and shall require all SUBLICENSEES to defend, indemnify and hold harmless LICENSORS, their board members, officers, employees and agents, from and against any and all claims of any kind arising out of or related to the exercise of any rights granted LICENSEE under this Agreement or the breach of this Agreement by LICENSEE.

11.2 LICENSORS are entitled to participate at their option and expense through counsel of their own selection, and may join in any legal actions related to any such claims, demands, damages, losses and expenses under Paragraph 11.1 above.

11.3 LICENSEE shall at its sole cost and expense, obtain and maintain in full force and effect during the continuance of this Agreement and thereafter in accordance with Section 11.4 hereof, commercial general liability insurance with coverage. Within [***] days of execution of this Agreement, LICENSEE shall provide LICENSORS with written notice of the amount of insurance LICENSEE intends to obtain and which LICENSEE believes to be consistent with industry practice for the respective stage of development of LICENSED PRODUCTS or LICENSED PROCESSES. LICENSORS shall have the right to review this amount and shall have the right to require LICENSEE to increase the amount, consistent with what LICENSORS believe is current industry practice. In case of disagreement, the parties will settle the dispute as provided in Paragraph 15.1. Both LICENSORS and LICENSEE will bear its own costs of such dispute resolution and each party an equal part of the costs of the arbitration. LICENSEE shall furnish to LICENSORS a certificate of insurance evidencing that it has obtained the amount and type of insurance required pursuant to this Paragraph.

11.4 LICENSEE's indemnification obligation under Article 11.1 and LICENSEE's obligation to maintain general liability insurance under Article 11.3 hereof, shall survive the expiration or termination of this Agreement for any reason whatsoever for a period of [***] years after the date of expiration or termination hereof.

ARTICLE 12 - TERM AND TERMINATION

12.1 This Agreement, unless earlier terminated as provided herein, shall expiry on the expiration date of the last to expiry of the PATENT RIGHTS or COOPERATION PATENT RIGHTS.

12.2 If LICENSEE ceases to carry on its business (or that part of its business pertaining to LICENSED PRODUCTS and LICENSED PROCESSES), then this Agreement shall terminate upon written notice by LICENSORS.

12.3 If LICENSEE fails to make any payment due to LICENSORS, LICENSORS shall have the right to terminate this Agreement jointly but not solely effective on [***] days' written notice, unless LICENSEE makes all such payments within the [***] day period to LSU or as set out in Article 3.9 of this Agreement to an escrow agent. If LICENSEE has not made all such payments to LSU by the time the [***] day period expires, LICENSORS may terminate this Agreement upon written notice to LICENSEE.

12.4 Upon any material breach or default of this Agreement by LICENSEE other than those occurrences listed in Paragraphs 12.2 and 12.3 (the terms of which shall take precedence over this Paragraph 12.4, where applicable), LICENSORS shall have the right to terminate this Agreement effective on [***] days' written notice to LICENSEE jointly but not solely unless LICENSEE cures the material breach or default before the [***] day period expires.

12.5 In the event LICENSEE brings a civil action seeking, through ordinary, declaratory or any other form of relief, to invalidate any PATENT RIGHTS under this Agreement, LICENSORS may immediately terminate this Agreement jointly but not solely upon written notice to LICENSEE.

12.6 LICENSEE has the right to terminate this Agreement at any time on [***] days' written notice to either LICENSORS, with or without cause. In such a case, LICENSEE shall:

- (a) pay all amounts due LICENSORS through the effective date of the termination;
- (b) submit a final report in compliance with Paragraph 4.2;
- (c) return any confidential or trade secret materials provided to LICENSEE by LICENSORS in connection with this Agreement; or, with prior written approval by LICENSORS, destroy such materials, and certify in writing that such materials have all been returned or destroyed ; and
- (d) suspend its use of the LICENSED PROCESS(ES) AND LICENSED PRODUCT(S).

12.7 Upon any termination of this Agreement, and except as expressly provided herein to the contrary, all rights and obligations of the parties hereunder shall cease, except any previously accrued rights and obligations and further as follows:

- (1) Obligations to pay running royalties and other sums accruing hereunder through the day of termination, and to make a final report under Paragraph 4.2;
- (2) LICENSORS' rights to inspect books and records as described in Article 4, and LICENSEE's obligations to keep such records for the required time;
- (3) Obligations to hold harmless, defend and indemnify LSU and the University of Warsaw and their board members, officers, employees and agents, and to maintain insurance, and all other obligations under Article 11;
- (4) Any cause of action or claim of LICENSEE or LICENSORS accrued or to accrue because of any breach or default by the other party hereunder;
- (5) The provisions of Articles 1, 9, 14 and 15; and
- (6) All other terms, provisions, representations, rights and obligations contained in this Agreement that by their sense and context are intended to survive until performance thereof by either or both parties.

ARTICLE 13 - REGISTRATION AND RECORDATION

13.1 If the terms of this Agreement, or any assignment or license under this Agreement are or become such as to require that the Agreement or license or any part thereof be registered with or reported to a national or supranational agency of any area in which LICENSEE or SUBLICENSEES would do business, then LICENSEE will, at its own expense, undertake such registration or report. Prompt notice and appropriate verification of the act of registration or report or any agency ruling resulting from it will be supplied by LICENSEE to LICENSORS.

13.2 LICENSEE shall also carry out, at its expense, any formal recordation of this Agreement or any license herein granted that the law of any country requires as a prerequisite to enforceability of the Agreement or license in the courts of any such country or for other reasons, and shall promptly furnish to LICENSORS appropriately verified proof of recordation.

ARTICLE 14 - NOTICES

14.1 Any notice, request or report required or permitted under this Agreement shall be effective when deposited in the United States Mail, first class prepaid to the address set forth below, or such other address as such party specifies by written notice given in conformity herewith. Any notice, request or report given by any other means is not effective until actually received by an authorized representative of a party.

TO LSU: [***]

TO UW: [***]

TO LICENSEE: [***]

ARTICLE 15 - MISCELLANEOUS PROVISIONS

15.1 LICENSORS and LICENSEE shall attempt to resolve any dispute controversy or claim arising under, out of or relating to this Agreement and any subsequent amendments of this Agreement, including, without limitation, its formation, validity, binding effect, interpretation, performance, breach or termination, as well as non-contractual claims, arising out of or relating to this Agreement through negotiations between senior executives of the parties, who have authority to settle the same.

If the matter has not been resolved by the executives within [***] days of the initiation of the negotiations, or if any party does not participate in the negotiations, the dispute may be referred to arbitration by any party. The dispute, controversy or claim shall then be referred to and finally determined by binding arbitration in Baton Rouge, Louisiana in accordance with the CPR's Rules for Non-Administered Arbitration of Patent and Trade Secret Disputes then in effect, before a sole arbitrator in case of a dispute according to Paragraph 6.3 or 11.3, or before three arbitrators in all other cases.

Nothing in this clause shall be construed as prohibiting a party or its AFFILIATE from applying to a court for interim injunctive relief.

This clause does not apply to disputes, controversy or claims solely relating to COOPERATION PATENTS, the rights granted thereunder or payments made therefore.

15.2 LICENSORS and LICENSEE agree that this Agreement sets forth their entire understanding concerning the subject matter of this Agreement, and that no modification of the Agreement will be effective unless LSU, the University of Warsaw and LICENSEE all agree to it in writing. LICENSEE shall reimburse LICENSORS for any legal expenses incurred in connection with negotiating any amendments to this Agreement that may be requested by LICENSEE, regardless of whether the amendment is ultimately executed by the parties.

15.3 If a court of competent jurisdiction or an arbitrator finds any term of this Agreement invalid, illegal or unenforceable, that term will be curtailed, limited or deleted, but only to the extent necessary to remove the invalidity, illegality or unenforceability, and without in any way affecting or impairing the remaining terms.

15.4 LICENSEE agrees to mark all LICENSED PRODUCTS sold in the United States with all applicable United States patent numbers. All LICENSED PRODUCTS shipped to or sold in other countries shall be marked to comply with the patent laws and practices of the countries of manufacture, use and sale.

15.5 No waiver by either party of any breach of this Agreement, no matter how long continuing nor how often repeated, is a waiver of any subsequent breach thereof, nor is any delay or omission on the part of either party to exercise or insist on any right, power, or privilege hereunder a waiver of such right, power or privilege.

15.6 LICENSEE agrees to refrain from using and to require SUBLICENSEES to refrain from using the name of LSU or the University of Warsaw in publicity or advertising without the prior written approval of LSU and the University of Warsaw. Reports in scientific literature and presentations of joint research and development work are not considered to be “publicity” for this purpose. Notwithstanding this provision, without prior written approval of LICENSORS, LICENSEE and SUBLICENSEES may use LICENSORS’ name in any submission to a government agency as required by law.

15.7 LICENSEE shall comply with all applicable laws and regulations and shall be solely responsible for any violation of such laws and regulations by LICENSEE or its SUBLICENSEES, and shall defend, indemnify and hold harmless LSU and the University of Warsaw and its board members, officers, employees and agents if any legal action of any nature results from the violation

15.8 The relationship between the parties is that of independent contractors. Neither party is an agent or employee of the other in connection with the exercise of any rights hereunder, and neither has any right or authority to assume or create any obligation or responsibility on behalf of the other.

15.9 Neither party hereto is in default of any provision of this Agreement for any failure in performance resulting from acts or events beyond the reasonable control of such party, such as Acts of God, acts of civil or military authority, civil disturbance, war, strikes, fires, natural catastrophes or other “force majeure” events.

15.10 LICENSEE may not assign this Agreement other than to one of its Affiliates without the prior written consent of LICENSORS and shall not pledge any of the license rights granted in this Agreement as security for any creditor. Any attempted pledge of any of the rights under this Agreement or any attempted assignment of this Agreement without the prior written consent of LICENSORS will be void from the beginning. No assignment by LICENSEE will be effective until the intended assignee agrees in writing to accept all of the terms and conditions of this Agreement.

15.11 If during the term of this Agreement, LICENSEE makes or attempts to make an assignment for the benefit of creditors, or if proceedings in voluntary or involuntary bankruptcy or insolvency are instituted on behalf of or against LICENSEE, or if a receiver or trustee is appointed for the property of LICENSEE, LICENSORS may, at their option, terminate this Agreement and revoke the license(s) herein granted by written notice to LICENSEE. LICENSEE shall notify LICENSORS of any such event mentioned in this Paragraph 15.11 as soon as reasonably practicable, and in any event within [***] days after any such event.

15.12 Whereas LSU and the University of Warsaw are academic institutions, LICENSORS shall be free to make such publications as LICENSORS sees fit concerning the technology disclosed in the PATENT RIGHTS.

15.13 If it becomes necessary for one party to employ the services of an attorney for the protection and enforcement of its rights under the Agreement, or to compel performance of the other party's obligations under the Agreement, upon final judgment or award by a court of competent jurisdiction or by an arbitrator, the court or arbitrator in its discretion may order the defaulting party to pay the other party's reasonable attorney's fees at both trial and appellate levels.

15.14 LICENSORS will entertain requests by LICENSEE to allow LICENSORS employees, acting independently of their employment at LSU or the University of Warsaw, to serve as consultants to LICENSEE. The terms and conditions of such a consulting agreement shall be negotiated between LICENSEE and the prospective consultant, and shall be consistent with the rules, regulations, and policies of LSU or the University of Warsaw. It is understood that LSU or the University of Warsaw employees who act as consultants may not ordinarily grant rights in intellectual property to an outside employer.

15.15 During the term of the Agreement, LICENSORS will offer to LICENSEE an exclusive license in any sole or joint inventions and patent rights filed therefore (hereinafter "IMPROVEMENTS") developed by one of the inventors of PATENT RIGHTS that are covered by claims of PATENT RIGHTS unless such sole or joint inventions are covered by the regulations of the RESEARCH COOPERATION AGREEMENT under terms and conditions that are comparable to the standards of licensing agreements between academic institutions and biotechnology companies. LICENSEE shall have [***] days during which to accept said offer. If LICENSEE does not accept said offer within said period, LICENSORS shall be free to solely or jointly negotiate an exclusive or non-exclusive license agreement with a third-party. LICENSORS should not enter into an exclusive or non-exclusive license agreement on terms that are more favourable to the third party than the terms previously offered to LICENSEE with respect to PATENT RIGHTS.

ARTICLE 16 - PRIOR AGREEMENTS

16.1 With its Effective Date, this Agreement abrogates and replaces the PRIOR AGREEMENTS. Furthermore this agreement contains all arrangements between the parties regarding the PATENT RIGHTS and replaces all other prior, oral or written agreements.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement in duplicate originals by their duly authorized officers or representatives.

LICENSEE

BOARD OF SUPERVISORS OF
LOUISIANA STATE UNIVERSITY AND
AGRICULTURAL AND MECHANICAL
COLLEGE [***]

By _____ [***]
(authorized representative)

By _____ [***]
(authorized representative)

[***]

[***]

Title: [***]

Title: [***]

Date 6/8/15

Date 5/13/15

[***]

By _____ [***]
(authorized representative)

Typed Name: [***]

Title: [***]

Date 5/25/15

APPENDIX A
RESEARCH COOPERATION AGREEMENT

[***]

APPENDIX B

TO THE LICENSE AGREEMENT FOR LSU FILE
LSUHSC-S- 07-006
and
LSUHSC-S-09-015
12th DAY OF May, 2015
BETWEEN BIONTECH AG,
THE BOARD OF SUPERVISORS OF LOUISIANA STATE UNIVERSITY AND
AGRICULTURAL AND MECHANICAL COLLEGE ,
AND THE UNIVERSITY OF WARSAW

PATENTS AND PATENT APPLICATIONS WITHIN THE PATENT RIGHTS

[***]

APPENDIX C

PRIOR AGREEMENTS

[***]

THE SYMBOL “[*]” DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED**

LICENSE AND COLLABORATION AGREEMENT

by and between

BioNTech AG

and

Genmab A/S

Effective as of: 19th May 2015

LIST OF EXHIBITS

- Exhibit 1 **Terms for Unilateral Development**
- Exhibit 2 **Biontech Patents**
- Exhibit 3 **Genmab Patents**
- Exhibit 4 **Antibody Panel**
- Exhibit 5 **Research Plan**
- Exhibit 6 **Development Plan and Budget**
- Exhibit 7 **Company Announcement and Media Release**

LICENSE and COLLABORATION AGREEMENT

This License and Collaboration Agreement (**Agreement**) is made and entered into as of 19th May 2015 (**Effective Date**) by and between

BioNTech AG, a German corporation having its principal office at An der Goldgrube 12, 55131 Mainz, Germany (**Biontech**)

and

Genmab A/S, CVR no. 21023884, a Danish corporation having its principal office at Bredgade 34E, P.O. Box 9068, DK-1260 Copenhagen K, Denmark, (**Genmab**).

(Biontech and Genmab each a **Party** and together the **Parties**)

PREAMBLE

WHEREAS, the Parties desire to jointly research, develop and commercialize polypeptide-based bispecific antibodies using Genmab's proprietary DuoBody® platform technology against certain target combinations in combination with Genmab's proprietary inert format technology for the treatment of cancer.

WHEREAS, the Parties have previously entered into a Letter of Intent (**LOI**) dated 19 January 2015 and a Materials Transfer Agreement dated 19 January 2015 (the **MTA**) (the LOI and the MTA together referred to as the **Prior Agreement**).

WHEREAS, the joint research, development and commercialization shall be based on a 50/50 sharing of costs and profits, whereby either Party shall have the right to exit its participation in further development costs at certain pre-defined opt-out points during development.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants set forth below, the Parties hereby agree as follows:

1. DEFINITIONS

- 1.1** **Adverse Event** means any unfavorable and unintended medical occurrence in a human patient or subject who is administered a Collaboration Product or Unilateral Product, including any undesirable sign (including abnormal laboratory findings of clinical concern), symptom or disease temporally associated with the use of such Collaboration Product or Unilateral Product, whether or not considered related to such Collaboration Product or Unilateral Product.

- 1.2 **Affiliate** shall mean, with respect to any person or entity, any other person or entity which directly or indirectly controls, is controlled by, or is under common control with such person or entity. A person or entity shall be regarded as in control of another person or entity if it owns, or directly or indirectly controls, more than fifty percent (50%) of the voting stock or other ownership interest of the other person or entity, or if it directly or indirectly possesses the power to direct or cause the direction of the management and policies of the other person or entity by any means whatsoever.
- 1.3 **Alliance Manager** has the meaning set forth in Section 8.1.
- 1.4 **Antibody** means a polypeptide-based antibody or a derivative thereof identifiable by a unique amino acid sequence [***].
- 1.5 **Applicable Law** means any law or statute, any rule or regulation issued by a government authority (including courts and Regulatory Authorities), any GxP regulations or guidelines as well as and any judicial, governmental, or administrative order, judgment, decree or ruling, in each case as applicable to the subject matter and the parties at issue.
- 1.6 **Approved Subcontractor** means a subcontractor engaged by a Party that has been approved by the Joint Research Committee or Joint Steering Committee, as applicable, to perform specific obligations of the subcontracting Party.
- 1.7 **Assigned Patents** shall have the meaning set forth in Sections 9.1f and 9.1h.
- 1.8 **Back-up Candidate** shall mean a Clinical Candidate that has been selected by the Joint Steering Committee as back-up candidate for a Collaboration Product or by the Continuing Party as a back-up candidate for a Unilateral Product in accordance with Section 2.9.
- 1.9 **Bidding Criteria** has the meaning set forth in Section 15.9c.
- 1.10 **Biontech** has the meaning set forth in the introduction to this Agreement.
- 1.11 **Biontech Antibodies** mean the Antibodies proprietary to Biontech listed in the Research Plan.
- 1.12 **Biontech Improvement Technology** is defined in Section 9.1c.
- 1.13 **Biontech Know-How** means any and all technical information, processes, formulae, data, inventions, methods, chemical compounds, biological or physical materials, know-how and other trade secrets, in each case that are not in the public domain, that relate to or are useful to research, develop, use, manufacture or commercialize the Biontech Antibodies, to the extent not disclosed or claimed by a Biontech Patent. Biontech Know-How shall include all Biontech Improvement Technology and Biontech's interest in any Collaboration IP and Assigned Patents (in each case to the extent not disclosed or claimed by a Biontech Patent).
- 1.14 **Biontech Patents** means:

- a. any Patent Rights listed in Exhibit 2 to this Agreement to the extent that they claim Biontech Antibodies, which shall be amended from time to time to reflect any other Patent Rights;
- b. any Patent Rights covering Biontech Improvement Technology; and
- c. Biontech's interest in any Joint Patents and in any Patent Rights claiming Assigned Patents.

- 1.15 **BiontechTechnology** means the Biontech Patents and the Biontech Know-How.
- 1.16 **Biontech Unilateral Product** means a Unilateral Product which is being Developed and Commercialized solely by Biontech.
- 1.17 **Bispecific Antibody** means an Antibody comprising antigen-binding sites of two different monoclonal Antibodies. The term Bispecific Antibody further includes the subtypes of [***] Antibodies having additional binding affinities to antigens or cells expressing such antigens.
- 1.18 **BLA** means a Biologics License Application or equivalent submission filed with the FDA and/or EMA in connection with seeking Marketing Approval of a Collaboration Product or Unilateral Product, or an equivalent application filed with any equivalent regulatory agency or governmental authority in any jurisdiction other than the United States.
- 1.19 **Budget** shall mean the budget attached to the Research Plan or Development Plan or Commercialization Plan, as applicable.
- 1.20 **Calendar Quarter** means any of the three month periods beginning on January 1, April 1, July 1 or October 1 of any year.
- 1.21 **Cap during Divestment** is defined in Section 15.4.
- 1.22 **Ceased Product** is defined in Section 14.3.
- 1.23 **Claims** has the meaning set forth in Section 13.1a.
- 1.24 **Clinical Candidate** means any Bispecific Antibody targeting any of the Target Combinations.
- 1.25 **Collaboration Accounting Policies** means the accounting policies as agreed to by the Parties and approved by the Joint Steering Committee to be used in determining Shared Costs and Shared Profits, which will be, in all material respects, consistent with IFRS and any Applicable Laws.
- 1.26 **Collaboration IP** has the meaning set forth in Section 9.1c.
- 1.27 **Collaboration Product** means a Clinical Candidate which the Parties have selected for further joint development in Phase B.
- 1.28 **Collaboration Product Trademark** has the meaning set forth in Section 9.11.

- 1.29 **Collaboration Targets** [***]
- 1.30 **Commercialization** means (i) all activities directed to the marketing, detailing, promotion (including co-promotion), advertising, selling and distribution of a Collaboration Product in a country or region after all Marketing Approvals have been obtained in such country or region (including making, having made, using, importing, selling, having sold, offering for sale, and having offered for sale such Collaboration Product), and will include marketing research, customer service, administering and commercially selling such Collaboration Product, post-approval clinical trials and other additional research and development activities undertaken solely and to the extent necessary to meet local regulatory requirements, importing, exporting or transporting such Collaboration Product for commercial sale, and all regulatory compliance with respect to the foregoing; it being understood and agreed that such activities may occur pre- or post-launch of such Collaboration Product; and (ii) the conclusion of one or more Partnership Agreements. When used as a verb, “**Commercialize**” means to engage in Commercialization.
- 1.31 **Commercialization Agreement** is defined in Section 4.5.
- 1.32 **Commercialization Plan** means, with respect to a Collaboration Product, a commercialization plan to be prepared and agreed between the Parties, and updated by the Joint Commercialization Committee, once such committee is in place, and endorsed by the Joint Steering Committee which describes the envisaged form of Commercialization (e.g. through own sales forces, third party sales forces, conclusion of Partnership Agreements, etc.), the responsibilities of each Party, timelines, budgets for Commercialization costs, target volumes, territories and other relevant items agreed between the Parties. The Commercialization Plan shall be carried out by the Joint Commercialization Committee and shall be updated at least annually by the Joint Commercialization Committee, once such committee is in place, and all changes to the Commercialization Plan must be approved by the Joint Steering Committee.
- 1.33 **Commercially Reasonable Efforts** means the level of efforts and resources that a similarly situated company in the biotechnology industry would normally use to accomplish a similar objective, and in particular with respect to a product: to develop, manufacture and commercialize a product of similar market potential at a similar stage in its development or product life cycle taking into account all relevant factors then prevailing, including without limitation efficacy, competition, intellectual property position, likelihood of Marketing Approval, profitability, alternative products and product candidates and other relevant factors.
- 1.34 **Confidential Information** means all information, data, documents including Know-how and the subject-matter of any unpublished invention, or any material in tangible form that is disclosed or made available under this Agreement by the Disclosing Party to the Receiving Party and that is marked as “Confidential” at the time it is disclosed or delivered to the Receiving Party (or, if disclosed orally, is identified as confidential when disclosed and such disclosure is confirmed in writing within thirty (30) days by the Disclosing Party) or ought in good faith to be treated as confidential taking account of its content or the circumstances of disclosure. The term Confidential Information shall also include the existence and contents of this Agreement.

- 1.35 **Continuing Party** is defined in Section 14.6.
- 1.36 **Control** means, with respect to any information or intellectual property right, possession by a person or entity of the ability to grant the right to access or use, or to grant a license or a sublicense to, or to use such information or intellectual property right as provided for herein without violating the terms of any agreement or other arrangement with any other person or entity.
- 1.37 **Development** means, with respect to a Collaboration Product, any and all drug development activities and manufacturing activities undertaken pursuant to the relevant Development Plan in order to develop a Collaboration Product up to and including obtaining Marketing Approval for such Collaboration Product for an indication and to perform manufacturing scale up to enable commercial scale manufacturing prior to launch (except that inventory build shall be considered a Commercialization activity). These activities shall include preclinical research, stability testing, toxicology testing, formulation activities, reformulation activities, process development, manufacturing scale up activities, development stage manufacturing, quality assurance/quality control development, clinical studies (including Phase III Studies and other studies (e.g., pharmacovigilance programs and outcome studies) that the Joint Steering Committee considers necessary or economically justifiable and other activities to obtain the applicable Marketing Approvals; in each case in accordance with the applicable Development Plan, as applicable. When used as a verb, **Develop** means to engage in Development.
- 1.38 **Development Plan** means, with respect to a Collaboration Product, a written development plan agreed between the Parties which describes the development and manufacturing work to be performed by each Party during Phase B, as well as the Budgets, approved Shared Costs, timelines, allocation of FTEs and other relevant items agreed between the Parties, as set forth in Exhibit 6.
- 1.39 **Development Project Manager** has the meaning set forth in Section 8.4.
- 1.40 **Disclosing Party** is defined in Section 11.1.
- 1.41 **Divesting Party** has the meaning set forth in Section 15.2.
- 1.42 **Divestment** shall mean the economic valorization of the value of the rights and obligations of a Party under this Agreement by that Party, by granting the rights to Develop and/or Commercialize a Collaboration Product to an independent Third Party in any legal way possible, including but not limited to by licensing, assigning or transferring such rights. When used as a verb, **Divest** means to engage in Divestment.
- 1.43 **Divestment Executive** has the meaning set forth in Section 15.9a.
- 1.44 **Divestment Notice** has the meaning set forth in Section 15.2.
- 1.45 **Divestment Process** has the meaning set forth in Section 15.2.
- 1.46 **Dual- or Triple-Binder** [***]

- 1.47 **DuoBody Platform** means Genmab's proprietary technology that is generally applicable to the discovery, modification, optimization, generation and manufacturing of Bispecific Antibodies of the IgG subtype, [***]
- 1.48 **Effective Date** is defined in the introductory paragraph of this Agreement.
- 1.49 **EMA** means the European Medicines Agency, and any successor agency thereto.
- 1.50 **Establishment of Clinical Proof of Concept** means the point in time during Development, where the [***] from the first Phase I/II Clinical Trial becomes available.
- 1.51 **EU** means all the countries in the Territory that as of the receipt of the European Marketing Approval for a Collaboration Product are members of the European Union.
- 1.52 **Events of Force Majeure** has the meaning set forth in Section 16.6.
- 1.53 **Exclusive Negotiation Period** has the meaning set forth in Section 15.2.
- 1.54 **Fall Back Terms** has the meaning set forth in Section 14.4c).
- 1.55 **FDA** means the U.S. Food and Drug Administration, or any successor agency thereto.
- 1.56 **Field** means the treatment of cancer in humans.
- 1.57 **Financial Representative** has the meaning set forth in Section 7.5.
- 1.58 **First Commercial Sale** means, on a Unilateral Product-by-Unilateral Product basis, the first sale of the Unilateral Product for which revenue has been recognized by a Party or any of its Affiliates to any Third Party after all required Marketing Approvals have been granted. For the avoidance of doubt, First Commercial Sale shall not include the transfer or sale of any Unilateral Product (i) by a Party to an Affiliate, Sublicensee or Third Party Collaborator unless the Affiliate, Sublicensee or Third Party Collaborator is the last entity in the distribution chain of the Unilateral Product, (ii) for use in clinical trials or non-clinical development activities (e.g., material transfer agreements) or a bona fide charitable purpose, or (iii) for compassionate use.
- 1.59 **FTE** means a full-time employee of a Party working over the course of a twelve (12) month period, or several employees of a Party collectively working the equivalent of such full-time employee. FTEs shall be calculated based on the time an employee of the Parties spends working on a billable effort as recorded by such Parties' project time reporting system. An FTE is measured on the basis of a total of [***] hours per year for employees.
- 1.60 **FTE Rates** shall mean the rates set forth in Sections 7.2 and Exhibit 1, as applicable.
- 1.61 **FTO Notification** has the meaning set forth in Section 10.1 of this Agreement.

- 1.62 **Generic Product** means (a) for a product sold in the United States, a biological product approved under the Public Health Service Act 351(k) that is highly similar to a Unilateral Product, notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences between the generic product and the Unilateral Product in terms of the safety, purity and potency; (b) for a product sold in the EU, a biological product approved under Article 10(4) of Directive 2001/83/EC and Section 4, Part II, Annex I to such Directive based on the demonstration of the similar nature to the Unilateral Product; and (c) for a generic product sold outside the United States and the EU, a biological product approved under a similar regulatory pathway as in the United States and in the EU, if such pathway exists.
- 1.63 **Genmab** has the meaning set forth in the introduction to this Agreement.
- 1.64 **Genmab Antibodies** mean the Antibodies proprietary to Genmab listed in the Research Plan, if any.
- 1.65 **Genmab Improvement Technology** is defined in Section 9.1c.
- 1.66 **Genmab Know-How** means all technical information, processes, formulae, data, inventions, methods, chemical compounds, biological or physical materials, know-how and other trade secrets, in each case, that relate to or are useful to research, develop, manufacture or commercialize the Genmab Antibodies, the DuoBody Platform and/or the [***] Technology, to the extent not disclosed or claimed by a Genmab Patent. Genmab Know-How shall include all Genmab Improvement Technology and Genmabs' interest in any Collaboration IP and Assigned Patents (in each case to the extent not disclosed or claimed by a Genmab Patent).
- 1.67 **Genmab Patents** means:
- a. any Patent Rights listed in Exhibit 3 to this Agreement to the extent that they claim Genmab Antibodies, the DuoBody Platform or the Inert Format Technology, which shall be amended from time to time to reflect any other Patent Rights;
 - b. any Patent Rights covering Genmab Improvement Technology; and
 - c. Genmab's interest in any Joint Patents and in any Patent Rights claiming Assigned Patents.
- 1.68 **Genmab Technology** means the Genmab Patents and the Genmab Know-How.
- 1.69 **Genmab Unilateral Product** means a Unilateral Product which is being developed and commercialized solely by Genmab.
- 1.70 **Good Clinical Practice** or **GCP** shall mean any and all laws, rules, regulations, guidelines and generally accepted standards and requirements regarding the ethical conduct of clinical trials, including without limitation the U.S. Code of Federal Regulations (CFR) Title 21, ICH GCP Guidelines E6(R1), current step 4 version, dated 10 June 1996, as amended from time to time, national legislation implementing European Community Directive 2001/20/EC of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, European Community Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards to investigational medicinal products for human use.

- 1.71 **Good Laboratory Practice** or **GLP** shall mean any and all laws, rules, regulations, guidelines and generally accepted standards and requirements regarding quality control for laboratories to ensure the consistency and reliability of results, including without limitation the CFR Title 21, national legislation implementing European Community Directive 2004/9/EC of 11 February 2004 on the inspection and verification of good laboratory practice (GLP) as amended and European Community Directive 2004/10/EC of 11 February 2004 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances as amended, OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring.
- 1.72 **Good Manufacturing Practice** or **GMP** shall mean any and all laws, rules, regulations, guidelines and generally accepted standards and requirements regarding the quality control and manufacturing of pharmaceutical products, including without limitation the CFR Title 21, ICH GMP Guidelines Q7, current step 4 version, dated 10 November 2000, as amended from time to time, national legislation implementing European Community Directive 91/356/EEC of 13 June 1991 laying down the principles and guidelines of good manufacturing practice for medicinal products for human use as amended by European Community Directives 2003/94/EC, the Rules Governing Medicinal Products in the European Community, Volume 4, including annexes.
- 1.73 **GxP** means GCP, GLP or GMP or any combination thereof, as applicable.
- 1.74 **IFRS** means the international financial reporting standards.
- 1.75 **IND** means an Investigational New Drug application filed with the FDA, EMA or their equivalent in any country where a regulatory filing is required or obtained for commencement of human clinical trials of a pharmaceutical product.
- 1.76 **Indication** means an application for a label or label expansion indicating the applicable drug for an initial, expanded or additional patient population, or indicating the drug for use in combination with another treatment or drug, or different route of administration in each case that requires a pivotal clinical trial for Marketing Approval. For the avoidance of doubt, the Parties acknowledge that there may be more than one Indication for any given histology or tumor type. By way of example, and not limitation, mono-therapy, various combination therapies, front-line treatment and maintenance treatment of the same histology or tumor type are different Indications for the purposes of this Agreement.
- 1.77 **Indemnified Party** shall have the meaning set forth in Section 13.3.
- 1.78 **Indemnites** shall have the meaning set forth in Section 13.1.
- 1.79 **Indemnitor** shall have the meaning set forth in Section 13.3.
- 1.80 **[***] Technology** means Genmab's proprietary **[***]** technology to control the immune response induced by antibodies **[***]**

- 1.81 **Infringement Attack** has the meaning set forth in Section 10.2.
- 1.82 **Infringement Proceedings** has the meaning set forth in Section 9.9d.
- 1.83 **Interested Party** shall have the meaning set forth in Section 2.11.
- 1.84 **IP Budget** has the meaning set forth in Section 9.6d.
- 1.85 **Joint Commercialization Committee** is defined in Section 8.5.
- 1.86 **Joint Development Team** has the meaning set forth in Section 8.4.
- 1.87 **Joint Divestment Process** has the meaning set forth in Section 15.9.
- 1.88 **Joint Patents** means any patents and patent applications claiming Collaboration IP.
- 1.89 **Joint Research Committee** means the joint research committee established under Section 8.2.
- 1.90 **Joint Steering Committee** has the meaning set forth in Section 8.3.
- 1.91 **Lead Commercialization Party** has the meaning set forth in Section 4.3.
- 1.92 **Lead IP Party** has the meaning set forth in Section 9.6a.
- 1.93 **Lead Regulatory Party** means, with respect to a country or region, the Party with the main responsibility for carrying out regulatory activities in accordance with Section 5.
- 1.94 **Liabilities** has the meaning set forth in Section 13.1a.
- 1.95 **Major Market Country** means any of the following: [***]
- 1.96 **Marketing Approval** means any regulatory approval of any Regulatory Authority or other government authority of any country or jurisdiction in the world that is necessary to be obtained before the commercial sale of a pharmaceutical product for an Indication in that country or jurisdiction.
- 1.97 **Material Adverse Change** means a change in circumstances or events relating to a Collaboration Product Developed under this Agreement, that a Party reasonably believes materially adversely affects the net present value of such Collaboration Product, where such Party could not reasonably previously have known about such change. Such changes in circumstances could include, for example, the approval for marketing of a competing product, a successful challenge to the validity of a patent covering such Collaboration Product or new clinical data relating to the Collaboration Product which raise serious concerns with respect to safety and/or efficacy of the Collaboration Product.

- 1.98** **Net Sales** means the gross amounts invoiced in arms-length transactions by a Party or any of its Affiliates, Third Party Collaborators or Sublicensees to Third Party customers for sales of a Collaboration Product or Unilateral Product, less the following deductions for:
- a. discounts (including trade, quantity and cash discounts) actually allowed, cash and non-cash coupons, retroactive price reductions, and charge-back payments and rebates granted to any Third Party (including to governmental entities or agencies, purchasers, reimbursers, customers, distributors, wholesalers, and group purchasing and managed care organizations or entities);
 - b. credits or allowances, if any, on account of price adjustments, shelf stock adjustment, recalls, claims, damaged goods, rejections or returns of items previously sold (including products returned in connection with recalls or withdrawals) and amounts written off by reason of uncollectible debt, provided that if the debt is thereafter paid, the corresponding amount will be added to the Net Sales of the period during which it is paid;
 - c. product-related administrative fees, rebates or other similar allowances granted (including to governmental authorities, purchasers, reimbursers, customers, distributors, wholesalers, and managed care organizations and entities) which effectively reduce the selling price or gross sales; and
 - d. insurance, customs charges, freight, postage, shipping, handling, and other transportation costs; and
 - e. import taxes, export taxes, excise taxes, sales taxes, value-added taxes, consumption taxes, duties or other taxes levied on, absorbed, determined and/or imposed with respect to sales of Collaboration Products (excluding income taxes of any kind).

If a Party receives non-cash consideration or in the case of transactions not at arm's length, Net Sales will be calculated based on the fair market value of such consideration or transaction, at the time of the transaction, assuming an arm's length transaction made in the ordinary course of business. Notwithstanding the foregoing, Net Sales shall not be imputed to any transfer of the Collaboration Product or Unilateral Product for use in clinical trials, non-clinical development activities (e.g. material transfer agreements) or other development activities with respect to the Collaboration Product or Unilateral Product by or on behalf of the respective Party, for bona fide charitable purposes or for compassionate use, if no monetary consideration is received for such transfers.

1.99 **Non-Divesting Party** has the meaning set forth in Section 15.2.

1.100 **Non-Lead Party** has the meaning set forth in Section 9.6b.

1.101 **Non-Interested Party** has the meaning set forth in Section 2.11.

1.102 **Opt-Out Date** is defined in Section 14.1.

1.103 **Opt-Out Notice** is defined in Section 14.1.

1.104 **Opt-Out Party** is defined in Section 14.1.

1.105 **Opt-Out Point** is defined in Section 14.1.

- 1.106** **Partnership Agreement** means a license agreement to be concluded jointly by both Parties (or by one of the Parties with approval of the other Party) with a Third Party (**Third Party Collaborator**) under which such Third Party Collaborator obtains an exclusive or non-exclusive (as agreed between the Parties and the Third Party Collaborator in accordance with Section 4.8) license or other right to a Collaboration Product and related Collaboration IP and assumes the obligation to Commercialize such Collaboration Product in certain defined parts of the Territory.
- 1.107** **Patent Right** means (a) all patent applications filed or having legal force in any country or jurisdiction, including all provisional patent applications; (b) all patents that have issued or in the future will be issued from such applications, including without limitation method, process, utility, model and design patents and certificates of invention; and (c) all divisionals, continuations, continuations in part, supplement protection certificates, reissues, reexaminations, renewals, extensions or additions to any such patent application and patents.
- 1.108** **Paying Party** has the meaning set forth in Exhibit 1.
- 1.109** **Phase I Clinical Trial** means, a human clinical trial that is conducted to evaluate the preliminary safety, tolerability and pharmacokinetics effect of a drug in healthy volunteer subjects or patients in accordance with the requirements of 21 CFR 312.21(a) or foreign equivalents. Typical elements of a Phase I Clinical Trial are described in more detail in Section 3.1.3.1 of ICH Topic E8 (GENERAL CONSIDERATIONS FOR CLINICAL TRIALS). The final design of Phase I Clinical Trials for a Collaboration Product will be agreed by the Joint Steering Committee.
- 1.110** **Phase I/II Clinical Trial** means a human clinical trial which has the following two (2) main objectives: (i) determining preliminary safety and (ii) determining preliminary efficacy parameters in appropriate patients. Such Phase I/II Clinical Trial will often be split into two (2) parts, where the first part is intended to determine the maximum tolerated dose, and the second part is intended to determine preliminary efficacy parameters and additional safety data. The final design of Phase I/II Clinical Trials for a Collaboration Product will be agreed by the Joint Steering Committee.
- 1.111** **Phase II Clinical Trial** means a potentially controlled human clinical trial involving a sufficient number of patients with the disease or condition of interest to obtain sufficient efficacy and safety data of a candidate drug in the targeted patient population to support a Phase III Clinical Trial of a candidate drug for its intended use, and to define the optimal dosing regimen, such as trials referred to in 21 C.F.R. §312.21(b) and foreign equivalents. Typical elements of a Phase II Clinical Trial are described in more detail in Section 3.1.3.2 of ICH Topic E8 (GENERAL CONSIDERATIONS FOR CLINICAL TRIALS). The final design of Phase II Clinical Trials for a Collaboration Product will be agreed by the Joint Steering Committee.
- 1.112** **Phase III Clinical Trial** means a controlled, and usually multi-center, clinical trial, involving patients with the disease or condition of interest intended to obtain sufficient efficacy and safety data to support Marketing Approval of a candidate drug whether or not designated as “Phase III”, such as trials referred to in 21 C.F.R. §312.21(c) and foreign equivalents. Typical elements of a Phase III Clinical Trial are described in more detail in Section 3.1.3.3 of ICH Topic E8 (GENERAL CONSIDERATIONS FOR CLINICAL TRIALS). The final design of Phase III Clinical Trials for a Collaboration Product will be agreed by the Joint Steering Committee.

- 1.113 **Phase A** means the research and evaluation phase pursuant to Section 2.
- 1.114 **Phase B** means the preclinical and clinical development phase pursuant to Section 3.
- 1.115 **Preferred Clinical Candidate** has the meaning set forth in Section 2.10 of the Agreement.
- 1.116 **Prior Agreement** has the meaning set forth in the preamble of the Agreement.
- 1.117 **Profit** means the profits resulting from the Commercialization of a Collaboration Product, which shall be equal to the Net Sales received by a Party from the Commercialization of a Collaboration Product:
- a. less manufacturing costs for the Collaboration Product sold,
 - b. plus profits received from Partnership Agreements in relation to the Collaboration Product,
- provided, however, that any costs that would otherwise be included as a Commercialization expense, but which, pursuant to the definition of “Net Sales”, are deducted from gross sales to determine the Net Sales of a Collaboration Product, shall not also be deducted as a Commercialization expense and thereby counted twice. For the avoidance of doubt, Profits received from Partnership Agreements shall include without limitation all up-front, milestone and royalty payments, but exclude (i) any arms’ length research and development funding paid by the Third Party Collaborator in consideration for research and development activities to be performed under the Partnership Agreement and (ii) any value added or other taxes paid by the Third Party Collaborator to a Party in connection with such Partnership Agreement. Further details of the Profit calculation shall be agreed in the Commercialization Agreement.
- 1.118 **Program Inventions** has the meaning set forth in Section 9.1b.
- 1.119 **Proposed IND Submission** has the meaning set forth in Section 3.7.
- 1.120 **Publication** has the meaning set forth in Section 11.6.
- 1.121 **Receiving Party** is defined in Section 11.1.
- 1.122 **Region** means either Asia (including, but not limited to India), the EU, North America (US, Mexico and Canada), South and Central America or ROW (including, but not limited to Russia, Australia, New Zealand, Africa, Middle East).
- 1.123 **Regulatory Authority** means any federal, national, multinational, state, county, city, provincial, or local regulatory agency, department, bureau or other governmental entity with authority over the marketing, commercialization, manufacture or sale of a pharmaceutical product in the Territory, including the FDA in the United States and the EMA in the EU.

1.124 **Research and Development Costs** means the actual costs and expenses incurred by a Party for research and Development activities in Phase A and Phase B, including:

- a. direct labor at the agreed FTE Rate plus agreed travel expenses pursuant to the Travel Policy of such employees,
- b. direct research and development costs paid to consultants, independent contractors and Third Party service providers,
- c. direct costs of supplies, equipment and materials and related expenditures (including taxes and duties),
- d. patent filing, prosecution and maintenance costs (but not defense and enforcement costs, unless otherwise set forth in this Agreement),
- e. scale-up and other manufacturing costs (solely up to and including scale-up activities prior to production of successful consistency batches which is understood to be the first production of batches of a Collaboration Product that may be used for Commercialization),
- f. Third Party contract costs required to perform Development activities related to the relevant Collaboration Product,
- g. regulatory costs, including costs for IND and BLA filing and other costs for obtaining Marketing Approvals,
- h. license payments (including but not limited to upfront payments, milestone payments and license maintenance fees) to Third Parties as necessary for Development and Commercialization of Collaboration Products

in each case (a) to (e) calculated in accordance with the Collaboration Accounting Policies, consistently applied and only to the extent such costs are directly attributable to the furtherance of a Research Plan or Development Plan, but excluding expenditures relating to general overhead, managerial, legal, financial and administrative expenses. For the avoidance of doubt, to the extent costs or salaries are partly directly attributable to a Research Plan or Development Plan and partly attributable to other activities of a Party, such costs and salaries shall constitute Research and Development Costs on a *pro rata* basis.

1.125 **Research Plan** means the written research plan agreed between the Parties which describes the work to be performed by each Party during Phase A as well as budgets, timelines, allocation of FTEs and other relevant items agreed between the Parties. The Research Plan shall be updated at least annually as shall be set forth in Exhibit 5.

1.126 **Royalty Reports** has the meaning set forth in Exhibit 1.

- 1.127 **Royalty Term** means on a Unilateral Product-by-Unilateral Product and country-by-country basis, the period commencing on the First Commercial Sale of the relevant Unilateral Product and ending on the later to occur of:
- a. the [***] anniversary of the date of the First Commercial Sale of such Unilateral Product in such country;
 - b. the expiration of the last to expire Valid Patent Claim of any Patent Right included in the [***] or the [***] (in case of an opt-out by Genmab) or [***] (in case of an opt-out by Biontech) that would be infringed by the manufacture, use, sale, offer for sale or import of the Unilateral Product in such country, if not for the licenses or assignments of intellectual property granted hereunder; and
 - c. the expiration of [***] for such Unilateral Product in such country.
- 1.128 **Selection of a Clinical Candidate** has the meaning set forth in Section 2.9.
- 1.129 **Serious Adverse Events** means any Adverse Event occurring at any dose in response to the administration of a Collaboration Product or Unilateral Product that: (a) results in death or threatens life; (b) results in persistent or significant disability/incapacity; (c) results in or prolongs hospitalization; (d) results in a congenital anomaly or birth defect; or (e) is otherwise medically significant.
- 1.130 **Shared Cost** is defined in Section 7.3a.
- 1.131 **Shared Profits** is defined in Section 7.3b.
- 1.132 **Sublicensee** means any person or entity that is granted a sublicense under (a) the Biontech Technology by Genmab or its Affiliates or (b) the Genmab Technology by Biontech or its Affiliates in accordance with the terms of this Agreement.
- 1.133 **Target Combination** means each of the combinations of two distinct targeted antigens selected from the Collaboration Targets as specifically set forth in the Research Plan; each distinct antigen defined by its unique UniProt/Swiss-Prot number.
- 1.134 **Term** has the meaning set forth in Section 16.1.
- 1.135 **Territory** means the world.
- 1.136 **Third Party** means any person or entity other than the Parties and their Affiliates.
- 1.137 **Travel Policy** means the policy as agreed to by the Parties and approved by the Joint Steering Committee to be used for travel costs and expenses incurred as part of a Party's activities under the applicable Research Plan or Development Plan, subject however to Sections 7.5 and 8.6.
- 1.138 **Unilateral Product** has the meaning set forth in Section 14.6.

1.139 **Valid Patent Claim** means (a) an unexpired claim of an issued patent (including any extension thereof pursuant to patent term extension or a supplementary protection certification) which has not been found to be unpatentable, invalid or unenforceable by an unreversed and unappealable decision (including a decision that was not appealed within the time allotted for an appeal) of a court or other authority in the subject country; or (b) a claim of an application for a patent that has been pending for less than [***] years as calculated from the earliest priority date.

2. PHASE A – RESEARCH AND EVALUATION

2.1 **Goal of Phase A.** The goal of Phase A is to jointly discover, research and develop in accordance with the Research Plan, Clinical Candidates against the Target Combinations for further preclinical and clinical development in Phase B, on the basis of a 50/50 cost sharing. During the initial term of Phase A (as defined in Section 2.4), the Parties expect to identify [***] Clinical Candidates. For the avoidance of doubt, these numbers of expected Clinical Candidates are non-binding estimates only and the collaboration between the Parties in Phase A shall not be subject to any binding minimum or maximum number of Clinical Candidates. The Parties agree that this Agreement shall replace the Prior Agreement upon execution, and that any initial research (as defined under the Prior Agreement) conducted under the Prior Agreement shall be deemed covered by Phase A and the terms and conditions thereof, and any rights and obligations of the Parties under the Prior Agreement shall be replaced with the rights and obligations of the Parties set forth in this Agreement. In case of discrepancy between this Agreement and the Prior Agreement, this Agreement shall prevail.

2.2 **Research Plan.** Within [***] days after the Effective Date, the Parties shall prepare and agree an initial Research Plan, which shall be endorsed by the Joint Research Committee and added to Exhibit 5. On an annual basis, or more frequently as necessary and agreed by the Parties, but no later than by 30 September (in order for the Parties to prepare their respective budgets for the coming [***] calendar years), the Joint Research Committee shall review the Research Plan in order to make annual updates to the Research Plan for the then current calendar year, if any, plus the following two (2) calendar years. Furthermore, each Party may recommend changes to the Research Plan at any time; provided, however, that such changes shall be effective only upon the approval by the Joint Research Committee.

2.3 **FTE Allocation During Phase A.** The Parties intend to contribute and commit the required resources to meet the objectives as stipulated by the Joint Research Committee and in the applicable Research Plan. Details in relation to the number and allocation of FTEs during Phase A shall be set forth in the Research Plan. For the avoidance of doubt, the allocation of FTEs pursuant to the Research Plan shall not alter the 50/50 cost sharing in Phase A as set forth in Section 7.3a.

2.4 **Subcontracting During Phase A.** Either Party may perform some or all of its obligations under the Research Plan through any of its Affiliates or one or more Approved Subcontractors; provided, that (a) none of the rights of the other Party hereunder are diminished or are otherwise adversely affected as a result of such subcontracting and (b) the Affiliate or Approved Subcontractor undertakes in writing all obligations of confidentiality and non-use regarding both Parties' Confidential Information which are substantially the same as those undertaken by the Parties hereunder. In the event that a Party performs one or more of its obligations under the Research Plan through any such Affiliate or Approved Subcontractor, then such Party

shall at all times be responsible for the performance by such Affiliate or Approved Subcontractor of such Party's obligations hereunder. Provided that the Research Plan specifically includes reference to such Affiliate or Approved Subcontractor and the activities and services to be carried out by such Affiliate or Approved Subcontractor, then the Party subcontracting does not need to consult with the other Party before entering into an agreement with such Affiliate or Approved Subcontractor, provided that the terms of this Section 2.4 are adhered to.

2.5 **Duration of Phase A.** The joint research and development activities in Phase A are scheduled for an initial term of [***] years starting on the Effective Date. The Parties shall discuss in good faith an extension of Phase A at the latest [***] months before the end of the initial term, provided that any extension of Phase A shall require the written mutual agreement between the Parties.

2.6 **General Obligations of the Parties in Phase A.** During Phase A, each Party shall

- a. use its Commercially Reasonable Efforts to discover, research and develop Clinical Candidates and to perform its respective activities pursuant to the Research Plan, and
- b. perform its activities under the Research Plan in good scientific manner, and in compliance with all requirements of Applicable Laws, and
- c. contribute such personnel, equipment, facilities and other resources as reasonably necessary to perform its obligations under the Research Plan and to achieve efficiently the objectives thereof, provided that each Party shall only be obliged to contribute those FTEs set forth in Section 2.3 above and in the Research Plan,
- d. provide the other Party with such materials, information and other assistance required to be provided under the Research Plan.

2.7 **Results and Reporting Under Phase A.** Each Party shall keep the other Party fully informed as to its progress, results (including the development of any technology or Program Inventions), status and plans for performing and implementing the Research Plan. Such information shall be given by periodic, informal oral reports, and by a quarterly written report, which may be in the form of a power point presentation during meetings of the Joint Research Committee, delivered not later than thirty (30) days following the end of every Calendar Quarter during which any activities are performed under the Research Plan.

2.8 **Records.** Each Party shall maintain records, in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, which shall be complete and accurate and shall fully and properly reflect all work done and results achieved in its performance of the Research Plan. Each Party shall make such records available to the other Party for inspection upon reasonable written request of the other Party (but not more than once per calendar year) for the purpose of ensuring the Party's compliance with its research obligations hereunder. Upon request, each Party shall deliver to the other Party copies of all records described in this Section 2.8. All such records shall be jointly owned.

- 2.9** **Liability.** In connection with the conduct of the Development activities, hereunder, each Party shall be responsible for, and hereby assumes, any and all risks of personal injury or property damage attributable to the negligent acts or omissions of that Party or its Affiliates, and their respective directors, officers, employees and agents.
- 2.10** **Nomination of Collaboration Products.** Each Party may at any time during Phase A propose that one or more Clinical Candidates which meet the relevant specifications defined in the Research Plan is/are nominated by the Joint Research Committee as Collaboration Product(s) for further preclinical and clinical development in Phase B (such proposal to be considered **Selection of a Clinical Candidate** for the purpose of the financial terms set forth in Exhibit 1). Upon such proposal, the Joint Research Committee will (i) review and confirm whether the proposed Clinical Candidate(s) meet the relevant specifications defined in the Research Plan, (ii) if several proposed Clinical Candidates targeting the same Target Combination meet such specifications: decide which of these Clinical Candidates is best suited for further preclinical and clinical development (**Preferred Clinical Candidate**), and (iii) decide whether the Preferred Clinical Candidate(s) shall be developed as Collaboration Product(s). The Joint Research Committee shall make the decisions according to (i) to (iii) in good faith and shall not take into consideration whether any of these decisions would trigger the payment according to Section 7.1d. For the avoidance of doubt, if only one proposed Clinical Candidate targeting a certain Target Combination meets the relevant specifications defined in the Research Plan, such Clinical Candidate shall automatically be the Preferred Clinical Candidate for such Target Combination. If and when the Joint Research Committee decides that a Preferred Clinical Candidate shall be developed as Collaboration Product (as documented in the minutes of the Joint Research Committee), the Parties obligations under the Research Plan shall terminate, and Phase B shall be initiated with respect to such Preferred Clinical Candidate. For the avoidance of doubt, neither Party may propose to the Joint Research Committee a Clinical Candidate targeting a Target Combination for which a Preferred Clinical Candidate has already been selected.
- 2.11** **Unilateral Development.**
- a. If a Party (**Non-Interested Party**) – through the Joint Research Committee pursuant to Section 2.10 – decides not to develop a Preferred Clinical Candidate as a Collaboration Product and move it to Phase B, the other Party (**Interested Party**) shall be permitted to unilaterally continue development of the Preferred Clinical Candidate on the pre-defined terms and conditions set forth in Exhibit 1. In such case, the Preferred Clinical Candidate will become a Unilateral Product and Section 14.6 shall apply *mutatis mutandis*.
 - b. If the Interested Party is not willing to continue development of the Preferred Clinical Candidate on the pre-defined terms and conditions set forth in Exhibit 1, a mandatory joint Divestment of the Preferred Clinical Candidate shall take place and Section 15.9 shall apply *mutatis mutandis*, unless the Parties decide otherwise. If the mandatory joint Divestment fails, the Preferred Clinical Candidate will be considered a Ceased Product under Section 14.5.

- c. If the Parties agree not to advance a certain Clinical Candidate to Phase B, then such Clinical Candidate shall be considered a Ceased Product and Section 14.5 shall apply *mutatis mutandis*.

2.12 Back-Up Candidates. Concurrently with the decision to develop a proposed Clinical Candidate as Collaboration Product or Unilateral Product, as applicable, the Joint Research Committee (if both Parties wish to develop such Clinical Candidate) or the Interested Party (if only one Party wishes to develop such Clinical Candidate) shall be entitled to also designate [***] further Clinical Candidate (if available) as Back-up Candidate for the respective Target Combination (and in such event, the Joint Research Committee or the Interested Party, as applicable, may decide at any time that the Back-up Candidate shall replace the originally selected Clinical Candidate as Collaboration Product or Unilateral Product for the purposes of this Agreement).

3. PHASE B – PRECLINICAL AND CLINICAL DEVELOPMENT

3.1 Goal of Phase B. The goal of Phase B is to jointly develop on a Collaboration Product-by-Collaboration Product basis, a Collaboration Product in accordance with the applicable Development Plan through preclinical and clinical phase on the basis of a 50/50 cost sharing.

3.2 Development Plans. Without undue delay after nomination of a Collaboration Product, and on a Collaboration Product-per-Collaboration Product basis, the Parties shall agree on the initial Development Plan and Budget, both including clinical and manufacturing activities until Establishment of Proof of Concept, taking into consideration either Party's capabilities and resources. Such initial Development Plan and Budget shall be endorsed by the Joint Steering Committee and added to Exhibit 6 of this Agreement. Each Party may recommend changes to a Development Plan at any time; provided, however, that such changes shall be effective only upon the approval by the Joint Steering Committee.

3.3 Duration of Phase B. Phase B shall begin on a Collaboration Product-by-Collaboration Product basis upon nomination of the respective Collaboration Product pursuant to Section 2.10 and shall end upon the earlier of (i) opt-out of a Party pursuant to Section 14 and/or Divestment of a Party's share in the collaboration pursuant to Section 15 (in each case subject to the provisions on unilateral development by the Continuing/Non-Divesting Party and on continued funding by the Opt-Out/Divesting Party as set forth in Sections 14 and 15), (ii) abandonment of the Phase B Development activities by mutual agreement between the Parties, (iii) completion of all Development activities for all countries in which the Collaboration Product shall be Commercialized, (iv) conclusion of a Joint Divestment Process, and (v) any other date specified in the applicable Development Plan.

3.4 General Obligations of the Parties in Phase B. Each Party shall

- a. use its Commercially Reasonable Efforts to develop the respective Collaboration Product during the necessary preclinical and clinical stages and to perform its respective activities pursuant to the applicable Development Plan,

- b. perform its activities under the applicable Development Plan in good scientific manner, and in compliance with all requirements of Applicable Law,
- c. contribute such personnel, equipment, facilities and other resources as reasonably necessary to perform its obligations under the applicable Development Plan and to achieve efficiently the objectives thereof, provided that each Party may only incur Shared Costs as provided in Section 7.4,
- d. refrain from using in any capacity in connection with the Development, manufacture or Commercialization of a Collaboration Product, any person or entity who has been debarred pursuant to Section 306 of the United States Federal Food, Drug, and Cosmetic Act or a similar legislation in another jurisdiction, or who is the subject of a conviction described in such section, and
- e. provide to the other Party such materials, information and other assistance required to be provided under the applicable Development Plan.

3.5 **Reference to Certain Provisions of Phase A.** Sections 2.4, 2.7, 2.8 and 2.9 shall apply *mutatis mutandis* to Phase B.

3.6 **Ad Hoc and Annual Updates to the Development Plan.** On an annual basis, or more frequently as necessary and agreed by the Parties, but no later than by 30 September (in order for the Parties to prepare their respective budgets for the coming [***] calendar years), the Joint Steering Committee shall review the Development Plan and the related Budget in order to make annual updates to the Development Plan and Budget for the then current calendar year, if any, plus the following [***] calendar years both to be approved by the Joint Steering Committee. In the event that the Joint Steering Committee cannot agree on an annual update to the Development Plan and Budget, then the most recent version of the Development Plan and Budget will be deemed the Development Plan and Budget for the period, until the Parties are able to reach an agreement on any update to the Development Plan and Budget. The Parties agree that no later than [***] months prior to the anticipated Establishment of Clinical Proof of Concept, the Parties, via the Joint Development Team and the Joint Steering Committee, shall agree on an update to the Development Plan, including the Budget, to cover the period after Establishment of Clinical Proof of Concept, such plan to cover various clinical scenarios depending on whether Establishment of Clinical Proof of Concept shall be followed by Phase II Clinical Trial(s) or a pivotal clinical trial. Such update to the Development Plan and Budget shall form the basis of any continued Development after the Establishment of Clinical Proof of Concept by both Parties or during a Divestment Process by the Non-Divesting Party, if applicable.

3.7 **Preparation of IND.** The Parties shall jointly be responsible via the Joint Steering Committee for producing the initial version of the proposed IND submission as well as a work plan and budget for the clinical phase of the Development of a Collaboration Product, including but not limited to the CMC costs. Once such an IND submission package has been agreed on by the Joint Steering Committee, ***Proposed IND Submission*** for the purposes of Section 14 and the financial terms set forth in Exhibit 1 shall be deemed reached.

- 3.8** **Third Party as Supplier.** In the case where the Joint Steering Committee elects to designate a Third Party to be responsible for manufacturing of a Collaboration Product (or any component thereof), one Party or both Parties, to be determined by the Joint Steering Committee, shall enter into a supply agreement with such Third Party on customary and reasonable terms and conditions. The Joint Steering Committee shall determine the strategy, timing and other matters relating to identifying such Third Party and entering into the supply agreement. At such time as the Joint Steering Committee determines to recruit a Third Party, the Joint Steering Committee shall determine whether to designate a Party to take the lead in negotiating and entering into the supply agreement or to allocate such responsibilities between the Parties. If one Party is designated to take the lead in negotiating such agreement, such Party shall provide the other Party with term sheets and substantive agreement drafts during the negotiations (including any proposed execution version) for review and comment and the designated Party shall not enter into any such supply agreement (or any amendment, waiver or other modification thereof) without the written approval of the other Party, which approval shall not be unreasonably withheld. No contractual or other obligations will be entered into vis-à-vis a Third Party and the Joint Steering Committee will not designate nor authorize a Party to enter into such obligations, before such obligations have been financially covered in the Budget.
- 3.9** **Companion Diagnostic and Biomarkers.** To the extent that biomarker analysis or a companion diagnostic will be required as per the Research Plan or the Development Plan, the Joint Research Committee or the Joint Steering Committee, as applicable, will consider Biontech's capabilities for biomarker testing and diagnostic development as well as alternative proposals and will make the decision as to whether Biontech in the sole interest of the applicable Collaboration Product shall be the preferred choice to determine biomarkers and develop a companion diagnostic. If Biontech is selected by the Joint Steering Committee to determine biomarkers and develop a companion diagnostic for the applicable Collaboration Product, Biontech will use Commercially Reasonable Efforts to develop a companion diagnostic to be tested in clinical trials and shall have the exclusive right to manufacture and commercialize such companion diagnostic. The costs incurred by Biontech in developing such a companion diagnostic shall be considered Shared Costs for the purposes of this Agreement and shall be included in the then current Budget. However, any costs incurred or profit obtained during the commercial manufacturing or commercialization of any such companion diagnostic by Biontech shall be incurred and obtained at Biontech's sole expense and benefit, and shall not be considered Shared Costs nor Shared Profits.
- 4. COMMERCIALIZATION**
- 4.1** **General.** The Parties agree to jointly Commercialize Collaboration Products and share equally all Commercialization expenses (as further defined in the Commercialization Agreement) and Profits.
- 4.2** **Strategy and Commercialization Plans.** The Joint Commercialization Committee shall decide on an overall Commercialization strategy (including the overall marketing and pricing strategy), which shall be submitted to the Joint Steering Committee for endorsement. The Parties shall in due time during Phase B but no later than [***] days after the initiation of the first Phase III Clinical Trial, on a Collaboration Product-by-

Collaboration Product basis, agree through the Joint Commercialization Committee on an initial Commercialization Plan, such plan also to be submitted to endorsement to the Joint Steering Committee. Each Party may recommend changes to a Commercialization Plan at any time; provided, however, that such changes shall be effective only upon the approval by the competent Joint Commercialization Committee and the Joint Steering Committee. The Joint Commercialization Committee shall be authorized to execute any activities or decisions with regard to the Commercialization Plan, provided that such activities or decisions are within the latest Commercialization Plan as endorsed by the Joint Steering Committee. The Parties shall instruct their representatives in the Joint Commercialization Committee to use reasonable efforts to reach consensus on matters under the governance and decision-authority of the Joint Commercialization Committee.

- 4.3 **Lead Commercialization Party.** At least [***] months prior to the anticipated start of any pivotal trial that may be used for BLA filing to a Regulatory Authority, the Parties will agree as part of the Commercialization Agreement on which Party will become **Lead Commercialization Party** for which Region. Within the framework of the overall Commercialization strategy, cf. Section 4.2 above, the Lead Commercialization Party shall be responsible for setting-up and operating the distribution network in its Region, including, but not limited to, the following: warehousing and distribution logistics, supply and packaging, invoicing and collection, preparing of marketing materials, handling reimbursement issues as well arranging for medical affairs functions to support the commercial endeavors in such Region. The Lead Commercialization Party shall in addition be responsible for preparing, supervising, implementing and adapting the regional marketing strategy for the relevant Region in compliance with the overall marketing strategy as approved by the competent Joint Commercialization Committee and endorsed by the Joint Steering Committee pursuant to Section 4.2. Regional marketing strategy includes, but is not limited to, key opinion leader development, pre-launch advisory board meetings, primary market research with customers, health economic and reimbursement studies, local customary discounts, local advertising strategy, competitor analysis, un-met need analysis, local product positioning, other promotional strategies (such as sampling, give-away items, PR) and prescribing guideline inclusion. Notwithstanding the above, the Parties agree that Genmab shall book worldwide sales.
- 4.4 **Co-Promotion.** Notwithstanding the existence of a Lead Commercialization Party for each Region, both Parties may utilize their sales representatives on a 50/50 basis to co-promote Collaboration Products in any Region pursuant to the provisions of the Commercialization Agreement.
- 4.5 **Commercialization Agreement.** The Parties shall negotiate in good faith and enter into a separate global commercialization agreement (the **Commercialization Agreement**) at least [***] months prior to the anticipated start of any pivotal trial that may be used for BLA filing to a Regulatory Authority, which shall be consistent with the applicable provisions of this Agreement, reflect any mechanism or structure agreed upon by the Joint Steering Committee and shall include customary provisions relating to joint Commercialization, including, among others, the following matters: amendment to and updates of the Commercialization Plan, report and audit rights, co-promotion (including, among others, performance metrics, sales force compensation strategies, division of the

applicable Region between the Parties' respective sales forces on a 50/50 basis, sales force training), co-branding, marketing, recalls and medical inquiries, commercialization expenses, further details on the calculation of Profits, labeling, public statements and other information concerning the Collaboration Product, liability, indemnification, use of subcontractors and the responsibilities and powers of the Joint Commercialization Committee and the Lead Commercialization Party.

4.6 General Commercialization Obligations. During the Commercialization phase, each Party shall

- a. use its Commercially Reasonable Efforts to Commercialize the Collaboration Products and to perform its respective activities pursuant to the applicable Commercialization Plan and Commercialization Agreement, as applicable, and in accordance with all Applicable Laws, including GxPs;
- b. contribute such personnel, equipment, facilities and other resources as reasonably necessary to perform its obligations under the applicable Commercialization Plan and to achieve efficiently the objectives thereof; and
- c. provide to the other Party such materials, information and other assistance required to be provided under the applicable Commercialization Plan.

4.7 Divestment to Third Party. During a Divestment Process, a Third Party which is interested in licensing or acquiring the Divesting Party's share of a Collaboration Product may through the Divesting Party approach the Non-Divesting Party in order to attempt to re-negotiate the allocation of Commercialization responsibilities for Regions. The Non-Divesting Party may at its sole discretion enter into, and conduct, such negotiations in good faith.

4.8 Partnership Agreements. If a Collaboration Product is planned by the Joint Commercialization Committee to be Commercialized wholly or partly through Partnership Agreements, unless expressly set forth otherwise in the applicable Commercialization Plan, the following principles shall apply:

- a. Each Party shall use Commercially Reasonable Efforts to identify Third Parties which may be interested in concluding a Partnership Agreement and shall disclose such Third Parties to the other Party for further evaluation and discussion.
- b. Unless otherwise agreed, the Lead Commercialization Party for the Region to which the potential Partnership Agreement pertains shall be responsible for initiating and engaging in discussions with the potential Third Party Collaborator (including without limitation all business and scientific meetings) and for negotiating the respective Partnership Agreement, provided that such Party shall (i) keep the other Party at all times fully informed as to the status of any discussions or negotiations with the potential Third Party Collaborator, (ii) notify the other Party reasonably in advance of any meetings (whether in person, per telephone or otherwise) with the potential Third Party Collaborator and the other Party shall have the right (but not the obligation) to attend and participate in all such meetings, (iii) closely cooperate with the other Party in the preparation and negotiation of the Partnership Agreement (and any term sheets or similar documents relating to such

Partnership Agreement), (iv) promptly provide the other Party with copies of all relevant drafts and mark-ups of the Partnership Agreement (or any term sheets or similar documents relating to such Partnership Agreement) that are exchanged in the course of the negotiations, and (v) consult with the other Party as to the terms of the Partnership Agreement (or any term sheets or similar documents relating to such Partnership Agreement) and incorporate any reasonable suggestions or requirements.

- c. No Partnership Agreement may be concluded without approval of both Parties (such approval not to be unreasonably withheld).

5. REGULATORY MATTERS

5.1 General

- a. The Joint Steering Committee shall be responsible for the overall regulatory strategy and for overseeing, monitoring and coordinating the actions of the Parties, in particular the design of any pivotal clinical trial intended to support Marketing Approval in the Major Market Countries. Genmab shall be the Lead Regulatory Party for the Territory. Unless otherwise agreed by the Joint Steering Committee, the Lead Regulatory Party shall be responsible for all regulatory actions, communications and filings and submissions to, all applicable Regulatory Authorities with respect to a given Collaboration Product.
- b. Unless otherwise agreed by the Joint Steering Committee, the Lead Regulatory Party shall be named “Sponsor” of the regulatory filing as per 21 CFR 312.3 (Part B) and/or 21 CFR 312.50 or similar rules and regulations with respect to a given Collaboration Product. The Parties will work together to transfer and assign all regulatory documents, contracts, materials and information that relates to a Collaboration Product to the Lead Regulatory Party or its designees to the extent necessary for the Lead Regulatory Party to assume such role.

5.2 **Ownership of Marketing Approvals.** Unless otherwise proposed by the Joint Steering Committee and agreed to by the Parties, the Lead Regulatory Party shall own all INDs, BLAs and other Marketing Approvals for a Collaboration Product (but, for the avoidance of doubt, all dossiers submitted to any Regulatory Authority and all data and information contained therein shall be jointly owned by the Parties). The Lead Regulatory Party shall promptly license, transfer, provide a letter of reference with respect to, or take other action necessary to make available such Marketing Approvals (including INDs and BLAs) to the other Party as may be reasonably necessary to enable such other Party to fulfill its research, Development and Commercialization obligations or perform its Commercialization rights hereunder.

5.3 Regulatory Coordination

- a. **Responsibilities of Lead Regulatory Party.** Subject to oversight by the Joint Steering Committee, the Lead Regulatory Party shall oversee, monitor and coordinate all regulatory actions, communications and filings with, and submissions to, all applicable Regulatory Authorities with respect to a Collaboration Product. The Lead Regulatory Party shall also be responsible for interfacing, corresponding

and meeting with the applicable Regulatory Authorities with respect to a Collaboration Product. The Lead Regulatory Party will use its Commercially Reasonable Efforts to include up to two (2) representatives of the other Party in all meetings and material telephone discussions between representatives of the Lead Regulatory Party and such Regulatory Authority related to a Collaboration Product.

- b. Review of Correspondence. The Lead Regulatory Party shall regularly inform the other Party of its current and planned regulatory activities and shall provide the other Party with drafts of any material documents and other material correspondence to be submitted to a Regulatory Authority pertaining to a Collaboration Product, sufficiently in advance of submission so that the other Party may review and comment on such documents or other correspondence and have a reasonable opportunity to influence the substance of such submissions. The Lead Regulatory Party shall promptly provide the other Party with copies of any documents or other correspondence received from or submitted to a Regulatory Authority pertaining to a Collaboration Product.

5.4 Assistance. Each Party shall cooperate with the other Party to provide all reasonable assistance and take all actions reasonably requested by the other Party that are reasonably necessary to enable such Party to comply with any regulatory requirements under Applicable Law with respect to each Collaboration Product, including (a) obtaining and maintaining Marketing Approvals, (b) submitting annual reports, (c) performing pharmacovigilance activities and (d) sharing any relevant regulatory intelligence. Such assistance and actions shall include, among other things, notifying the other Party within [***] hours of any information it receives from a Regulatory Authority which (i) raises any material concerns regarding the safety or efficacy of the Collaboration Product, (ii) indicates or suggests a potential material liability for either Party to Third Parties arising in connection with the Collaboration Product or (iii) is reasonably likely to lead to a recall or market withdrawal of the Collaboration Product.

5.5 Adverse Events relating to Collaboration Products or Unilateral Products

- a. Reporting to Government Authorities. Each Party shall, and shall cause its respective Affiliates to, furnish timely notice as required by Applicable Law (i.e., currently not later than [***] calendar days for deaths and immediately life threatening Adverse Events and not later than [***] calendar days for Serious Adverse Events) to all competent governmental agencies in those parts of the Territory in which it is the Lead Regulatory Party of all Adverse Events identified or suspected with respect to any Collaboration Products administered, distributed, marketed and sold under authority of any IND or Marketing Approval. Each Party shall provide the other Party with all necessary assistance in complying with all Adverse Event reporting requirements established by, or required under, any applicable IND and/or Marketing Approval in the Territory. Accordingly, each Party shall provide the other with timely information, in accordance with the time frames set forth below, on any Serious Adverse Events relating to any Collaboration Product to the extent that such Serious Adverse Events could affect the Marketing Approval for the Collaboration Product, or relate to the safety, efficacy or potency of the Collaboration Product. The Parties agree that with regards to the Unilateral Products, the obligations set forth in this Section 5.5a shall only apply to the Continuing Party.

- b. Reporting to Other Party. Each Party shall, and shall cause its respective Affiliates to, furnish the other Party written notice of all Serious Adverse Events regarding any Collaboration Product reported to such Party or its Affiliates. Each Party shall also use its Commercially Reasonable Efforts to obtain, and to furnish to the other Party hereto, such information reasonably sufficient to permit that other Party to evaluate such Serious Adverse Events of the Collaboration Product, including, but not limited to, information about the affected patients, the circumstances surrounding the Serious Adverse Events, the consequences thereof and the sources of information. Each Party shall retain all documents, reports, studies and other materials relating to any and all such Serious Adverse Events, as the case may be. Upon reasonable written notice, each Party shall permit the other Party hereto to inspect, and to make copies of, all such documents, reports, studies and other materials, subject to all Applicable Laws regarding patient confidentiality, data protection and privacy. The Parties agree that with regards to the Unilateral Products, the obligations set forth in this Section 5.5b shall only apply to the Continuing Party.
- c. Pharmacovigilance Agreement. Without limiting the generality of the foregoing, no later than [***] months prior to the anticipated filing of the first IND for a Collaboration Product, the Parties shall enter into a pharmacovigilance agreement detailing each Party's pharmacovigilance responsibilities in connection with the Collaboration Product. The pharmacovigilance agreement will prevail in case of discrepancy with the provisions set forth in sub-sections (a) and (b) above with regards to Collaboration Products.

6. EXCLUSIVITY
[***]

7. FINANCIAL PROVISIONS

7.1 Upfront Payment. As consideration for entering into this Agreement and contributing Biontech's Technology and the existing projects to the collaboration hereunder, Genmab shall pay to Biontech the following non-refundable upfront payments:

- a. Ten million US dollars (\$10,000,000) within [***] of the Effective Date; and
- b. One million US dollars (\$1,000,000) within [***] following agreement by the Parties that at least one of the antibodies in the current available panel as attached hereto in Exhibit 4 targeting [***] that are not covered by the claims in the relevant third party patents identified by the Parties prior to the execution of this Agreement; and

- c. One million US dollars (\$1,000,000) within [***] following the conclusion by the Parties that at least one of the [***] in the current available panel as attached hereto in Exhibit 4 is non-agonistic. Agonistic [***] antibodies are defined to be able to activate the [***] signaling by binding to the [***], which is physiologically expressed on T-cells. Agonistic anti-[***] without further need for [***]. For the avoidance of doubt, the decision on which and how many of the antibodies of the panel in Exhibit 4 will be tested for being non-agonistic will be made by the Joint Research Committee.
- d. Three million US dollars (\$3,000,000) within [***] following the date on which the Joint Research Committee for the first time and in accordance with Section 2.10 (as documented by the minutes of the Joint Research Committee) selects a Preferred Clinical Candidate which wholly or partly is derived from [***] developed by or on behalf of Biontech; and such Preferred Clinical Candidate is either (i) advanced to a Collaboration Product pursuant to Section 2.10 or a Unilateral Product (whether a Genmab Unilateral Product or a Biontech Unilateral Product) pursuant to Section 2.11; or (ii) successfully Divested to a Third Party. [***]:
[***]

Furthermore, Phase A may lead to the identification of [***] listed in Exhibit 4; these antibodies will likewise qualify for the payment of the three million US dollars according to this Section 7.1d if Biontech demonstrates using flow cytometry that [***].

For the avoidance of doubt, the payment under this Section 7.1d shall not be considered a milestone payment, and shall not become due nor payable upon the achievement of any other milestones set forth in this Agreement, but only upon occurrence of the events set forth in this Section 7.1d.

7.2 FTE Rate. The Parties agree that the mutual annual rate per FTE of either Party who performs research, Development, consultation or support work under any Research or Development Plan is [***]. Commencing upon the [***] anniversary of the Effective Date and upon every anniversary thereafter, the fee will be adjusted in accordance with the percentage change over the applicable annual period in the consumer price inflation in the euro area as measured by the Harmonised Index of Consumer Prices (“HICP”).

7.3 Allocation of Research and Development Costs, Commercialization Costs and Profits. Unless otherwise set forth in this Agreement,

- a. all Research and Development Costs incurred by the Parties in the performance of the Research Plan or any Development Plan as well as all Commercialization costs according to the provisions of the respective Commercialization Plan and/or Commercialization Agreement (collectively the **Shared Costs**) shall be shared equally by the Parties; and
- b. all Profits received by the Parties from the Commercialization of Collaboration Products shall be accounted for by the Parties and shared equally between them (**Shared Profits**).

- 7.4 **Control of Shared Costs by Joint Research Committee or Joint Steering Committee or Joint Commercialization Committee.** The Parties are obligated to each fund fifty percent (50 %) of costs associated with the research and Development of a Collaboration Product and equally share all Commercialization costs. The Parties shall only be entitled to incur Shared Costs which are either (i) set forth in the annual Research Plan, the applicable annual Development Plan or the applicable Commercialization Plan, (ii) have been agreed and approved in advance by the competent Joint Research Committee, Joint Steering Committee or Joint Commercialization Committee, as applicable, or (iii) are in accordance with the Travel Policy. The Joint Steering Committee, if such committee is in place, if not the Joint Research Committee shall review on a quarterly basis the Research and Development Costs and the Commercialization costs, as applicable, against the Budget for such expenses in the applicable calendar year. If in the course of such quarterly review, the Joint Steering Committee determines that the actual amounts incurred for Research and Development Costs or Commercialization costs are likely to be higher than budgeted or if either Party reasonably considers that it is likely to exceed the Budget of any Shared Costs set forth in the applicable Research Plan or Development Plan or Commercialization Plan or approved by the competent Joint Research Committee or Joint Steering Committee or Commercialization Committee, as applicable, it shall promptly notify the competent Joint Research Committee or Joint Steering Committee or Commercialization Committee thereof and shall provide such Joint Research Committee or Joint Steering Committee or Commercialization Committee with details of the additional Shared Costs that it expects to incur and the reason for such increase. The Joint Research Committee or Joint Steering Committee or Commercialization Committee shall then review the information submitted and may, if appropriate, amend the Research Plan or the affected Development Plan or the affected Commercialization Plan for the Collaboration Product to permit such overrun or to reduce such activities such that no overrun is expected. If the Joint Research Committee or Joint Steering Committee or Commercialization Committee does not approve the additional Shared Costs, the requesting Party shall have the right to incur such costs on its own behalf (so that the relevant costs items will not form part of the Shared Costs mechanism agreed hereunder). However, if the budget overrun is due to a delay or an advance in timing as to the planned activities, which activities are in accordance with the Research Plan or the relevant Development Plan or the relevant Commercialization Plan, then such excess Research and Development Costs or Commercialization costs shall be shared equally by the Parties regardless of which Party has incurred such costs. For the avoidance of doubt, if a Joint Steering Committee or Joint Commercialization Committee is in place for a certain Collaboration Product, then all matters set forth in this Section 7.4 pertaining to such Collaboration Product, shall be handled by the such Joint Steering Committee or Commercialization Committee, as applicable, whereas all other matters, if any, pertaining to Shared Costs on Clinical Candidates shall be handled by the Joint Research Committee.
- 7.5 **Financial Representatives.** Each Party will appoint a representative (a *Financial Representative*) with expertise in the areas of accounting, cost allocation, budgeting and financial reporting. Such Financial Representatives shall work under the direction of the Joint Steering Committee and provide services to and consult with the Joint Steering Committee, in order to address the financial, budgetary and accounting issues which arise in connection with the Development Plan or the Commercialization. Each Financial Representative may be replaced at any time by the represented Party by

providing written notice thereof to the other Party. The Financial Representatives will meet at least once each Calendar Quarter or as they or the Joint Steering Committee may agree. The Financial Representatives shall agree upon the timing and agenda for all regular meetings. The location of regularly scheduled meetings shall alternate between the offices of the Parties, unless otherwise agreed. Meetings may be held telephonically or by video conference. One of the Financial Representatives shall record (or cause to have recorded) the minutes of the meeting in writing. Such minutes shall be circulated to the other Financial Representative promptly following the meeting for review, comment and approval. If no comments are received within [***] days of the minutes' receipt by the other Financial Representative, unless otherwise agreed, they shall be deemed to be approved by such Financial Representative. Following their approval, the minutes shall be provided to each Party's Alliance Manager. Each Party shall bear its own costs associated with its Financial Representative, including without limitation travel time and travel expenses, preparation for meetings, reading and approving meetings minutes.

7.6 Shared Costs Reports. Following the Effective Date, within [***] calendar days after the end of every Calendar Quarter, each Party's Financial Representative shall deliver to the competent Joint Research Committee or Joint Steering Committee or Commercialization Committee, as applicable a written report showing in reasonable detail the Shared Costs that it has incurred during such Calendar Quarter. The Shared Costs Reports will be in such form as the Joint Steering Committee may reasonably agree from time to time. Within [***] days of the receipt of both Parties' Shared Costs Reports, the Joint Steering Committee (or the Party appointed by the Joint Steering Committee) shall provide to each Party one consolidated financial report for the Shared Costs consistent with Collaboration Accounting Principles. The Joint Research Committee or Joint Steering Committee or Commercialization Committee, as applicable shall review such reports and shall determine any compensation amount due by one Party to the other for such Calendar Quarter to reflect the equal sharing agreed under Section 7.3a. The Party entitled to any such compensation amount shall invoice the relevant compensation amount (plus any value-added tax, if applicable) to the other Party. Invoices are payable within [***] days after receipt. Notwithstanding the procedure described in this Section 7.6above, the Parties agree that during Phase A, each Party will no later than twenty-eight (28) calendar days after the end of every Calendar Quarter automatically issue and send to the other Party an invoice corresponding to fifty percent (50%) of the costs incurred by the invoicing Party, provided that such incurred costs are in accordance with the activities approved by the Joint Research Committee as set forth in Section 7.4.

7.7 Profit Reports and Payment. The Parties shall mutually agree, through the Joint Steering Committee, a mechanism or structure under which they will share equally (50:50) in all Shared Profits created by each Collaboration Product. In reaching this agreement the Parties shall also define and mutually agree, through the Joint Steering Committee, the appropriate arrangements for making reports and payments between the Parties.

7.8

Audit.

- a. Shared Costs and Shared Profits Records. For so long as any research, Development and/or Commercialization activities are conducted hereunder and for a period of [***] years thereafter, each Party shall keep and maintain, and shall require its Affiliates to keep and maintain, accurate and complete cost records of activities performed by each such Party (including Shared Costs and Shared Profits incurred and FTEs utilized) in connection with its research, Development and Commercialization activities hereunder. Not more than once per calendar year, each Party shall have the right to engage an independent certified public accounting firm of internationally recognized standing and reasonably acceptable to the other Party, which shall have the right to examine in confidence the relevant books, records or other relevant reports, of such other Party and its respective Affiliates as may be reasonably necessary to determine and/or verify the accuracy of the reports submitted to the Joint Steering Committee, Joint Research Committee or Commercialization Committee, as applicable, in connection with the performance of a Party's Development obligations and Commercialization rights hereunder.
- b. Audit Procedure. Such examination shall be conducted, and each Party shall make its records available, during normal business hours, after at least [***] days prior written notice shall have been provided by the other Party, as applicable, and shall take place at the facility(ies) where such records are maintained. Each such examination shall be limited to pertinent books, records and reports for any year ending not more than [***] months prior to the date of request; provided, that, no Party shall be permitted to audit the same period of time more than once. Before permitting such independent accounting firm to have access to such books and records, the non-requesting Party may require such independent accounting firm and its personnel involved in such audit to sign a confidentiality agreement (in form and substance reasonably acceptable to such Party) as to any confidential information which is to be provided to such accounting firm or to which such accounting firm will have access while conducting the audit under this paragraph. The accounting firm shall provide both Biontech and Genmab with a written report stating whether the reports submitted by Biontech or Genmab, as applicable, are correct or incorrect and the specific details concerning any discrepancies. Such accounting firm may not reveal to the other Party any information learned in the course of such audit other than the amount of any such discrepancies. Each Party agrees that all such information shall be Confidential Information of the other Party and further agrees to hold in strict confidence all information disclosed to it in accordance with Section 11.
- c. Cost of Audit. The Party initiating such audit shall bear the full cost of such audit unless such audit discloses that the actual expenses incurred in the conduct of the other Party's obligations under the Research Plan or a Development Plan, as applicable, are lower than that reported by such Party by [***] percent ([***]%) or more, in which case the other Party shall reimburse the initiating Party for all costs incurred by the initiating Party in connection with such audit. Furthermore, the amount in excess of the actual expenses shall be deducted from the Shared Costs reported by that Party and reconciled between the Parties.

- 7.9** **Dispute Resolution.** In the event of any dispute between the Parties in relation to the determination of Shared Costs or Shared Profits or either Party's share in the Shared Costs or Shared Profits, the Parties shall appoint an international firm of independent certified accountants as Third Party expert to decide on the issue in dispute (and if the Parties cannot agree on such expert, each party shall appoint one accounting firm and both accounting firms so appointed shall select the relevant expert). The Third Party expert shall be entitled to request any information and documents from either Party that it deems relevant for rendering its decision, and each Party shall be obliged to provide such information and documents as quickly as possible. Prior to rendering a decision, the Third Party expert shall provide each Party with reasonable opportunity to comment on its preliminary findings. The decision of the Third Party expert shall be final and binding upon both Parties. The costs of the Third Party expert shall be borne by the losing Party or, if the Third Party expert does not fully confirm either Parties view, shall be shared on a *pro rata* basis between the Parties as reasonably determined by the Third Party expert.
- 7.10** **General Payment Terms.** All payments under this Agreement shall be made in United States Dollars (except for any FTE costs to be reimbursed by one Party to the other hereunder under the cost sharing mechanism which shall be made in Euro) and are exclusive of applicable statutory value-added tax (VAT), if any, which shall be listed separately on each invoice. Each payment under this Agreement shall be made by electronic transfer in immediately available funds via bank wire transfer to such bank account as the respective Party shall designate in writing to the other Party. All amounts accruing in a currency other than United States Dollars or Euro, as applicable, will be expressed in such currency and converted to United States Dollars or Euro, as applicable, using the exchange rate mechanism generally applied by such Party, provided that such mechanism is in compliance with IFRS. The conversion calculations will be provided in any statement reporting converted amounts. Any undisputed payments or portions thereof due hereunder which are not paid on the date such payments are due under this Agreement will bear interest at a rate equal to five (5) percent points above the then-applicable base lending rate of the European Central Bank, or (b) the maximum rate permitted by law, calculated on the number of days such payment is delinquent, compounded monthly using a three hundred sixty five (365) day year.
- 7.11** **Tax Matters.** Except as otherwise provided below, all amounts due from any paying Party to any receiving Party under this Agreement are gross amounts. The paying Party shall be entitled to deduct the amount of any withholding taxes payable or required to be withheld by it, its Affiliates, licensees, or Sublicensees (as applicable) to the extent such paying Party, its Affiliates, licensees, or Sublicensees (as applicable) actually pay such withheld amounts to the appropriate governmental authority on behalf of the receiving Party. The paying Party shall use Commercially Reasonable Efforts to minimize any such taxes, levies or charges required to be withheld on behalf of the receiving Party. The paying Party promptly shall deliver to the receiving Party proof of payment of all such taxes, levies and other charges, together with copies of all communications from or with such governmental authority with respect thereto, and shall cooperate with the receiving Party in seeking any related tax credits that may be available to the receiving Party with respect thereto.

8. GOVERNANCE

8.1 **Alliance Managers.** Each Party shall appoint a person to coordinate its part of the activities under this Agreement (**Alliance Manager**). The Alliance Managers shall be the primary contacts between the Parties with respect to all activities performed under this Agreement and shall be responsible for overseeing the operation of the collaboration and the organization of the committees. The Alliance Managers will meet in person or per telephone or video conference as necessary to fully comply with their responsibilities. They shall report to the Joint Research Committees and Joint Steering Committee. Either Party may change its Alliance Manager upon written notice to the other Party. The Alliance Managers shall have no authority to amend or modify the terms and conditions of the Research Plan, any Development Plan or of this Agreement.

8.2 **Joint Research Committee.** Within [***] days following the Effective Date, the Parties shall establish a joint research committee (**Joint Research Committee**). The Joint Research Committee shall have a total of up to [***] members. Up to [***] members of the Joint Research Committee shall be appointed by Genmab, and up to [***] members of the Joint Research Committee shall be appointed by Biontech. Each Joint Research Committee member shall have sufficient authority to ensure acceptance and execution of Joint Research Committee decisions within its organization. Each Party may appoint substitutes or alternates for its Joint Research Committee members at any time by written notice the other Party. The Parties may mutually agree to change the size of the Joint Research Committee at any time. The Joint Research Committee shall be established for the entire term of Phase A as set forth in Section 2.5. For the avoidance of doubt, the Joint Research Committee may co-exist with one or several Joint Steering Committees.

- a. **Responsibilities of the Joint Research Committee.** The Joint Research Committee shall be responsible for directing, coordinating and supervising the research and development activities of the Parties during Phase A. In particular, the Joint Research Committee shall
- (i) review and endorse the initial Research Plan proposed by the Parties according to Section 2.2;
 - (ii) review and update the Research Plan on an ongoing basis as set forth in Section 2.2,
 - (iii) receive regular reports from each Party's Alliance Manager on, and monitor, the conduct, progress and results of each Party's activities under the Research Plan,
 - (iv) agree in advance, review and approve the Shared Costs that the Parties are entitled to incur in Phase A,
 - (v) resolve any issues referred to it by the Parties in accordance with Section 17.9.

- b. **Meetings of the Joint Research Committee.** Meetings of the Joint Research Committee shall be scheduled from time to time by mutual agreement of the Parties or upon request of one Party, but in no event less than once every [***] months. The meetings may be held in person, per telephone or video conference. The chair shall alternate at [***] month intervals between representatives of each Party, starting with a Genmab representative as the chair. The Alliance Manager of the Party hosting any Joint Research Committee meeting shall attend the meeting and record the minutes of the meeting in writing. Such minutes shall be circulated to the other Party's Alliance Manager no later than [***] calendar days following the meeting for review, comment and approval of the other Party. If no comments are received within [***] calendar days of the receipt of the minutes by a Party, unless otherwise agreed, they shall be deemed to be approved by such Party. Furthermore, if the Parties are unable to reach agreement on the minutes within [***] calendar days of the applicable meeting, the sections of the minutes that have been mutually agreed between the Parties by that date shall be deemed approved and, in addition, each Party shall record in the same document its own version of those sections of the minutes on which the Parties were not able to agree.
- c. **Decisions of the Joint Research Committee.** A quorum of at least [***] Joint Research Committee member appointed by each Party shall be present at or shall otherwise participate in each Joint Research Committee meeting. Each Party has one vote in the decisions of the Joint Research Committee. Decisions of the Joint Research Committee shall be unanimous. If the members of the Joint Research Committee cannot agree on a particular issue, the issue shall be escalated pursuant to Section 17.9. The Joint Research Committee shall have no authority to amend or modify the terms and conditions of this Agreement.

8.3 Joint Steering Committee. No later than [***] days after the first initiation of Phase B for a Collaboration Product (as documented in the minutes of the Joint Research Committee), the Parties shall establish a joint steering committee (**Joint Steering Committee**) having a total of up to [***] members which shall have sufficient authority to ensure acceptance and execution of Joint Steering Committee decisions within its organization. Up to [***] members of the Joint Steering Committee shall be appointed by Genmab, and up to [***] members of the Joint Steering Committee shall be appointed by Biontech. Each Party may appoint substitutes or alternates for its Joint Steering Committee members at any time by written notice the other Party. The Parties may mutually agree to change the size of the Joint Steering Committee at any time.

- a. **Responsibilities of Joint Steering Committee.** The Steering Committee shall be responsible for directing, coordinating and supervising the research and Development activities of the Parties during Phase B. In particular, the Joint Steering Committee shall
- (i) review and approve strategies for the Development of each Collaboration Product;
 - (ii) review and endorse the initial Development Plan and Budget proposed by the Parties according to Section 3.2;
 - (iii) review and agree the Development Plan as proposed by the Joint Development Team, including the Budget for a Collaboration Product and authorize necessary updates or amendments thereto;

- (iv) receive regular reports from the Joint Development Team on, and monitor, the conduct, progress and results of each Party's activities under the applicable Development Plan;
 - (v) agree in advance, review on a quarterly basis and approve the Shared Costs that the Parties are entitled to incur in Phase B;
 - (vi) review and approve the regulatory strategies for each Collaboration Product in the Territory, including design of the pivotal studies that are intended to support Marketing Approval in such territories and ensuring that such strategies are compatible;
 - (vii) review and discuss the goals and strategy for the manufacture of the Collaboration Product;
 - (viii) approve protocols for, and prioritization of, clinical trials and indications for the Collaboration Product;
 - (ix) review and approve the regulatory strategies for the Collaboration Product in the Territory;
 - (x) review and endorse the goals and strategy for the Commercialization of the Collaboration Product as submitted by the Joint Commercialization Committee and approve an initial Commercialization Plan for the Collaboration Product as well as oversee the Joint Commercialization Committee, once such is established;
 - (xi) review and endorse the overall IP strategy as prepared by the Joint IP Committee;
 - (xii) oversee and handle a Joint Divestment Process as set forth in Section 15.9;
 - (xiii) oversee the Joint Development Team and all subcommittees, if any, as deemed necessary;
 - (xiv) serve as the forum for the settlement of disputes or disagreements that are unresolved by the Joint Development Team or any of the subcommittees;
 - (xv) approve the Collaboration Accounting Policies and the Travel Policy;
 - (xvi) resolve any issues referred to it by the Parties in accordance with Section 17.9, and
 - (xvii) review the various possibilities and decide upon the nomination of a company for the development of companion diagnostics, if any.
- b. For the avoidance of doubt, the Joint Steering Committee shall have no responsibilities with respect to any Unilateral Products.

- c. Subcommittees. The Joint Steering Committee may, from time to time, establish subcommittees not already dealt with pursuant to this Agreement. The Joint Steering Committee may determine the charter, composition and other provisions relating to any such subcommittee in its discretion.
- d. Role after End of Development and Commercialization. The Joint Steering Committee shall continue to operate after the end of all Development and/or Commercialization activities for the last Collaboration Product to the extent needed in order to deal with any subsequent issues. Following the end of such Development and/or Commercialization, the Joint Steering Committee shall however not be obliged to convene at the times stipulated above, but merely when needed in order to address the issues at hand. Once the Joint Steering Committee unanimously decides that its responsibilities have been exhausted, then the Joint Steering Committee may dissolve itself.
- e. Meetings and Decisions of the Joint Steering Committee. Sections 8.2b and 8.2c shall apply *mutatis mutandis* to the Joint Steering Committee.

8.4 Joint Development Team. Concurrently with the establishment of the Joint Steering Committee or as soon as possible after an additional Collaboration Product has been selected by the Joint Research Committee pursuant to Section 2.10, as applicable, on a Collaboration Product-by-Collaboration Product basis, the Parties shall – on a project level – establish a joint development team, to coordinate and implement all activities for the Development of a Collaboration Product according to the Joint Development Plan (the **Joint Development Team**). One representative from each Party shall be designated as that Party’s **Development Project Manager** to act as the primary Joint Development Team contact for that Party. The Joint Development Team shall consist of such number of representatives of each Party as are reasonably necessary to accomplish the goals of the Joint Development Team hereunder. Either Party may replace any or all of its representatives at any time upon notice to the other Party

- a. Joint Development Team Responsibilities. The Joint Development Team shall perform the following functions:
 - (i) oversee and manage the work under, monitor the progress of, and implement the Development Plan, including compliance with budget and timelines;
 - (ii) develop an overall strategy and detailed plans for the Development of Collaboration Product for review by the Joint Steering Committee;
 - (iii) formulate any changes to the Development Plan (including allocation of Development activities between the Parties) and the budget for review and approval by the Joint Steering Committee, such plan to always take into account the potential Development scenarios in the [***] year Development of the Collaboration Product, even to the extent such Development scenarios extend beyond completion of the first Phase I/II Clinical Trial;
 - (iv) make recommendations for further Development of the Collaboration Product, including Development of the Collaboration Product for indications that are not contemplated in the then current Development Plan;
 - (v) review forecasts of clinical supplies requirements for Development, review the supply of Collaboration Product for Development;

- (vi) discuss and exchange information regarding the conduct of ongoing clinical trials;
 - (vii) exchange information regarding the Collaboration Product and facilitate cooperation and coordination between the Parties relating to the Development of the Collaboration Product as they exercise their respective rights and meet their respective obligations under the Development Plan and this Agreement;
 - (viii) provide status updates to the Joint Steering Committee regarding Development activities; and
 - (ix) perform such other functions as appropriate to further the purposes of this Agreement as determined by the Parties.
- b. Meetings and Decisions of the Joint Development Team. Sections 8.2b and 8.2c shall apply *mutatis mutandis* to the Joint Development Team, except for the fact that it is not the Alliance Manager, but instead the Development Project Manager of the current Party in the chair of the Joint Development Team that shall record the minutes of the meeting in writing. Also, in the event that the Joint Development Team members do not reach consensus with respect to a matter that is within the purview of the Joint Development Team within [***] calendar days after they have met and attempted to reach such consensus, such matter shall be presented to the Joint Steering Committee for resolution.
- c. Duration of Joint Development Team Operations. The Joint Development Team will be in existence commencing upon its date of formation and shall continue in existence until the date on which both Parties have completed all their activities as provided for in the Development Plan, unless the Joint Steering Committee agrees to extend the term further.

8.5 Joint Commercialization Committee. The Parties shall in due time during Phase B but no later than thirty (30) days after initiation of the first Phase III Clinical Trial with respect to a Collaboration Product, establish a joint commercialization committee (**Joint Commercialization Committee**). The Joint Commercialization Committee shall have a total of up to [***] members. Up to [***] members of a Joint Commercialization Committee shall be appointed by Genmab, and up to [***] members of a Joint Commercialization Committee shall be appointed by Biontech. Each Joint Commercialization Committee member shall have sufficient authority to ensure acceptance and execution of Joint Commercialization Committee decisions within its organization. Each Party may appoint substitutes or alternates for its Joint Commercialization Committee members at any time by written notice the other Party. The Parties may mutually agree to change the size of the Joint Commercialization Committee at any time.

- a. Responsibilities of Joint Commercialization Committee. The Joint Commercialization Committee shall be responsible for coordinating and supervising the Commercialization of the respective Collaboration Product. In particular, the Joint Commercialization Committee shall

- (i) review and approve the Commercialization Plan and authorize necessary updates or amendments thereto,
 - (ii) agree on the overall strategy for Commercialization of a Collaboration Product, including but not limited to pricing and marketing matters,
 - (iii) review and approve the Shared Profits reported by the Parties in accordance with Section 7.7, and
 - (iv) resolve any issues referred to it by the Parties in accordance with Section 17.9.
- b. For the avoidance of doubt, the Joint Commercialization Committee shall have no responsibilities with respect to any Unilateral Products.
 - c. Meetings and Decisions of the Joint Commercialization Committee. Sections 8.2b and 8.2c) shall apply *mutatis mutandis* to the Joint Commercialization Committee.

8.6 Costs. Each Party shall bear its own costs associated with its own personnel, the preparation for, holding of, and participation in any meetings under this Section 8, travel time, travel expenses and other expenses relating to Alliance Managers, Joint Research Committee, Joint Steering Committee, Joint Development Team and Joint Commercialization Committee meetings as well as the writing, reading and approving of minutes from such committee meetings.

9. INTELLECTUAL PROPERTY

9.1 Ownership

- a. Ownership of [***] Technology and [***] Technology. Genmab shall during the Term of this Agreement and thereafter exclusively own all right, title and interest in and to the [***] Technology. Biontech shall during the Term of this Agreement and thereafter exclusively own all right, title and interest in and to the [***] Technology.
- b. Disclosure of Program Inventions. Each Party shall promptly disclose to the other Party the making, conception or reduction to practice of any inventions directly arising out of activities conducted under this Agreement or the Prior Agreement (**Program Inventions**).
- c. Ownership of [***] Inventions. All right, title and interest in all Program Inventions shall be owned as follows:
 - (i) Except as set forth in subsections (ii) and (iii) below, Genmab and Biontech shall jointly own all [***] Inventions (**Collaboration IP**).
 - (ii) Genmab shall own all [***] Inventions that are not [***] and that are invented solely or jointly by employees, agents or consultants of Genmab and/or Biontech and solely relate to the [***] Technology ([***] **Improvement Technology**). To the extent that any such Program Inventions relating solely to the [***] Technology shall have been invented by Biontech and/or are owned by Biontech, Biontech hereby assigns all of its right, title and interest therein to Genmab.

- (iii) Biontech shall own all [***] Inventions that are not [***] and that are invented solely or jointly by employees, agents or consultants of Genmab and/or Biontech and solely relate to the [***] Technology ([***] **Improvement Technology**). To the extent that any Program Inventions relating solely to the [***] Technology shall have been invented by Genmab and/or are owned by Genmab, Genmab hereby assigns all of its right, title and interest therein to Biontech.
- d. Terms of Joint Ownership. The Collaboration IP shall, subject to the terms and conditions of this Agreement, be equally and undividedly owned by the Parties, but a Party cannot exploit or transfer its interest in the Collaboration IP, unless specifically permitted under this Agreement or otherwise agreed in writing. A Party shall not assign, mortgage, sell or otherwise transfer or dispose of any of its right, title or interest in any Collaboration IP without the other Party's prior written consent (not to be unreasonably withheld or delayed), save that such consent shall not be required in respect of any transfer to: (a) an Affiliate of the Party; or (b) a Third Party successor or purchaser of all or substantially all of its business or assets to which the Agreement relates, whether in a merger, sale of stock, sale of assets or other similar transaction; or (c) a Third Party that through a Divestment Process pursuant to the Agreement acquires, by purchase or license, rights to further develop or commercialize the related Collaboration Product; provided that, in each case, any such transfer shall be made subject to the license granted to the other Party pursuant to the Agreement, as applicable, and that the Affiliate or Third Party, as applicable, agrees, by written notice to the other Party, to be bound by the terms of such license and all other terms of this Agreement to the extent that such terms are applicable to the assigned Collaboration IP. Nothing herein shall entitle a Party to take any other action under the Collaboration IP other than explicitly permitted in the Agreement, and the other Party is entitled to oppose any exploitation of the Collaboration IP falling outside the scope of the Agreement. Notwithstanding the above, the Parties may have an interest in using the Collaboration IP outside the collaboration in combination with its own products such as for Biontech RNA vaccines, TLR ligands and/or cell therapies. Upon the request of a Party, the Joint Steering Committee or Joint Research Committee, if no Joint Steering Committee is in place, shall arrange for negotiations in good faith of a license under the Collaboration IP for such purposes on reasonable terms.
- e. Filing of Patent Applications. Unless otherwise agreed by the Joint IP Committee, any patent application disclosing, covering or claiming Collaboration IP shall not be filed until the respective Clinical Candidate has been selected as a Collaboration Product.
- f. Assignment of Collaboration IP following Completion of a Divestment Process. If a Non-Divesting Party is successful in negotiating an acquisition of the Divesting Party's share of a Collaboration Product by the Non-Divesting Party in accordance with Section 15, then the Non-Divesting Party shall be the sole owner going forward of the Collaboration IP related to such acquired Collaboration Product and the

Divesting Party shall arrange for the transfer of (i) all of its rights, title and interest in any such Collaboration IP, and (ii) all substantive documentation pertaining to such former Collaboration Product, if any. Following assignment of the applicable Collaboration IP to the Non-Divesting Party (the **Assigned Patents**), the Non-Divesting Party shall be solely responsible for the further preparation, filing, prosecution and maintenance of any Assigned Patents at its own costs. The Divesting Party may negotiate in good faith licenses to use the Assigned Patents outside of the collaboration hereunder; the last two sentences of Section 9.1d shall apply *mutatis mutandis*. Should the Continuing Party decide not to file or to abandon or let lapse an Assigned Patent regarding such Unilateral Product, the Continuing Party shall notify the Opt-Out Party of such decision at least [***] calendar days prior to the expiration of any deadline relating to such activities, and the Opt-Out Party shall thereafter have the right, but not the obligation, to assume responsibility for filing, prosecuting and maintaining such Assigned Patent, at its sole expense. If the Opt-Out Party does elect to pursue such filing, prosecution or maintenance of such Assigned Patent, then it shall notify the Continuing Party of such election, and the Continuing Party shall execute such documents of transfer or assignment and perform such acts as may be reasonably necessary to preserve and transfer to the Opt-Out Party free of charge all its right, title and interest to any such Assigned Patent in such country. Biontech agrees and acknowledges that Genmab shall remain the sole owner of the DuoBody Platform and the Inert Format Technology, and that any activities by Biontech as the Non-Divesting Party under this Section 9.1f that pertains to the DuoBody Platform and/or the Inert Format Technology shall at all times be subject to Genmab's prior consultation, review and written consent, such consent not to be unreasonably withheld.

- g. Divestment to a Third Party. If the Divesting Party's share of a Collaboration Product is divested to a Third Party following a successful completion of a Divestment Process, the Non-Divesting Party will, unless otherwise agreed with the Third Party, be the Lead IP Party (as defined below) for any Collaboration IP going forward.
- h. Assignment of Collaboration IP for Unilateral Products. In case of an opt-out pursuant to Section 14, the Continuing Party shall be the sole owner of Collaboration IP solely related to the relevant Unilateral Product. Such Collaboration IP shall be regarded as Assigned Patents and Section 9.1f shall apply *mutatis mutandis* to such Collaboration IP. Biontech agrees and acknowledges that Genmab shall remain the sole owner of the DuoBody Platform and the [***] Technology, and that any activities by Biontech as the Continuing Party under this Section 9.1h that pertains to the DuoBody Platform and/or the [***] Technology shall at all times be subject to Genmab's prior consultation, review and written consent, such consent not to be unreasonably withheld.
- i. Ceased Products. With regards to Collaboration IP on Ceased Product(s), provided that such Ceased Product(s) have not previously been a Collaboration Product for which Development has been ceased, the Parties agree to [***]

- 9.2** **License to Genmab.** For the purpose of the Research under Phase A and subsequently on a Collaboration Product-by-Collaboration Product basis and subject to the terms of this Agreement, Biontech hereby grants Genmab a worldwide, co-exclusive (with Biontech and subject to the exclusivities set forth in Section 6), royalty-free license, including the right to sublicense in the course of subcontracting (as approved by the Joint Steering Committee), under the Biontech Technology to (a) perform its obligations hereunder with respect to activities under the Research Plan and each Collaboration Product in accordance with the relevant Development Plan, (b) to conclude Partnership Agreements in accordance with the procedures set forth in Section 4.7 and (c) to research, Develop, have Developed, make, have made, import, use, offer for sale, have sold and sell such Collaboration Product within the Field in the Territory. The license for a Collaboration Product shall continue, on a country-by-country basis, for so long as there are Development or Commercialization activities contemplated. Biontech hereby agrees and acknowledges that Genmab has granted a sublicense for the purpose of performing the Research Plan and further Development activities to its wholly owned subsidiary, Genmab B.V., the Netherlands.
- 9.3** **License to Biontech.** For the purpose of the Research under Phase A and subsequently on a Collaboration Product-by-Collaboration Product basis and subject to the terms of this Agreement, Genmab hereby grants to Biontech a worldwide, co-exclusive (with Genmab and subject to the exclusivities set forth in Section 6), royalty-free license, including the right to sublicense in the course of subcontracting (as approved by the Joint Steering Committee), under the Genmab Technology to (a) perform its obligations hereunder with respect to activities under the Research Plan and each Collaboration Product in accordance with the relevant Development Plan, (b) to conclude Partnership Agreements in accordance with the procedures set forth in Section 4.7 and (c) to research, Develop, have Developed, make, have made, import, use, offer for sale, have sold and sell such Collaboration Product within the Field in the Territory. The license for a Collaboration Product shall continue, on a country-by-country basis, for so long as there are Development or Commercialization activities contemplated. The licenses granted to Biontech under this Section 9.3 with regards to the DuoBody Platform are only granted for the [***]. Use of other [***] under the DuoBody Platform can only take place upon Genmab's prior written consent. The license granted under the Inert Format Technology is to the embodiment wherein the [***]
- 9.4** **No Further Rights.** This Agreement shall not be construed to convey any right or license to Biontech to use and/or exploit the Genmab Technology or to Genmab to use and/or exploit the Biontech Technology except as specifically stipulated in this Agreement.
- 9.5** **Joint IP Committee.**
- a. Within [***] days of the Effective Date, the Parties shall establish a joint IP committee (the ***Joint IP Committee***). The Joint IP Committee shall have a total of [***] members. [***] members of the Joint IP Committee shall be appointed by Genmab, and [***] members of the Joint IP Committee shall be appointed by Biontech. Each Joint IP Committee member shall have sufficient authority to ensure acceptance and execution of Joint IP Committee decisions within its organization. Each Party may appoint substitutes or alternates for its Joint IP Committee members at any time by written notice the other Party. The Parties may mutually agree to change the size of the Joint IP Committee at any time.

- b. The Joint IP Committee shall convene with no less than [***] weeks' notice unless shorter notice is required under the circumstances, for example in order to allow the Lead IP Party necessary time to act towards the authorities. The Joint IP Committee shall hold meetings at least [***] times per year, or as otherwise agreed in writing between the Parties. Unless otherwise agreed in writing, such meetings shall alternate between a location selected by Genmab and a location selected by Biontech or take place via telephone or video conference or such other means as may be agreed in writing between the Parties. The meetings shall be prepared and convened by the chairman of the Joint IP Committee. The chair shall alternate at [***] month intervals between representatives of each Party, starting with a Genmab representative as the chair. Within [***] of every meeting, the chairman shall prepare and send minutes of the meeting to the other members of the Joint IP Committee. The minutes shall be considered as approved by the members of the Joint IP Committee, unless the chairman has received objections and/or comments to the minutes within [***] after the minutes have been sent to the members of the Joint IP Committee. With respect to the decisions of the Joint IP Committee and costs, Sections 8.2c and 8.6 shall apply *mutatis mutandis*.
- c. The Joint IP Committee shall prepare an overall IP strategy for all Collaboration IP to be endorsed by the Joint Steering Committee. In particular, the Joint IP Committee shall discuss and decide on all material issues pertaining to the governance of the Collaboration IP, including, but not limited to, the filing, prosecution, maintenance, defense and/or enforcement of the Collaboration IP, and shall agree on the IP Budget related thereto in accordance with the procedures set forth in Section 9.6d.
- d. The decisions of the Joint IP Committee shall be binding on the Parties to the extent they pertain to the overall IP strategy and the governance of the Collaboration IP. In all other respects, the Joint IP Committee may make recommendations which shall not be binding on the Parties, but the Parties shall take due account of these recommendations when performing their rights and obligations set forth in this Agreement.

9.6 Lead IP Party

- a. Designation of Lead IP Party. The Parties agree that it is appropriate to designate one of the Parties to be responsible for (i) implementing the decisions of the Joint IP Committee, (ii) taking emergency measures in order to prosecute, maintain and defend the Collaboration IP, provided that such measures are of a preliminary nature where possible and shall be reviewed and approved by the Joint IP Committee without undue delay, and (iii) to act as the common representative towards the applicable authorities (such Party to be referred to as the **Lead IP Party**). The Joint IP Committee shall appoint a Lead IP Party for each Program Invention which is part of the Collaboration IP, taking into consideration the capabilities of each Party's IP department and each Party's specific expertise with respect to the relevant Program Invention.

- b. **Power of Attorney.** The Lead IP Party is hereby granted by the other Party (the **Non-Lead Party**) a power of attorney to conduct all such acts which rest with the Lead IP Party as specified in these terms. The Lead IP Party is only authorized to act within the frames of the overall IP strategy as adopted by the Joint IP Committee and all other decisions of the Joint IP Committee pertaining to the governance of the Collaboration IP. Unless otherwise agreed in writing, the Lead IP Party shall be responsible during the Term of the Agreement.
- c. **Responsibilities of the Lead IP Party.** The Lead IP Party shall – within the scope of its appointment by the Joint IP Committee – be responsible for the preparation, filing, prosecution and/or maintenance of Joint Patents and/or, if applicable, any other Collaboration IP in accordance with the decisions of the Joint IP Committee and subject always to Section 9.8c. In particular, the Lead IP Party shall, in each case in accordance with the decisions of the Joint IP Committee:
- (i) prepare and file applications, including without limitation divisional applications, continuation applications, continuation-in-part applications, and RCEs, relating to the Collaboration IP, including without limitation any Joint Patents, with applicable intellectual property office(s) or authority(ies);
 - (ii) maintain Joint Patents and/or, if applicable, any other Collaboration IP, including without limitation taking such steps as may be reasonably necessary to ensure possible patent term extensions, renewals, supplementary protection certificates etc. in respect of Joint Patents;
 - (iii) prosecute Joint Patents and/or, if applicable, any other Collaboration IP with national and/or regional intellectual property offices, including appeal to the courts, and prosecution hereof;
 - (iv) coordinate the payment of maintenance fees and other official fees or costs with national and/or regional intellectual property offices in respect of Joint Patents and/or, if applicable, any other Collaboration IP, and ensure that all maintenance fees are paid promptly when due, unless otherwise agreed in writing between the Parties; and
 - (v) provide the Joint IP Committee with all material information, and copies of material correspondence to and from patent/intellectual property offices and external patent attorneys and agents, pertaining to the filing, prosecution and maintenance of the Joint Patents and/or, if applicable, any other Collaboration IP, for review and approval. All patent filings have to be submitted to the Joint IP Committee as soon as possible before the filing date, if possible.
- d. **IP Budget.** The Lead IP Party shall prepare (and continuously update as appropriate) a yearly budget for implementation of the overall IP strategy and the governance of the Collaboration IP (hereinafter, the **IP Budget**). The IP Budget shall be sent to the Joint IP Committee in due time to enable the Joint IP Committee to discuss and agree on the IP Budget for the coming calendar year at a meeting that shall take place at least [***] months before the end of the previous year.

- e. The Parties agree to act in good faith toward each other and to cooperate fully with each other in relation to the filing, prosecution and maintenance of the Joint Patents and/or, if applicable, any other Collaboration IP taking into consideration that both Parties have ownership interests in such intellectual property rights. In case of a dispute, the matter shall be referred to the Joint IP Committee, which in turn shall refer any unresolved matter to the Joint Steering Committee. In case actions need to be taken during such dispute period to prevent Joint Patents from going abandoned, the Lead IP Party shall have final decision-making authority taking into due account the dispute and making efforts to keep status quo to the extent possible.
- f. Assistance. The Non-Lead Party shall, as reasonably requested by the Lead IP Party, assist the Lead IP Party and the Lead IP Party's external patent counsel (if applicable) in the preparation, filing, prosecution and/or maintenance of Joint Patents and/or, if applicable, any other Collaboration IP, and the Parties shall cooperate with one another jointly to maintain the Joint Patents and/or, if applicable, any other Collaboration IP in force. The Parties shall perform such acts, execute such further instruments, documents or certificates, and provide such cooperation and assistance as may be reasonably requested by the other Party in order to give effect to the terms of Section 9.6. Such assistance shall be deemed Shared Costs for the purposes of this Agreement.

9.7 Inventor Compensation. Each Party shall be responsible for payment of any consideration which it is required to pay to its employees or independent consultants or subcontractors as compensation for the assignment of rights to any Program Invention according to the legal provisions applicable in the relevant country and/or a contractual obligation.

9.8 Patent Prosecution and Maintenance

- a. Biontech Patents. Biontech shall be solely responsible for and shall solely control the preparation, filing, prosecution, grant, maintenance and defense of all Biontech Patents excluding Biontech's share in Joint Patents. Biontech shall, at its sole expense, prepare, file, prosecute and maintain such Biontech Patents in good faith consistent with its customary patent policy and its reasonable business judgment, and shall consider in good faith the interests of Genmab in so doing.
- b. Genmab Patents. Genmab shall be solely responsible for and shall solely control the preparation, filing, prosecution, grant, maintenance and defense of all Genmab Patents excluding Genmab's share in Joint Patents. Genmab shall, at its sole expense, prepare, file, prosecute and maintain such Genmab Patents in good faith consistent with its customary patent policy and its reasonable business judgment, and shall consider in good faith the interests of Biontech in so doing.
- c. Collaboration IP. The Parties shall be jointly responsible and shall jointly control the preparation, filing, prosecution, grant, maintenance and defense of all Joint Patents and/or, if applicable, any other Collaboration IP, through the Joint IP Committee and the Lead IP Party, in accordance with the provisions of Section 9.5 and Section 9.6. Unless otherwise agreed upon in writing between the Parties, any application for a Joint Patent and/or, if applicable, any other Collaboration IP shall be filed under the name of both Parties.

- d. Common Interest Disclosures. With regard to any information or opinions disclosed pursuant to this Agreement by one Party to the other regarding intellectual property and/or technology owned by Third Parties, Biontech or Genmab (or their respective Affiliates), Biontech and Genmab agree that they have a common legal interest in coordinating prosecution of their respective patent applications, as set forth in this Section 9, and in determining whether, and to what extent, Third Party intellectual property rights may affect the conduct of the development, manufacturing, marketing and/or sale of Collaboration Products and Unilateral Products, and have a further common legal interest in defending against any actual or prospective Third Party claims based on allegations of misuse or infringement of intellectual property rights relating to the development, manufacturing, marketing and/or sale of Collaboration Products and Unilateral Products. Accordingly, Biontech and Genmab agree that all such information and opinions obtained by Biontech and Genmab from each other will be used solely for purposes of the Parties' common legal interests with respect to the conduct of the Agreement. All information and opinions will be treated as protected by the attorney-client privilege, the work product privilege, and any other privilege or immunity that may otherwise be applicable. By sharing any such information and opinions, neither Party intends to waive or limit any privilege or immunity that may apply to the shared information and opinions. Neither Party shall have the authority to waive any privilege or immunity on behalf of the other Party without such other Party's prior written consent, nor shall the waiver of privilege or immunity resulting from the conduct of one Party be deemed to apply against any other Party.

9.9

Enforcement of Patents

- a. Notification. Each Party shall promptly inform the other Party in writing of any allegation(s) or claim(s) from or proceeding(s) initiated by a Third Party which comes to its attention and which challenges the validity or enforceability of, or the Parties' entitlement to, either Genmab Technology, Biontech Technology or any Collaboration IP, to the extent relevant for a Collaboration Product or a Unilateral Product for which the other Party is responsible, including without limitation (if applicable) pre-grant opposition, post-grant opposition, re-examination, interference or revocation proceedings (whether before any applicable intellectual property office or the courts), and shall provide the other Party with any available evidence thereof.
- b. Enforcement of [***] Patents. [***] shall have the sole right, at its sole expense, but not the obligation, to determine the appropriate course of action to enforce the [***] Patents (other than its interests in the Joint Patents) or otherwise abate the infringement thereof, to take (or refrain from taking) appropriate action to enforce such [***] Patents, to control any litigation or other enforcement action and to enter into, or permit, the settlement of any such litigation or other enforcement action with respect to the [***] Patents so long as this does not adversely affect [***]'s rights under this Agreement. [***] shall fully cooperate with [***], at [***]'s sole expense, in any action to enforce the [***] Patents. All monies recovered upon the final judgment or settlement of any such suit to enforce such [***] Patents shall be retained by [***].

- c. Enforcement of [***] Patents. [***] shall have the sole right, at its sole expense, to determine the appropriate course of action to enforce [***] Patents (other than its interest in Joint Patents), or otherwise to abate the infringement thereof, to take (or refrain from taking) appropriate action to enforce such [***] Patents, to control any litigation or other enforcement action and to enter into, or permit, the settlement of any such litigation or other enforcement action with respect to such [***] Patents. All monies recovered upon the final judgment or settlement of any such suit to enforce such [***] Patents shall be retained by [***]. [***] shall fully cooperate with [***], at [***]'s sole expense, in any action to enforce the [***] Patents.
- d. Enforcement of Joint Patents.
- (i) If a Party becomes aware of any actual or suspected infringement or unauthorized use by a Third Party of any Collaboration IP, then such Party shall promptly notify the other Party in writing of all the relevant facts and circumstances in connection with such infringement or unauthorized use known to that Party and shall provide the other Party with all available evidence supporting such infringement or unauthorized use.
 - (ii) The Joint IP Committee shall determine any required or desirable action to any such Third Party infringement, which action shall be then be implemented by the Lead IP Party (***Infringement Proceedings***). The Parties shall share equally (50:50) all costs, both internally and externally, associated with any such joint Infringement Proceedings, unless otherwise agreed in writing. The Parties shall also share equally (50:50) any damages, royalties, settlement fees or other consideration resulting from any such joint Infringement Proceedings, unless otherwise agreed in writing.
 - (iii) The Lead IP Party shall keep the Non-Lead Party informed of the status of any such joint Infringement Proceedings and, upon request, shall (to the extent permitted under applicable law) provide the Non-Lead Party, at no cost to the Non-Lead Party, with copies of all documents filed in, and all material written communications between the parties relating to, such Infringement Proceedings. The Non-Lead Party shall, at the Lead IP Party's request, give the Lead Party all reasonable assistance in any such joint Infringement Proceedings.
 - (iv) No settlement shall be entered into by the Lead IP Party without the prior written consent of the Non-Lead Party (such consent not to be unreasonably withheld or delayed).

9.10 Assignment of Inventor's Rights. To the extent the assignment of inventions is not effected by statutory law (e.g. the German Employees' Inventions Act), each Party will maintain valid and enforceable written agreements with all persons acting by or on behalf of such Party or its Affiliates which require such person to assign to such Party their entire right, title and interest in and to all Collaboration IP, Biontech Improvement Technology (in case of Genmab) and Genmab Improvement Technology (in case of Biontech). Each Party agrees to claim and keep valid and enforceable any invention relating to any Collaboration IP, Biontech Improvement Technology (in case of Genmab) and Genmab Improvement Technology (in case of Biontech) conceived, reduced to practice, developed, made or created in the conduct of the activities under this Agreement.

- 9.11** **Product Trademarks.** With regards to Collaboration Product(s), the Parties shall propose and through the Joint Steering Committee select the trademark, trade dress, logos and slogans under which each Collaboration Product shall be exclusively marketed (each a **Collaboration Product Trademark**). Such activities shall be handled by the Lead Commercialization Party of such Region. The Lead Commercialization Party shall register the Collaboration Product Trademark and shall take all such actions as are required to continue and maintain in full force and effect the trademarks and the registrations thereof as well as enforce such trademarks and registrations. The Parties shall jointly own the trademarks which are specifically directed to Collaboration Products and the other Party shall execute all documents and take all actions as are reasonably requested by the Lead Commercialization Party to effectuate such joint ownership in such trademarks unless such joint ownership would not be practicable in any such jurisdiction, in which case the Lead Commercialization Party for the applicable Region shall have sole ownership. Collaboration Product Trademarks shall be used only pursuant to the terms of this Agreement and the Commercialization Agreement to identify, and in connection with the marketing of, Collaboration Products and shall not be used by either Party to identify, or in connection with the marketing of, any other products. In case a Party Divests its share of a Collaboration Product to the other Party, it shall be obliged to assign its title to and interest in the Collaboration Product Trademarks to the other Party free of charge, provided the other Party pays the out-of-pocket costs of assignment.
- 10. INFRINGEMENT ACTIONS BROUGHT BY THIRD PARTIES**
- 10.1** **Third Party License.** Each Party shall promptly inform the other Party in writing if it deems that a license of any intellectual property rights owned or Controlled by a Third Party is needed to Commercialize a Collaboration Product or a Unilateral Product for which the other Party is responsible (**FTO Notification**). If the FTO Notification concerns a Collaboration Product, the Parties will discuss and agree any required or advisable measures in the Joint IP Committee and/or the relevant Joint Steering Committee. If the FTO Notification concerns a Unilateral Product, the respective Continuing Party shall be solely responsible for the course of action but will closely consult with the respective Opt-Out Party.
- 10.2** **Collaboration Product.** Each Party will notify the other Party in writing if it becomes aware of any Third Party alleging that the performance of this Agreement infringes Third Party intellectual property rights (**Infringement Attack**). If an Infringement Attack is directed against the manufacture, use, handling, storage, Development, Commercialization or other disposition of a Collaboration Product, the Parties shall consult in good faith through the Joint IP Committee with a view to agreeing any required or desirable defense to any such Infringement Attack. Each Party shall have the right to defend itself against the Infringement Attack in accordance with the decisions and instructions of the Joint IP Committee. Notwithstanding the preceding sentence, Genmab shall be solely responsible for the defense against Infringement Attacks directed against the use of [***] Technology [***] and Biontech shall be solely responsible for the defense against Infringement Attacks directed against the use of [***] Technology [***], in both scenarios in close consultation with the other Party. In no event may a Party settle or otherwise consent to an adverse judgment that diminishes the rights or interests of the other Party without the express written consent of the other Party not to be unreasonably withheld.

- 10.3** **Defense Costs.** If the alleged infringement relates to a Collaboration Product and is not subject to an indemnification pursuant to Section 13.2a, all reasonable costs associated with the defense of the Infringement Attack and approved by the Joint IP Committee, including any payment due to such Third Party as damages or in settlement allocated to sales of the Collaboration Product, will be shared equally (50:50) between the Parties as part of the Shared Costs. Each Party will individually bear the risks and costs of infringing Third Party patents for its activities which are outside the scope of this Agreement.
- 10.4** **Genmab Unilateral Product.** If an Infringement Attack is directed against the manufacture, use, handling, storage, development, commercialization or other disposition of a Genmab Unilateral Product, Genmab shall be solely responsible for the defense and all costs associated therewith, except that:
- a. this shall be carried out in close consultation with Biontech, unless instructed otherwise in writing by Biontech; and
 - b. Biontech shall have the first right to control at its sole cost the defense against such Infringement Attack to the extent it is directed against the use of Biontech Technology, provided that Genmab shall be entitled to participate in such defense. If Biontech chooses not to defend against Infringement Attacks related to the Biontech Technology, then Genmab shall have the right to control such defense on its own.
- 10.5** **Biontech Unilateral Product.** If an Infringement Attack is directed against the manufacture, use, handling, storage, development, commercialization or other disposition of a Biontech Unilateral Product, Biontech shall be solely responsible for the defense and all costs associated therewith, except that:
- a. this shall be carried out in close consultation with Genmab, unless instructed otherwise in writing by Genmab; and
 - b. Genmab shall have the first right to control at its sole cost the defense against such Infringement Attack to the extent it is directed against the use of Genmab Technology, provided that Biontech shall be entitled to participate in such defense. If Genmab chooses not to defend against Infringement Attacks related to the Genmab Technology, then Biontech shall have the right to control such defense on its own.
- 11. CONFIDENTIALITY**
- 11.1** **Confidentiality and Restricted Use.** Each Party (*Receiving Party*) shall protect the Confidential Information of the other Party (*Disclosing Party*) from unauthorized use or disclosure and use at least the same standard of care as it uses to protect its own Confidential Information and to make sure that its and its Affiliates' employees, agents, consultant and clinical investigators only make use of the Disclosing Party's Confidential Information for the purposes expressly authorized or contemplated by this Agreement.

- 11.2** **Disclosure to Third Parties.** Neither Party shall, except with the express prior written consent of the Disclosing Party, disclose any Confidential Information of the Disclosing Party to any person or entity other than its officers, directors, employees, agents, consultants, Sublicensees and Approved Subcontractors who need to know such information for the performance of this Agreement and who are bound by a written confidentiality agreement not less stringent than the terms of this Agreement or by professional rules of secrecy.
- 11.3** **Permitted Disclosures.** The above confidentiality obligations shall not apply to information which, as can be established by the Receiving Party,
- a. was rightfully communicated to the Receiving Party from a Third Party; or
 - b. was already in the public domain or subsequently entered the public domain through no fault of the Receiving Party and its Affiliates; or
 - c. was already known by the Receiving Party before the effective date of the Prior Agreement or developed independently by the Receiving Party without reference to or reliance upon Confidential Information provided by the Disclosing Party; or
 - d. is to be disclosed pursuant to any Applicable Law or legal, regulatory or stock exchange requirement, provided that the Receiving Party shall wherever possible provide prior written notice of such disclosure to the Disclosing Party and take reasonable and lawful actions to avoid or minimize the degree of disclosure. The Parties agree that nothing in this Section 11.3d is intended to require a Party to not comply with any Applicable Law; or
 - e. are required to be disclosed solely to the extent reasonably necessary in a patent application claiming Program Inventions made hereunder to be filed with the United States Patent and Trademark Office and/or any similar foreign agency, provided that the Party filing the patent shall provide at least thirty (30) days prior written notice of such disclosure to the other Party and take reasonable and lawful actions to avoid or minimize the degree of disclosure.
- 11.4** **Terms of the Agreement.** Genmab and Biontech shall not disclose the existence of nor any terms or conditions of this Agreement to any Third Party without the prior consent of the other Party, except as required by Applicable Law or to comply with rules of a securities exchange or regulatory authority, in which case the Disclosing Party shall to the extent possible provide notice to the other Party and take reasonable and lawful actions to avoid or minimize the degree of such disclosures. Notwithstanding the foregoing, each Party may disclose the existence of and terms and conditions of this Agreement, without such consent, to advisors, existing and potential investors, licensees, assignees and/or acquirers on a need to know basis under circumstances that reasonably ensure the confidentiality thereof.

- 11.5** **Press releases, references.** Upon execution of this Agreement, Genmab will issue a company announcement and Biontech intends to issue an initial media release the wordings of such announcement and release have been approved by the Parties and are set forth in Exhibit 7. In addition, each Party shall be entitled to disclose the other Party's name as collaboration partner under this Agreement to Third Parties and use the other Party's name solely for such purposes. All other use of the other Party's name in any advertising or promotional material, or any other publicity relating to this Agreement, shall require the other Party's prior written consent. Except for the initial media release and company announcement permitted above, neither Biontech nor Genmab will, without the prior consent of the other, issue any press release or make any other public announcement or furnish any statement to any person or entity (other than either Parties' respective Affiliates) concerning the existence of this Agreement, its terms and the transactions contemplated hereby, except for disclosures expressly permitted hereunder.
- 11.6** **Publication regarding Collaboration Products.** The Parties shall only jointly make publications regarding any Collaboration Product(s). Neither Party may on its own publish, present or announce results of Collaboration Products developed hereunder either orally or in writing (a **Publication**) without complying with the provisions of this Section 11.6. The other Party shall have [***] days from receipt of a proposed Publication to provide comments and/or proposed changes to the publishing Party. The publishing Party shall take into account the comments and/or proposed changes made by the other Party on any Publication and shall agree to designate employees or others acting on behalf of the other Party as co-authors on any Publication describing results to which such persons have contributed in accordance with standards applicable to authorship of scientific publications. If the other Party reasonably determines that the Publication would entail the public disclosure of such Party's Confidential Information and/or of a patentable invention upon which a patent application should be filed prior to any such disclosure, submission of the concerned Publication to Third Parties shall be delayed for such period as may be reasonably necessary for deleting any such Confidential Information of the other Party (if the other Party has requested deletion thereof from the proposed Publication), and/or the drafting and filing of a patent application covering such invention, provided such additional period shall not exceed [***] days from the date the publishing Party first provided the proposed Publication to the other Party. For clarity, Section 11.3d, but not this Section 11.6, is intended to apply to any announcements required by either Party under Applicable Law, including but not limited to notifications to the relevant stock exchanges.
- 11.7** **Publication regarding Unilateral Products.** A Continuing Party may on its own make a Publication on a Unilateral Product developed hereunder. However, the Opt-Out Party shall have [***] days from receipt of a proposed Publication to provide comments and/or proposed changes to the Continuing Party. To the extent such comments and/or proposed changes pertain to the Opt-Out Party's technology, the Continuing Party shall take into account the comments and/or proposed changes made by the Opt-Out Party on any Publication. If the Opt-Out Party reasonably determines that the Publication would entail the public disclosure of such Party's Confidential Information and/or of a patentable invention upon which a patent application should be filed prior to any such disclosure, submission of the concerned Publication to Third Parties shall be delayed for such period as may be reasonably necessary for deleting any such Confidential Information of the Opt-Out Party (if such Party has requested deletion thereof from the

proposed Publication), and/or the drafting and filing of a patent application covering such invention, provided such additional period shall not exceed [***] days from the date the Continuing Party first provided the proposed Publication to the Opt-Out Party. For clarity, Section 11.3d, but not this Section 11.7, is intended to apply to any announcements required by either Party under Applicable Law, including but not limited to notifications to the relevant stock exchanges.

11.8 **Prior Agreement.** As of the Effective Date, the above confidentiality obligations shall supersede any oral or written confidentiality agreements concluded between the Parties prior to this Agreement. As far as under such prior confidentiality agreement or the Prior Agreement information has already been exchanged, the above provisions of this Section 11 shall apply also to such information.

12. REPRESENTATIONS AND WARRANTIES

12.1 **Mutual Representations and Warranties.** Each Party hereby represents and warrants to the other Party that

- a. it has the legal right to enter into and deliver this Agreement and constitutes the valid and binding obligation of each Party;
- b. the execution, delivery and performance of this Agreement as well as the licenses granted hereunder do not conflict with any agreement, instrument or understanding, oral or written, to which such Party may be bound.

12.2 **Biontech Representations and Warranties.** Biontech represents and warrants that as of the Effective Date:

- a. it has the right to grant the licenses granted herein;
- b. the Biontech Technology licensed hereunder is free and clear of any security interests, claims, encumbrances or charges of any kind;
- c. it has not assigned and/or granted licenses, nor shall it assign and/or grant licenses under the Biontech Technology to any Third Party that would restrict or impair the rights granted to Genmab hereunder;
- d. to its actual knowledge no Third Party has infringed the Biontech Technology;
- e. it has not received any written notice of (i) any claim that any patent or trade secret right owned or Controlled by a Third Party would be infringed or misappropriated by the manufacture, use, sale, offer for sale or importation of Biontech Antibodies or Collaboration Products or Unilateral Products containing Biontech Antibodies, or (ii) any threatened administrative proceedings or litigation seeking to invalidate or otherwise challenge the Biontech Patents;
- f. none of the Biontech Patents are the subject of any pending re-examination, opposition, interference or litigation proceedings; and

- g. to the best of its knowledge it has provided all the necessary licenses under the Biontech Technology herein to ensure the anticipated Development and Commercialization of Collaboration Products and the development and commercialization of Unilateral Products.

12.3 Genmab Representations and Warranties. Genmab represents and warrants that as of the Effective Date:

- a. it has the right to grant the licenses granted herein;
- b. the Genmab Technology licensed hereunder is free and clear of any security interests, claims, encumbrances or charges of any kind;
- c. it has not assigned and/or granted licenses, nor shall it assign and/or grant licenses under the Genmab Technology to any Third Party that would restrict or impair the rights granted to Biontech hereunder;
- d. to its actual knowledge no Third Party has infringed the Genmab Technology;
- e. it has not received any written notice of (i) any claim that any patent or trade secret right owned or Controlled by a Third Party would be infringed or misappropriated by the manufacture, use, sale, offer for sale or importation of the Genmab Antibodies, Collaboration Products or Unilateral Products containing Genmab Antibodies, the DuoBody Platform, or the Inert Format Technology (the DuoBody Platform and the Inert Format Technology as used with the preferred mutation and embodiment) or (ii) any threatened administrative proceedings or litigation seeking to invalidate or otherwise challenge the Genmab Patents;
- f. none of the Genmab Patents are the subject of any pending re-examination, opposition, interference or litigation proceedings; and
- g. to the best of its knowledge it has provided all the necessary licenses under the Genmab Technology herein to ensure the anticipated Development and Commercialization of Collaboration Products or the development and commercialization of Unilateral Products.

12.4 Covenant. Each Party covenants to the other Party that it will not include any additional intellectual property rights owned or Controlled by it or its Affiliates not currently included in the licenses granted under this Agreement in any Clinical Candidate or Collaboration Product without the prior written consent of the other Party. If such consent is not sought or obtained, then any additional intellectual property rights included anyway shall be licensed to the other Party on a free and perpetual basis.

12.5 Disclaimers. The Parties acknowledge and agree that the research and development to be conducted under this Agreement is experimental in nature, and that neither Party can guarantee a successful outcome thereof. Except as expressly provided in this Agreement, the know-how, Confidential Information and intellectual property rights provided by each Party are provided “as is” and except as otherwise expressly set forth herein, neither Party makes any representations or extends any warranties of any kind, either express or implied, to the other Party, and each Party hereby disclaims all implied warranties, including warranties of merchantability, fitness for a particular purpose or non-infringement.

13. INDEMNITY and LIMITATION of LIABILITY**13.1 Indemnity for Unilateral Products**

- a. With respect to Unilateral Products, each Party shall defend, indemnify and hold harmless the other Party, its Affiliates and their respective directors, officers, employees and agents (collectively, the **Indemnitees**) from and against all liabilities, losses, damages, and expenses, including reasonable attorneys' fees and costs, (collectively, the **Liabilities**) resulting from all Third Party claims, suits, actions, terminations or demands (collectively, the **Claims**) that are incurred, relate to or arise out of (a) the material breach of any material provision of this Agreement by the indemnifying Party, including [***] made by such Party in this Agreement, or (b) the gross negligence, recklessness or wilful misconduct of the indemnifying Party in connection with the performance of its obligations hereunder.
- b. Genmab shall defend, indemnify and hold harmless the Biontech Indemnitees from and against all Liabilities resulting from all Claims that are incurred, relate to or arise out of the development, manufacture or commercialization of Genmab Unilateral Products by Genmab, its Affiliates or Sublicensees; except to the extent such Liabilities must be indemnified by Biontech pursuant to Sections 13.1a.
- c. Biontech shall defend, indemnify and hold harmless the Genmab Indemnitees from and against all Liabilities resulting from all Claims that are incurred, relate to or arise out of the development, manufacture or commercialization of Biontech Unilateral Products by Biontech, its Affiliates or Sublicensees; except to the extent such Liabilities must be indemnified by Genmab pursuant to Sections 13.1a.

13.2 Indemnity for Collaboration Products

- a. Each Party hereby agrees to indemnify, defend, and hold harmless the other Party's Indemnitees from and against any and all Liabilities, incurred as a result of any Claims relating to the manufacture, use, handling, storage, Development, Commercialization or other disposition of any Collaboration Product by the indemnifying Party, its Affiliates, employees, agents or Sublicensees, but only to the extent such Claims result from: (a) the gross negligence, recklessness or wilful misconduct of the indemnifying Party, its Affiliates, employees, agents or Sublicensees; or (b) any material breach by the indemnifying Party of any material provision of this Agreement, including a [***] made by such Party in this Agreement; except, in each case, to the extent of any such Claim resulting from the gross negligence or willful misconduct of the Indemnitees.
- b. Except for those Claims subject to Section 13.2a, the Parties shall share equally any Liabilities in connection with any Claim brought against either Party by a Third Party resulting directly or indirectly from the manufacture, use, handling, storage, Development, Commercialization or other disposition of any given Collaboration Product.

- c. If either Party receives notice of a Claim with respect to any Collaboration Product, such Party shall inform the other Party in writing as soon as reasonably practicable. The Parties shall confer through the Joint Steering Committee how to respond to the Claim and how to handle the Claim in an efficient manner. In the absence of such an agreement, each Party shall have the right to take such action as it deems appropriate, subject to Section 13.3.
- d. For the avoidance of doubt, defense against Infringement Attacks shall be solely subject to Section 10.

13.3 Procedure. A Party (the **Indemnified Party**) that intends to claim indemnification under this Section 13 shall promptly provide notice to the other Party (the **Indemnitor**) of any Liability or action in respect of which the Indemnified Party intends to claim such indemnification, which notice shall include a reasonable identification of the alleged facts giving rise to such Liability, and the Indemnitor shall have the right to control and participate in, and, to the extent the Indemnitor so desires, jointly with any other Indemnitor similarly noticed, to assume the defense thereof with counsel selected by the Indemnitor. However, notwithstanding the foregoing, the Indemnified Party shall have the right to retain its own counsel, with the fees and expenses to be paid by the Indemnified Party, unless the representation of such Indemnified Party by the counsel retained by the Indemnitor would be inappropriate due to actual differing interests between such Indemnified Party and any other party represented by such counsel in such proceedings, in which case the reasonable fees and expenses shall be paid by the Indemnitor. The Indemnified Party cannot settle any Liability for which it intends to claim indemnification by the Indemnitor without the prior written consent of the Indemnitor. Any settlement of a Liability for which any Indemnified Party seeks to be indemnified, defended or held harmless under this Section 13 that could adversely affect the Indemnified Party shall be subject to prior consent of such Indemnified Party, provided that such consent shall not be withheld unreasonably.

13.4 No Liability for Indirect Losses. Neither Party shall be liable to the other, whether in tort, contract or otherwise, for any consequential, indirect, punitive, exemplary or incidental damages, lost profits or lost business opportunities. The provisions of this Section 13.4 shall not apply to cases of wilful misconduct, any breach of [***], or any breach of [***].

14. OPT-OUT

14.1 Opt-Out Options. No later than thirty (30) calendar days after either Proposed IND Submission or Establishment of Clinical Proof of Concept (the **Opt-Out Points**), as applicable, and on a Collaboration Product-by-Collaboration Product basis, each Party (the **Opt-Out Party**) shall have the right to provide the other Party with irrevocable (subject to Section 15.6) notice in writing that it wishes to discontinue its participation in the further Development and Commercialization of such Collaboration Product (the **Opt-Out Notice**). The effective date of such opt-out (the **Opt-Out Date**) shall be the date thirty (30) days after the date of the Opt-Out Notice. In its Opt-Out Notice the Opt-Out Party shall also notify the other Party whether continued Development and Commercialization of the Collaboration Product can take place on the pre-defined financial terms, as set forth in Exhibit 1, or whether the Opt-Out Party wants to Divest

its share of the Collaboration Product. Upon receipt of the Opt-Out Notice, the other Party shall, within thirty (30) days following its receipt of the Opt-Out Notice, notify the Opt-Out Party in writing whether or not it elects to assume sole responsibility for, and all costs and obligations of, the continued Development and Commercialization of such Collaboration Product, and (if the Opt-Out Party has offered that continued Development and Commercialization of the Collaboration Product can take place on the pre-defined terms set forth in Exhibit 1), whether it accepts to continue Development and Commercialization of the Collaboration Product on such pre-defined terms.

14.2 Postponement of Opt-Out. Only applicable for opt-out in connection with Establishment of Clinical Proof of Concept, the Parties may agree in writing to postpone the window, within which a Party can opt-out of the Development, in order to perform an additional clinical trial. The Parties agree and acknowledge that the pre-defined financial terms for opt-out at Establishment of Clinical Proof of Concept will remain applicable for the agreed postponed opt-out point.

14.3 Opt-Out at Proposed IND Submission.

- a. If the Opt-Out Party has notified the other Party that continued Development and Commercialization of the Collaboration Product may take place on the pre-defined terms in Exhibit 1, and the other Party elects to assume sole responsibility for, and all costs and obligations of the continued Development and Commercialization of the Collaboration Product on such pre-defined financial terms, then the Collaboration Product shall become a Unilateral Product and Section 14.6 shall apply.
- b. If the Opt-Out Party has notified the other Party that continued Development and Commercialization of the Collaboration Product may take place on the pre-defined terms in Exhibit 1, and the other Party is not willing to accept such pre-defined terms, then a mandatory joint Divestment of the Collaboration Product shall take place pursuant to Section 15.9. If the mandatory joint Divestment fails, the Collaboration Product shall be considered a Ceased Product.
- c. If the Opt-Out Party has notified the other Party that continued Development and Commercialization of the Collaboration Product cannot take place on the pre-defined terms in Exhibit 1, the Opt-Out Party may Divest its share of the Collaboration Product pursuant to Sections 15.1 to 15.8, including for the avoidance of doubt the Exclusive Negotiation Period pursuant to Sections 15.2 and 15.3. If such Divestment is not successful, as an exception to Section 15.6, the Opt-Out Party may either continue the Development and Commercialization of the Collaboration Product pursuant to the conditions of this Agreement, or notify the other Party that it wishes to opt-out of the collaboration on the basis of the pre-defined terms and conditions set forth in Exhibit 1. In such scenario, Sections 14.3a) or 14.3b) shall apply respectively, depending on whether the other Party accepts the pre-defined terms and conditions set forth in Exhibit 1.

14.4 Opt-Out at Establishment of Clinical Proof of Concept.

- a. If the Opt-Out Party has notified the other Party that continued Development and Commercialization of the Collaboration Product may take place on the pre-defined terms in Exhibit 1, and the other Party elects to assume sole responsibility for, and all costs and obligations of the continued Development and Commercialization of the Collaboration Product on such pre-defined financial terms, then the Collaboration Product shall become a Unilateral Product and Section 14.6 shall apply.
- b. If the Opt-Out Party has notified the other Party that continued Development and Commercialization of the Collaboration Product may take place on the pre-defined terms in Exhibit 1, and the other Party is not willing to accept such pre-defined terms, both Parties shall be released from any further Development and funding obligation under this Agreement and the Parties shall negotiate exclusively with each other for [***] months as set forth in Sections 15.2 and 15.3. If such negotiations are unsuccessful, the Opt-Out Party shall seek to Divest both Parties' share of the Collaboration Product, such Divestment to be handled by the Opt-Out Party on behalf of both Parties. The Opt-Out Party shall use Commercially Reasonable Efforts to maximize the value obtained in the Divestment. The other Party shall be allowed to submit bids during such Divestment. Section 15.5 shall apply *mutatis mutandis*, except that the Opt-Out Party shall be allowed to extend the Divestment period pursuant to Section 15.5b) with additional [***] months by documenting that at the expiry of the original Divestment period term sheet(s) from one or more Third Party/ies are subject to ongoing negotiations. If the Divestment fails, the Collaboration Product shall be considered a Ceased Product. For the avoidance of doubt, Sections 15.4 (Funding Obligations) and 15.6 (Failure to Divest) shall not apply to any Divestment pursuant to this Section 14.4b).
- c. If the Opt-Out Party has notified the other Party that continued Development and Commercialization of the Collaboration Product cannot take place on the pre-defined terms in Exhibit 1, the Opt-Out Party may Divest its share of the Collaboration Product pursuant to Sections 15.1 to 15.8, including for the avoidance of doubt the Exclusive Negotiation Period pursuant to Sections 15.2 and 15.3. If such Divestment is not successful, as an exception to Section 15.6, the Opt-Out Party may either continue the Development and Commercialization of the Collaboration Product pursuant to the conditions of this Agreement, or notify the other Party that it wishes to opt-out of the collaboration on the basis of the pre-defined terms and conditions set forth in Exhibit 1, provided that the milestone payments applicable to opt-out at [***] shall each be reduced by [***], and the royalty rates applicable to opt-out at Establishment of Proof of concept shall each be reduced by [***] percentage point (**Fall-Back Terms**). In such scenario, the Sections 14.4a) or 14.4b) shall apply *mutatis mutandis*, depending on whether the other Party accepts such Fall-Back Terms.

14.5 Ceased Product. A Collaboration Product shall become a **Ceased Product**, if and when (i) upon receipt of an Opt-Out Notice the other Party either notifies the Opt-Out Party that it does not elect to assume sole responsibility for, and all costs and obligations of, the continued Development and Commercialization of the respective Collaboration Product or does not notify the Opt-Out Party in writing within thirty (30) days that it wishes to assume sole responsibility for, and all costs and obligations of, the continued

Development and Commercialization of the respective Collaboration Product; or (ii) in any other scenario under which a Collaboration Product shall be considered a Ceased Product and/or which refers to this Section 14.5 pursuant to this Agreement. With respect to any Ceased Product:

- a. the Parties shall decide on whether or not to attempt a joint Divestment pursuant to Section 15.9. If the Divestment of a Ceased Product fails, or the Parties jointly decide not to attempt to Divest, the exclusivity obligations under Section 6 shall no longer apply to such Ceased Product or the relevant Target Combination; and
- b. both Parties shall be released from any further Development and funding obligation under this Agreement, provided they shall work together to ensure that any ongoing activities related to a Ceased Product are properly wound down, and shall share costs related to such winding down, if any.

14.6 **Continuation of Development and Commercialization by other Party.** If a party (the *Continuing Party*) elects to assume sole responsibility for, and all costs and obligations of the continued Development and Commercialization of the Collaboration Product, whether on the pre-defined terms set forth in Exhibit 1, or on other terms agreed with the Opt-Out Party pursuant to the scenarios set forth in Sections 14.3 and 14.4, then:

- a. such Collaboration Product will become a ***Unilateral Product***;
- b. the Continuing Party will be entitled to continue the development and commercialization of the Unilateral Product in its sole discretion and Sections 3 and 4 shall no longer apply, provided that the Continuing Party shall use Commercially Reasonable Efforts to further develop and commercialize the Unilateral Product, including without limitation to achieve filing of the first IND for such Unilateral Product within [***] years after selection of the respective Clinical Candidate according to Section 2.10. The Continuing Party may extend the date by which the first IND for such Unilateral Product should be filed by [***] year by paying to the other Party [***]. Such payment shall be made no later than [***] years after selection of the respective Clinical Candidate according to Section 2.10. If the Continuing Party materially breaches its obligations under this Section 14.6b and fails to cure such breach within [***] days following its receipt of written notice thereof from the Opt-Out Party, the Opt-Out Party shall have the right, exercisable by written notice to the Continuing Party, to request that the Unilateral Product as well as all rights and data relating thereto shall be Divested through a Joint Divestment Process;
- c. the Continuing Party may terminate at any time in its sole discretion the development and/or commercialization of the Unilateral Product by written notice to the Opt-Out Party. Such termination shall not constitute a breach of applying Commercial Reasonable Efforts as set forth in Section 14.6b. In the event of any such termination the Unilateral Product shall become a Ceased Product and Section 14.5 shall apply;

- d. all rights and obligations of the Opt-Out Party under this Agreement with respect to the Unilateral Product will end except for the Opt-Out Party's continuing obligations under Sections 2.7, 2.8, 3.5 (to the extent it refers to Sections 2.7 and 2.8) and 11 or otherwise provided for in this Section 14.6 or Exhibit 1; in particular, the licenses set forth in Section 9.2 and Section 9.3 will terminate, and will be replaced by the licenses set forth in Section 14.7;
- e. the Collaboration IP solely relating to the Unilateral Product will be assigned to the Continuing Party in accordance with Section 9.1h;
- f. the prosecution, maintenance, enforcement and defense of Patent Rights solely relating to the Unilateral Product will be subject to Sections 9.8a, 9.8b, 9.9a, 9.9c, 10.4 and 10.5;
- g. the terms and conditions set forth in Exhibit 1 will apply (except to the extent the Parties have agreed on different financial terms pursuant to the scenarios set forth in Section 14.3 and 14.4);
- h. promptly after the Continuing Party's election, the Parties will work together to transfer and assign all regulatory documents, contracts, materials and information related to such former Collaboration Product to the Continuing Party or its designees to the extent necessary for the Continuing Party to assume such sole responsibility;
- i. the Opt-Out Party will not be refunded or repaid any amounts it has paid for the Development of such former Collaboration Product;
- j. for [***] after the date of the Opt-Out Notice, the Opt-Out Party shall provide development, consultation or support work for a Unilateral Product of the Continuing Party, as reasonably requested by the Continuing Party, and the Continuing Party shall pay for such work at the then current annual rate per FTE as set forth in Exhibit 1.

14.7 Licenses for Unilateral Products.

- a. License to Genmab for Unilateral Products. On a Genmab Unilateral Product-by-Genmab Unilateral Product basis and subject to the terms of this Agreement, Biontech hereby grants to Genmab a royalty bearing (subject to the terms and conditions set forth in Exhibit 1) license under the Biontech Technology, with the right to sublicense (through multiple tiers), to develop, have developed, make, have made, import, use, offer for sale, have sold and sell Genmab Unilateral Products within the Field in the Territory. The license for a Genmab Unilateral Product shall be exclusive in accordance with Section 6.3.
- b. Genmab's Rights to Sublicense. Genmab shall have the right to grant a sublicense of the license granted pursuant to subsection a above to any Affiliate or other Third Party, provided that Genmab agrees to contractually obligate any Sublicensee of a Genmab Unilateral Product to make all payments due to Biontech pursuant to this Agreement, as well as to comply with all terms of this Agreement applicable to Genmab. For the sake of clarification, such payments shall be made to Genmab and not directly to Biontech. Genmab shall also require any such Sublicensee to agree in writing to keep books and records and permit either Genmab or Biontech or both

to audit the information concerning such books and records in accordance with the terms of this Agreement. If one of the Parties conducts such an audit of the books and records of a Sublicensee without the other Party's participation, the Party conducting the audit shall upon the other Party's request share the results of such audit. In addition, a sublicense to an Affiliate must provide that it will automatically terminate if the relevant Sublicensee ceases to be an Affiliate of Genmab. For sublicenses permitted hereunder, Genmab shall (a) notify Biontech of each sublicense granted (both to Affiliates and Third Parties) hereunder, and (b) provide Biontech with the [***] of each Sublicensee (both Affiliates and Third Parties) and a description of [***] by each Sublicensee.

- c. License to Biontech for Unilateral Products. On a Biontech Unilateral Product-by-Biontech Unilateral Product basis and subject to the terms of this Agreement, Genmab hereby grants to Biontech a royalty bearing (subject to the terms and conditions set forth in Exhibit 1) license under the Genmab Technology, with the right to sublicense (through multiple tiers), to develop, have developed, make, have made, import, use, offer for sale, have sold and sell Biontech Unilateral Products within the Field in the Territory. The license for a Biontech Unilateral Product shall be exclusive in accordance with Section 6.3. The licenses granted to Biontech hereunder with regards to the DuoBody Platform are only granted for the [***]. Use of other [***] under the DuoBody Platform can only take place upon Genmab's prior written consent. The license granted under the [***] Technology is to the embodiment wherein the [***]
- d. Biontech's Rights to Sublicense. Biontech shall have the right to grant a sublicense of the license granted pursuant to subsection c above to any Affiliate or other Third Party, provided that Biontech agrees to contractually obligate any Sublicensee of a Biontech Unilateral Product to make all payments due to Genmab pursuant to this Agreement, as well as to comply with all terms of this Agreement applicable to Biontech. For the sake of clarification, such payments shall be made to Biontech and not directly to Genmab. Biontech shall also require any such Sublicensee to agree in writing to keep books and records and permit either Genmab or Biontech or both to audit the information concerning such books and records in accordance with the terms of this Agreement. If one of the Parties conducts such an audit of the books and records of a Sublicensee without the other Party's participation, the Party conducting the audit shall upon the other Party's request share the results of such audit. In addition, a sublicense to an Affiliate must provide that it will automatically terminate if the relevant Sublicensee ceases to be an Affiliate of Biontech. For sublicenses permitted hereunder, Biontech shall (a) notify Genmab of each sublicense granted (both to Affiliates and Third Parties) hereunder, and (b) provide Genmab with the name and address of each Sublicensee (both Affiliates and Third Parties) and a description of the rights granted and the territory covered by each Sublicensee.

15. DIVESTMENT OF COLLABORATION PRODUCTS

- 15.1 Divestment. Each Party may, at any time during the Development of a Collaboration Product, seek to Divest its then current ownership share of the Collaboration Product to a Third Party and exit the collaboration hereunder without further obligations.

- 15.2 **Right of First Negotiation.** A Party that wishes to Divest its ownership share of a Collaboration Product (the **Divesting Party**), shall first grant the other Party (the **Non-Divesting Party**) a right of first exclusive negotiation to obtain exclusive, worldwide Development and Commercialization rights to the Collaboration Product on terms and conditions that shall be negotiated in good faith at the time the Non-Divesting Party exercises its right of first negotiation. The Divesting Party shall by written notice inform the Non-Divesting Party that it wishes to Divest its ownership share of the Collaboration Product (the **Divestment Notice**). Following receipt of such notice the Non-Divesting Party shall have an option for a sixty (60) day period to negotiate exclusively with the Divesting Party to acquire the Divesting Party's share of the Collaboration Product (the **Exclusive Negotiation Period**). During the Exclusive Negotiation Period, the Parties shall negotiate in good faith to arrive at a non-binding term sheet that includes all key financial terms for the Divestment agreement, and that specifies a closing date [***] months from the date on which such term sheet is executed by the Parties. Neither Party shall be obligated to agree to such a term sheet, to agree to any particular terms therein, or to agree to execute a binding agreement contemplated by such a term sheet. The Non-Divesting Party may in its sole discretion waive the right to the Exclusive Negotiation Period, in which case the Divesting Party may proceed with the desired Divestment process (the **Divestment Process**).
- 15.3 **Information to Third Parties.** During the Exclusive Negotiation Period only the Non-Divesting Party will be allowed access to any data room containing Confidential Information regarding the Collaboration Product, and no Confidential Information will in any other way be disclosed to, and no term sheet discussions can take place with any Third Parties.
- 15.4 **Funding Obligations During Divestment Process.** During a Divestment Process, the Non-Divesting Party will have the [***] on the Joint Development Team and Joint Steering Committee with regards to any decisions on the continued Development of the Collaboration Product within the framework of the clinical scenarios stipulated in the updated Development Plan, cf. Section 3.6. During a Divestment Process, whether initiated pursuant to Sections 14.3c, 14.4c or 15.1, the Divesting Party will remain responsible to the Non-Divesting Party for its share of the agreed Research and Development Costs as per the then current Development Plan as updated pursuant to Section 3.6 and as set forth in the then current Budget, but subject to a cap of [***] on such Research and Development Costs to be [***] during the Divestment Process (the **Cap during Divestment**). Once the Cap during Divestment has been reached, and if the Divestment Process is still ongoing, the Divesting Party may either (i) Divest its share of the Collaboration Product to the Non-Divesting Party on terms to be agreed by the Parties, or (ii) continue to fund its part of the Research and Development Costs until the share has been Divested, in which case the Divesting Party may elect to defer payment of its funding obligations during the remainder of the Divestment Process. In such case, the Divesting Party shall notify the Joint Steering Committee that it wishes to defer any payment of Research and Development Costs beyond the Cap during Divestment until finalization of the Divestment Process. Once the Divestment Process has been finalized, whether or not successfully, the Divesting Party shall immediately pay its deferred share of the Research and Development Costs to the Non-Divesting Party whether such share can be covered by the proceeds from the Divestment or not. The amount to be paid shall be calculated as deferred payment with an interest rate of [***] percent ([***]%) above EUBOR.

- 15.5 **Duration of Divestment Process.** A Divestment Process shall end upon the earlier of:
- a. completion of a binding Divestment agreement between the Divesting Party and the Non-Divesting Party or a Third Party; and
 - b. expiration of [***] months after the end of the Exclusive Negotiation Period.
- 15.6 **Failure to Divest.** Unless otherwise specifically stipulated in this Agreement, upon failure to conclude a binding Divestment agreement within [***] months after the end of the Exclusive Negotiation Period pursuant to Section 15.5b), the Divesting Party shall continue the Development and Commercialization of the Collaboration Product pursuant to the terms and conditions of this Agreement.
- 15.7 **Bids.** The Non-Divesting Party may participate as a bidder in the Divestment Process.
- 15.8 **Third Party Acquirer.** A Third Party that licenses or acquires the Divesting Party's ownership share of a Collaboration Product shall adhere to all terms and conditions of this Agreement, including but not limited to the fulfillment of its obligations under the then current Development Plan and Budget, as of the completion of the relevant Divestment agreement.
- 15.9 **Joint Divestment Process.** In the event that both Parties wish to opt-out of Development or Divest their respective ownership shares of a certain Collaboration Product or in any other scenario pursuant to this Agreement which provides for a joint Divestment and/or refers to this Section 15.9, the Parties shall jointly initiate a Divestment process (the **Joint Divestment Process**), which shall be performed by the Parties as follows:
- a. Both Parties shall upon initiation of the Joint Divestment Process be released from any further research, Development and funding obligation under this Agreement, provided they shall work together to ensure that any ongoing activities related to the Collaboration Product to be Divested are properly wound down to the extent applicable, and shall share costs related to such winding down, if any.
 - b. Unless otherwise agreed by the Parties at the time of initiation of the Joint Divestment Process, each Party shall designate a divestment executive (**Divestment Executive**) who shall not be a Joint Steering Committee member, and who shall be the point of contact for such Parties in the Joint Divestment Process and who shall report to the Joint Steering Committee.
 - c. The Parties may engage a Third Party advisor, on terms acceptable to both Parties, to coordinate the Joint Divestment Process for the purpose of licensing rights to the Collaboration Product. The Divestment Executives and the Third Party advisor shall present to the Joint Steering Committee for approval detailed criteria for evaluating, comparing and selecting potential offers, which shall include financial and nonfinancial factors (**Bidding Criteria**).

- d. Neither Party may [***].
- e. The Parties shall use Commercially Reasonable Efforts to maximize the value obtained in the Joint Divestment Process.
- f. The Joint Steering Committee shall unanimously decide on which offer to accept under the Joint Divestment Process, using the Bidding Criteria. Once the Joint Steering Committee has decided which offer to accept, the Parties shall together appoint an external legal counsel to handle, on behalf of both Parties and at a cost equally shared the drafting, negotiation and finalization of the agreement with the Third Party that made the winning offer. Both Parties shall be signatories to the agreement with such Third Party.
- g. If the Joint Divestment Process has not been finalized within [***] months after its initiation, the Parties shall discuss in good faith the terms and conditions for continuing the Joint Divestment Process, or for continuing the Development of the Collaboration Product, or any alternative solution, including the winding-up of the Development of the Collaboration Product.

16. TERM AND TERMINATION

16.1 Term. This Agreement shall become effective on the Effective Date and shall continue until the later of (i) the last to expire Royalty Term for a Unilateral Product and, (ii) when no Collaboration Products are being Developed and/or Commercialized any longer, unless terminated earlier in accordance with the provisions of this Agreement (*the Term*).

16.2 Termination for Breach. Either Party may terminate this Agreement in its entirety or on a Collaboration Product-by-Collaboration Product and/or Unilateral Product-by-Unilateral Product basis at any time by written notice to the other Party with immediate effect if:

- a. the other Party materially breaches any material provision of this Agreement and fails to cure such breach within [***] days following its receipt of written notice thereof from the terminating Party.
- b. the other Party becomes insolvent, is compelled to file bankruptcy or is determined otherwise imminently subject to control by a bankruptcy trustee or its equivalent to the laws of the jurisdiction in which such Party is doing business. Notwithstanding the foregoing, the Parties intend for this Agreement and the licenses granted herein to remain in full force and effect so long as the non-insolvent Party remains in material compliance with the terms and conditions hereof.

16.3 Effect of Expiration and Termination

- a. Except where explicitly provided within this Agreement, termination of this Agreement (whether in its entirety or with respect to a Collaboration Product and/or Unilateral Product) for any reason, or expiration of this Agreement, will not affect any: (i) obligations, including payment of any royalties or other sums which have accrued as of the effective date of termination or expiration, and (ii) rights and

obligations which, from the context thereof, are intended to survive termination or expiration of this Agreement, including the provisions of Sections 1, 2.7, 3.5 (to the extent it refers to Section 2.7), 7.8, 7.9, 9.10, 10 (as to actions arising during the term of this Agreement or in the course of a Party practicing any licenses retained by such Party thereafter), 11, 12, 16.3a and 17.

- b. Upon termination of this Agreement partly or wholly for any reason, save as expressly provided herein, all licenses granted to each of the Parties in respect of the affected terminated Collaboration Product(s) and/or Unilateral Product(s), and all sublicenses granted to Affiliates by a Party hereunder in respect of the affected terminated Collaboration Product(s) and/or Unilateral Product(s) will immediately cease and terminate. In the event the termination is to the Agreement in its entirety or else in respect of the affected terminated Collaboration Product(s) and/or Unilateral Product(s), the Parties shall promptly return to one another or destroy all Confidential Information of the other Party and antibodies and other materials created under the Prior Agreement or this Agreement that are in a Party's or its Affiliates' possession or control in respect of the affected terminated Collaboration Product(s) and/or Unilateral Product(s). The Parties shall jointly decide how a termination of this Agreement partly or wholly shall affect any Joint Patents.

- 16.4** **Rights of Sublicensees.** Upon the termination of this Agreement any sublicenses granted by a Party to Third Parties hereunder shall survive, provided that each sublicensee is then in full compliance with its sublicense and promptly agrees in writing to be bound by the applicable terms of this Agreement and agrees to pay directly to the other Party or the Parties, as applicable, the same amounts that would have been due to such other Party under this Agreement with respect to such sublicense had the Agreement not been terminated.
- 16.5** **Winding Down.** To the extent not prohibited by Applicable Law, the Parties shall wind down any clinical trials that are underway in respect of the terminated Collaboration Product and/or Unilateral Product, taking into account the health and safety of the subjects enrolled therein and Good Clinical Practice. In the event that a Party is Commercializing Collaboration Products and/or Unilateral Products under this Agreement, and in accordance with the foregoing provisions of this Section 16.3, a license is terminated then such Party shall be entitled to, and the licenses shall be deemed to survive to the extent necessary for such Party to wind down the activities in an orderly manner, including the right to sell off inventory, but in no event for a period longer than six (6) months from the effective date of termination.
- 16.6** **Force Majeure.** No Party (or any of its Affiliates) shall be held liable or responsible to the other Party (or any of its Affiliates), or be deemed to have defaulted under or breached the Agreement, for failure or delay by such Party in fulfilling or performing any term of the Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party (or any of its Affiliates), including fire, floods, embargoes, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, acts of God, earthquakes, or omissions or delays in acting by any governmental authority (collectively, **Events of Force Majeure**); provided, however, that the affected Party shall promptly advise the other Party of the existence of such Event of Force Majeure and shall exert all Commercially Reasonable Efforts to

damage liability. Upon the Effective Date and not later than [***] days prior to the first use in humans of the first Collaboration Product, Genmab Unilateral Product or Biontech Unilateral Product, as the case may be, each Party shall provide to other Party a certificate(s) evidencing all required coverage hereunder. Each Party shall maintain such insurance coverage without interruption during the Term and for a period of at least [***] years thereafter. Each Party shall, at the request of the other Party, provide the other Party at least [***] days' prior written notice of any cancellation or material change in the insurance policy. For the avoidance of doubt, the term, "product liability insurance" as used in this Section 17.2 shall not include clinical trial insurances; the Parties will each obtain and maintain clinical trial insurance to the extent required by Applicable Law.

- 17.3 **Entire Agreement.** This Agreement, including the Exhibits to this Agreement, represents the entire understanding between the Parties with respect to the subject matter hereof and supersedes all previous oral or written communication or agreements, and all contemporaneous oral communication and agreements between the Parties.
- 17.4 **Form Requirement.** This Agreement may only be amended, modified or supplemented by the Parties in writing. The same applies to this Section 17.4.
- 17.5 **Assignment.** Neither Party may assign its contractual rights and obligations or parts thereof without the prior written consent of the other Party, except for permitted subcontracting and provided, however, that either Party may, without such consent, assign this Agreement and all of its rights and obligations hereunder (i) to any Affiliate or (ii) in connection with the transfer or sale of all or substantially all of its business to which this Agreement relates, or in the event of its merger, consolidation, or other similar transaction. For clarification, any assignment to Third Parties which is not expressly allowed above requires the approval of the other Party, which approval shall not be withheld unreasonably if the Third Party assignee assumes all rights and obligations of this Agreement.
- 17.6 **Profit Sharing Rights.** Either Party may transfer its share of the Shared Profits hereunder to any Affiliate or Third Party (including for purposes of providing security to investors or financing parties), provided that the transferring Party shall remain Party to this Agreement and shall remain bound by all obligations hereunder, and that the non-transferring Party shall not be obligated to make any payment directly to, or perform any other obligation directly towards, the receiving Affiliate or Third Party.
- 17.7 **Severability.** If any provision of this Agreement is found to be invalid or otherwise unenforceable, in whole or in part, the validity of the remainder of the Agreement shall not be affected. Furthermore, the Parties agree that the invalid or unenforceable provision or part thereof shall be superseded by an adequate provision that, to the legally permitted extent, comes closest to what the Parties would have desired at the time of conclusion of the Agreement had they considered the issue concerned.
- 17.8 **Independent Contractor.** Nothing in this Agreement shall create, or be deemed to create, a partnership, joint venture, or the relationship of principal and agent or employer and employee between the Parties. Each Party agrees to perform under this Agreement solely as independent contractor.

- 17.9** **Dispute Resolution.** Any dispute arising between the Parties in connection with this Agreement shall be referred to the Joint Research Committee or the competent Joint Steering Committee or Joint Commercialization Committee, as applicable. If the competent committee is unable to negotiate in good faith and settle the dispute within [***] days after being requested to do so, either Party may submit the dispute to the Parties' [***] who shall meet in order to attempt to resolve the dispute. If the dispute is not settled, at the latest, within [***] weeks from the date that the dispute has been escalated to the [***], either Party may pursue legal action in accordance with Section 17.10 below. For the avoidance of doubt, if the dispute is with respect to an amendment of the Research Plan or any Development Plan, the current version of such Research Plan or Development Plan shall remain in effect until the dispute is finally settled.
- 17.10** **Governing Law, Arbitration.** This Agreement shall be governed by the laws of England and Wales without reference to its conflict of laws provisions. All disputes arising out or in connection with this Agreement shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in the accordance with said Rules. The place of the Arbitration Tribunal shall be London, England. The language of the arbitration proceeding shall be English.

[End of Agreement – Signatures on the following page]

IN WITNESS WHEREOF, authorized representatives of the Parties have duly executed this Agreement as of the Effective Date

For Genmab A/S:

For Biontech AG:

By: [***] _____

By: [***] _____

Name: [***]
(Print or Type)

Name: [***]

Title: CEO & President

Title: COO

Exhibit 1: Terms for Continued Development in Case of an Opt-Out

1. Financial Terms

1.1 Milestone Payments

- a. Allocation. As partial consideration for the licenses, rights and privileges granted to it hereunder, a Continuing Party shall promptly inform the Opt-Out Party of the achievement of any of the below milestones and pay to the Opt-Out Party the following milestone payments on a Unilateral Product-by-Unilateral Product basis within [***] days of the first occurrence of each event set forth below with respect to a Unilateral Product to achieve such event, whether such events are achieved by the Continuing Party, its Affiliates, or Sublicensees, as follows:

In case of Continuing Party developing from **Selection of a Clinical Candidate**:

[***]

In case of Continuing Party developing from **Proposed IND Submission**:

[***]

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[***]

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[***]

- b. Clarifications. All milestone payments shall only become due and payable once per Unilateral Product and Indication. If any of the development milestone events is achieved before the previous development milestones having become payable, the previous development milestones shall become due and payable with the achievement of such milestone event. If a development milestone has not been achieved, but the Continuing Party decides to continue the development in spite of such failure to achieve the milestone, the relevant development milestone shall be deemed to be achieved. For the avoidance of doubt, if a Unilateral Product is replaced by a Back-up Candidate only such milestones not already paid for the Unilateral Product shall become payable for the Back-up Candidate.

1.2 Royalties.

- a. **Royalties Payable on Net Sales of Unilateral Products.** In partial consideration for the license for a Unilateral Product granted to the Continuing Party herein, during the Royalty Term and subject to (b) below, the Continuing Party shall pay to the other Party royalties on the aggregate Net Sales of all Unilateral Products, on a country-by-country basis. Such royalties shall be paid at the following rates as set forth below:
- (i) In case of Continuing Party developing from **Selection of a Clinical Candidate:**
[***]
 - (ii) In case of Continuing Party developing from **Proposed IND Submission:**
[***]
 - (iii) In case of Continuing Party developing from **Establishment of Clinical Proof of Concept:**
[***]
- b. **Royalty Offsets and Reductions**
- (i) Subject to the royalty offset set forth in (ii) and (iii) below, the Continuing Party shall be solely responsible for paying all amounts, including any license fees, milestones and royalties owed to Third Parties by either Genmab or Biontech on account of developing and commercializing a Unilateral Product, including any royalties owed due to use of the Biontech Technology or Genmab Technology, without reduction of, or offset against, the royalties payable to the Opt-Out Party hereunder.
 - (ii) Notwithstanding Section (i) and only if Biontech has opted-out at Establishment of Clinical Proof of Concept, on a Calendar Quarter-by-Calendar Quarter and country-by-country basis, Genmab [***] for intellectual property rights that are necessary to ensure product compound improvements and overcome freedom to operate obstacles (excluding for the

avoidance of doubt intellectual property rights necessary for manufacturing formulation or processes) with respect to a Genmab Unilateral Product against the royalties that would otherwise be payable to Biontech pursuant to Section 1.2(a) for such Genmab Unilateral Product. Notwithstanding anything to the contrary in this subsection (ii), in no event shall the royalty payments due and payable to Biontech pursuant to Section 1.2(a) with respect to a Genmab Unilateral Product in any Calendar Quarter and country be [***].

- (iii) Notwithstanding Section (i) and only if Genmab has opted-out at Establishment of Clinical Proof of Concept, on a Calendar Quarter-by-Calendar Quarter and country-by-country basis, Biontech [***] by Biontech to Third Parties for intellectual property rights that are necessary to ensure product compound improvements and overcome freedom to operate obstacles (excluding for the avoidance of doubt intellectual property rights necessary for manufacturing formulation or processes) with respect to a Biontech Unilateral Product against the royalties that would otherwise be payable to Genmab pursuant to Section 1.2(a) for such Biontech Unilateral Product. Notwithstanding anything to the contrary in this subsection (iii), in no event shall the royalty payments due and payable to Genmab pursuant to Section 1.2(a) with respect to a Biontech Unilateral Product in any Calendar Quarter and country be reduced by [***].
 - (iv) In the event that at any time during the applicable Royalty Term, in respect to a Unilateral Product in a specific country, the following has occurred; (a) the market share of such Product is less [***] in such country in a calendar year; and (b) the decline in such market share is attributable to the marketing or sale in such country of a Generic Product of such Unilateral Product by a Third Party, the applicable royalty rate shall be reduced by [***] in such country for the remainder of the Royalty Term applicable for such Unilateral Product in such country.
 - (v) In the event that a Valid Patent Claim of a patent covering composition of matter or method of use with respect to a Unilateral Product in the country of sale does not exist at any time during the applicable Royalty Term, the applicable royalty rate shall be [***] in such country for the remainder of the Royalty Term applicable for such Unilateral Product in such country.
- c. Reference to Certain Provisions of the Agreement. Sections 7.8 and 7.9 of the Agreement shall apply correspondingly to royalty payments.
- d. Royalty Reports, Exchange Rates
- (i) Royalty Reports. During the Royalty Term, any Party paying royalties hereunder (the **Paying Party**) shall furnish to the non-Paying Party, with respect to each Calendar Quarter, a written report showing, on a consolidated basis in reasonably specific detail and on a country-by-country basis, (a) the Net Sales of Unilateral Products sold by the Paying Party, its Affiliates and its Sublicensees in the Territory during the corresponding Calendar Quarter

on a Unilateral Product-by-Unilateral Product and country-by-country basis to calculate Net Sales; (b) the royalties payable in US Dollars, if any, which shall have accrued hereunder based upon such Net Sales of Unilateral Products; (c) the withholding taxes, if any, required by Applicable Law to be deducted in respect of such royalties; (d) the dates of the First Commercial Sale of each Unilateral Product in each country in the Territory, if it has occurred during the corresponding Calendar Quarter; and (e) the exchange rates used in determining the royalty amount expressed in Dollars (collectively the *Royalty Reports*).

- (ii) **Report Due Date.** Royalty Reports and royalty payments shall be due on the [***] day following the end of the Calendar Quarter to which such Royalty Report relates. The Parties shall keep complete and accurate records in sufficient detail to properly reflect all gross sales and Net Sales and to enable the royalties payable hereunder to be determined. The provisions on audit and dispute resolution in Sections 7.8 and 7.9 of the Agreement shall apply *mutatis mutandis*.
- (iii) **Exchange Rates.** With respect to sales of Unilateral Products invoiced in US Dollars, the gross sales, Net Sales, and royalties payable shall be expressed in US Dollars. With respect to sales of Unilateral Products invoiced in a currency other than US Dollars, the gross sales, Net Sales and royalties payable shall be expressed in the currency of the invoice issued by the Party making the sale together with the US Dollars equivalent of the royalty due, calculated as described in Section 7.10 of the Agreement.

1.3 FTE Rate. A Continuing Party shall pay the Opt-Out Party at an annual rate of [***] per FTE who performs consultation or support work for Unilateral Products in the pre-clinical phase as requested by the Continuing Party pursuant to this Agreement and an annual rate of [***] per FTE who performs development, consultation or support work for Unilateral Products after the pre-clinical phase as requested by the Continuing Party pursuant to this Agreement (the **FTE Fee**). Such development, consultation or support work shall be at the sole discretion of the Opt-Out Party. Commencing upon the [***] anniversary of the Effective Date and upon [***] anniversary thereafter, the fee will be adjusted in accordance with the percentage change over the applicable annual period in the consumer price inflation in the euro area as measured by the Harmonised Index of Consumer Prices (“HICP”).

2. Other Terms

2.1 Conduct. A Continuing Party shall comply with all Applicable Laws (including GxPs to the extent applicable) in the development and commercialization of Unilateral Products, and shall cause its Affiliates and Sublicensees to do the same.

2.2 Funding and Progress Reports. A Continuing Party shall be solely responsible for funding all costs of the development and commercialization of its Unilateral Product(s). A Continuing Party shall keep the other Party’s Alliance Manager informed on a quarterly basis on the progress of development as well as any milestone projections. Annually and no later than January 15 in the subsequent calendar year a Continuing

Party shall send a written report on the progress of the development of its Unilateral Product(s) in the previous calendar year. Also, if the Continuing Party decides to cease development of the Unilateral Product, the other Party's Alliance Manager shall be informed in writing thereof with [***] calendar days.

- 2.3 Manufacturing.** A Continuing Party shall be responsible for all manufacturing and supply of its Unilateral Product(s).
- 2.4 Regulatory.** A Continuing Party shall be solely responsible for, and shall solely own, all applications for Regulatory Approval with respect to its Unilateral Product(s), and the Opt-Out Party shall, if applicable, have the obligation to transfer and assign any regulatory documents, contracts, etc. that has been assigned to it pursuant to Section 5.1b of the Agreement to the Continuing Party. Should a Continuing Party desire to file an IND or an application for Regulatory Approval, or equivalents of the foregoing, for a Unilateral Product, the Opt-Out Party agrees to provide at the Continuing Party's request, any and all technical information the Opt-Out Party has created or possesses that is reasonably required by the Continuing Party. The sharing of such information can be by exchange of documents and/or through telephone or personal meetings. The Continuing Party shall reimburse the Opt-Out Party for any out of pocket costs incurred by the Opt-Out Party in providing any such information or assistance pursuant to this Section 2.4, plus an amount equal to the then current FTE Fee for personnel engaged in such activities. If ownership of a regulatory filing for a former Collaboration Product cannot be assigned to a subsequent Continuing Party in any country, the Opt-Out Party shall grant to the Continuing Party a permanent, exclusive and irrevocable right of access and reference to such regulatory filing for such former Collaboration Product in such country.
- 2.5** Notwithstanding that a Continuing Party shall be solely responsible for the clinical development and commercialization of its Unilateral Product(s), Section 5.5 of the Agreement shall apply to the reporting of Adverse Events and Serious Adverse Events relating to such Unilateral Product(s).
- 2.6 Expiry of Royalty Term.** Upon the expiration of the Royalty Term for a certain Unilateral Product, the Opt-Out Party shall grant, and shall by this provision be deemed to have granted, to the Continuing Party a royalty free, perpetual, worldwide, non-exclusive license to use the Joint Patents, if any, Assigned Patents, and Biontech Technology or Genmab Technology, as applicable, to make, use, sell, offer for sale and import such Biontech Unilateral Product or Genmab Unilateral Product, as applicable, with no further obligations to the Opt-Out Party.

Exhibit 2: Biontech Patents

Exhibit 3: Genmab Patents

[***]

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Exhibit 4: Antibody Panel

Table 1: List of all available antibodies [***] from BioNTech ([***] antibodies).

[***]

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Table 4: Current list of antibodies, which were identified to be agonistically targeting [***] antibodies)

[***]

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Table 5: Current list of antibodies, which were identified to bind to [***], but were not shown to agonistically targeting so far ([***] antibodies)

[***]

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Table 6: Current list of antibodies, which were identified to [***], but were not shown to agonistically targeting so far ([***] antibodies)

[***]

Table 7: Current list of antibodies, which were identified to [***], but were not shown to agonistically targeting so far ([***] antibodies).

[***]

List of so far identified [***] or [***]:

[***]

Exhibit 5: Research Plan

[to be inserted in due course in accordance with Section 2.2 of the Agreement]

Exhibit 6: Joint Development Plan and Budget

[to be inserted in due course]

Exhibit 7: Company Announcement and Media Release

THE SYMBOL “[*]” DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED**

Amendment No 1

to the License and Collaboration Agreement of 19th May 2015

by and between

BioNTech AG

and

Genmab A/S

This Amendment No 1 is made the 18th day of May 2017 (the “Amendment No 1 Effective Date”), by and between

GENMAB A/S, a Danish corporation having its principal Office at Bredgade 34E, 1260 Copenhagen K, Denmark, CVR no. 2102 3884 (“Genmab”), and

BIONTECH AG, a German corporation having its principal office at An der Goldgrube 12, 55131 Mainz, Germany (“BioNTech”)

(Genmab and BioNTech are sometimes hereinafter referred to collectively as the “Parties” or individually as a “Party”)

RECITALS:

- A. Genmab and BioNTech entered into a License and Collaboration Agreement on 19 May 2015 to jointly research, develop and commercialize polypeptide-based bispecific antibodies using Genmab’s proprietary DuoBody® Platform technology against certain target combinations in combination with Genmab’s proprietary [***] Technology for the treatment of cancer (“the Agreement”);
- B. Genmab and BioNTech entered into a Side Letter on 8 January 2016 regarding New Collaboration IP; and
- C. Genmab and BioNTech entered into a Side Letter No 2 on 13 May 2016 to include Genmab B.V.’s [***] Technology in Phase A of the collaboration to investigate the applicability of this technology and combination of this technology with the Inert Format Technology and/or DuoBody Platform technology with respect to certain Collaboration Targets expressed on the same cell (the cis concept);

NOW, THEREFORE, in consideration of the premises and the mutual covenants and agreements herein contained, and for good and valuable consideration the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, hereby agree to amend the Agreement as follows:

1. Except as otherwise defined herein, the words and phrases in the Agreement shall have the same meaning in this Amendment No 1.
2. Section 2.5 of the Agreement is deleted in its entirety and replaced by the below new Section 2.5 with retroactive effect from the Effective Date:

“2.5 Duration of Phase A. The joint research and development activities in Phase A are scheduled for an initial term of [***] years starting on the Effective Date. The Parties shall discuss in good faith an extension of Phase A at the latest [***] months before the end of the initial term, provided that any extension of Phase A shall require the written mutual agreement between the Parties.”

3. The Research Plan is hereby amended by adding the below additional research activities:

For the trans product concepts, additional *in vivo* POC, *in vitro* immunogenicity screening and *in vitro* MoA studies will be performed to support clinical candidate nomination.

For the tumor targeting approach, additional *in vitro* and *in vivo* POC experiments will be performed for [***] support selection of preferred target and antibody combinations. In case POC is established, selected clone(s) will be humanized and tested in *in vivo* models and exploratory toxicity studies.

The Joint Research Committee (JRC) shall decide and document:

- the specific details of the agreed additional research activities to be performed
- the budget for the additional research activities
- the allocation of FTEs for the additional research activities,
- the relevant criteria to be met for establishing POC, and
- the relevant specifications to be met for nominating a Clinical Candidate

4. Save as set forth in this Amendment No 1, all other terms and conditions of the Agreement shall remain in full force and effect.

5. This Amendment No 1 may be signed in any number of counterparts with the same effect as if the signatures to each counterpart were upon a single instrument, and all such counterparts together shall be deemed an original of this Amendment No 1.

IN WITNESS WHEREOF, authorized representatives of the Parties have duly executed this Amendment No 1 as of the Amendment No 1 Effective Date.

For GENMAB A/S:

By: _____ [***]
Name: _____ [***]
Title: _____ [***]

For BIONTECH AG:

By: _____ [***]
Name: _____ [***]
Title: _____ [***]

THE SYMBOL “[*]” DENOTES PLACES WHERE CERTAIN IDENTIFIED
INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i)
NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE
COMPANY IF PUBLICLY DISCLOSED**
AMENDMENT No 2

to

the License and Collaboration Agreement of 19th May 2015

by and between

BioNTech AG

and

Genmab A/S

1

This Amendment No 2 is made and entered into as of [###] (Amendment No 2 Effective Date) by and between BioNTech AG, a German corporation having its principal office at An der Goldgrube 12, 55131 Mainz, Germany (Biontech) and Genmab A/S, CVR no. 21023884, a Danish corporation having its principal office at Bredgade 34E, DK-1260 Copenhagen K, Denmark, (Genmab) (Biontech and Genmab each a Party and together the Parties).

PREAMBLE

WHEREAS, Biontech and Genmab are parties to a certain License and Collaboration Agreement of 19th May 2015 by and between BioNTech AG and Genmab A/S, as amended by the Amendment No 1 dated May 18, 2017 (the “Agreement”) as well as a Side Letter dated January 8, 2016 and a Side Letter No 2 dated May 13, 2016 (as amended by the Amendment No 1 to Side Letter No 2 dated May 19, 2017;

WHEREAS, Biontech and Genmab wish to include Genmab’s proprietary [***] antibody panel (the “[***] Antibodies”) in the collaboration, and the Parties may want to include further proprietary antibody panels in the collaboration in the future upon prior written mutual agreement;

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants set forth below, the Parties, intending to be legally bound, hereby agree to amend the Agreement as follows:

1. Except as otherwise defined herein, the words and phrases in the Agreement shall have the same meaning as in this Amendment No 2.
2. New Exhibit 8 as attached to this Amendment No 2 shall be included as an integral part of the Agreement.
3. Section 1.29 is hereby deleted and restated in its entirety as follows:
“1.29 Collaboration Targets means the following antigens: [***] (also known as [***] (also known as [***] and [***]. Further Collaboration Targets may be added through written amendment of the Research Plan.”
4. The following new Section 1.49A shall be inserted immediately after Section 1.49:
“1.49A [*] Tumor Targeting Product Concept** means any one of the product concepts listed below:
[***]
5. Section 1.64 is hereby deleted and restated in its entirety as follows:

“Genmab Antibodies means the [***] Antibodies and [***] Antibodies as well as further Antibodies proprietary to Genmab that may be included in the collaboration and listed in the Research Plan upon prior written mutual agreement.”

6. The following new Section 1.97A shall be inserted immediately after Section 1.97:

“1.97A [*] Agreement** means the Amended and Restated Evaluation and Commercialization Agreement, entered into as of July 12, 2012, but effective as of February 25, 1999 by and between [***] and Genmab A/S for using [***] for generating and developing antibodies for treatment of humans. A redacted copy of the [***] Agreement shall be provided to Biontech upon request.”

7. The following new Section 1.101A shall be inserted immediately after Section 1.101:

“1.101A [*] Agreement** means the Platform License Agreement entered into by Genmab A/S, Genmab B.V. and [***] (“[***]”), dated October 1, 2014 for the development and commercialization of products generated by Genmab A/S and/or Genmab B.V. using the [***] Technology (as that term is defined in the [***] Agreement). A summary of the financial terms for the development and commercialization of products generated under this [***] Agreement is set forth in Exhibit 8. A redacted copy of the [***] Agreement shall be provided to Biontech upon request.”

8. The following new Sections 1.108A and 1.108B shall be inserted immediately after Section 1.108:

“1.108A [*] Antibodies** means the 39 Antibodies against [***] proprietary to Genmab, which have been generated by Genmab using the [***] technology pursuant to the [***] Agreement.”

“1.108B [*] Tumor Targeting Product Concept** means any one of the product concepts listed below:

[***]

For the avoidance of doubt, the term [***] **Tumor Targeting Product Concept** shall also include abovementioned product concepts whose mode-of-action may rely, in whole or in part, on transactivation of T cells and antigen-presenting cells, or, as the case may be, on any other mode-of-action as may be revealed by future preclinical and/or clinical research.

9. The following new Section 1.140 shall be inserted immediately after Section 1.139:

“1.140 [***] **Antibodies** means the [***] Antibodies against [***] proprietary to Genmab, which have been generated by Genmab using [***] transgenic mouse technology pursuant to the [***] Agreement.”

10. The following new Sections 7.1A-7.1E shall be inserted immediately after Section 7.1:

“7.1A Upfront payment by [*] for use of [***] Antibodies**

[***] shall pay to [***] the following non-refundable payments on a Collaboration Product-by-Collaboration Product or [***] Unilateral Product-by-[***] Unilateral Product basis incorporating a [***] Antibody in a [***] Tumor Targeting Product Concept:

- a. [***] within [***] following the date on which the Joint Research Committee for the first time and in accordance with Section 2.10 (as documented by the minutes of the Joint Research Committee) selects a Preferred Clinical Candidate which incorporates a Genmab Antibody in a Tumor Targeting Product Concept; and such Preferred Clinical Candidate is either (i) advanced to a Collaboration Product pursuant to Section 2.10 or (ii) a [***] Unilateral Product pursuant to Section 2.11;
- b. [***] within [***] following the date on which (i) the Joint Steering Committee determines that there is Freedom-to-Operate for the [***] Antibody included in the Collaboration Product in accordance with the criteria set forth and agreed by the Joint IP Committee or (ii) [***] determines that there is Freedom-to-Operate for the [***] Antibody included in the Unilateral Product in accordance with the criteria set forth and agreed by the Joint IP Committee. The criteria shall stipulate that there shall be Freedom-to-Operate provided no claims of a patent issued in the [***] or [***] expiring after [***] disclose the [***] Antibody included in the Collaboration Product or Unilateral Product or use thereof for the treatment of cancer indications contemplated for the Collaboration Product or Unilateral Product as reflected in the applicable development plan, and provided no [***] application, [***] application or [***] application exists expiring after [***] with narrow and concrete claims covering the Genmab Antibody included in the Collaboration Product or Unilateral Product or use thereof for the treatment of cancer indications contemplated for the Collaboration Product or Unilateral Product as reflected in the applicable development plan. Further criteria may be defined and agreed by the Joint IP Committee in connection with the Selection of a Clinical Candidate. The Freedom-to-Operate determination shall be made prior to the filing of an IND. Should Biontech determine that there is not Freedom-to-Operate with respect to a Unilateral Product it shall provide Genmab with written evidence in support of that finding under a joint defense agreement to be entered into by the Parties.

For the avoidance of doubt, the payment under Section 7.1A.a and Section 7.1A.b shall not be considered a milestone payment, and shall not become due or payable upon the achievement of any other milestones set forth in this Agreement, but only upon occurrence of the events set forth in this Section 7.1A.a or Section 7.1A.b.

7.1B Payment by [*] for use of [***] Antibodies**

[***] shall pay to [***] the following non-refundable payment on a Collaboration Product-by-Collaboration Product or [***] Unilateral Product-by-[***] Unilateral Product basis incorporating a [***] Antibody in a [***] Tumor Targeting Product Concept:

[***] within [***] following the dosing of the [***] patient in the first Phase I Clinical Trial (or the first part of a Phase I/II Clinical Trial) for the [***] Indication.

This payment shall be in addition to any payments due for a Unilateral Product as set forth in Exhibit 1.

For the avoidance of doubt, the payment under Section 7.1B shall not be considered a milestone payment, and shall not become due or payable upon the achievement of any other milestones set forth in this Agreement, but only upon occurrence of the events set forth in this Section 7.1B.

7.1C Upfront payment by [*] for use of [***] Antibodies in a Tumor Targeting Product Concept**

[***] shall pay to [***] the following non-refundable payments on a Collaboration Product-by-Collaboration or [***] Unilateral Product-by [***] Unilateral Product basis incorporating an [***] Antibody in a Tumor Targeting Product Concept:

- a. [***] within [***] following the date on which the Joint Research Committee for the first time and in accordance with Section 2.10 (as documented by the minutes of the Joint Research Committee) selects a Preferred Clinical Candidate which incorporates an [***] Antibody in an [***] Tumor Targeting Product Concept; and such Preferred Clinical Candidate is either (i) advanced to a Collaboration Product pursuant to Section 2.10 or (ii) a [***] Unilateral Product pursuant to Section 2.11;
- b. [***] within [***] following the date on which (i) the Joint Steering Committee determines that there is Freedom-to-Operate for the [***] Antibody included in the Collaboration Product in accordance with the criteria set forth and agreed by the Joint IP Committee or (ii) Genmab

determines that there is Freedom-to-Operate for the [***] Antibody included in the Unilateral Product in accordance with the criteria set forth and agreed by the Joint IP Committee. The criteria shall stipulate that there shall be Freedom-to-Operate provided no claims of a patent issued in the [***] or [***] expiring after [***] disclose the [***] Antibody included in the Collaboration Product or Unilateral Product or use thereof for the treatment of cancer indications contemplated for the Collaboration Product or Unilateral Product as reflected in the applicable development plan, and provided no [***] application, [***] application or [***] application exists expiring after [***] with narrow and concrete claims covering the [***] Antibody included in the Collaboration Product or Unilateral Product or use thereof for the treatment of cancer indications contemplated for the Collaboration Product or Unilateral Product as reflected in the applicable development plan, and provided no [***] application, [***] application or [***] application exists expiring after [***] with narrow and concrete claims covering the [***] Antibody included in the Collaboration Product or Unilateral Product as reflected in the applicable development plan. Further criteria may be defined and agreed by the Joint IP Committee in connection with the Selection of a Clinical Candidate. The Freedom-to-Operate determination shall be made prior to the filing of an IND. Should Genmab determine that there is not Freedom-to-Operate with respect to a Unilateral Product it shall provide Biontech with written evidence in support of that finding under a joint defense agreement to be entered into by the Parties.

For the avoidance of doubt, the payment under Section 7.1C.a and Section 7.1C.b shall not be considered a milestone payment, and shall not become due or payable upon the achievement of any other milestones set forth in this Agreement, but only upon occurrence of the events set forth in this Section 7.1C.a or Section 7.1C.b.

7.1D Payment by [*] for use of [***] Antibodies in [***] Tumor Targeting Product Concept**

[***] shall pay to [***] the following non-refundable payment on a Collaboration Product-by-Collaboration Product or [***] Unilateral Product-by-[***] Unilateral Product basis incorporating an [***] Antibody in an [***] Tumor Targeting Product Concept:

[***] within [***] weeks following the dosing of the first patient in the first Phase I Clinical Trial (or the first part of a Phase I/II Clinical Trial) for the first Indication.

This payment shall be in addition to any payments due for a Unilateral Product as set forth in Exhibit 1.

For the avoidance of doubt, the payment under Section 7.1D shall not be considered a milestone payment, and shall not become due or payable upon the achievement of any other milestones set forth in this Agreement, but only upon occurrence of the events set forth in this Section 7.1D.

For the avoidance of doubt, if a Collaboration Product becomes a Unilateral Product, the payments already made for the Collaboration Product pursuant to Sections 7.1A-7.1D, as applicable, shall be deemed paid for the Unilateral Product and shall not become payable again.

7.1E Future Collaboration Products or Unilateral Products using additional proprietary antibodies

In case the Parties decide, by prior written agreement, to include further Antibodies proprietary to either of the Parties in the collaboration, the principles outlined in Sections 7.1A-7.1D and Section 9.1j shall apply with respect to such proprietary Antibodies, and the Agreement shall be amended accordingly to reflect this. For the avoidance of doubt, if any such further proprietary Antibodies are to be used in combination with an [***] Antibody, a [***] Antibody or a [***] Antibody, payments are still due for the use of an [***] Antibody, a [***] Antibody or a [***] F Antibody in accordance with the principles outlined in Sections 7.1A-7.1D.”

11. New Section 9.1j shall be inserted immediately after Section 9.1i:

“j. The Parties agree, with respect to any joint patent filings on any Collaboration Product or Unilateral Product incorporating a [***] Antibody in an [***] Tumor Targeting Product Concept or an [***] Antibody in an [***] Tumor Targeting Product Concept, that the Parties shall only be allowed to specifically disclose the Preferred Clinical Candidate and one (1) Back-up Candidate, if applicable, in such joint patent filings, unless the Parties mutually agree that further Bispecific Antibodies may be included.“

12. New Sections 10.A, 10.B and 10.C shall be inserted immediately after Section 10:

“**10A. [***] Antibodies** The Parties acknowledge that the use of any [***] Antibodies in a Collaboration Product or Unilateral Product shall be subject to the terms and conditions of the [***] Agreement, including the financial terms as outlined in Exhibit 8. The Parties shall share the payments pursuant to the [***] Agreement [***] in case of a Collaboration Product. [***] shall be solely responsible for the payments pursuant to the [***] Agreement with respect to a [***] Unilateral Product, and [***] shall be solely responsible for the payments pursuant to the [***] Agreement with respect to a [***] Unilateral Product, and shall reimburse [***] for all payments due under the [***] Agreement for such Biontech Unilateral Product. Genmab hereby grants to Biontech a sublicense under its rights under the [***] Agreement for the [***] Antibodies it being understood that Sections 9.3, 14.7c and 14.7d of this Agreement shall apply *mutatis mutandis* to this sublicense, except that the payment structure with respect to the [***] Agreement shall be as set forth in this Section 10.A.”

10B. [*] Antibodies** The Parties acknowledge that the use of any [***] Antibodies in a Collaboration Product or Unilateral Product shall be subject to the terms and conditions of the [***] Agreement. [***] is an [***] (as that term is defined in the [***] Agreement). Genmab hereby grants to Biontech a sublicense under its rights under the [***] Agreement for the [***] Antibodies it being understood that Sections 9.3, 14.7c and 14.7d of this Agreement shall apply *mutatis mutandis* to this sublicense.

10C. [*] Antibodies** Biontech declares that the use of any [***] Antibodies in a Collaboration Product or Unilateral Product are not subject to any special terms or conditions of an underlying agreement.”

13. Save as set forth in this Amendment No 2, all other terms and conditions of the Agreement shall remain in full force and effect.
14. This Amendment No 2 may be signed in any number of counterparts with the same effect as if the signatures to each counterpart were upon a single instrument, and all such counterparts together shall be deemed an original of the Amendment No 2.

[REST OF PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, authorized representatives of the Parties have duly executed this Amendment No 2 as of the Amendment No 2 Effective Date.

For BioNTech AG:

Date: AUGUST 4, 2017

Signature: _____ [***] _____

Print name: _____ [***] _____

Title: _____ [***] _____

Genmab A/S

Date: 4 AUGUST 2017

Signature: _____ [***] _____

Print name: _____ [***] _____

Title: _____ [***] _____

[***]

THE SYMBOL “[*]” DENOTES PLACES WHERE CERTAIN IDENTIFIED
INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i)
NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE
COMPANY IF PUBLICLY DISCLOSED**
AMENDMENT No 3

to

the License and Collaboration Agreement of 19th May 2015

by and between

BioNTech AG

and

Genmab A/S

1

This Amendment No 3 is made and entered into as of the 18 May 2018 (Amendment No 3 Effective Date) by and between BioNTech AG, a German corporation having its principal office at An der Goldgrube 12, 55131 Mainz, Germany (Biontech) and Genmab A/S, CVR no. 21023884, a Danish corporation having its principal office at Kalvebod Brygge 43, DK-1560 Copenhagen V, Denmark, (Genmab).

(Biontech and Genmab each a “Party” and together the “Parties”).

PREAMBLE

WHEREAS, Biontech and Genmab are parties to a certain License and Collaboration Agreement of 19th May 2015 by and between BioNTech AG and Genmab A/S, as amended by the Amendment No 1 dated May 18, 2017 and Amendment No 2 dated August 4, 2017 (the “Agreement”) as well as a Side Letter dated January 8, 2016, a Side Letter No 2 dated May 13, 2016 (as amended by the Amendment No 1 to Side letter No 2 dated May 19, 2017) and a Side Letter No 3 dated September 25, 2017;

WHEREAS, Biontech and Genmab wish to extend the Duration of Phase A;

NOW, THEREFORE, in consideration of the premises and the mutual covenants and agreements herein contained, and for good and valuable consideration the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, hereby agree to amend the Agreement as follows:

1. Except as otherwise defined herein, the words and phrases in the Agreement shall have the same meaning in this Amendment No 3.
2. Section 2.5 of the Agreement is deleted in its entirety and replaced by the below new Section 2.5 with retroactive effect from the Effective Date.

“**2.5 Duration of Phase A.** The joint research and development activities in Phase A are scheduled for an initial term of four (4) years starting on the Effective Date. The Parties shall discuss in good faith an extension of Phase A at the latest three (3) months before the end of the initial term, provided that any extension of Phase A shall require the written mutual agreement between the Parties.”
3. Save as set forth in this Amendment No 3, all other terms and conditions of the Agreement shall remain in full force and effect.
4. This Amendment No 3 may be signed in any number of counterparts with the same effect as if the signatures to each counterpart were upon a single instrument, and all such counterparts together shall be deemed an original of the Amendment No 3.

IN WITNESS WHEREOF, authorized representatives of the Parties have duly executed this Amendment No 3 as of the Amendment No 3 Effective Date.

For BioNTech SE:

Date: 10 December 2018

Signature: [***]_____

Print name: [***]_____

Title: [***]_____

Genmab A/S

Date: 11 December 2018

Signature: [***]_____

Print name: [***]_____

Title: [***]_____

THE SYMBOL “[***]” DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED

EXECUTION COPY

COLLABORATION AND LICENSE AGREEMENT

This COLLABORATION AND LICENSE AGREEMENT (this **Agreement**) is entered into effective as of November 2nd, 2015 (the **Effective Date**), by and between Sanofi, having a place of business at 54, rue La Boétie, 75008 Paris, France (**Sanofi**), and Biontech RNA Pharmaceuticals GmbH, having a place of business at An der Goldgrube 12, 55131 Mainz, Germany (**Biontech**). Sanofi and Biontech shall each individually be referred to herein as a **Party**, and shall be referred to jointly as the **Parties**.

RECITALS

A. Sanofi is a global leader in the pharmaceutical industry with expertise in research, development, manufacturing and marketing of innovative therapeutics in a range of areas including oncology.

B. Biontech, a wholly-owned subsidiary of BioNTech AG, is a drug discovery and development company that has expertise in immunotherapies and owns a number of technologies, know-how and patent rights relating to RNA-based compounds, constructs and methods including a Ribological® drug platform using proprietary mRNA modifications for pharmacologically optimized synthetic mRNA drugs to generate effective, long-term protein expression, an in-house Ribotransporter formulation platform enabling targeted mRNA delivery *in vivo*, and clinical-grade platforms for organ-specific mRNA delivery.

C. The Parties desire to collaborate in the research, development and commercialization of RNA-based therapeutics for the treatment of cancer.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants set forth below, the Parties hereby agree as follows:

1. Definitions.

For purposes of this Agreement, the terms defined in this Section 1 shall have the respective meanings set forth below:

1.1 **Affiliate** shall mean, with respect to any person or entity, any other person or entity, which directly or indirectly controls, is controlled by, or is under common control with, such person or entity. A person or entity shall be regarded as in control of another person or entity if it owns, or directly or indirectly controls, more than fifty percent (50%) of the voting stock or other ownership interest of the other person or entity, or if it directly or indirectly possesses the power to direct or cause the direction of the management and policies of the other person or entity by any means whatsoever. Notwithstanding the foregoing, AT Impf GmbH, Am Rosenheimer Platz 6, 81669 Munich, Germany, and any person or entity controlled by AT Impf GmbH (other than Biontech or any person or entity controlled by Biontech), shall not be Affiliates of Biontech and shall be regarded as Third Parties for the purposes of this Agreement.

1.2 **Alliance Manager** is defined in Section 11.1.

1.3 **Anti-Corruption Laws** shall mean the U.S. Foreign Corrupt Practices Act, as amended, the UK Bribery Act 2010, as amended, and any other applicable anti-corruption laws and laws for the prevention of fraud, racketeering, money laundering or terrorism.

1.4 **Applicable Law** means any law or statute, any rule or regulation issued by any government authority (including Regulatory Authorities), any GCP, GLP or GMP regulations or guidelines as well as any judicial, governmental, or administrative order, judgment, decree or ruling, in each case as applicable to the subject matter and the Party at issue.

1.5 **Approved Subcontractor** shall mean a subcontractor engaged by a Party that has been approved by the Joint Steering Committee to perform specific obligations of the subcontracting Party.

1.6 **Background Technology** shall mean all Intellectual Property Rights Controlled by a Party on the Effective Date and all Intellectual Property Rights over which a Party has gained Control outside the scope of the collaboration hereunder until the end of the Research Term.

1.7 **Biontech Background Technology** shall mean Background Technology Controlled by Biontech.

1.8 **Biontech Collaboration Know-how** shall mean any Joint Collaboration Know-how assigned to Biontech pursuant to Section 7.2.3(c).

1.9 **Biontech Collaboration Patent** is defined in Section 7.1.

1.10 **Biontech Collaboration Technology** shall mean the Biontech Collaboration Patents and the Biontech Collaboration Know-how.

1.11 **Biontech Field Mixture** is defined in Section 4.2.1.

1.12 **Biontech Foreground Technology** shall mean all Intellectual Property Rights made, conceived and first reduced to practice by Biontech alone or together with a Third Party in the conduct of the Development and Commercialization of (a) Licensed Products outside of the Field, and/or (b) Discarded Mixtures and/or Option Products in the Field or outside of the Field, in each case (a) and (b) following the end of the Research Term.

1.13 **Biontech Indemnities** is defined in Section 10.1.1.

1.14 **Biontech Non-Field Mixture** is defined in Section 4.2.2.

1.15 **Biontech Option Product** is defined in Section 4.1.

1.16 **Biontech Royalties** is defined in Section 6.9.1.

1.17 **Biontech Technology** shall mean (i) the Biontech Background Technology, (ii) the Biontech Collaboration Technology and (iii) Biontech's interest in the Joint Collaboration Technology, but excluding for the avoidance of doubt the Biontech Foreground Technology.

1.18 **Biontech Territory** shall mean Germany, France, Italy, Spain, the United Kingdom, [***] and the United States of America.

1.19 **Biontech Transferred Product** is defined in Section 12.4.2.

1.20 **BLA** means a Biologics License Application filed with the FDA in connection with seeking Marketing Approval of a product, or an equivalent application filed with any equivalent Regulatory Authority.

1.21 **Commercialization** means all activities directed to the marketing, detailing, promotion (including co-promotion), advertising, selling and distribution of a product in a country or region after all Marketing Approvals have been obtained in such country or region (including making, having made, using, importing, selling, having sold, offering for sale, and having offered for sale such product), and will include marketing research, customer service, administering and commercially selling such product, importing, exporting or transporting such product for commercial sale, and all regulatory compliance with respect to the foregoing; it being understood and agreed that such activities may occur pre- or post-launch of such product. When used as a verb, **Commercialize** shall mean to engage in Commercialization.

1.22 **Commercially Reasonable Efforts** means with respect to the Development or Commercialization by each Party under this Agreement of Licensed Product Candidates, Mixtures, Option Products and Licensed Products, the level of efforts and resources that a similarly situated company in the biotechnology or pharmaceutical industry of similar resources would reasonably use to accomplish a similar objective, for such similar company's own products (including internally developed, acquired and in-licensed products) of similar market potential at a similar stage in their development or product life cycle taking into account all relevant factors then prevailing, including without limitation safety and efficacy, product profile, competitiveness of alternative Third Party products and product candidates in the market place, intellectual property position, difficulty in developing or manufacturing the applicable Product, regulatory requirement and likelihood of Marketing Approval, profitability, and other relevant factors. Further, to the extent that the performance of a Party's obligations hereunder is adversely affected by the other Party's failure to perform its obligations hereunder, the impact of such performance failure will be taken into account in determining whether such Party has used its Commercially Reasonable Efforts to perform any such affected obligations.

1.23 **Confidential Information** shall mean all information of any kind whatsoever relating to the subject matter of this Agreement, and all tangible and intangible embodiments thereof of any kind whatsoever, that (i) is identified as confidential at the time of disclosure, or (ii) in the event of oral disclosures, is summarized by the Disclosing Party in a written summary delivered by the Disclosing Party to the Receiving Party within thirty (30) days after disclosure to the Receiving Party, or (iii) has been disclosed in circumstances of confidence. Notwithstanding the foregoing, Confidential Information shall not include information which the Receiving Party can establish by written documentation (i) to have been publicly known before disclosure of such information by the Disclosing Party to the Receiving Party, (ii) to have become publicly known, without fault on the part of the Receiving Party, after disclosure of such information by the Disclosing Party to the Receiving Party, (iii) to have been received by the Receiving Party at any time from a source, other than the Disclosing Party, rightfully having possession of and the right to disclose such information, (iv) to have been otherwise known by

the Receiving Party before disclosure of such information by the Disclosing Party to the Receiving Party, or (v) to have been independently developed by employees or agents of the Receiving Party without access to or use of such information disclosed by the Disclosing Party to the Receiving Party (each, a **Confidentiality Exception**). Without limiting the foregoing, (i) all information or materials within or which embody the Sanofi Technology or Sanofi Foreground Technology which do not fall within the scope of a Confidentiality Exception shall be Confidential Information of Sanofi, (ii) all information or materials within or which embody the Biontech Technology which do not fall within the scope of a Confidentiality Exception shall be Confidential Information of Biontech, and (iii) all information or materials within or which embody the Joint Collaboration Technology which does not fall within the scope of a Confidentiality Exception shall be Confidential Information of both Parties.

1.24 **Confidentiality Exception** is defined in Section 1.23.

1.25 **Control** shall mean with respect to a subject item, the ability of a Party, whether arising by ownership, possession or pursuant to a license or sublicense, to grant the licenses or sublicenses to the other Party with respect to such subject item as provided in this Agreement, without violating the terms of any agreement or other arrangement with any Third Party. When used as a verb, **Control** shall mean to exercise Control.

1.26 **Development** shall mean all drug development and other activities undertaken in order to (i) develop a product up to Marketing Approval (including obtaining Marketing Approval for such product), and (ii) conduct post-approval clinical trials. These activities shall include without limitation stability testing, toxicology testing, formulation activities, reformulation activities, process development, quality assurance/quality control development and clinical studies (including pharmacovigilance programs and outcome studies), but shall exclude all activities to be undertaken under the Research Plan or any Process Development and Supply Agreement. When used as a verb, **Develop** shall mean to engage in Development.

1.27 **Discarded Mixture** is defined in Section 6.9.2.

1.28 **Disclosing Party** is defined in Section 8.1.

1.29 **Early Opt-in Package** means a reasonably detailed written scientific and/or clinical rationale for the selection of mRNAs to be included in any Biontech Field Mixture, Biontech Non-Field Mixture, Sanofi Option Combination Product or Licensed Product outside of the Field for which Biontech intends to initiate research activities according to Section 4.2, including published reports and other relevant data obtained by Biontech.

1.30 **EBIT** means earnings before interest and taxes.

1.31 **EMA** shall mean the European Medicines Agency, and any successor agency thereto.

1.32 **Existing Biontech Affiliate** shall mean any Affiliate of Biontech as of the Effective Date.

1.33 **Expert** is defined in Section 2.8.

1.34 **Enforcing Party** is defined in Section 7.4.3(b).

1.35 **FDA** means the U.S. Food and Drug Administration, or any successor agency thereto.

1.36 **Field** shall mean the Intratumoral Administration of a Mixture for the treatment of solid Tumors in humans [***].

1.37 **First Commercial Sale** shall mean, on a product-by-product basis, the first sale of the product for which revenue has been recognized by a Party or any of its Affiliates or any of such Party or such Party's Affiliates' (sub-)licensees to any Third Party after all required Marketing Approvals have been granted. For the avoidance of doubt, First Commercial Sale shall not include the transfer or sale of the product (i) by a Party to an Affiliate or (sub-)licensee unless the Affiliate or (sub-)licensee is the last entity in the distribution chain of the product, (ii) for use in clinical trials or non-clinical development activities (e.g. material transfer agreements) or a *bona fide* charitable purpose, or (iii) for compassionate use.

1.38 **Four Quarter Period** shall mean any time period of four (4) consecutive calendar quarters commencing on January 1, April 1, July 1 or October 1, as applicable.

1.39 **FTE** shall mean a full-time employee of a Party working over the course of a twelve (12) month period, or several employees of a Party collectively working the equivalent of such full-time employee. FTEs shall be calculated based on the time an employee of the Parties spends working on a billable effort as recorded by such Parties' project time reporting system. An FTE is measured on the basis of a total of [***] hours per year for employees.

1.40 **Fusion Protein** shall mean a protein [***].

1.41 **Generic Biological Product** shall mean with respect to a Licensed Product in a given country, any product that (i) is sold under a Marketing Approval granted by a Regulatory Authority; (ii) contains the same mRNAs as such Licensed Product, notwithstanding minor differences in clinically inactive components such as diluents, buffers etc.; and (iii) is approved in reliance, in whole or in part, on (A) a prior Marketing Approval (or on any safety or efficacy data submitted in support of a prior Marketing Approval) of such Licensed Product or reference to other publicly available clinical data with respect to such Licensed Product, or (B) a demonstration of clinical equivalence to or interchangeability with such Licensed Product.

1.42 **Good Clinical Practice or GCP** shall mean any and all laws, rules, regulations, guidelines and generally accepted standards and requirements regarding the ethical conduct of clinical trials, including without limitation the U.S. Code of Federal Regulations (CFR) Title 21, ICH GCP Guidelines E6(R1), current step 4 version, dated 10 June 1996, as amended from time to time, national legislation implementing European Community Directive 2001/20/EC of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, European Community Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards to investigational medicinal products for human use.

1.43 **Good Laboratory Practice** or **GLP** shall mean any and all laws, rules, regulations, guidelines and generally accepted standards and requirements regarding quality control for laboratories to ensure the consistency and reliability of results, including without limitation the CFR Title 21, national legislation implementing European Community Directive 2004/9/EC of 11 February 2004 on the inspection and verification of good laboratory practice (GLP) as amended and European Community Directive 2004/10/EC of 11 February 2004 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances as amended, OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring.

1.44 **Good Manufacturing Practice** or **GMP** shall mean any and all laws, rules, regulations, guidelines and generally accepted standards and requirements regarding the quality control and manufacturing of pharmaceutical products, including without limitation the CFR Title 21, ICH GMP Guidelines Q7, current step 4 version, dated 10 November 2000, as amended from time to time, national legislation implementing European Community Directive 91/356/EEC of 13 June 1991 laying down the principles and guidelines of good manufacturing practice for medicinal products for human use as amended by European Community Directives 2003/94/EC, the Rules Governing Medicinal Products in the European Community, Volume 4, including annexes.

1.45 **Government Official** is defined in Section 9.4.1.

1.46 **Improvement** shall mean any Biontech Collaboration Patent which constitutes an improvement, enhancement or extension of the Biontech Background Technology and which could not be practiced without a license under a Patent Right included in the Biontech Background Technology.

1.47 **IND** means an Investigational New Drug application filed with the FDA or their equivalent in any country where a regulatory filing is required or obtained for commencement of human clinical trials of a pharmaceutical product.

1.48 **Indemnified Party** is defined in Section 10.2.

1.49 **Indemnification Claim Notice** is defined in Section 10.2.

1.50 **Initial Research Term** shall mean the initial research term as further defined in Section 2.10.1.

1.51 **Intellectual Property Rights** shall mean Patent Rights and Know-how.

1.52 **International Financial Reporting Standards** or IFRS shall mean the accounting rules and standards as issued by the International Accounting Standard Board (IASB) and as adopted by the European Union.

1.53 **Intratumoral Administration** shall mean a local administration of a therapeutic directly into the Tumor [***].

1.54 **Joint Collaboration Know-how** shall mean all Know-how generated by either Party, their Affiliates or their subcontractors under the collaboration of the Parties under the Research Plan.

1.55 **Joint Collaboration Patent** is defined in Section 7.2.3(d).

1.56 **Joint Collaboration Technology** shall mean the Joint Collaboration Know-how and the Joint Collaboration Patents.

1.57 **Joint Foreground Technology** shall mean all Intellectual Property Rights made, conceived or first reduced to practice jointly by the Parties, their Affiliates or their subcontractors in the conduct of a Development plan in relation to an Option Product or a Licensed Product following the end of the Research Term.

1.58 **Joint Steering Committee** is defined in Section 11.2.1.

1.59 **Know-how** shall mean any confidential technical or scientific information, including but not limited to processes, formulae, inventions and methods, discoveries, data, information (including scientific, technical or regulatory information), trade secrets, means, practices, instructions, procedures, techniques, materials, technology, results, analyses, designs, drawings, computer programs, apparatuses, specifications, technical assistance, laboratory, pre-clinical and clinical data (including laboratory notes and notebooks), and other material or know-how, in written, electronic or any other form, whether or not patentable, that are necessary or useful to Develop or Manufacture any Mixture, Licensed Product or Option Product, including without limitation any such Know-How that relates to any method of making any Mixture, Licensed Product or Option Product, any composition or formulations of any Mixture, Licensed Product or Option Product, or any method of using or administering any Mixture, Licensed Product or Option Product, including without limitation: development technology; biology, chemistry, pharmacology, toxicology, drug stability, Manufacturing and formulation, test procedures, synthesis, purification and isolation techniques, quality control data and information, methodologies and techniques; information regarding clinical and non-clinical safety and efficacy studies, including study designs and protocols, marketing studies, absorption, distribution, metabolism and excretion studies; assays and biological methodology and other information and data which is not generally known, in each case to the extent not disclosed or claimed by a Patent Right.

1.60 **Licensed Product** shall mean a Licensed Product Candidate or other Mixture which has been selected for further Development and Commercialization by Sanofi pursuant to Section 2.9.

1.61 **Licensed Product Candidate** shall mean a Mixture that meets the Preclinical Milestone Criteria. For the avoidance of doubt, different formulations in the Field of the same Mixture will be regarded as one Licensed Product Candidate.

1.62 **Licensed Product Patents** is defined in Section 7.1

1.63 **Losses** is defined in Section 10.1.1.

1.64 **Manufacture** or **Manufacturing** shall mean all activities in connection with the synthesis, manufacture, processing, formulating, testing (including, without limitation quality control, quality assurance and lot release testing), labeling, bulk packaging or storage and delivery of Mixture, Licensed Product Candidate or Licensed Product, or any intermediate thereof, or any finished product including any of the above.

1.65 **Marketing Approval** means any regulatory approval of any Regulatory Authority or other government authority of any country or jurisdiction in the world that is necessary to be obtained before the commercial sale of a pharmaceutical product for an indication in that country or jurisdiction.

1.66 **Mixture** shall mean two or more mRNAs administered together in the same solution [***].

1.67 **mRNA** shall mean messenger ribonucleic acid molecules encoding a polypeptide [***].

1.68 **Net Sales** shall mean the gross amounts invoiced in arms-length transactions by a Party or any of its Affiliates or any of such Party's or such Party's Affiliates' (sub-)licensees to non-Affiliated customers for sales of Licensed Products or Option Products, less the following deductions for: (i) credits, price adjustments, allowances, discounts, reimbursements and rebates to, and charge backs from the account of, customers for spoiled, damaged, outdated, rejected, or returned products; (ii) freight, postage, packing, shipping and insurance costs incurred in transporting the products, to the extent such costs are itemized in the invoiced sales price; (iii) cash, quantity, and trade discounts, chargeback payments and rebates granted to managed healthcare organizations, trade customers including wholesales and chain and pharmacy buying groups, federal, state/provincial, local and other government or agencies, refunds, billing errors, and other price reductions; (iv) wholesaler fees; (v) sales, use, value-added, and other direct taxes; (vi) customs duties, surcharges, and other governmental charges incurred in connection with the exportation or importation of the products; (vii) bad debt and uncollectable invoiced amounts actually written off; and (viii) that portion of the annual fee on prescription drug manufacturers imposed by the United States Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (as amended) or other similar governmental fee based on revenues from pharmaceutical products that a Party allocates to sales of the Licensed Products or Option Products in accordance with its policies and procedures; all as determined in accordance with International Financial Reporting Standards consistently applied. If a Party

receives non-cash consideration or in the case of transactions not at arm's length, Net Sales will be calculated based on the fair market value of such consideration or transaction, at the time of the transaction, assuming an arm's length transaction made in the ordinary course of business. Notwithstanding the foregoing, Net Sales shall not be imputed to any transfer of a product for use in clinical trials, non-clinical development activities (e.g. material transfer agreements) or other development activities with respect to a product by or on behalf of the respective Party, for bona fide charitable purposes or for compassionate use, if no monetary consideration is received for such transfers.

1.69 **Non-Enforcing Party** is defined in Section 7.4.3(b).

1.70 **Option Product** shall mean a Biontech Option Product or a Sanofi Option Product, or any or all of them, as applicable.

1.71 **Party Representatives** is defined in Section 9.4.1.

1.72 **Patent Rights** shall mean (i) all patent applications filed or having legal force in any country or jurisdiction, including all provisional patent applications; (ii) all patents that have issued or in the future will be issued from such applications, including without limitation method, process, utility, model and design patents and certificates of invention; and (iii) all divisionals, continuations, continuations in part, supplement protection certificates, reissues, reexaminations, renewals, extensions or additions to any such patent application and patents.

1.73 **Patient Population** shall mean, with respect to any Licensed Product, the targeted patient population as defined in (i) the respective draft or approved study protocol for a Phase II Clinical Trial or Phase III Clinical Trial or (ii) the respective draft or approved product label (as approved by the competent Regulatory Authority).

1.74 [***].

1.75 **Phase I Clinical Trial** shall mean a human clinical trial that is conducted to evaluate the preliminary safety, tolerability and pharmacokinetics effect of a drug in healthy volunteer subjects or patients in accordance with the requirements of 21 CFR 312.21(a) or foreign equivalents. Typical elements of a Phase I Clinical Trial are described in more detail in Section 3.1.3.1 of ICH Topic E8 (GENERAL CONSIDERATIONS FOR CLINICAL TRIALS).

1.76 **Phase I/II Clinical Trial** shall mean a human clinical trial which has the following two (2) main objectives: (i) determining preliminary safety and (ii) determining preliminary efficacy parameters in appropriate patients.

1.77 **Phase II Clinical Trial** shall mean a potentially controlled human clinical trial involving a sufficient number of patients with the disease or condition of interest to obtain sufficient efficacy and safety data of a candidate drug in the targeted patient population to support a Phase III Clinical Trial of a candidate drug for its intended use, and to define the optimal dosing regimen, such as trials referred to in 21 C.F.R. §312.21(b) and foreign equivalents. Typical elements of a Phase II Clinical Trial are described in more detail in Section 3.1.3.2 of ICH Topic E8 (GENERAL CONSIDERATIONS FOR CLINICAL TRIALS).

1.78 **Phase III Clinical Trial** shall mean a controlled, and usually multi-center, clinical trial, involving patients with the disease or condition of interest intended to obtain sufficient efficacy and safety data to support Marketing Approval of a candidate drug whether or not designated as “Phase III”, such as trials referred to in 21 C.F.R. §312.21(c) and foreign equivalents. Typical elements of a Phase III Clinical Trial are described in more detail in Section 3.1.3.3 of ICH Topic E8 (GENERAL CONSIDERATIONS FOR CLINICAL TRIALS).

1.79 **Preclinical Milestone Criteria** shall mean the criteria described in Schedule A.

1.80 **Process Development and Supply Agreement** is defined in Section 3.3.1.

1.81 **Product Sublicense Agreement** shall mean a (sub)license agreement between a Party and a (sub)licensee, as permitted under Section 7.3.4(b) under which such (sub)licensee shall obtain the right to Develop and/or Commercialize a Licensed Product or an Option Product.

1.82 **Proof of Concept** or **POC** shall mean molecular evidence of immune modulator activity and/or signs of clinical activity as outlined in the objectives of a Phase I Clinical Trial, a Phase I/II Clinical Trial or a Phase II Clinical Trial (if such Phase II Clinical Trial is required before initiating a Phase III Clinical Trial).

1.83 **Receiving Party** is defined in Section 8.1.

1.84 **Regulatory Authority** means any federal, national, multinational, state, county, city, provincial, or local regulatory agency, department, bureau or other governmental entity with authority over the marketing, Commercialization, manufacture or sale of a pharmaceutical product in any country of the world, including without limitation the FDA in the United States and the EMA in the EU.

1.85 **Research Phase** shall mean the phase of research activities of the Parties under the Research Plan as set forth in Section 2.

1.86 **Research Plan** shall mean a written research work plan which describes the work to be performed in the Research Phase, an initial copy of which is attached hereto as Schedule B.

1.87 **Research Term** shall mean the Initial Research Term and any extension period pursuant to Section 2.10.2, if applicable.

1.88 **Royalty Term** shall mean on a Licensed Product-by-Licensed Product and country-by-country basis, the period commencing on the First Commercial Sale of the Licensed Product and ending on the later of: (i) the tenth (10th) anniversary of the date of the First Commercial Sale of such Licensed Product in such country; (ii) the expiration of the last to expire Valid Patent Claim [***]. (iii) the expiration of regulatory data exclusivity [***] and (iv) market entry [***] of a Generic Biological Product to such Licensed Product [***] in such country. This definition shall apply *mutatis mutandis* to any royalty payment obligation incurred by either Party pursuant to Sections 12.4.2(c) and 12.4.5(c) in connection with the termination of any co-Development and/or co-Commercialization rights or obligations with respect to an Option Product.

1.89 **Sanofi Background Technology** shall mean Background Technology Controlled by Sanofi.

1.90 **Sanofi Foreground Technology** shall mean all Intellectual Property Rights made, conceived and first reduced to practice by Sanofi alone or with a Third Party in the conduct of the Development and Commercialization of (a) Licensed Products in the Field or (b) Option Products, in each case following the end of the Research Term.

1.91 **Sanofi Indemnitee** is defined in Section 10.1.2.

1.92 **Sanofi Option Combination Product** is defined in Section 4.2.3.

1.93 **Sanofi Option Product** shall mean any Biontech Field Mixture, Biontech Non-Field Mixture, Sanofi Option Combination Product or Licensed Product in relation to which Sanofi has exercised its co-Development and co-Commercialization option in accordance with Section 4.2.1, 4.2.2, 4.2.3 or 4.2.4, as applicable.

1.94 **Sanofi Royalties** are defined in Section 6.8.1.

1.95 **Sanofi Technology** shall mean (i) the Sanofi Background Technology, and (ii) Sanofi's interest in the Joint Collaboration Technology, but excluding for the avoidance of doubt the Sanofi Foreground Technology.

1.96 **Sanofi Transferred Product** is defined in Section 12.4.5.

1.97 **Selection Term** shall mean the time period between the Effective Date and the last day on which Sanofi may still select a Licensed Product pursuant to Section 2.9. For the avoidance of doubt, the Selection Term shall end upon the earlier of [***].

1.98 **Single mRNA** shall mean [***].

1.99 **Third Party** shall mean any person or entity other than the Parties and their respective Affiliates.

1.100 **Third Party Claim** is defined in Section 10.1.1.

1.101 **Tumor** shall mean any solid neoplasm.

1.102 **Valid Patent Claim** means an unexpired claim of an issued patent (including any extension thereof pursuant to patent term extension or a supplementary protection certification or similar proceedings) which has not been found to be unpatentable, invalid or unenforceable by an unreversed and unappealable decision (including a decision that was not appealed within the time allotted for an appeal) of a court or other authority in the subject country.

2. Research Phase—Generation of Licensed Product Candidates.

2.1 Goal of Research Phase. The goal of the Research Phase is to identify, characterize and validate, in accordance with the Research Plan, up to five (5) Licensed Product Candidates from which Sanofi may then select Licensed Products for further Development and Commercialization.

2.2 Conduct of Research. The initial Research Plan is attached hereto as Schedule B. Either Party may recommend changes to the Research Plan at any time; provided however, that such change shall only be effective upon the approval of the Joint Steering Committee in accordance with Section 11.2; and provided further that, except with respect to Fusion Proteins, Sanofi may in its sole discretion decide to modify the list of mRNAs to be evaluated under the Research Plan.

2.3 General Obligations of the Parties. During the Research Term, Biontech shall (i) use its Commercially Reasonable Efforts to identify, characterize and validate up to five (5) Licensed Product Candidates in accordance with the Research Plan, (ii) perform all other tasks and obligations assigned to it in the Research Plan in good scientific manner and in compliance with all Applicable Laws, and (iii) contribute such personnel, equipment, facilities and other resources as reasonably necessary to perform its obligations under the Research Plan and to achieve efficiently the objectives thereof. Sanofi shall (i) provide all reasonable assistance to Biontech in connection with Biontech's performance of the Research Plan and (ii) provide to Biontech such materials and information required to be provided by Sanofi under the Research Plan. Each Party will bear its own costs and expenses incurred in the performance of the tasks assigned to it in the Research Plan.

2.4 Results and Reporting during Research Phase. Biontech shall keep Sanofi fully informed as to its progress, results (including the development of any technology or inventions), status and plans for performing and implementing the Research Plan. Such information shall be given by periodic, informal oral reports, and by a quarterly written report delivered not later than [***] following the end of every calendar quarter during which any activities are performed under the Research Plan.

2.5 Maintenance of Records. Biontech shall maintain records, in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, which shall reflect the work done and the results achieved in the performance of the Research Plan in a reasonable level of detail customary for companies engaged in pharmaceutical research. Biontech shall make such records available for inspection upon reasonable written request of Sanofi for the purpose of ensuring Biontech's compliance with its research obligations hereunder. Upon request by Sanofi, Biontech shall deliver to Sanofi copies of all records described in this Section.

2.6 Subcontracting during Research Phase. Either Party may perform some or all of its obligations under the Research Plan through any of its Affiliates or one or more Approved Subcontractors; provided that (i) none of the rights of the other Party hereunder are diminished or are otherwise adversely affected as a result of such subcontracting and (ii) the Affiliate or Approved Subcontractor undertakes in writing all obligations of confidentiality and non-use regarding both Parties' Confidential Information which are substantially the same as those undertaken by the Parties hereunder. In the event that a Party performs one or more of its obligations under the Research Plan through any such Affiliate or Approved Subcontractor, then such Party shall at all times be responsible for the performance by such Affiliate or Approved Subcontractor of such Party's obligations hereunder.

2.7 Supply of mRNA constructs. As part of its obligations under this Agreement, Biontech shall provide at no charge to Sanofi all Mixtures or mRNA components of the Mixtures required for the research and Development of Licensed Product Candidates up to the completion of the respective GLP toxicology studies.

2.8 Review of Licensed Product Candidates by Joint Steering Committee. Each Party may at any time during the Research Term propose that one or more Mixtures which meet the Preclinical Milestone Criteria are approved by the Joint Steering Committee as Licensed Product Candidates, by submitting documents supporting the achievement of the Preclinical Milestone Criteria to the Joint Steering Committee. Upon such submission, the Joint Steering Committee will review and confirm in good faith whether the proposed Mixture(s) meet the Preclinical Milestone Criteria and are therefore approved as Licensed Product Candidates within reasonable time not to exceed [***] after the submission and will render its decision in writing. If the Joint Steering Committee cannot make a unanimous decision within the above mentioned period and the Parties cannot otherwise agree on whether a proposed Mixture meets the Preclinical Milestone Criteria despite having gone through the dispute resolution procedures set forth in Section 13.7, the Parties shall through the Joint Steering Committee engage an independent Third Party expert with appropriate expertise and reputation in the relevant subject matter, that is reasonably acceptable to both Parties (the **Expert**), for the sole purpose of determining whether the proposed Mixture meets the Preclinical Milestone Criteria. If the Joint Steering Committee cannot agree on the Expert, each Party shall be entitled to appoint one expert and the two experts so appointed shall collectively designate the Expert. The Expert shall execute a customary confidentiality agreement and agree to render its determination with [***] after the engagement. Each Party shall bear fifty percent (50%) of the costs incurred in the engagement of the Expert. The determination of the Expert shall be binding on both Parties.

2.9 Selection of Licensed Products by Sanofi. With respect to each Licensed Product Candidate approved pursuant to Section 2.8, Sanofi may at its sole discretion decide to conduct GLP toxicology studies in non-human primates or other relevant species and, if Sanofi decides to conduct such studies with respect to a Licensed Product Candidate, Sanofi shall complete such studies within [***] after delivery of the relevant Licensed Product Candidate material. Sanofi may at any time during the Research Term or thereafter, however at the latest within the earlier of [***] after completion of the respective GLP toxicology studies (as characterized by the issuance of the corresponding final GLP toxicology report) and

[***] months after delivery of the relevant Licensed Product Candidate material, by written notice to Biontech and subject to the payment of the selection fees pursuant to Section 6.6, select Licensed Products from Licensed Product Candidates or other Mixtures (up to a maximum amount of five (5) Licensed Products) for further Development and Commercialization in accordance with this Agreement. For clarity, Sanofi may also select as a Licensed Product, at the end of the Selection Term, any Licensed Product Candidate that was previously reviewed under Section 2.8 and not selected as a Licensed Product at that time. For the avoidance of doubt, any decision by Sanofi to select a Licensed Product from Licensed Product Candidates or other Mixtures under this Section 2.9 shall always be at Sanofi's sole discretion.

2.10 Research Term.

[***].

3. Development and Commercialization of Licensed Products.

3.1 Development and Commercial Activities.

3.1.1 By Sanofi for Licensed Products. After selection of a Licensed Product, Sanofi shall be responsible, and shall bear all costs and expenses (except as expressly set forth otherwise in this Agreement), for all further Development work and Commercialization activities for such Licensed Product in the Field. Sanofi shall use Commercially Reasonable

Efforts to Develop and Commercialize at least one therapeutic product encompassing a Licensed Product in the Field in the United States of America or the European Union. Sanofi may, at its sole discretion, discontinue the Development and Commercialization of any Licensed Product at any time for any reason, and Sanofi will promptly notify Biontech of such decision in writing. Upon such notice, Biontech may request that the discontinued Licensed Product becomes a Biontech Transferred Product in which case Section 12.4.2 shall apply *mutatis mutandis*.

3.1.2 Under Co-Development Options. To the extent Sanofi and/or Biontech exercise any of their co-Development options pursuant to Sections 4.1 or 4.2, the provisions of Section 3.1.1 above shall apply *mutatis mutandis* to the Development obligations of either Party in relation to the relevant Option Product. Further details of such Development obligations will be agreed in the relevant Development agreement pursuant to Section 4.1.1 or 4.2.5(a).

3.2 Results and Reporting – Pharmacovigilance.

3.2.1 By Sanofi. Following the commencement of the Sanofi Development and Commercialization activities, Sanofi shall keep Biontech reasonably informed as to its progress results (including the development of any technology or inventions, the summary results of any key studies when available, or the occurrence of any adverse event), status and plans for fulfilling such activities, by delivering to Biontech a [***] written report delivered not later than [***] following the end of every [***] during which any such activities are performed. Sanofi shall maintain records, in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, which shall reflect the work done and the results achieved in the performance of the Sanofi Development and Commercialization activities in a reasonable level of detail.

3.2.2 Under Co-Development Agreements. To the extent Sanofi and/or Biontech exercise any of their co-Development options pursuant to Sections 4.1 or 4.2, the Parties will agree on specific reporting obligations within the framework of the Development agreement to be negotiated pursuant to Section 4.1.1 or 4.2.5(a).

3.2.3 Pharmacovigilance. Prior to any clinical Development activities conducted by any of the Parties under this Agreement, the Parties agree to negotiate and execute a Safety Data Exchange Agreement (the “SDEA”) which will describe the responsibilities and detailed procedures to be followed by the Parties to ensure safety surveillance for Licensed Products, Option Products and Discarded Mixtures under this Agreement as well as safety reporting obligations. In the meantime, the Parties shall promptly exchange any information related to safety for any Licensed Product, Option Product or Discarded Mixtures.

3.3 Manufacturing and Supply.

3.3.1 Phase I Clinical Batches. Biontech shall Manufacture and supply to Sanofi, at Sanofi’s expense, clinical batches of the final drug product (including fill and finish) necessary to conduct Phase I Clinical Trials for all Licensed Products [***] after Sanofi has conducted a satisfactory quality audit of Biontech’s Manufacturing site(s). The details of such supply shall be agreed between the Parties sufficiently in advance to permit Biontech the proper planning of the relevant Manufacturing in accordance with its usual business practices. All such clinical batches will be supplied under a Process

Development and Supply Agreement, including at least the terms and conditions attached as Schedule C hereto, and a Quality Agreement, to be both entered into by the Parties within [***] from the Effective Date. For the avoidance of doubt, Biontech's obligation under this Section 3.3.1 shall apply only to the first clinical batch for the first Phase I Clinical Trial for each Licensed Product; for any further clinical batches, the commercial terms set forth in Section 3.3.2 below shall apply *mutatis mutandis*.

3.3.2 Phase II Clinical Batches. For each Licensed Product for which Biontech has Manufactured and supplied clinical batches for Phase I Clinical Trials pursuant to Section 3.3.1, Biontech shall also Manufacture and supply to Sanofi all clinical batches of the final drug product (including fill and finish) necessary to conduct Phase II Clinical Trials for such Licensed Product (based on a price so determined as to provide Biontech with [***]). All such clinical batches will be supplied under the Process Development and Supply Agreement and Quality Agreement to be entered into by the Parties pursuant to Section 3.3.1.

3.3.3 Phase III Clinical Batches and Commercial Batches. In addition, subject to Section 3.3.4, Biontech shall have the right to Manufacture and supply to Sanofi (i) all clinical batches of the final drug product (including fill and finish) necessary to conduct Phase III Clinical Trials for such Licensed Product and (ii) commercial batches of final drug products (including fill and finish) required for the Commercialization of Licensed Products, on an exclusive basis and subject to separate supply and quality agreements at market standard terms and conditions to be negotiated and agreed in good faith between the Parties on a product-by-product basis following completion of Phase I Clinical Trials (or Phase I/II Clinical Trials, as applicable) of the respective Licensed Product. For the purposes of this Section 3.3.3, **exclusive** shall mean that Sanofi may not Manufacture itself or through Affiliates (subject to Section 3.3.4 below), and may not engage any Third Party Manufacturer with the Manufacture and supply of, drug products (including active ingredients and other intermediates) required for the Phase III Clinical Trials or Commercialization of Licensed Products.

3.3.4 Take-over of Manufacturing by Sanofi. Following completion of Phase I Clinical Trials (or Phase I/II Clinical Trials, as applicable) for a Licensed Product, Sanofi shall review, in cooperation with Biontech, whether and to what extent it wishes to Manufacture final drug product (including fill and finish) necessary to conduct Phase III Clinical Trials and/or the Commercialization of Licensed Products and may decide, on a Licensed Product-by-Licensed Product basis, to transfer the Manufacture of any such final drug product (or any active ingredient or intermediate thereof) to Sanofi or any of its Affiliates. If Sanofi makes any such decision, it shall promptly inform Biontech thereof in writing. In such event, the Parties shall agree on a transfer plan to transfer all relevant Manufacturing processes to Sanofi or the relevant Affiliate and Biontech shall reasonably assist Sanofi in such transfer process, provided that Biontech may apply appropriate measures to protect its proprietary manufacturing and process know-how. In addition, the following shall apply:

(a) If, at the time of the decision by Sanofi to assume Manufacturing of the Licensed Products, Biontech (X) can show that it has successfully passed FDA and EMA inspections for the commercial supply of any biologic pharmaceutical product, (Y) is prepared to offer, according to plans previously approved by Biontech's Managing Directors (*Geschäftsführer*), sufficient capacity and resources (human and financials) to supply the required volumes of the relevant final drug product to Sanofi, and (Z) offers reasonable commercial rates for its supply of such volumes ([***]), Sanofi shall make the following payments to Biontech:

(i) [***] per Licensed Product for [***] Licensed Products for which any Manufacturing shall be transferred to Sanofi or its Affiliates, of which (X) [***] shall be payable within [***] of Sanofi's notification of its decision to transfer such Manufacturing and (Y) [***] shall be payable within [***] of the first Marketing Approval for such Licensed Product;

(ii) [***] per Licensed Product for any Licensed Product after the [***] Licensed Products for which any Manufacturing shall be transferred to Sanofi or its Affiliates, of which (X) [***] shall be payable within [***] of Sanofi's notification of its decision to transfer such Manufacturing and (Y) [***] shall be payable within [***] of the first Marketing Approval for such Licensed Product;

(iii) On a Licensed Product-by-Licensed Product basis, (x) [***] per each [***] Term following Marketing Approval during which the Net Sales of the Licensed Product are equal to or more than [***] but less than [***], or (y) [***]. per each [***] Term following Marketing Approval during which the Net Sales of the Licensed Product are above [***]; each such payment, where due, shall be made within [***] after the end of the respective [***] Term following Marketing Approval during which such Licensed Product reaches the required level of Net Sales, for the [***] consecutive [***] Terms immediately following Marketing Approval; and

(iv) Reimbursement of all reasonable costs incurred by Biontech in connection with the relevant Manufacturing transfer (payable quarterly after receipt of an appropriate invoice from Biontech).

(b) If the conditions set forth in sub-section (a) (X) to (Z) above are not met by Biontech, Sanofi shall not be obliged to make any payments to Biontech in connection with the relevant Manufacturing transfer except that Sanofi shall reimburse to Biontech all reasonable costs incurred by Biontech in connection with such Manufacturing transfer (provided, however, that Sanofi shall not be obliged to reimburse such costs if and to the extent the Manufacturing transfer is required because Biontech has failed to offer the relevant Manufacturing and supply at commercially reasonable rates (based on a price so determined as to provide Biontech with an [***]) and provided further that any dispute on whether such failure has occurred shall first be escalated to the Joint Steering Committee and a resolution of the dispute has to be sought according to the procedures set forth in Section 13.7).

(c) Except with Biontech's prior written consent, Sanofi shall not be entitled to engage any Third Party Manufacturer with the Manufacture and supply of any mRNA or any active ingredient required for the Development and/or Commercialization of Licensed Products and shall not have the right to disclose, transfer or otherwise make available to any Third Party any Manufacturing know-how related thereto and disclosed by Biontech within the framework of the Manufacturing transfer or otherwise under this Agreement. For the avoidance of doubt, the foregoing prohibition shall not prevent Sanofi from engaging a Third Party Manufacturer with fill and finish and/or formulation manufacturing of Phase III and/or Commercialization batches of Licensed Products.

3.3.5 Subcontracting. Biontech may subcontract all or part of the Manufacture and supply set forth in Section 3.3: (a) to any of its Affiliates (in particular: [***]) without Sanofi's consent or (b) to any Third Party, upon prior written notice to Sanofi and subject to Sanofi prior consent (not to be unreasonably withheld); provided, that under either circumstance described under (a) or (b) above, (i) none of the rights of Sanofi hereunder are diminished or are otherwise adversely affected as a result of such subcontracting, (ii) the subcontractor undertakes in writing all obligations of confidentiality and non-use regarding both Parties' Confidential Information which are substantially the same as those undertaken by the Parties hereunder, (iii) Biontech shall at all times be responsible for the performance by such subcontractor of such Biontech's obligations hereunder, and (iv) Biontech shall cause each subcontractor to accept being audited by Sanofi on terms essentially similar to Section 4.5 hereof.

3.3.6 Information on Technical Development and Manufacturing. Biontech shall keep the JSC fully informed as to its progress, results (including the development of any technology or inventions), status and plans for performing and implementing Manufacturing activities hereunder, and any decisions relating to such Manufacturing activities shall be made unanimously, with (i) Sanofi having final decision making with respect to the Manufacturing process to be used for any Licensed Product which is under Sanofi's regulatory responsibility and (ii) Biontech having final decision making with respect to the Manufacturing process to be used for any Licensed Product which is under Biontech's regulatory responsibility. Biontech shall provide information to the JSC by periodic, informal oral reports, and by a [***] written report delivered not later than [***] following the end of every calendar [***] during which any activities are performed under the Research Plan.

3.3.7 Manufacturing of Option Products. Except as may be otherwise mutually agreed between the Parties in any Development agreement, the provisions of this Section 3.3 shall apply *mutatis mutandis* to the Manufacture of any Option Product.

4. Co-Development and Co-Commercialization.

4.1 Biontech Option Products. Biontech has the option, exercisable once per Licensed Product by written notice to Sanofi prior [***] such Licensed Product (which shall be notified by Sanofi to Biontech in writing no less than [***] for the Biontech Territory, to co-Develop and co-Commercialize such Licensed Product in the Field in the Biontech Territory, up to a maximum of two (2) Licensed Products and subject to the payment of the option exercise fee pursuant to Section 6.4.1 (upon the exercise of such option such Licensed Products to become, with respect to the countries of the Biontech Territory, the **Biontech Option Products**). Any such option shall be exercised by Biontech in writing within [***]. upon Biontech's receipt of Sanofi's IND filing notice. With respect to each Biontech Option Product:

4.1.1 The Parties shall without undue delay after Biontech having exercised the option pursuant to Section 4.1 in good faith negotiate a Development agreement setting forth the Development work to be performed by each Party, as well as budgets, timelines, allocation of FTEs, governance, subcontracting and other relevant items. Each such Development agreement shall include provisions pursuant to which Sanofi shall have final decision on any Development matters relating to Biontech Option Products;

4.1.2 Sanofi shall own all clinical data generated in the co-Development of Biontech Option Products, and shall grant Biontech the right [***]

4.1.3 Biontech shall at least [***] before the anticipated start of any pivotal clinical trial that may be used for BLA filing to a Regulatory Authority provide Sanofi with a detailed written memorandum describing Biontech then current resources and capabilities that Biontech plans to dedicate to the conduct of its co-Development and co- Commercialization activities. The Parties shall on that basis in good faith negotiate and enter into a Commercialization agreement which shall be consistent with the applicable provisions of this Agreement [***]. Each such Commercialization agreement shall include provisions pursuant to which Sanofi shall have final decision on any Commercialization related matters with respect to Biontech Option Products;

4.1.4 Sanofi shall book all sales of the Biontech Option Product worldwide;

4.1.5 All Biontech Option Products to be sold in the Biontech Territory shall be co-branded with Biontech's and Sanofi's brand which shall appear on each product labelling and packaging with equal visibility, subject to branding guidelines to be set forth in the applicable Commercialization agreement;

4.1.6 The Parties shall on a country-by-country basis share (i) all costs which are incurred in the Development or Commercialization of each Biontech Option Product after the exercise of the relevant option, and (ii) all profits generated in the Commercialization of each Biontech Option Product (such profits to be calculated in accordance with Sanofi's consistent business practices, unless otherwise agreed in the relevant Development and/or Commercialization agreement pursuant to Sections 4.1.1 and 4.1.3), pursuant to the following key:

[***]

4.1.7 Further details of the cost and profit sharing, including without limitation (i) reimbursements procedures between the Parties for costs which exceed one Party's agreed cost share and (ii) guidelines for the determination of costs and profits of either Party, shall be agreed in the relevant Development and/or Commercialization agreement.

4.2 Sanofi Option Products.

4.2.1 Sanofi Option on Mixtures in the Field. If Biontech alone or in collaboration with an Affiliate or a Third Party develops a Mixture in the Field which is not a Licensed Product but which includes [***] of mRNAs of a Licensed Product (***Biontech Field Mixture***), Sanofi has the exclusive option to co-Develop and co-Commercialize such Biontech Field Mixture on a worldwide basis, subject to the terms and conditions of this Section 4.2.1. The option shall be exercisable by written notice to Biontech at the following opt-in points: (a) prior to initiation of the first research program for such Biontech Field Mixture (which shall be notified by Biontech to Sanofi in writing no less than [***] prior to the intended date of initiation, with the Early Opt-in Package joined to such notification) and subject to payment of [***] of the option exercise fee pursuant to Section 6.4.2; and (b) if Sanofi has rejected or failed to exercise the option at the opt-in point indicated under (a) above, prior to the [***] of such Biontech Field Mixture (which shall be notified by Biontech to Sanofi in writing no less than [***] prior to the intended date of [***]) and subject to the payment of [***] of the option exercise fee pursuant to Section 6.4.2, provided that [***] has occurred within [***] after selection of the corresponding Licensed Product. For the purposes of this Section 4.2.1, "exclusive option" shall mean that Biontech or any of its Affiliates may not Commercialize a Biontech Field Mixture or enter into any arrangement with any Third Party to Commercialize a Biontech Field Mixture without having first complied with the provisions of this Section 4.2.1. Any such option shall be exercised by Sanofi in writing within [***] upon Sanofi's receipt of Biontech's respective notice as indicated in (a) and (b) above. Subject to the provisions of Section 4.6 below, Biontech shall be free to conduct Development or Commercialization of any Biontech Field Mixture without any further option rights of Sanofi after Sanofi has finally declined or failed to exercise the two-step option according to the foregoing terms and conditions.

4.2.2 Sanofi Option on Mixtures outside the Field. If Biontech alone or in collaboration with an Affiliate or a Third Party Develops outside of the Field a Mixture which is not a Licensed Product but which includes [***] of mRNAs of a Licensed Product (but excluding, for the avoidance of doubt, any Sanofi Option Combination Products) (***Biontech Non-Field Mixture***), Sanofi has the exclusive option to co-Develop and co-Commercialize such Biontech Non-Field Mixture on a worldwide basis, subject to the terms and conditions of this Section 4.2.2. The option shall be exercisable by written notice to Biontech at the following opt-in points: (a) prior to initiation of the first research program for such Biontech Non-Field Mixture (which shall be notified by Biontech to Sanofi in writing no less than [***] prior to the intended date of initiation, with the Early Opt-in Package joined to such notification) and subject to payment of [***] of the option exercise fee pursuant to Section 6.4.3; and (b) if Sanofi has rejected or failed to exercise the option at the opt-in point indicated under (a) above, prior to [***] of such Biontech Non-Field Mixture (which shall be notified by Biontech to Sanofi in writing no later than [***] prior to the intended date [***]) and subject to the payment of [***] of the option exercise fee pursuant to Section 6.4.3, provided that [***] has occurred within [***] after selection by Sanofi of the corresponding Licensed Product according to Section 2.9. For the purposes of this Section 4.2.2, "exclusive option" shall mean that Biontech or any of its

Affiliates may not Commercialize a Biontech Non-Field Mixture or enter into any arrangement with any Third Party to Commercialize a Biontech Non-Field Mixture without having first complied with the provisions of this Section 4.2.2. Any such option shall be exercised by Sanofi in writing within [***] upon Sanofi's receipt of Biontech's respective notice as indicated in (a) and (b) above. Subject to the provisions of Section 4.6 below, Biontech shall be free to conduct Development or Commercialization of any Biontech Non-Field Mixture without any further option rights of Sanofi after Sanofi has finally declined or failed to exercise its two- step option according to the foregoing terms and conditions.

4.2.3 Sanofi Option on Combination Products. If Biontech alone or in collaboration with an Affiliate or a Third Party develops a combination product which (i) is administered by [***] (ii) comprises both a [***] of a Licensed Product for the treatment of [***] and (iii) is formulated as [***] (such product, a **Sanofi Option Combination Product**), Sanofi has the exclusive option to co-Develop and co- Commercialize such Sanofi Option Combination Product on a worldwide basis, subject to the terms and conditions of this Section 4.2.3. The option shall be exercisable by written notice to Biontech at the following opt-in points: (a) prior to initiation of the first research program for such Sanofi Option Combination Product (which shall be notified by Biontech to Sanofi in writing no less than [***] prior to the intended date of initiation, with the Early Opt-in Package joined to such notification) and subject to payment of [***] of the option exercise fee pursuant to Section 6.4.4; and (b) if Sanofi has rejected or failed to exercise the option at the opt-in point indicated under (a) above, prior to the [***] for the considered Sanofi Option Combination Product (which shall be notified by Biontech to Sanofi in writing no less than [***] before [***], and subject to the payment of [***] of the option exercise fee pursuant to Section 6.4.4, provided that an IND filing has occurred within [***] from the date on which Sanofi selected the corresponding Licensed Product. Any such option shall be exercised by Sanofi in writing within [***] upon Sanofi's receipt of Biontech's respective notice as indicated in (a) and (b) above. For the purposes of this Section 4.2.3, "exclusive option" shall mean that Biontech or any of its Affiliates may not Commercialize a Sanofi Option Combination Product or enter into any arrangement with any Third Party to Commercialize a Sanofi Option Combination Product without having first complied with the provisions of this Section 4.2.3. Subject to the provisions of Section 4.6 below, Biontech shall be free to conduct Development or Commercialization of any Sanofi Option Combination Product without any further option rights of Sanofi after Sanofi has finally declined or failed to exercise its two-step option according to the foregoing terms and conditions. [***].

4.2.4 Sanofi Option on Licensed Product outside the Field. If Biontech alone or in collaboration with an Affiliate or a Third Party Develops a Licensed Product outside of the Field, Sanofi has the exclusive option to co-Develop and co-Commercialize such Licensed Product outside of the Field on a worldwide basis, subject to the terms and conditions of this Section 4.2.4. The option shall be exercisable by written notice to Biontech at the following opt-in points: (a) prior to initiation of the first research program for such Licensed Product outside of the Field (which shall be notified by Biontech to Sanofi in writing no less than [***] prior to the intended date of initiation, with the Early Opt-in Package joined to such notification) and subject to payment of [***] of the option exercise fee pursuant to Section 6.4.5; and (b) if Sanofi has rejected or failed to exercise the option at the opt-in point indicated under (a) above, prior to the [***] for such Licensed Product (which shall be notified by Biontech to Sanofi in writing promptly no later than [***], prior to the [***].) and subject to the payment of [***] of the option exercise fee pursuant to Section 6.4.5, provided that [***] has occurred (a) within [***] after selection of the corresponding Licensed Product for Development in the Field pursuant to Section 2.9, or (b) before Sanofi has obtained the first Marketing Approval for the corresponding Licensed Product in the United States of America (whichever of (a) or (b) is later). For the purposes of this Section 4.2.4, “exclusive option” shall mean that Biontech or any of its Affiliates may not Commercialize a Licensed Product outside the Field or enter into any arrangement with any Third Party to Commercialize a Licensed Product outside the Field without having first complied with the provisions of this Section 4.2.4. Any such option shall be exercised by Sanofi in writing within [***] upon Sanofi’s receipt of Biontech’s respective notice as indicated in (a) and (b) above. Subject to the provisions of Section 4.6 below, Biontech shall be free to conduct Development or Commercialization of any Licensed Product outside the Field without any further option rights of Sanofi after Sanofi has finally declined or failed to exercise its two-step option according to the foregoing terms and conditions.

4.2.5 General Rules for Sanofi Option Products. With respect to each Sanofi Option Product:

(a) The Parties shall without undue delay after Sanofi having exercised the option pursuant to Section 4.2.1, 4.2.2, 4.2.3 or 4.2.4, as applicable, in good faith agree on a Development agreement setting forth the Development work to be performed by each Party, as well as budgets, timelines, allocation of FTEs, governance, subcontracting and other relevant items; each such Development agreement shall include provisions pursuant to which:

(i) Sanofi shall have final decision on any Development matters relating to Sanofi Option Products that are Licensed Products or Biontech Field Mixtures (provided that, for the avoidance of doubt, Sanofi shall always exercise Commercially Reasonable Efforts in the Development of such Sanofi Option Product);

(ii) Biontech shall have final decision on any Development matters relating to Sanofi Option Combination Products (provided that, for the avoidance of doubt, Biontech shall always exercise Commercially Reasonable Efforts in the Development of such Sanofi Option Combination Product);

(iii) Any decision on any Development matters relating to Sanofi Option Products that are Biontech Non-Field Mixtures shall be made unanimously or, in case where a consensus cannot be achieved, by a Third Party Expert (and the procedure set forth in Section 2.8 shall apply *mutatis mutandis*);

(b) The Party having responsibility and final decision-making with respect to Development of a Sanofi Option Product shall own all clinical data generated in the co-Development of that Sanofi Option Products, and shall grant the other Party the right to access, use and reference such clinical data to the extent necessary or useful for the Development or Commercialization of any Licensed Product, Discarded Mixture or Option Product.

(c) The Parties shall at least [***] before the anticipated start of any pivotal clinical trial that may be used for BLA filing to a Regulatory Authority in good faith negotiate and enter into a Commercialization agreement which shall be consistent with the applicable provisions of this Agreement; each such Commercialization agreement shall include provisions pursuant to which:

(i) Sanofi shall have final decision on any Commercialization matters relating to Licensed Products and Sanofi Option Products that are Biontech Field Mixtures;

(ii) Biontech shall have final decision on any Commercialization matters relating to Sanofi Option Combination Products;

(iii) Any decision on any Commercialization matters relating to Sanofi Option Products that are Biontech Non-Field Mixtures shall be made unanimously or, in case where a consensus cannot be achieved, by a Third Party Expert (and the procedure set forth in Section 2.8 shall apply *mutatis mutandis*);

(d) Biontech shall book all sales of the Sanofi Option Products worldwide;

(e) All Sanofi Option Products shall be co-branded with Biontech's and Sanofi's brand which shall appear on each product packaging with equal visibility, subject to branding guidelines to be set forth in the applicable commercialization agreement;

(f) The Parties shall on a country-by-country basis share [***] (i) all costs which are incurred in the Development or Commercialization of each Sanofi Option Product after the exercise of the relevant option and (ii) all profits generated in the Commercialization of each Sanofi Option Product (such profits to be calculated in accordance with Biontech's consistent business practices, unless otherwise agreed in the relevant Development and/or Commercialization agreement pursuant to Sections 4.2.5(a) and 4.2.5(c)). Further details of the cost and profit sharing, including without limitation (i) reimbursements procedures between the Parties for costs which exceed one Party's agreed cost share and (ii) guidelines for the determination of costs and profits of either Party, shall be agreed in the relevant Development and/or Commercialization agreement.

4.3 No Transfer of Rights to Option Products. If and insofar as a Party has exercised its option rights under Sections 4.1 or 4.2, neither Party shall be entitled to transfer or sublicense its rights in relation to the relevant Option Product to any Third Party without the other Party's prior written consent.

4.4 [***]

4.5 Audit Rights. Each Party shall make all records as may be reasonably necessary to verify the accuracy of the costs associated to its Development and Commercialization activities available for inspection by an independent auditor of a nationally recognized auditing firm, upon reasonable written request of the other Party (but not more than [***] per calendar year). The Party requesting the audit shall pay all audit expenses; provided however, that in the event the audit reveals a greater than [***] shortfall in the amounts owed by the audited Party during the relevant period, the audited Party shall pay all audit expenses. All information subject to review under this Section 4.5 shall be treated as confidential, and the Party requesting the audit shall cause its accounting firm to retain all such information in confidence under Section 8 below.

4.6 Restrictive Covenant. Notwithstanding anything to the contrary herein, neither Biontech nor any of its Affiliates shall, either by itself or through a Third Party, during the term of any of the exclusive options granted to Sanofi under Sections 4.2.1, 4.2.2, 4.2.3 or 4.2.4 respectively, conduct any Development in respect of, or Commercialize or otherwise exploit, (i) a Biontech Field Mixture, (ii) a Biontech Non-Field Mixture, (iii) a Licensed Product, or (iv) a Sanofi Option Combination Product outside of the Field in the case that such Mixture, Licensed Product or Sanofi Option Combination Product shall obtain Marketing Approval in the same therapeutic indication and for the same Patient Population as the corresponding Licensed Product in the Field. Any disagreement between the Parties as to whether a Mixture, a Licensed Product or a Sanofi Option Combination Product fulfills the criteria of this Section 4.6 shall be settled according to the provisions of Section 13.7.

5. Exclusivity.

5.1 Exclusivity During Initial Research Term. During the Initial Research Term, Biontech will not engage in any activity comprising the research and Development of (i) Single mRNAs or Mixtures in the Field or (ii) [***] whether alone or in collaboration with Affiliates or Third Parties, outside of the collaboration hereunder.

5.2 [***]

5.3 Limited Extension of Exclusivity for Licensed Product Candidates. Sanofi may by written notice to Biontech, and subject to the payments of the extension fees set forth in Section 6.3, extend the above exclusivity solely with respect to one or more Licensed Product Candidates, on a Licensed Product Candidate-by-Licensed Product Candidate basis, for a period of [***] commencing as of the end of the Initial Research Term.

6. Financial Provisions.

6.1 Upfront Payment. In consideration for entering into this Agreement, for Biontech's willingness to collaborate with Sanofi in the development and commercialization of RNA-based therapeutics in the Field, for providing Confidential Information, non-confidential information, scientific data and Know-how, for performing research services in accordance with the Research Plan, for sharing risks and costs associated with potential freedom to operate obstacles, for providing various administrative services such as e.g. preparation, maintenance and review of documents and reports, for maintenance and administration of the Biontech Background Technology, for granting the option rights and exclusivities set forth in this Agreement, and for other goods and services to be provided hereunder, Sanofi shall pay to Biontech a one-time, non-refundable, non-creditable upfront payment in the amount of EUR 26,100,000 within [***] after the Effective Date, subject to receipt of the corresponding invoice emitted by Biontech.

6.2 Feasibility Milestone Payments. On a per target basis, Sanofi shall pay to Biontech a one-time, non-refundable, non-creditable feasibility milestone payment in the amount of [***] for each of the [***] priority human targets as defined by the Research Plan set forth in Schedule B for which the design, synthesis and release of a first batch of research grade mRNAs has been completed (so that the maximum payment due under this Section 6.2 will be [***]). Such payment shall become payable within [***] following Sanofi's receipt of the corresponding invoice from Biontech. If the Joint Steering Committee cannot make a unanimous decision whether the above criteria have been met with respect to a target, the issue shall be decided by an Expert in accordance with the procedure described in Section 2.8 above.

6.3 Exclusivity Extension Fees. Sanofi shall pay to Biontech within [***] after giving written notice of an exclusivity extension pursuant to Section 5.3, subject to receipt of the corresponding invoice emitted by Biontech, the following non-refundable, non-creditable extension fees per Licensed Product Candidate:

6.3.1 Extension of exclusivity for the first [***] Licensed Product Candidates: [***] per Licensed Product Candidate;

6.3.2 Extension of exclusivity for each further Licensed Product Candidate: [***] per Licensed Product Candidate.

6.4 Option Exercise Fees.

6.4.1 Biontech Option Products. Biontech shall pay to Sanofi within [***] after the option exercise pursuant to Section 4.1, subject to receipt of the corresponding invoice emitted by Sanofi, a one-time, non-refundable, non-creditable option exercise fee per Biontech Option Product in the amount of [***].

6.4.2 Biontech Field Mixtures. Sanofi shall pay to Biontech within [***] after the option exercise pursuant to Section 4.2.1, subject to receipt of the corresponding invoice emitted by Biontech, a one-time, non-refundable, non-creditable option exercise fee per Biontech Field Mixture in the amount of [***].

6.4.3 Biontech Non-Field Mixtures. Sanofi shall pay to Biontech within [***] after the option exercise pursuant to Section 4.2.2, subject to receipt of the corresponding invoice emitted by Biontech a one-time, non-refundable, non-creditable option exercise fee per Biontech Non-Field Mixture in the amount of [***].

6.4.4 Sanofi Option Combination Products. Sanofi shall pay to Biontech within [***] after the option exercise pursuant to Section 4.2.3, subject to receipt of the corresponding invoice emitted by Biontech, a one-time, non-refundable, non-creditable option exercise fee per Sanofi Option Combination Products in the amount of [***].

6.4.5 Licensed Product. Sanofi shall pay to Biontech within [***] after the option exercise pursuant to Section 4.2.4, subject to receipt of the corresponding invoice emitted by Biontech, a one-time, non-refundable, non-creditable option exercise fee per Licensed Products in the amount of [***].

6.5 Pre-clinical Milestone Payment. Sanofi shall pay to Biontech a one-time, non-refundable, non-creditable milestone payment in the amount of [***] for each of the first [***] Licensed Product Candidates approved according to the process described under Section 2.8, due and payable within [***] after approval, subject to receipt of the corresponding invoice emitted by Biontech. The milestone payment shall also be paid for each Mixture which is not approved as Licensed Product Candidate under Section 2.8 but nevertheless selected by Sanofi as a Licensed Product under Section 2.9, within [***] after such selection, subject to receipt of the corresponding invoice emitted by Biontech, except for Licensed Products covered by Section 6.6.2 below.

6.6 Selection Fees. Sanofi shall pay to Biontech the following one-time, non-refundable, non-creditable selection fees per Licensed Product:

6.6.1 For each Licensed Product except for those covered by Section 6.6.2 below: [***] for each of the first [***] selected Licensed Products and [***] for each further selected Licensed Product, according to the following payment schedule: (i) [***] within [***] of selection and (ii) [***] within [***] upon POC of Biontech's mRNA technology platform having been demonstrated in a Phase I Clinical Trial with a (i.e. any) Licensed Product (in both cases, subject to receipt of the corresponding invoice emitted by Biontech). If such POC has been demonstrated before selection of the Licensed Product, then [***] of the selection fee shall be payable within [***] selection of the relevant Licensed Product, subject to receipt of the corresponding invoice emitted by Biontech.

6.6.2 For each Licensed Product selected on the basis of a Mixture that (i) has not been approved as Licensed Product Candidate and (ii) was within the scope of the Research Plan (including, where applicable, as amended pursuant to Section 2.10.2), and (iii) has been the subject of Biontech's research activities for a total of at least [***] at any time during the Research Term, provided that such selection takes place within a period of [***] following the end of the extended Research Term pursuant to Section 2.10.2: [***] due and payable within [***] of selection of the relevant Licensed Product, subject to receipt of the corresponding invoice emitted by Biontech.

6.7 Development and Sales Milestone Payments. Sanofi shall pay to Biontech the following one-time, non-refundable, non-creditable milestone payments per Licensed Product, in each case upon the occurrence of the following milestone events:

6.7.1 Only for the [***]. Licensed Products:

[***]

6.7.2 For each Licensed Product:

[***]

[***]

6.7.3 Clarifications. All milestone payments shall only become due and payable once per Licensed Product.

6.7.4 Timing of Milestone Payments. Each milestone payment set forth in this Section 6.7 shall be payable by Sanofi to Biontech within [***] of the occurrence of the respective milestone event, subject to receipt of the corresponding invoice emitted by Biontech. Sanofi shall promptly notify Biontech in writing of the occurrence of any milestone event including a reasonably detailed description and reasonable evidence of such occurrence.

6.8 Sanofi Royalties.

6.8.1 Royalties on Net Sales. During the Royalty Term and subject to Section 6.8.2 below, Sanofi shall pay to Biontech royalties on Sanofi's and Sanofi's Affiliates' and Sanofi's and Sanofi's Affiliates' (sub-)licensees' aggregate Net Sales of all Licensed Products (excluding for the avoidance of doubt any sales of Biontech Option Products in the Biontech Territory), on a License Product-by-Licensed Product as well as on a country-by-country basis, at the following rates (**Sanofi Royalties**):

[***]

6.8.2 Royalty Offset.

[***]

6.8.3 Reporting and Payment Terms.

(a) Revenue and Sales Reports. Following the First Commercial Sale of a product containing a Licensed Product, within [***] after the end of each calendar [***] Sanofi shall deliver to Biontech a written report showing in reasonable detail the calculation of (i) the aggregate Net Sales of each product containing a Licensed Product in each country for such calendar [***], and (ii) the calculation of Sanofi Royalties owing by Sanofi to Biontech pursuant to Section 6.8.1 above for such calendar [***].

(b) Payment Timing. All amounts of Sanofi Royalties shown to have accrued by each report provided for pursuant to Section 6.8.3(a) shall be due and payable within [***] from receipt of the corresponding invoice emitted by Biontech.

(c) Records and Audit. Sanofi shall maintain records, in sufficient detail, which shall be complete and accurate and shall fully and properly reflect all Net Sales reflected in such [***] reports described in Section 6.8.3(a). For each [***] report, Sanofi shall maintain records reflecting the Net Sales contained in such [***] report for [***] following the date that such [***] report is delivered to Biontech.

(d) Withholding Taxes. If laws, rules or regulations require withholding of income taxes or other taxes imposed upon payments of Sanofi Royalties, Sanofi shall make such withholding payments as required and subtract such withholding payments from the payments of Sanofi Royalties. Sanofi shall use reasonable efforts to minimize any such taxes required to be withheld on behalf of Biontech. Sanofi shall promptly deliver to Biontech proof of payment of all such taxes together with copies of all communications from or with such governmental authority with respect thereto, and shall provide such other information and documents as Biontech may reasonably request in connection with Biontech's efforts to claim the tax benefits associated with such payments.

(e) Audit Rights. Sanofi shall make such [***] reports described in Section 6.8.3(a) as well as all records as may be reasonably necessary to verify the accuracy of such [***] reports available for inspection by an independent auditor of a nationally recognized auditing firm, upon reasonable written request of Biontech (but not more than [***] per calendar year). Such audit shall be for the purpose of ensuring Sanofi's compliance with its payment obligations hereunder. Biontech shall pay all audit expenses; provided however, that in the event the audit reveals a greater than [***] shortfall in the amounts owed to Biontech by Sanofi during the relevant period, Sanofi shall pay all audit expenses. Biontech shall treat all financial information subject to review under this Section 6.8.3(e) as confidential, and shall cause its accounting firm to retain all such financial information in confidence under Section 8 below.

(f) Payment Exchange Rate. All payments to be made by Sanofi to Biontech under this Agreement shall be made in Euros by bank wire transfer [***] to such bank account designated in writing by Biontech from time to time. In the case of sales or revenues which are invoiced in a foreign currency, exchange conversion of such sales into Euros will be made on a [***] basis and shall be made consistent with Sanofi's normal practices used to prepare its audited financial statements for internal and external reporting purposes, which uses a widely accepted source of published exchange rates.

6.9 Biontech Royalties.

6.9.1 For each Licensed Product which Biontech Develops and Commercializes outside the Field (whether alone or in collaboration with an Affiliate or Third Party), but excluding any Sanofi Option Products and Sanofi Option Combination Products, Biontech shall, during the Royalty Term and subject to Section 6.9.3 below, pay to Sanofi royalties on Biontech's and Biontech's Affiliates' and Biontech's and Biontech's Affiliates' (sub-)licensees' aggregate Net Sales of all products containing such Licensed Products, on a Licensed Product-by-Licensed Product as well as on a country-by-country basis, at the following rates (***Biontech Royalties***):

[***]

6.9.2 For each Licensed Product Candidate or Mixture produced in the conduct of the Research Plan but not selected by Sanofi as Licensed Product pursuant to Section 2.9 (**Discarded Mixtures**), which (i) Biontech Develops and Commercializes in the Field or outside the Field (whether alone or in collaboration with an Affiliate or Third Party) and (ii) is covered by a Patent Right relating to an invention made by Sanofi or its Affiliates (whether alone or jointly with Biontech or its Affiliates), Biontech shall, subject to Section 6.9.3 below, pay to Sanofi a royalty of [***] on Biontech's and Biontech's Affiliates' and Biontech's and Biontech's Affiliates' (sub-)licensees' aggregate Net Sales of all products containing such Discarded Mixtures, on a Discarded Mixture-by-Discarded Mixture and on a country-by-country basis, for as long as such Discarded Mixture is covered by such Patent Right in such country.

6.9.3 Sections 6.8.2 and 6.8.3 shall apply *mutatis mutandis* to Biontech Royalties.

7. Intellectual Property.

7.1 Overview. The Parties have agreed to organize the protection and the allocation of ownership of any Intellectual Property Rights created under this Agreement in a manner to ensure that [***]. In order to achieve these objectives, the Parties agree that [***].

7.2 Ownership Rights.

7.2.1 Biontech's Ownership Rights. Biontech shall solely own, during the term of this Agreement and thereafter, all right title and interest in and to the Biontech Background Technology, the Biontech Collaboration Technology and the Biontech Foreground Technology.

7.2.2 Sanofi's Ownership Rights. Sanofi shall solely own, during the term of this Agreement and thereafter, all right title and interest in and to the Sanofi Background Technology, the Licensed Products Patents, and the Sanofi Foreground Technology.

7.2.3 Joint Ownership Rights.

(a) The Parties shall jointly own, [***], all right title and interest in and to the Joint Collaboration Know-how, [***]

(b) [***]

(c) [***]

(d) [***]

(e) The Parties shall jointly own all right, title and interest in and to all Joint Foreground Technology.

(f) The Joint Collaboration Technology shall, subject to the terms and conditions of this Agreement, be equally and undividedly owned by both Parties, but a Party cannot exploit or transfer its interest in the Joint Collaboration Technology, except within the scope of the licenses granted pursuant to Section 7.3 or unless otherwise specifically permitted under this Agreement. A Party shall not assign, mortgage, sell or otherwise transfer or dispose of any of its right, title or interest in any Joint Collaboration Technology without the other Party's prior written consent (not to be unreasonably withheld or delayed), except that such

consent shall not be required in respect of any transfer to: (i) an Affiliate of the Party; or (ii) a Third Party successor or purchaser of all or substantially all of its business or assets to which the Agreement relates, whether in a merger, sale of stock, sale of assets or other similar transaction; provided that, in each case, any such transfer shall be made subject to the licenses granted to the other Party pursuant to the Agreement, as applicable, and that the Affiliate or Third Party, as applicable, agrees, by written notice to the other Party, to be bound by the terms of such license and all other terms of this Agreement to the extent that such terms are applicable to the assigned Joint Collaboration Technology.

7.2.4 Except as expressly provided hereunder, a Party (i) shall not acquire pursuant to this Agreement any right, title or interest to any Intellectual Property Rights solely owned by the other Party as set forth in this Section 7.2, (ii) shall not (and shall not attempt to purport to) transfer, assign, sell, have sold, lease, offer to sell or lease, distribute, license, sublicense or otherwise transfer title in, or clinically Develop, Commercialize or otherwise exploit any Intellectual Property Rights solely owned by the other Party as set forth in this Section 7.2 other than as permitted under this Agreement, and (iii) shall not file, prosecute, or maintain, in any country, any Patent Rights included in such Intellectual Property Rights solely owned by the other Party as set forth in this Section 7.2.

7.3 Licenses.

7.3.1 Licenses to Sanofi.

(a) Research License. Biontech hereby grants to Sanofi a royalty-free, non-exclusive, non-transferable (except through assignment of this Agreement pursuant to Section 13.4), worldwide license, with the right to sublicense (subject to Section 7.3.4 below), under the Biontech Technology to the extent required for the performance of the Research Plan.

(b) Licensed Products.

(i) Biontech hereby grants to Sanofi, with effect as of the selection of each Licensed Product, an exclusive, non-transferable (except through assignment of this Agreement pursuant to Section 13.4), worldwide license, with the right to sublicense (subject to Section 7.3.4 below), under the Biontech Background Technology set forth in Schedule D, Biontech's interest in the Joint Collaboration Technology, Biontech Collaboration Patents, Biontech's Foreground Technology and Biontech's interest in the Joint Foreground Technology to Develop, have Developed, make, have made, Commercialize and have Commercialized such Licensed Product in the Field.

(ii) Biontech hereby grants to Sanofi, with effect as of the selection of each Licensed Product, the non-exclusive, non-transferable (except through assignment of this Agreement pursuant to Section 13.4), worldwide license, with the right to sublicense (subject to Section 7.3.4 below), under the Biontech Background Technology which is not set forth in Schedule D to Develop, have Developed, make, have made, Commercialize and have Commercialized such Licensed Product in the Field.

(iii) Biontech hereby grants to Sanofi, with effect as of the exercise by Sanofi of any option described in Section 4.2, a non-exclusive, non-transferable, worldwide license, with the right to sublicense (subject to Section 7.3.4 below), under the Biontech Technology and Biontech Foreground Technology to the extent required by Sanofi for the co-Development and/or co-Commercialization of the relevant Sanofi Option Product in accordance with the Development and/or Commercialization agreement concluded in relation to such Sanofi Option Product. Further details of such license may be set forth in the relevant Development and/or Commercialization agreement.

(iv) With respect to each Licensed Product Candidate approved pursuant to Section 2.8, Sanofi may no more than [***] during the Selection Term request that the Parties review in good faith whether to amend Schedule D (such amendment be made by mutual agreement between the Parties), so that, upon such amendment and for the purposes of the exclusive license granted to Sanofi pursuant to Section 7.3.1(b)(i), Schedule D will set forth only that part of the Biontech Background Technology (but excluding, for the avoidance of doubt, any Intellectual Property Rights over which Biontech has gained Control outside the scope of the collaboration hereunder after the Effective Date and until the end of the Research Term) that is necessary for Sanofi to Develop, have Developed, make, have made, Commercialize and have Commercialized the respective Licensed Product in the Field.

7.3.2 Licenses to Biontech.

(a) Research License. Sanofi hereby grants to Biontech:

(i) a royalty-free, non-exclusive, non-transferable (except through assignment of this Agreement to an Existing Biontech Affiliate pursuant to Section 13.4 (i)), worldwide license, with the right to sublicense (subject to Section 7.3.4 below), under the Sanofi Background Technology, to the extent required for the performance of the Research Plan; and

(ii) a royalty-free, non-exclusive, non-transferable (except through assignment of this Agreement pursuant to Section 13.4, or as otherwise agreed between the Parties), worldwide license, with the right to sublicense (subject to Section 7.3.4 below), under Sanofi's interest in the Joint Collaboration Technology, to the extent required for the performance of the Research Plan.

(b) Commercial Licenses. Sanofi hereby grants to Biontech:

(i) with effect upon expiration of the Selection Term, an exclusive, transferable, worldwide, license (with the right to sublicense) under the Licensed Products Patents, and Sanofi's right, title and interest in any Joint Collaboration Technology, for any purpose other than conducting the Development or Commercialization of a Licensed Product in the Field, subject to Section 4.6; and

(ii) with effect as of the exercise by Biontech of any option described in Section 4.1, a non-exclusive, non-transferable, worldwide license, with the right to sublicense (subject to Section 7.3.4 below), under the Sanofi Technology and Sanofi Foreground Technology to the extent required by Biontech for the co-Development and/or co- Commercialization of the relevant Biontech Option Product in accordance with the Development and/or Commercialization agreement concluded in relation to such Biontech Option Product. Further details of such license may be set forth in the relevant Development and/or Commercialization agreement.

7.3.3 De-Blocking Licenses.

(i) Sanofi hereby grants to Biontech the non-exclusive, fully paid-up, non-transferable (except through assignment of this Agreement to an Existing Biontech Affiliate pursuant to Section 13.4 (i), or as otherwise agreed between the Parties), worldwide, royalty-free license, with the right to sublicense (subject to Section 7.3.4 below), under the Sanofi Foreground Technology as well as under Sanofi's right, title and interest in any Joint Foreground Technology to research, Develop and Commercialize any Licensed Product outside of the Field and any Discarded Mixture in and outside the Field.

(ii) Biontech hereby grants to Sanofi the non-exclusive, fully paid-up, non-transferable (except through assignment of this Agreement to an Existing Sanofi Affiliate pursuant to Section 13.4 (i), or as otherwise agreed between the Parties), worldwide, royalty-free license, with the right to sublicense (subject to Section 7.3.4 below), under the Biontech Foreground Technology as well as under Biontech's right, title and interest in any Joint Foreground Technology to research, Develop and Commercialize any Licensed Product in the Field.

7.3.4 Right to Sublicense.

(a) To Affiliates and Service Providers. Each Party shall have the right, without the consent of the other Party, to sublicense the rights granted to such Party pursuant to Section 7.3.1 to 7.3.3, as applicable, to (i) any subcontractor or other service provider, but only for the purpose of performing services under this Agreement on its behalf or for its benefit, and subject to the considered subcontractor or service provider undertaking irrevocably to assign to the sub-licensing Party any and all Know-how specifically relating to any Mixture that may be conceived, created or reduced to practice in the course of performing such service and (ii) any of its Affiliates; provided however, that the sub-licensing Party shall in all circumstances remain primarily responsible for all acts and omissions of such sublicensees under the respective sublicenses.

(b) To Other Parties. In addition, subject to Section 4.3, each Party shall be permitted to sublicense the rights granted to it under Section 7.3.1(b) or 7.3.2(b) above respectively in connection with any Product Sublicense Agreement, provided that the following conditions are met:

(i) The sub-licensee shall be bound by license terms and conditions which are at least as restrictive as those imposed on the sub-licensing Party under this Agreement; and

(ii) the sub-licensing Party shall remain fully responsible for the performance of its obligations hereunder, and shall remain responsible for all acts and omissions of the sub-licensee under the sublicense.

(c) Notice to Other Party. Upon entering into any permitted sublicense pursuant to Section 7.3.4(b) above, the sub-licensing Party shall deliver written notice thereof to the other Party.

7.4 Patent Matters.

7.4.1 Solely Owned Patents. Unless otherwise set forth below, each Party shall have the right (but not the obligation), at its sole expense and sole discretion, to control the preparation, filing, prosecution, maintenance and enforcement of all Patent Rights applicable to all technology solely owned by it pursuant to Section 7.2 above. For the avoidance of doubt:

[***]

7.4.2 Cooperation with Respect to Licensed Product Patents and Biontech Collaboration Patents.

(a) Prosecution.

(i) With respect to the Licensed Product Patents and Biontech Collaboration Patents, each Party shall (a) provide the other Party with written notice reasonably in advance of any filing of such Patent Rights for which it controls the preparation and filing pursuant to Section 7.4.1 above; (b) provide the other Party with any draft of an application for such Patent Right to be filed reasonably in advance of filing and consider in good faith the incorporation of reasonable comments by the other Party thereon; (c) provide the other Party with a copy of all the documents as filed relating to the filing of any application for such Patent Right once filed; (d) provide the other Party with copies of any material communications received from or filed in patent office(s) with respect to such filings; [***] and (f) provide the other Party with written notice as early as possible prior to abandoning any such Patent Rights. Each Party shall cause its employees, agents or consultants, at its expense, to execute such documents and to take such other actions as reasonably necessary or appropriate to enable the other Party to prepare, file, prosecute and maintain such Patent Rights.

(ii) In the event that either Party provides the other Party with the written notice described in clause (f) of paragraph (i) above prior to abandoning any Patent Rights, then the other Party shall have the option, exercisable by delivery of written notice thereof within [***] thereafter, to assume the right (but not the obligation), at its sole expense and sole discretion, to control the preparation, filing, prosecution and maintenance of such Patent Right.

(b) Enforcement. Sanofi shall have the first right (but not the obligation), at its sole expense and sole discretion, to control the enforcement of the Licensed Product Patents to abate any infringement thereof. [***]

7.4.3 Jointly Owned Technology.

(a) Prosecution.

(i) [***]. Each Party shall regularly notify the other Party in writing of any newly created Joint Foreground Technology. Each Party shall cause its employees, agents or consultants, at its sole expense, to execute such documents and to take such other actions as reasonably necessary or appropriate to enable the jointly selected external counsel to prepare, file, prosecute and maintain such Patent Rights. [***].

(ii) [***]

(b) Enforcement.

(i) Each Party (**Enforcing Party**) shall have the first right (but not the obligation), at its sole discretion, to control the enforcement or otherwise abate the infringement of any Patent Rights prosecuted by it in accordance with Section 7.4.3(a)(i) above. [***]

(ii) [***].

7.4.4 Patent Assistance. Each Party shall perform such lawful acts and execute such documents as requested by the other Party from time to time in order to reasonably assist the other Party in the preparation, filing, prosecution, maintenance and enforcement activities described in this Section 7.4.

7.5 Assignment of Inventor's Rights. Each Party shall ensure that all employees and other persons acting on its behalf in performing its obligations under this Agreement shall be obligated, either pursuant to Applicable Law or pursuant to a binding written agreement, to assign to it, or as it shall direct, all inventions made or conceived by such employees or other persons.

7.6 No Implied Licenses. No rights or licenses with respect to any Intellectual Property Rights Controlled by either Party are granted or shall be deemed granted hereunder or in connection herewith, other than those rights expressly granted in this Agreement.

8. Confidentiality.

8.1 Confidential Information. During the term of this Agreement and for a period of [***] thereafter, each Party (the **Receiving Party**) shall, and shall cause its officers, directors, employees, agents, Affiliates, and sublicensees to, maintain in confidence all Confidential Information disclosed by the other Party (the **Disclosing Party**). The Receiving Party shall not use, disclose or allow others to use the Disclosing Party's Confidential Information, except on a need-to-know basis by its Affiliates and its and its Affiliates' directors,

officers, employees, consultants, distributors or permitted assignees, and then only to the extent such disclosure is reasonably necessary in connection with the Receiving Party's activities as expressly authorized by this Agreement and provided that such Affiliates, directors, officers, employees, consultants, distributors or permitted assignees are bound by obligations of confidentiality and non-use of Confidential Information substantially similar to those hereunder. The Receiving Party shall notify the Disclosing Party promptly upon discovery of any unauthorized use or disclosure of the Disclosing Party's Confidential Information.

8.2 Terms of this Agreement. Except as otherwise provided in Section 8.1, during the term of this Agreement and for a period of [***] thereafter, neither Party shall disclose any terms or conditions of this Agreement to any Third party without the prior consent of the other Party. Notwithstanding the foregoing, the Parties may agree in writing upon the substance of information that can be used to describe the terms of this transaction, and each Party may disclose such information, by way of a press release or otherwise, without the other Party's consent. Further, the Parties may make disclosures as permitted by Section 8.3.

8.3 Permitted Disclosures. The confidentiality obligations contained in this Section 8 shall not apply to the extent that disclosure by the Receiving Party of the Disclosing Party's Confidential Information is reasonably necessary in the following instances: (i) compliance (by the Receiving Party or its Affiliates) with Applicable Law, regulation of a governmental agency (including in connection with a public stock offering) or a court of competent jurisdiction, provided that the Receiving Party shall first give written notice thereof to the Disclosing Party such that the Disclosing Party shall have an opportunity to seek a protective order limiting any such disclosure; (ii) disclosure to investment bankers, investors and potential investors, each of whom before disclosure must be bound by similar obligations of confidentiality and non-use of Confidential Information at least equivalent in scope to those set forth in this Section 8; (iii) disclosure to a patent office for the purposes of filing or enforcing Patent Rights as permitted in this Agreement; (iv) disclosure to a Regulatory Authority for the purposes of any filing, application or request for Marketing Approval for Licensed Products as permitted in this Agreement and (v) disclosure made by either Party or its Affiliates or sublicensees to Third Parties as may be necessary or useful in connection with the exploitation of the Licensed Products, Mixtures or Option Products as permitted by this Agreement, including subcontracting or sublicensing transactions in connection therewith.

8.4 Termination of Prior Agreement. This Agreement supersedes the Confidentiality Agreement between Biontech and Sanofi dated as of [***] (the "CDA"). All information exchanged between the Parties under the CDA shall be deemed Confidential Information and shall be subject to the terms of this Article 8.

9. Representations and Warranties.

9.1 Mutual Representations. Each Party hereby represents and warrants to the other Party that, as of the Effective Date:

(a) Such Party is a company duly organized, validly existing and in good standing under the laws of its jurisdiction of incorporation or formation.

(b) Such Party has all requisite corporate power and corporate authority to enter into this Agreement and to carry out its obligations under this Agreement.

(c) All requisite action on the part of such Party, its directors and stockholders required by Applicable Law to authorize the execution and delivery by such Party of this Agreement, and the performance of all obligations of such Party under this Agreement, has been taken.

(d) This Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms.

(e) The execution, delivery and performance of this Agreement, and compliance with the provisions of this Agreement, by such Party do not and shall not: (A) violate any provision of Applicable Law or any ruling, writ, injunction, order, permit, judgment or decree of any governmental authority, (B) constitute a breach of, or default under (or an event which, with notice or lapse of time or both, would become a default under) or conflict with, or give rise to any right of termination, cancellation or acceleration of, any agreement, arrangement or instrument, whether written or oral, by which such Party or any of its assets are bound, or (C) violate or conflict with any of the provisions of such Party's organizational documents (including any articles or memoranda of organization or association, charter, bylaws or similar documents).

9.2 Additional Representations of Biontech. Biontech represents and warrants to Sanofi that, as of the Effective Date:

9.2.1 Biontech has the right to grant to Sanofi the licenses it purports to grant pursuant to this Agreement, and Biontech has not granted any Third Party rights that would otherwise interfere or be inconsistent with Sanofi's rights hereunder.

9.2.2 Biontech is the sole and exclusive owner of, or otherwise Controls, the Biontech Background Technology.

9.2.3 There is no (A) claim, demand, suit, proceeding, arbitration, inquiry, investigation or other legal action of any nature, civil, criminal, regulatory or otherwise, pending or, to Biontech's knowledge, threatened against Biontech or any of its Affiliates or (B) judgment or settlement against or owed by Biontech or any of its Affiliates, in each case in connection with the Biontech Background Technology.

9.2.4 All of Biontech's and its Affiliates' employees, officers, subcontractors, consultants and any other person who have participated in any respect in the invention or authorship of any Biontech Background Technology or who will participate in the Research Plan are obliged by applicable law to assign, or have executed written agreements assigning, to Biontech or its Affiliates, as applicable, all inventions made during the course of and as the result of such person's association with Biontech Background Technology and are under written and existing obligations restricting disclosure and use by such person of Biontech's Confidential Information as well as confidential information of other parties (including Sanofi and its Affiliates) which such person may receive, to the extent required to comply with Biontech's obligations under this Agreement.

9.2.5 Neither Biontech, nor any person(s) who have performed work related to the Biontech Background Technology on behalf of Biontech, is or has been debarred or, to Biontech's knowledge, has engaged in any conduct that has resulted, or would reasonably be expected to result, in such debarment under Applicable Law. No actions that would reasonably be expected to result in such debarment are pending or threatened against Biontech or any person(s) who have performed work related to the Biontech Background Technology on behalf of Biontech and, to Biontech's knowledge, there are no facts that could reasonably give rise to such an action.

9.2.6 All application, registration, maintenance and renewal fees in respect of Patent Rights included in the Biontech Background Technology licensed pursuant to Section 7.3.1(b)(i), and Controlled by Biontech of the Effective Date have been paid and all necessary documents and certificates have been filed with the relevant agencies for the purpose of maintaining such Patent Rights. To Biontech's knowledge, there are no claims, challenges, oppositions, interference or other proceedings pending or threatened in relation to such Patent Rights, and Biontech has filed and prosecuted all such Patent Rights in good faith and complied with its duties of disclosure with respect thereto.

9.2.7 The Biontech Background Technology comprises all of the Intellectual Property Rights Controlled by Biontech which is used by Biontech, its Affiliates, consultants, subcontractors and sublicensees in the research and Development of the Mixtures, as of the Effective Date.

9.2.8 Biontech has not received any written notice alleging that the making, use, sale, offering for sale, importing, exporting, or other research, Development, Manufacture and Commercialization of the Licensed Product Candidates infringe or misappropriate the intellectual property rights of any Third Party, and to the knowledge of Biontech, there is no such infringement or misappropriation.

9.2.9 Biontech has not initiated or been involved in any proceedings, actions or claims in which it alleges that any Third Party is or was infringing or misappropriating any Biontech Background Technology, nor have any such proceedings, actions or claims been threatened by Biontech, nor does Biontech know of any valid basis for any such proceeding.

9.2.10 Biontech has received no government or other funding relationships to which it is a party that would result in rights to any Licensed Product residing in a governmental or quasi-governmental authority that would interfere or be inconsistent with Sanofi's rights hereunder.

9.3 Disclaimer of Warranties. The Parties acknowledge and agree that the research and Development to be conducted under this Agreement is experimental in nature, and that neither Party can guarantee a successful outcome thereof. Except for those warranties set forth in Sections 9.1 and 9.2 of this Agreement, neither Party makes any warranties, written, oral, express or implied, with respect to its performance under this Agreement or the results thereof. EACH PARTY DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT.

FURTHERMORE, BIONTECH AND SANOFI ACKNOWLEDGE AND AGREE THAT NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS REPRESENTING AN ESTIMATE OR PROJECTION OF ANTICIPATED COMMERCIAL SALES OF ANY LICENSED PRODUCT, AND THAT THE MILESTONES AND NET SALES LEVELS SET FORTH IN ARTICLE 6 OR ELSEWHERE IN THIS AGREEMENT OR THAT HAVE OTHERWISE BEEN DISCUSSED BY THE PARTIES ARE MERELY INTENDED TO DEFINE THE MILESTONE PAYMENTS OR ROYALTY OBLIGATIONS IN THE EVENT SUCH MILESTONES OR NET SALES LEVELS ARE ACHIEVED. NEITHER BIONTECH NOR SANOFI MAKES ANY REPRESENTATION OR WARRANTY, EITHER EXPRESS OR IMPLIED, THAT EITHER PARTY WILL BE ABLE TO SUCCESSFULLY RESEARCH, DEVELOP, MANUFACTURE OR COMMERCIALIZE ANY LICENSED PRODUCT, REGARDING THE LIKELIHOOD OF SUCCESS OF ANY APPLICATION FOR REGULATORY APPROVAL RELATING TO ANY LICENSED PRODUCT OR, IF COMMERCIALIZED, THAT ANY PARTICULAR NET SALES LEVEL OF SUCH LICENSED PRODUCT WILL BE ACHIEVED.

9.4 Anti-Bribery and Anti-Corruption Compliance.

9.4.1 Each Party agrees, on behalf of itself, its officers, directors and employees and on behalf of its Affiliates, agents, representatives, consultants and subcontractors hired in connection with the Development or Commercialization of the Licensed Products or the Option Products (together with such Party, the **Party Representatives**) that in connection with the performance of its obligations hereunder, the Party Representatives shall not directly or indirectly pay, offer or promise to pay, or authorize the payment of any money, or give, offer or promise to give, or authorize the giving of anything else of value, to:

(a) any person employed by or acting on behalf of a governmental body, government-controlled entity or public international organization (a **Government Official**) in order to influence official action;

(b) any Government Official (A) to influence such person to act in breach of a duty of good faith, impartiality or trust (“acting improperly”), (B) to reward such person for acting improperly, or (C) where such person would be acting improperly by receiving the money or other thing of value; or

(c) any other person while knowing or having reason to believe that all or any portion of the money or other thing of value will be paid, offered, promised or given to, or will otherwise benefit, a Government Official in order to influence official action for or against either Party in connection with the matters that are the subject of this Agreement.

9.4.2 The Party Representatives shall not, directly or indirectly, solicit, receive or agree to accept any payment of money or anything else of value in violation of the Anti-Corruption Laws

9.4.3 Each Party, on behalf of itself and its other Party Representatives, represents and warrants to the other Party that for the term of this Agreement and [***] thereafter, such Party shall and shall procure that its other Party Representatives keep and maintain accurate books and reasonably detailed records reasonably required to establish compliance with Sections 9.4.1 and 9.4.2 above.

9.4.4 Each Party shall promptly provide the other Party with written notice of the following events, subject to any obligations under Applicable Law or contractual obligations:

(a) Upon becoming aware of any breach or violation by the first Party or its Party Representative of any representation, warranty or undertaking set forth in Sections 9.4.1 or 9.4.2.

(b) Upon receiving a formal notification that it is the target of a formal investigation by a Regulatory Authority for a violation of Anti-Corruption Law Violation or upon receipt of information from any of its Party Representatives connected with this Agreement that any of them is the target of a formal investigation by a Regulatory Authority for a violation of Anti-Corruption Law.

9.4.5 Without prejudice to any auditing or inspection rights that are set forth elsewhere in this Agreement, each Party shall, for the term of this Agreement and [***] thereafter, for the purpose of allowing the other Party to audit and monitor the performance of its compliance with this Section 9.3 permit the other Party, its Affiliates, any auditors of any of them and any Regulatory Authority to have access, upon reasonable advance notice, during normal business hours to any premises of such first Party or its other Party Representatives used in connection with this Agreement, together with a right to access personnel and records that relate to this Agreement. The results of any such audit shall constitute Confidential Information of the audited Party, in respect of which the other Party shall comply with the provisions contained in Article 8 (subject to the terms and exceptions set forth therein).

9.4.6 Each Party shall be responsible for any breach of the Anti- Corruption Laws by its Party Representatives.

9.4.7 Each Party may disclose the terms of this Agreement or any action taken under this Section 9.4 to prevent a potential violation or address a continuing violation of applicable Anti-Corruption Laws, including the identity of the other Party and the payment terms, to any governmental authority if and to the extent the first Party reasonably determines, upon advice of counsel, that such disclosure is necessary.

10. Indemnification and Limitation of Liability.

10.1 Indemnification.

10.1.1 Indemnification by Sanofi. Sanofi will indemnify Biontech, its Affiliates and their respective directors, officers, employees, and agents, and their respective successors, heirs and assigns (collectively, **Biontech Indemnitees**), and defend and save each of them harmless, from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses) (collectively, **Losses**) in connection with any and all suits, investigations, claims or demands of Third Parties (collectively, **Third Party Claims**) to the extent arising from or occurring as a result of: (i) any Sanofi representation or warranty set forth herein being untrue in any material respect when made or deemed made or material breach by Sanofi of any of its covenants or obligations under this Agreement; (ii) any gross negligence, willful misconduct, or violation of Applicable Law, on the part of Sanofi in performing its obligations under this Agreement; or (iii) the Development or Commercialization

by Sanofi or any of its Affiliates or sublicensees of the Licensed Product Candidates or the Licensed Products; except in each case for those Losses as to which Biontech has an obligation to indemnify Sanofi pursuant to Section 10.1.2, as to which Losses each Party will indemnify the other to the extent of their respective liability; provided, however, that Sanofi will not be obligated to indemnify Biontech Indemnitees for any Losses to the extent that such Losses arise as a result of gross negligence or willful misconduct on the part of any Biontech Indemnitee.

10.1.2 Indemnification by Biontech. Biontech will indemnify Sanofi, its Affiliates and sublicensees and their respective directors, officers, employees and agents, and their respective successors, heirs and assigns (collectively, **Sanofi Indemnitees**), and defend and save each of them harmless, from and against any and all Losses in connection with any and all Third Party Claims to the extent arising from or occurring as a result of: (i) any Biontech representation or warranty set forth herein being untrue in any material respect or material breach by Biontech of any of its covenants or obligations under this Agreement; (ii) any gross negligence, willful misconduct, or violation of Applicable Law on the part of Biontech in performing its obligations under this Agreement; or (iii) the research, Development or Commercialization by Biontech or any of its Affiliates or sublicensees of the Licensed Product Candidates or the Licensed Products; except in each case for those Losses for which Sanofi has an obligation to indemnify Biontech pursuant to Section 10.1.1, as to which Losses each Party will indemnify the other to the extent of their respective liability; provided, however, that Biontech will not be obligated to indemnify Sanofi Indemnitees for any Losses to the extent that such Losses arise as a result of gross negligence or willful misconduct on the part of any Sanofi Indemnitee.

10.2 Notice of Claim. All indemnification claims provided for in Sections 10.1.1 and 10.1.2 will be made solely by such Party to this Agreement (the **Indemnified Party**). The Indemnified Party will promptly notify the indemnifying Party (such notice, an **Indemnification Claim Notice**) upon actual knowledge of any claim or proceeding resulting in Losses, it being understood and agreed that the failure to give such Indemnification Claim Notice will not relieve the indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that such indemnifying Party is actually and materially prejudiced as a result of such failure to give notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss is known at such time).

10.3 EXCEPT FOR A BREACH OF SECTION 8 (“CONFIDENTIALITY”) OR A BREACH BY A PARTY OF THE REPRESENTATIONS OR WARRANTIES UNDER SECTION 9, IN NO EVENT SHALL EITHER PARTY BE LIABLE OR OBLIGATED TO THE OTHER PARTY IN ANY MANNER FOR ANY SPECIAL, NON-COMPENSATORY, CONSEQUENTIAL, INDIRECT, INCIDENTAL, STATUTORY OR PUNITIVE DAMAGES OF ANY KIND, INCLUDING, WITHOUT LIMITATION, LOST PROFITS AND LOST REVENUE, REGARDLESS OF THE FORM OF ACTION, WHETHER IN CONTRACT, TORT, NEGLIGENCE, STRICT PRODUCT LIABILITY, OR OTHERWISE, EVEN IF INFORMED OF OR AWARE OF THE POSSIBILITY OF ANY SUCH DAMAGES IN ADVANCE. THE LIMITATIONS SET FORTH ABOVE SHALL BE DEEMED TO APPLY TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW AND NOTWITHSTANDING THE FAILURE OF THE ESSENTIAL PURPOSE OF ANY LIMITED REMEDIES. THE PARTIES ACKNOWLEDGE AND AGREE THAT THE FOREGOING LIMITATIONS ARE AN ESSENTIAL BASIS OF THE BARGAIN BETWEEN THE PARTIES.

11. Project Governance.

11.1 Alliance Managers. Each of the Parties shall appoint one representative to serve as a primary point of contact between the Parties (each, an **Alliance Manager**). Each Party may change its designated Alliance Manager from time to time upon reasonable written notice to the other Party. Any Alliance Manager may designate a substitute to temporarily perform his or her functions by written notice to the other Party. The Alliance Manager will attend all Joint Steering Committee meetings to support the Joint Steering Committee in the discharge of its responsibilities and will be a non-voting participant of such meetings. An Alliance Manager may bring any matter to the attention of the Joint Steering Committee if such Alliance Manager reasonably believes that such matter warrants the attention of the Joint Steering Committee. Each Alliance Manager will be charged with creating and maintaining a collaborative work environment within the Joint Steering Committee. In addition, each Alliance Manager: (i) will be the first point of contact for all matters beyond the day-to-day collaboration matters, (ii) will coordinate the relevant functional responsibilities of the Parties in developing and executing strategies and plans for the projects in an effort to ensure consistency and efficiency (iii) will plan and coordinate cooperative efforts and internal and external communications, and (iv) will take responsibility for ensuring that governance activities, such as the conduct of Joint Steering Committee meetings, and preparation and signature of the respective meeting minutes, occur as set forth herein, and that relevant action items resulting from the Joint Steering Committee are appropriately carried out or otherwise addressed

11.2 Joint Steering Committee.

11.2.1 Establishment and Composition of Joint Steering Committee. Within [***] following the Effective Date, the Parties shall establish a joint steering committee (**Joint Steering Committee**). The Joint Steering Committee shall have a total of up to [***] members. Up to [***] members of the Joint Steering Committee shall be appointed by Sanofi, and up to [***] members of the Joint Steering Committee shall be appointed by Biontech. Each Joint Steering Committee member shall have sufficient authority to ensure acceptance and execution of Joint Steering Committee decisions within its organization. Each Party may appoint substitutes or alternates for its Joint Steering Committee members at any time by written notice the other Party. The Parties may mutually agree to change the size of the Joint Steering Committee at any time. Each Party shall have the right to invite additional representatives (including, without limitation, representatives of its Patent or Manufacturing functions) to attend meetings of the Joint Steering Committee. The Joint Steering Committee shall be established for the entire Research Term and, unless replaced by one or several other *ad hoc* committees under the relevant Development or Commercialization agreements, the duration of any co-Development of a Biontech Option Product, Sanofi Option Product and Sanofi Option Combination Product.

11.2.2 Responsibilities of the Joint Steering Committee. The Joint Steering Committee shall be responsible for directing, coordinating and supervising the research activities of the Parties during the Research Phase and the co-Development of Biontech Option Products, Sanofi Option Products and Sanofi Option Combination Products. In particular, the

Joint Steering Committee shall (i) review and update the Research Plan; (ii) receive regular reports from each Party's Alliance Manager on, and monitor the conduct, progress and results of each Party's activities under the Research Plan; (iii) oversee and manage the work under, monitor the progress of, and implement any Development plan according to Section 4, including compliance with budget and timelines; (iv) review quarterly Manufacturing information produced in accordance with Section 3.3.6, including forecasts of clinical supplies requirements for the co-Development of Biontech Option Products, Sanofi Option Products and Sanofi Option Combination Products; (v) discuss and exchange information regarding the conduct of ongoing clinical trials; (vi) resolve any issues referred to it by the Parties in accordance with Section 13.7; and (vii) from time to time, establish one or more subcommittees or project teams to oversee particular projects or activities, as the JSC deems necessary or advisable. For the avoidance of doubt, the Joint Steering Committee shall not have any responsibilities with respect to Sanofi's Development and Commercialization of Licensed Products.

11.2.3 Meetings of the Joint Steering Committee. Meetings of the Joint Steering Committee shall be scheduled from time to time by mutual agreement of the Parties or upon request of one Party, but in no event less than once every [***]. The meetings may be held in person, per telephone or video conference. The chair shall alternate at [***] intervals between representatives of each Party, starting with a Biontech representative as the chair. The Alliance Managers shall attend the meetings and the Alliance Manager of the Party hosting any Joint Steering Committee meeting shall record the minutes of the meeting in writing. Such minutes shall be circulated to the other Party's Alliance Manager no later than [***] following the meeting for review, comment and approval of the other Party. If no comments are received within [***] of the receipt of the minutes by a Party, unless otherwise agreed, they shall be deemed to be approved by such Party. Furthermore, if the Parties are unable to reach agreement on the minutes within [***] of the applicable meeting, the sections of the minutes that have been mutually agreed between the Parties by that date shall be deemed approved and, in addition, each Party shall record in the same document its own version of those sections of the minutes on which the Parties were not able to agree.

11.2.4 Decisions of the Joint Steering Committee. A quorum of at least one (1) Joint Steering Committee member appointed by each Party shall be present at or shall otherwise participate in each Joint Steering Committee meeting. Each Party has one vote in the decisions of the Joint Steering Committee. Decisions of the Joint Steering Committee shall be unanimous. If the members of the Joint Steering Committee cannot agree on a particular issue, the issue shall be escalated pursuant to Section 13.7. The Joint Steering Committee shall have no authority to amend or modify the terms and conditions of this Agreement.

12. Term and Termination.

12.1 Natural Term. This Agreement shall become effective on the Effective Date and shall continue until the later of (i) expiration of the last to expire Royalty Term for any Sanofi Royalties or Biontech Royalties and (ii) completion of all co-Development and co- Commercialization activities hereunder; unless terminated earlier in accordance with the provisions of this Agreement.

12.2 Termination for Convenience.

12.2.1 Termination by Sanofi. Sanofi may terminate this Agreement in its entirety or on a Licensed Product-by-Licensed Product basis, with or without reason, at any time following the Effective Date upon [***] written notice to Biontech. In addition, Sanofi may terminate the co-Development of a Sanofi Option Product, on a Sanofi Option Product-by- Sanofi Option Product basis, with or without reason, at any time after the Effective Date upon [***] written notice to Biontech, except that a termination for convenience by Sanofi of the co-Development of a Sanofi Option Product during an ongoing clinical trial will only be effective at the end of such clinical trial. Termination rights with respect to co- Commercialization rights of Sanofi under Section 4.1or 4.2 shall be set forth in the relevant Commercialization agreement.

12.2.2 Termination by Biontech. Biontech may, on an Option Product-by- Option Product basis, terminate the co-Development of an Option Product, with or without reason, at any time upon [***] written notice to Sanofi, except that a termination for convenience by Biontech of the co-Development of an Option Product during an ongoing clinical trial will only be effective at the end of such clinical trial. Termination rights with respect to co-Commercialization rights of Biontech under Section 4.1or 4.2 shall be set forth in the relevant Commercialization agreement.

12.3 Termination for Breach.

12.3.1 Termination by Biontech. Biontech may terminate this Agreement in its entirety or on a Licensed Product-by-Licensed Product basis, with immediate effect by written notice to Sanofi if Sanofi materially breaches its financial obligations or any of its other material obligations hereunder (including its development obligations pursuant to Section 3.1.1), and fails to cure such breach within [***] following its receipt of written notice thereof from Biontech.

12.3.2 Termination by Sanofi. Sanofi may terminate this Agreement in its entirety or on a Licensed Product-by-Licensed Product basis, with immediate effect by written notice to Biontech if Biontech materially breaches its exclusivity obligations set forth in Section 5 or any of its other material obligations hereunder, and fails to cure such breach within [***] following its receipt of written notice thereof from Sanofi.

12.3.3 Termination by either Party. Either Party may terminate this Agreement if the other Party becomes insolvent, is compelled to file bankruptcy or is determined otherwise imminently subject to control by a bankruptcy trustee or its equivalent to the laws of the jurisdiction in which such Party is doing business.

12.3.4 Termination for breach of co-Development or co- Commercialization obligations. Either Party may terminate the co-Development of an Option Product, on an Option Product-by-Option Product basis, if the other Party materially breaches any of its material co-Development obligations set forth in Section 4 of this Agreement or the applicable Development agreement and fails to cure such breach within [***] following its receipt of written notice thereof from the terminating Party. The termination rights of each Party for breach of co-Commercialization obligations by the other Party with respect to any Option Product shall be detailed in the respective Commercialization agreement for such Option Product.

12.3.5 Clarification. If the breach of a Party (as set forth in Sections 12.3.1 to 12.3.4) is limited to a specific product (whether a Licensed Product or an Option Product), the other Party's right to terminate this Agreement shall be limited to such specific product.

12.4 Effect of Termination or Expiration. In case of any termination or expiration of this Agreement, all rights and obligations of the Parties shall cease immediately, unless otherwise indicated in this Section 12.4 or elsewhere in this Agreement. For ease of reference, a summary of the consequences applying in the event of a termination of this Agreement is set forth in Schedule E. In the event of any ambiguity, doubt or conflict, the terms and conditions of this Agreement shall take precedence over the terms and conditions set forth in Schedule E.

12.4.1 Natural Termination. If this Agreement expires in accordance with Section 12.1 above, the Parties' respective licenses contained in Section 7.3 shall survive as perpetual and fully paid-up licenses with respect to Know-how only.

12.4.2 Termination for Convenience by Sanofi relating to Licensed Products. If Sanofi terminates this Agreement in relation to one or more Licensed Products pursuant to Section 12.2.1, then:

(a) the licenses granted to Biontech under Section 7.3.2 shall survive; and

(b) Sanofi shall upon request of Biontech transfer its rights to the terminated Licensed Product (including any Biontech Option Product) in accordance with this Section 12.4.2 (such terminated Licensed Products hereinafter referred to as **Biontech Transferred Products**). With respect to any Biontech Transferred Product:

(i) Sanofi shall transfer and assign to Biontech all of its rights, title and interest in (X) the Licensed Product Patents covering such Licensed Product and (Y) the Joint Collaboration Technology to the extent comprising composition of matter claims specifically relating to the Biontech Transferred Product, and take any other action reasonably necessary to effect such transfer of ownership;

(ii) Sanofi shall transfer to Biontech reasonable copies or samples (as applicable) of all data, documents, materials or products relating to such Biontech Transferred Product developed by Biontech or Sanofi or any of Biontech's or Sanofi's Affiliates or subcontractors up to the effective date of termination, including without limitation, reasonable samples of any materials generated (or partially generated), in whatever stage of development relating to such Biontech Transferred Product;

(iii) Sanofi shall transfer to Biontech all of its right, title and interest in all regulatory filings and regulatory approvals then in its or its Affiliates' or sublicensees' name for the Biontech Transferred Product identified as of the date of termination, notify the appropriate regulatory authorities and take any other action reasonably necessary to effect such transfer of ownership;

(iv) Sanofi shall reasonably assist Biontech in the transfer of the Manufacturing of the Biontech Transferred Product from Sanofi or its subcontractors to Biontech, if applicable; and

(v) Sanofi shall grant Biontech an exclusive, worldwide, perpetual and fully paid-up license (including the right to grant sublicenses), under the Sanofi Technology and Sanofi Foreground Technology (to the extent not transferred to Biontech pursuant to Section 12.4.2(b)(i)), to research, Develop, make, have made, use, Commercialize and have Commercialized the Biontech Transferred Product in and outside the Field; and further Biontech shall have the first right (but not the obligation) to control the preparation, filing, prosecution, maintenance and enforcement of all Patent Rights in such licensed technology to the extent relating to the Biontech Transferred Product in accordance with Section 7.4.2(a) which shall apply to Biontech *mutatis mutandis*;

(c) Biontech shall pay to Sanofi with respect to each Biontech Transferred Product which Biontech subsequently Develops and Commercializes in the Field or outside the Field (whether alone or in collaboration with an Affiliate or Third Party), during the Royalty Term, a royalty of [***] on Biontech's and Biontech's Affiliates' and Biontech's and Biontech's Affiliates' (sub-)licensees' aggregate Net Sales of all products containing such Biontech Transferred Product, on a Biontech Transferred Product-by-Biontech Transferred Product as well as on a country-by-country basis.

12.4.3 Termination for Convenience by Sanofi relating to co- Development of Sanofi Option Product. If Sanofi terminates the Co-Development of any Sanofi Option Product pursuant to Section 12.2.2, then:

(a) All co-Development and co-Commercialization rights of Sanofi in relation to such Sanofi Option Product shall terminate, and

(b) Biontech shall pay to Sanofi a one-time payment in the amount of Sanofi's co-Development costs (but in any event not more than [***]) with respect to such Sanofi Option Product, such payment to become payable [***] after the First Commercial Sale of such Sanofi Option Product by Biontech or any Biontech Affiliates or sublicensee.

12.4.4 Termination for Convenience by Biontech relating to Biontech Option Product. If Biontech terminates the Co-Development of any Biontech Option Product pursuant to Section 12.2.2, then:

(a) All co-Development and co-Commercialization rights of Biontech in relation to such Biontech Option Product shall terminate,

(b) Sanofi shall pay to Biontech a one-time payment in the amount of Biontech's co-Development costs (but in any event not more than [***]) with respect to such Biontech Option Product, such payment to become payable [***] after the First Commercial Sale of such Biontech Option Product by Sanofi or any Sanofi Affiliates or sublicensees, and

(c) all other obligations of Sanofi in relation to the relevant Licensed Product (including, for the avoidance of doubt, the payment obligations pursuant to Section 6) shall remain unaffected.

12.4.5 Termination for Convenience by Biontech relating to Sanofi Option Product. If Biontech terminates the Co-Development of any Sanofi Option Product pursuant to Section 12.2.2, then:

(a) the licenses granted to Sanofi under Section 7.3.1 shall survive; and

(b) Biontech shall upon request by Sanofi transfer to Sanofi its rights to the terminated Sanofi Option Product in accordance with this Section 12.4.5 (such terminated Option Product hereinafter referred to as **Sanofi Transferred Product**). With respect to any Sanofi Transferred Product:

(i) Biontech shall transfer and assign to Sanofi all of its rights, title and interest in the Biontech Collaboration Technology and Joint Collaboration Technology to the extent comprising composition of matter claims specifically relating to the Sanofi Transferred Product, and take any other action reasonably necessary to effect such transfer of ownership;

(ii) Biontech shall transfer to Sanofi reasonable copies or samples (as applicable) of all data, documents, materials or products relating to such Sanofi Transferred Product up to the effective date of termination, including without limitation, reasonable samples of any materials generated (or partially generated), in whatever stage of development relating to such Sanofi Transferred Product;

(iii) Biontech shall transfer to Sanofi all of its right, title and interest in all regulatory filings and regulatory approvals then in its or its Affiliates' or sublicensees' name for the Sanofi Transferred Product identified as of the date of termination, notify the appropriate regulatory authorities and take any other action reasonably necessary to effect such transfer of ownership;

(iv) Biontech shall reasonably assist Sanofi in the transfer of the Manufacturing of the Sanofi Transferred Product from Biontech or its subcontractors to Sanofi, if applicable; and

(v) Biontech shall grant Sanofi an exclusive, worldwide, perpetual and fully paid-up license (including the right to grant sublicenses), under the Biontech Technology and Biontech Foreground Technology, to research, Develop, make, have made, use, Commercialize and have Commercialized the Sanofi Transferred Product in and outside the Field; and further Sanofi shall retain the first right (but not the obligation) to control the preparation, filing, prosecution, maintenance and enforcement of all Patent Rights in such technology to the extent relating to the Sanofi Transferred Products in accordance with Section 7.4.2(a);

(c) Sanofi shall pay to Biontech, with respect to each Sanofi Transferred Product which Sanofi subsequently Develops and Commercializes in the Field or outside the Field (whether alone or in collaboration with an Affiliate or Third Party), (i) as regards any Sanofi Transferred Products (including Sanofi Option Combination Products), a one-time payment in the amount of Biontech's co-Development costs (but in any event not more than [***]) such payment to become payable [***] after the First Commercial Sale of such Sanofi Option Product, and (ii) as regards Sanofi Transferred Products which are Sanofi Option Combination Products only, during the Royalty Term, a royalty at rates equal to [***] of the rates specified in Section 6.8.1 on Sanofi's and Sanofi's Affiliates' and Sanofi's and Sanofi's Affiliates' (sub-)licensees' aggregate Net Sales of all products containing such Sanofi Option Combination Product, on a Sanofi Option Combination Product-by-Sanofi Option Combination Product as well as on a country-by-country basis (provided that the royalty off-set set forth in Section 6.8.2 shall apply *mutatis mutandis*); and

(d) with respect to Sanofi Transferred Products which are Sanofi Combination Option Products only, Biontech shall supply Sanofi with all clinical and commercial quantities of any Sanofi Transferred Products needed by Sanofi for the Development and/or the Commercialization of such products at reasonable commercial terms under a manufacturing and supply agreement to be negotiated between the Parties in good faith.

12.4.6 Termination by Biontech for Breach relating to Licensed Product. If Biontech terminates this Agreement in relation to any Licensed Product (including any Biontech Option Product) pursuant to Section 12.3.1 or 12.3.3, then:

(a) Sanofi shall no longer have the right or the obligation to co-Develop or co-Commercialize any Sanofi Option Product and Sanofi shall not be entitled to any compensation for costs incurred in the co-Development of such Sanofi Option Product before such termination; and

(b) the provisions of Section 12.4.2 shall apply, except that the royalty rate payable with respect to each Biontech Transferred Product which Biontech subsequently Develops and Commercializes in the Field or outside the Field (whether alone or in collaboration with an Affiliate or Third Party) during the Royalty Term shall be [***] of the royalty rate specified in Section 12.4.2(c).

12.4.7 Termination by Biontech for Breach relating to Sanofi Option Product. If Biontech terminates this Agreement pursuant to Section 12.3.1 or 12.3.3 in relation to any Sanofi Option Product, then:

(a) Sanofi shall no longer have the right or the obligation to co-Develop or co-Commercialize any Sanofi Option Product and Sanofi shall not be entitled to any compensation for costs incurred in the co-Development of such Sanofi Option Product before such termination; and

(b) the provisions of Section 12.4.3 shall apply, except that the one-time payment payable with respect to each Sanofi Option Product shall be [***] of the amount specified in Section 12.4.3(b).

12.4.8 Termination by Sanofi for Breach in relation to Licensed Products. If Sanofi terminates this Agreement in relation to any Licensed Product (including Biontech Option Products) pursuant to Section 12.3.2 or 12.3.3, then:

(a) Biontech shall deliver to Sanofi any Licensed Product Candidates generated to date which have not been previously delivered to Sanofi under the Research Phase, in whatever stage of development, and Sanofi shall own all such materials; and

(b) the licenses granted to Sanofi under Section 7.3 shall survive;

(c) Biontech shall no longer have the right or the obligation to co-Develop or co-Commercialize any Biontech Option Product and Biontech shall not be entitled to any compensation for costs incurred in the co-Development of such Biontech Option Product before such termination; and

(d) All milestones and royalties to be paid by Sanofi pursuant to Section 6 shall be reduced by [***] (and all reporting and other obligations of Sanofi under Sections 6.8.3 shall continue to apply).

12.4.9 Termination by Sanofi for Breach in relation to co-Development of Biontech Option Product. If Sanofi terminates Biontech's co-Development rights in relation to any Biontech Option Product pursuant to Section 12.3.2 or 12.3.3, then the provisions of Section 12.4.4 shall apply, except that the one-time payments payable by Sanofi shall be [***] of the amount specified in Section 12.4.4(b).

12.4.10 Termination by Sanofi for Breach in relation to Sanofi Option Products. If Sanofi terminates Biontech's co-Development rights in relation to any Sanofi Option Product pursuant to Section 12.3.2 or 12.3.3, then:

(a) Biontech shall no longer have the right or the obligation to co-Develop or co-Commercialize any Biontech Option Product and Biontech shall not be entitled to any compensation for costs incurred in the co-Development of such Biontech Option Product before such termination; and

(b) the provisions of Section 12.4.5 shall apply, except that the payments to be made by Sanofi with respect to each Sanofi Option Product shall be [***] of the amounts specified in 12.4.5(c).

12.4.11 Further Claims Unaffected. For the avoidance of doubt, the rights of the terminating Party pursuant to Sections 12.4.6 to 12.4.10 shall not affect any damage claims that the terminating Party may have against the other Party as a result of the other Party's breach of contract under Applicable Laws.

12.4.12 General Effects of Termination.

(a) Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. Upon any expiration or termination of this Agreement, the provisions of Sections 1, 6.8.3(c) (to the extent self-limited in duration), 6.8.3(e) (for the duration that Section 6.8.3(c) survives), 7 (other than 7.3), 8, 9, 12.4 and 13 shall survive.

(b) Upon the expiration or termination of this Agreement, each Party shall immediately return or deliver to the other Party all of the other Party's Confidential Information, as well as any of the other Party's materials delivered by the other Party; provided however, that each Party shall be permitted to retain and use any Confidential Information of the other Party which is necessary or useful for such Party to exercise its rights under any rights or licenses granted under this Agreement, so long as such grant remains in force and provided, further, that each Party shall retain the right to practice any Joint Collaboration Know-how free of charge, to the extent such practice does not infringe on any Patent Rights transferred to, or otherwise owned by, the other Party.

13. General Provisions.

13.1 Notices. Any consent, notice or report required or permitted to be given or made under this Agreement by one of the Parties to the other shall be in writing and addressed to such other Party at its address indicated below, or to such other address as the addressee shall have last furnished in writing to the addressor, and shall be effective upon receipt by the addressee.

If to Sanofi:	Sanofi <u>Attn:</u> [***] 54, rue La Boétie 75008 Paris, France Facsimile: [***]
If to Biontech:	Biontech RNA Pharmaceuticals GmbH <u>Attn:</u> [***] An der Goldgrube 12 55131 Mainz, Germany facsimile: [***]

13.2 Entire Agreement. This Agreement, including the Exhibits to this Agreement, represents the entire understanding between the Parties with respect to the subject matter hereof and supersedes all previous oral or written communication or agreements, and all contemporaneous oral communication and agreements between the Parties.

13.3 Form Requirement. This Agreement may only be amended, modified or supplemented by the Parties in writing. The same applies to this Section 13.3.

13.4 Assignment. Neither Party may assign its contractual rights and obligations or parts thereof without the prior written consent of the other Party, except for permitted subcontracting and provided, however, that either Party may, without such consent, assign this Agreement and all of its rights and obligations hereunder (i) to any Affiliate or (ii) in connection with the transfer or sale of all or substantially all of its business to which this Agreement relates, or in the event of its merger, consolidation, or other similar transaction. For clarification, any assignment to Third Parties which is not expressly allowed above requires the approval of the other Party, which approval shall not be withheld unreasonably.

13.5 Severability. If any provision of this Agreement is found to be invalid or otherwise unenforceable, in whole or in part, the validity of the remainder of the Agreement shall not be affected. Furthermore, the Parties agree that the invalid or unenforceable provision or part thereof shall be superseded by an adequate provision that, to the legally permitted extent, comes closest to what the Parties would have desired at the time of conclusion of the Agreement had they considered the issue concerned.

13.6 Independent Contractor. Nothing in this Agreement shall create, or be deemed to create, a partnership, joint venture, or the relationship of principal and agent or employer and employee between the Parties. Each Party agrees to perform under this Agreement solely as independent contractor.

13.7 Dispute Resolution. Any dispute arising between the Parties in connection with this Agreement shall be referred to the Joint Steering Committee. If the Joint Steering Committee is unable to negotiate in good faith and settle the dispute within [***] after being requested to do so, either Party may submit the dispute to the Parties' CEOs who shall meet in order to attempt to resolve the dispute. If the dispute is not settled, at the latest, within [***] from the date that the dispute has been escalated to the executive officers, either Party may pursue legal action in accordance with Section 13.8 below. For the avoidance of doubt, if the dispute is with respect to an amendment of the Research Plan or any Development agreement or Commercialization agreement, the current version of such Research Plan, Development agreement or Commercialization agreement shall remain in effect until the dispute is finally settled.

13.8 Governing Law, Arbitration. This Agreement shall be governed by the laws of Germany without reference to its conflict of laws provisions. All disputes arising out or in connection with this Agreement shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in the accordance with said Rules. The place of the Arbitration Tribunal shall be Frankfurt, Germany. The language of the arbitration proceeding shall be English.

13.9 Construction. This Agreement will be fairly interpreted in accordance with its terms and without any strict construction in favor of or against any Party.

13.10 Counterparts; Facsimile. This Agreement may be executed in counterparts, all of which together shall constitute one and the same instrument. Signing and delivery of this Agreement may be evidenced by a pdf file of the signed signature page to the other Party.

[Signatures on the Following Page]

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

SANOFI

By: [***]
Name: [***]
Title: [***]

BIONTECH RNA PHARMACEUTICALS GMBH

By: [***]
Name: [***]
Title: [***]

Schedule A – Preclinical Milestone Criteria

[***]

Schedule B – Initial Research Plan

[***]

Schedule C

PROCESS DEVELOPMENT AND SUPPLY AGREEMENT TERMS

The following terms represent general principles to be included in the Process Development and Supply Agreement (“PDSA”). Specifically, the principles below will be included in each such agreement; provided, that the terms and conditions of the provisions setting forth those principles will be subject to the mutual agreement of the Parties.

Parties	Biontech Sanofi
Product	Licensed Products
Supply	Supply and purchase of clinical and commercial quantities of Licensed Products as defined in the Collaboration and License Agreement
Joint Manufacturing Committee	To be instituted promptly after execution of the Process Development and Supply Agreement. The JMC shall include representatives from Biontech and Sanofi’s Technical Development, Quality/Regulatory and Manufacturing functions.
Forecast for Development Supply	An agreed upon system to be defined to support the Development plan (including timelines for ordering)
Capacity	Manufacturing Party will maintain a sufficient capacity in accordance with the forecasts and otherwise to fulfill its obligations of supply for the term of the PDSA
Audit	Industry-standard right of audit of respective manufacturing sites of the Products
Key Performance Indicators	To be defined in the PDSA
Failure to Supply	To be defined in the PDSA

Schedule D – Biontech Background Technology Covered by Exclusive License

[***]

Schedule E – Overview of Termination Consequences

[***]

THE SYMBOL “[*]” DENOTES PLACES WHERE CERTAIN IDENTIFIED
INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i)
NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE
COMPANY IF PUBLICLY DISCLOSED
AMENDMENT**

This amendment (this *Amendment*) is effective as of December 22nd, 2018 (the *Amendment Effective Date*), entered into by and between Sanofi, having a place of business at 54, rue La Boétie, 75008 Paris, France (*Sanofi*), and BioNTech RNA Pharmaceuticals GmbH, having a place of business at An der Goldgrube 12, 55131 Mainz, Germany (*Biontech*). Sanofi and Biontech shall each individually be referred to herein as a *Party*, and shall be referred to together as the *Parties*.

RECITALS

A. On November 2nd, 2015, as amended by an amendment letter dated December 14th, 2017, the Parties entered into a Collaboration and License Agreement (the *Agreement*) with the desire to collaborate in the research, development and commercialization of RNA-based therapeutics for the treatment of cancer.

B. The Parties have agreed to amend the Agreement on the terms set out in this Agreement.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants set forth below, the Parties hereby agree as follows:

1. Definitions. Capitalized terms used in this Amendment shall have the meanings as defined herein, provided that capitalized terms which are used but not defined herein shall have the meanings ascribed to them in the Agreement.

2. Amendments. With effect from the Amendment Effective Date the Parties agree the following amendments to the Agreement:

Extension of Fusion Protein definition

2.1 Section 1.40 is amended and restated as follows:

“1.40 *Fusion Protein* shall mean a fusion protein as specified in Schedule F to this Agreement.”

Amendment of the Definition of “Mixture” and addition of related definitions

2.2 The definition of “Mixture” in Section 1.66 of the Agreement shall be amended and restated as follows:

“1.66 *Mixture* shall mean two or more mRNAs administered together in the same solution, [***]

2.3 The following definitions shall be added to Section 1 of the Agreement:

[***]

2.4 The Parties agree that Section 4.2 of the Agreement shall be amended as follows:

[***]

2.5 The following provision shall be added as a new clause (viii) to Section 11.2.2 of the Agreement:

“(viii) discuss any proposed amendment or update to the list of Fusion Proteins set out in Schedule F and the list of [***] set out in Schedule G.”

2.6 Within sixty (60) days following the Amendment Effective Date, the JSC shall agree to a revised Research Plan including activities for assessing the feasibility of using [***] (as defined above) in the Field and for researching and Developing Mixtures containing [***] in the Field. Either Party may recommend changes to the Research Plan at any time; provided however, that such change shall only be effective upon the approval of the Joint Steering Committee in accordance with Section 11.2 of the Agreement; and provided further that, except with respect to [***], Sanofi may in its sole discretion decide to modify the list of mRNAs to be evaluated under the Research Plan.

2.7 The definition of “Sanofi Background Technology” in Section 1.89 of the Agreement shall be amended and restated as follows:

“1.89 **Sanofi Background Technology** shall mean Background Technology Controlled by Sanofi [***]:

and Biontech shall not be required to perform [***].

Extension of the Research Term

2.8 Section 1.87 is amended and restated as follows:

“1.87 **Research Term** shall mean the research term as further defined in Section 2.10.”

2.9 Section 2.10 is deleted in its entirety and replaced as follows:

“2.10 **Research Term**. The Research Term shall begin on the Effective Date and shall end upon the earlier of: (i) November 2, 2021, and (ii) the date on which Sanofi has selected the fifth (5th) Licensed Product.”

2.10 As a consequence of the amendments in sections 2.4 and 2.5 of this Amendment:

(a) all references in the Agreement to the “Initial Research Term” shall be deemed to refer to the “Research Term”,

(b) the reference in Section 6.6.2 of the Agreement to the “extended Research Term pursuant to Section 2.10.2” shall be deemed to refer to the “Research Term”;

(c) all references to Section 2.10.1 or 2.10.2 of the Agreement shall be deemed to be a reference to Section 2.10 of the Agreement; and

(d) the reference to “the above exclusivity” in Section 5.3 of the Agreement shall be deemed to be a reference to “Biontech’s obligations not to engage in certain research and Development activities and not to grant certain rights to any Third Party as set out in Section 5.1”.

(e) Section 5.2 of the Agreement is deleted in its entirety and replaced with:

“ Omitted.”

Level of resource

2.11 The following provision shall be added to the end of Section 2.3 of the Agreement:

“Without limiting the foregoing, throughout the period beginning from December 21, 2018 and ending on the last day of the Research Term Biontech shall, at its own cost and expense, allocate not less than [***] FTEs of effort to the performance of its obligations under the Research Plan. For the avoidance of doubt, such FTEs shall be performed by research scientists directly involved in the [***] No later than [***]after the end of each calendar quarter during the Research Terms, Biontech shall provide to Sanofi a report setting forth in reasonable detail the activities performance by the FTEs set forth in the foregoing provisions.”

Publication approval rights

2.12 The following provision shall be added after Section 8.4 of the Agreement as a new Section 8.5:

“Each Party recognizes that the publication of reports regarding results of, and other information regarding, activities under this Agreement, including oral presentations and abstracts, may be beneficial to both Parties, provided such publications are subject to reasonable controls to protect Confidential Information. In the event a Party wishes to publish in a peer review journal or present at a scientific conference any results or information generated from or relating to clinical or other studies under this Agreement with respect to the Mixtures, Licensed Product Candidates or Licensed Products or that includes Joint Collaboration Know-how or Confidential Information of the other Party, the Party seeking to publish shall provide to the other Party the proposed publication (including, without limitation, manuscripts) at least [***] for abstracts, posters, slides, written descriptions of oral presentations and press releases only) prior to the date of submission for publication or the date of presentation, whichever is earlier, of any of such submitted materials. The other Party shall review such submitted materials and respond to the submitting Party as soon as reasonably possible, but in any case within [***] of receipt. At the option of the reviewing Party, the submitting Party shall (1) take into due consideration any comments made by the reviewing Party; (2) delete from such proposed publication or presentation any Confidential Information; and (3) delay the date of such submission for publication or the date of such presentation until the earliest of: [***] All such publications and presentations shall properly reference the other Party’s contribution to the studies which relate to such publication or presentation and, with the exception of scientific publications made in peer reviewed journals or where prohibited by Applicable Law, display the logo and the company name of both Parties.”

2.14. Section 13 (Projected Timelines and Deliverables) of the Research Plan (Schedule B) of the Agreement is hereby amended by deleting all references to “Process Development and GMP” contained therein.

2.15. Schedules F, G and H to this Amendment are added to the Agreement as new Schedules F, G and H to the Agreement respectively.

3. [***] Agreement. Biontech and Sanofi have entered into an Investment Agreement dated December 21, 2018 under which the Parties have agreed on Sanofi making an equity investment in Biontech (**Investment Agreement**). [***]

4. No other changes. This Amendment constitutes an amendment to the Agreement by the Parties made in writing, in accordance with Section 13.3 of the Agreement. Except as set out in Section 2, the Agreement shall continue in full force and effect.

5. Governing law. This Amendment shall be governed by the laws of Germany without reference to its conflict of laws provision. Any dispute arising out of this Amendment shall be constitute a dispute arising between the Parties in connection with the Agreement, and Sections 13.7 and accordingly Section 13.8 of the Agreement shall apply to any such dispute accordingly.

6. Miscellaneous. Sections 13.1, 13.4, 13.5, 13.6, 13.9 and 13.10 of the Agreement shall be incorporated by reference into this Amendment (and any reference to “this Agreement” in each such incorporated provision shall be construed as a reference to this Amendment).

[Signatures on the Following Page]

IN WITNESS WHEREOF, the Parties have executed this Amendment to the Agreement as of the Effective Date.

SANOFI

By: _____ [***] _____
Name: _____ [***] _____
Title: _____ [***] _____

By: _____ [***] _____
Name: _____ [***] _____
Title: _____ [***] _____

BIONTECH RNA PHARMACEUTICALS GMBH

By: _____ [***] _____
Name: _____ [***] _____
Title: _____ [***] _____

By: _____ [***] _____
Name: _____ [***] _____
Title: _____ [***] _____

Schedule F

Schedule H – Form of [*] Amendment**

This amendment (this [***] is effective as of _____ (the [***] **Amendment Effective Date**), entered into by and between Sanofi, having a place of business at 54, rue La Boétie, 75008 Paris, France (**Sanofi**), and BioNTech RNA Pharmaceuticals GmbH, having a place of business at An der Goldgrube 12, 55131 Mainz, Germany (**Biontech**). Sanofi and Biontech shall each individually be referred to herein as a **Party**, and shall be referred to together as the **Parties**.

RECITALS

A. On November 2nd, 2015, as amended by an amendment letter dated December 14th, 2017, the Parties entered into a Collaboration and License Agreement (the **Agreement**) with the desire to collaborate in the research, development and commercialization of RNA-based therapeutics for the treatment of cancer.

B. On December 22nd, 2018, the Parties entered into a further Amendment to the Agreement (the Amendment), which Amendment include a Schedule G: [***]

C. The Parties have agreed to further amend the Agreement by Amending Schedule F as set forth below.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants set forth below, the Parties hereby agree as follows:

1. **Definitions.** Capitalized terms used in this [***] Amendment shall have the meanings as defined herein, provided that capitalized terms which are used but not defined herein shall have the meanings ascribed to them in the Agreement as amended to date.

2. **Amendments.** With effect from the [***] Amendment Effective Date the Parties agree the following amendments to the Agreement:

[***]

2.1 Schedule G: [***] is amended and restated as follows:

[***]

3. **No other changes.** This [***] constitutes an amendment to the Agreement by the Parties made in writing, in accordance with Section 13.3 of the Agreement. Except as set out in Section 2, the Agreement shall continue in full force and effect.

4. **Governing law.** This Amendment shall be governed by the laws of Germany without reference to its conflict of laws provision. Any dispute arising out of this Amendment shall be constitute a dispute arising between the Parties in connection with the Agreement, and Sections 13.7 and accordingly Section 13.8 of the Agreement shall apply to any such dispute accordingly.

[Signatures on the Following Page]

IN WITNESS WHEREOF, the Parties have executed this Amendment to the Agreement as of the Effective Date.

SANOFI

By: _____

Name: _____

Title: _____

By: _____

Name: _____

Title: _____

BIONTECH RNA PHARMACEUTICALS GMBH

By: _____

Name: _____

Title: _____

By: _____

Name: _____

Title: _____

THE SYMBOL “[*]” DENOTES PLACES WHERE CERTAIN IDENTIFIED
INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i)
NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE
COMPANY IF PUBLICLY DISCLOSED**

DEVELOPMENT AGREEMENT

This development agreement (this **Agreement**) is effective as of March 29, 2018 (the **Effective Date**) and entered into by and between Sanofi, having a place of business at 54, rue La Boétie, 75008 Paris, France (**Sanofi**), and BioNTech RNA Pharmaceuticals GmbH, having a place of business at An der Goldgrube 12, 55131 Mainz, Germany (**Biontech**). Sanofi and Biontech shall each individually be referred to herein as a **Party**, and shall be referred to together as the **Parties**.

RECITALS

A. On November 2nd, 2015, as amended by an amendment letter dated December 14th, 2017, the Parties entered into a Collaboration and License Agreement (the **License Agreement**) with the desire to collaborate in the research, development and commercialization of RNA-based therapeutics for the treatment of cancer.

B. Under the License Agreement, a Mixture named Licensed Product #1 (as further defined below) has been approved by the Joint Steering Committee as a Licensed Product Candidate in accordance with Section 2.8 of the License Agreement.

C. On [***] Sanofi selected Licensed Product #1 as the first Licensed Product for further Development and Commercialization in accordance with Section 2.9 of the License Agreement and on [***] Biontech exercised its option to co-Develop and to co-Commercialize Licensed Product #1 in the Field in the Biontech Territory in accordance with Section 4.1 of the License Agreement.

D. The Parties now wish to enter into this Agreement in order to jointly Develop Licensed Product #1 in the Field pursuant to the terms and conditions of this Agreement. This Agreement constitutes the Development agreement with respect to Licensed Product #1 under Section 4.1.1 of the License Agreement.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants set forth below, the Parties hereby agree as follows:

1. Definitions.

Capitalized terms used in this Agreement shall have the meanings as defined herein, provided that capitalized terms which are used but not defined herein shall have the meanings ascribed to them in the License Agreement.

1.1 **Additional Co-Development Costs** is defined in Section 6.3.4.

1.2 **Approved Co-Development Third Party** means a Third Party subcontractor or other Third Party engaged by a Party to perform or assist with any of such Party’s obligations under this Agreement, and which (a) is listed in Schedule A; or (b) has been approved by the Joint Project Team under Section 6.2(h).

1.3 **Binding Budget** is defined in Section 3.3.1.

1.4 **Biontech Co-Development Know-how** is defined in Section 4.1.2.

1.5 **Biontech Co-Development Patents** is defined in Section 4.2.2.

1.6 **Biontech Co-Development Technology** means the Biontech Co-Development Know-how and the Biontech Collaboration Patents.

1.7 **Budget** means a rolling [***] budget set out in the Development Plan with respect to the forecasted Shared Development Costs to be incurred by each Party during each such Calendar Year during the Term, as amended or updated from time to time by the Joint Project Team or the Joint Steering Committee (as the case may be) in accordance with this Agreement.

1.8 **Calendar Quarter** means each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1, except that the first Calendar Quarter of the Term shall commence on the Effective Date and end on the day immediately prior to the first to occur of January 1, April 1, July 1 or October 1 after the Effective Date, and the last Calendar Quarter shall end on the last day of the Term.

1.9 **Calendar Year** means each successive period of twelve (12) calendar months commencing on January 1, except that the first Calendar Year of the Term shall commence on the Effective Date and end on the day immediately prior to the next to occur January 1, and the last Calendar Year shall end on the last day of the Term.

1.10 **Clinical Data** means [***] results and analyses [***] generated by or on behalf of either Party or at either Party's direction, or by or on behalf of the Parties together or at their direction, in the course of the performance of the clinical trials under the Development Plan.

1.11 **Clinical Supply Agreement** means the Clinical Development and Supply Agreement between the Parties, effective as of October 4th, 2017.

1.12 **CMC** means "Chemistry, Manufacturing, and Controls" as such term of art is used in the pharmaceutical industry.

1.13 **CMC Activities** means the activities with respect to Licensed Product #1 set out in the CMC Development Plan (or, for the purposes of Section 2.8.3, 2.8.4 and 2.8.5, the activities with respect to Licensed Product #1 proposed to be included in the CMC Development Plan).

1.14 **CMC Development Plan** means the development plan setting out the CMC and manufacturing process development activities with respect to Licensed Product #1 as set out in Schedule D, and amended by the Joint Manufacturing Committee or the Joint Steering Committee (as applicable) from time to time pursuant to Section 2.8.5.

1.15 **CMC Know-how** means the Know-how made, conceived or first reduced to practice by or on behalf of either Party (or its Affiliates), or jointly by or on behalf of the Parties (or their Affiliates), in the conduct of the activities under the CMC Development Plan.

1.16 **CMC Patents** is defined in Section 4.2.2.

1.17 **CMC Technology** means the CMC Know-how and CMC Patents.

1.18 **Co-Development Activities** means the Development and other activities with respect to the Licensed Product #1 in the Field as specified in or reasonably contemplated by the Development Plan. For the avoidance of doubt, Co-Development Activities exclude the activities set out in the CMC Development Plan.

1.19 **Co-Development Background Technology** means, with respect to a Party, all Intellectual Property Rights over which such Party has gained Control outside of the scope of the collaboration under the License Agreement (including the activities under this Agreement) during the Term, excluding any Background Technology.

1.20 **Co-Development Personnel** means the individuals engaged by a Party performing Co-Development Activities, including any of the foregoing who are Project Managers, members of the Joint Steering Committee, Joint Project Team, regulatory personnel, quality assurance personnel, quality control personnel, research personnel, and development personnel.

1.21 **Co-Development Report** is defined in Section 2.5.

1.22 **Co-Development Records** is defined in Section 2.6.1.

1.23 **CPI** means the Consumer Price Index – Urban Wage Earners and Clerical Workers, U.S. City Average, All Items, 1982-84 = 100, published by the United States Department of Labor, Bureau of Labor Statistics (or its successor equivalent index) in the United States.

1.24 **Development Plan** means the development plan set out in Schedule C and amended or updated from time to time (through the proposal of such amendments or updates to the Joint Steering Committee and the approval of such amendments or updates by the Joint Steering Committee), setting forth in reasonable detail: (i) the clinical Development strategy, (ii) the objectives for Development activities and market access, (iii) Development activities, including clinical trials and regulatory filings, (iv) the definition of countries or regions in which clinical trials shall be conducted, (v) an allocation of each Party's responsibilities and (vi) timelines and the associated Budget, in each case (i) to (vi), with respect to Licensed Product #1 in the Field intended for approval or Commercialization in the Biontech Territory. For the avoidance of doubt, the Development Plan excludes the CMC Development Plan.

1.25 **Effective Date** is defined in the introductory paragraph of this Agreement.

1.26 **Excluded Clinical Trial Costs** is defined in Section 1.48.

1.27 **FTE Costs** means the cost of the Co-Development Personnel incurred by either Party, calculated at the FTE Rate multiplied by the applicable number of FTEs of Co-Development Personnel of such Party (on the basis of actual hours worked by such Co-Development Personnel on the Co-Development Activities or the activities in support thereof). For the avoidance of doubt, when calculating FTE Costs, any full-time employee who works more than [***] hours over the course of a twelve (12) month period shall count as one (1) FTE.

1.28 **FTE Rate** means [***] per FTE. Such rate shall be automatically adjusted on an annual basis in accordance with Section 2.2.3.

1.29 **including** means “including without limitation” (and **include** means “include without limitation”).

1.30 **Initiation** means, with respect to a clinical trial, the first dosing of a human subject with Licensed Product #1 in such clinical trial.

1.31 **Joint Financial Committee** is defined in Section 6.5.

1.32 **Joint Manufacturing Committee** means the joint manufacturing committee established under the Clinical Supply Agreement.

1.33 **Joint Project Team** is defined in Section 6.2.

1.34 **License Agreement** is defined in the preamble.

1.35 **Licensed Product #1** means (a) the Mixture specified in Schedule B; or (b) any modified version of such Mixture as proposed by the Joint Project Team pursuant to Section 6.2(f) and approved by the Joint Steering Committee. For the avoidance of doubt, Licensed Product #1 includes any formulation in the Field of any Mixture described in (a) and (b).

1.36 **Patent Documentation** is defined in Section 4.8.

1.37 **Prosecution and Maintenance** (including variations such as **Prosecute and Maintain**) means, with respect to a Patent Right, the preparation, filing, prosecution and maintenance of such Patent Right, including paying all maintenance and/or governmental fees to maintain such Patent Right in force, and requests for patent term extensions, supplementary protection certificates, and the like with respect to such Patent Right, together with the conduct of reissue proceedings, derivation proceedings, the defense of oppositions, *ex parte* reexaminations, *inter partes* reviews, post-grant reviews, and other similar proceedings with respect to such Patent Right.

1.38 **Overspent Costs** is defined in Section 3.3.2.

1.39 **Overspent Costs Notice** is defined in Section 3.3.2.

1.40 **Project Manager** is defined in Section 6.1.

1.41 **Regulatory Documentation** means all (a) marketing authorizations or registrations or any other approval, registration or authorization which is granted or accepted by a Regulatory Authority in a country in the Biontech Territory that are required for the Development, Manufacture or Commercialization of a Licensed Product #1 in the Field in such country, and all filings and submissions to a Regulatory Authority with respect to any of the foregoing; (b) correspondence, reports and other filings submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) in order to Develop, Manufacture or Commercialize a Licensed Product #1 in the Field in the Biontech Territory.

1.42 **Right of Reference** means the non-exclusive right to cross reference, copy, incorporate by reference or rely upon any Clinical Data solely for the purposes of obtaining or maintaining Marketing Approval for a pharmaceutical product, including (1) a “Right of Reference or Use” as that term is defined in 21 C.F.R. §314.3(b) in the United States, (2) any analogous procedures with respect to biologics or BLAs in the United States and (3) any equivalents thereof outside the United States.

1.43 **SDEA** is defined in Section 7.2.

1.44 **Sanofi CMC Technology** means: (a) the CMC Know-how which is generated by or on behalf of Sanofi (or its Affiliates) or jointly by or on behalf of the Parties (or their Affiliates) in the conduct of the CMC Activities agreed by the Joint Manufacturing Committee (or, if the Joint Manufacturing Committee cannot agree on such matters, approved by the Joint Steering Committee pursuant to Section 6.3.2(c)) for performance by Sanofi under the CMC Development Plan; and (b) the CMC Patents claiming or covering such CMC Know-how.

1.45 **Sanofi Co-Development Know-how** is defined in Section 4.1.1.

1.46 **Sanofi Co-Development Patents** is defined in Section 4.2.1.

1.47 **Sanofi Co-Development Technology** means the Sanofi Co-Development Patents and the Sanofi Co-Development Know-how.

1.48 **Shared Development Costs** means the out-of-pocket costs and expenses and FTE Costs incurred by either Party or its Affiliate, in each case which are: (1) specifically identifiable to, or reasonably allocable to, any Co-Development Activity [***] and (2) calculated in accordance with IFRS consistently applied, including (to the extent they come within the foregoing):

(a) the costs and expenses associated with the conduct of non-clinical studies [***]

(b) the costs and expenses associated with the conduct of clinical trials [***]

(c) the costs and expenses associated with the preparation, filing, submission, obtaining or maintenance (as applicable) of Regulatory Documentation with respect to any Licensed Product #1 in the Field; and

(d) the costs and expenses with respect to Approved Co-Development Third Parties engaged in the performance of such Co-Development Activity.

Excluded Clinical Trial Costs

[***]

shall be referred to as the **Excluded Clinical Trial Costs**.

Notwithstanding the foregoing, "Shared Development Costs" shall exclude [***]

1.49 **Signing Date** means the date of the last signature to this Agreement.

1.50 **Tax** or **Taxes** means any federal, provincial, territorial, state, municipal, local, foreign or other taxes and other charges in the nature of a tax.

1.51 **Term** is defined in Section 9.1.

1.52 **VAT** is defined in Section 3.7.3.

1.53 **Withholding Tax** or **Withholding Taxes** is defined in Section 3.7.2.

2. Development of Licensed Product #1.

2.1 Development Activities Generally.

2.1.1 Each Party shall:

(a) perform the Co-Development Activities allocated to such Party under the Development Plan in accordance with the terms of this Agreement;

(b) contribute and commit the required resources and use Commercially Reasonable Efforts to meet the objectives set forth in the Development Plan; and

(c) perform its obligations under this Agreement in accordance with the Applicable Law.

2.1.2 The initial Development Plan is set out in Schedule C. No later than [***] (or such other period as agreed by the Joint Steering Committee under Section 6.3.2(f)) prior to the end of each Calendar Year, commencing [***] the Joint Project Team shall review the Development Plan and propose any updates to the Development Plan to the Joint Steering Committee pursuant to Section 6.2(c), such that the Joint Steering Committee can review and approve such proposed updated Development Plan pursuant to Section 6.3.2(b) no later than [***] prior to the end of such Calendar Year. In addition, from time to time, the Joint Project Team shall review any proposal from either Party to amend the Development Plan, for proposal to the Joint Steering Committee pursuant to Section 6.2(c). Upon approval of the Joint Steering Committee of any such update or amendment, the Development Plan shall be deemed to be amended to incorporate such update or amendment.

2.1.3 For clarity, the Development Plan, and accordingly, the Co-Development Activities, shall exclude any CMC Activities conducted under the CMC Development Plan.

2.2 Allocation of Resources/Subcontracting.

2.2.1 Each Party agrees to primarily use its or its Affiliates' internal resources and capacities to fulfil such Party's respective obligations under the Development Plan. Each Party shall use Commercially Reasonable Efforts to minimize the delegation of its obligations hereunder to a Third Party subcontractor (including contract research organizations).

2.2.2 Each Party may subcontract any of its obligations under this Agreement to any of its Affiliates or one or more Approved Co-Development Third Parties, provided that: (i) none of the rights of the other Party are diminished or are otherwise adversely affected as a result of such subcontracting and (ii) the Approved Co-Development Third Party undertakes in writing all obligations of confidentiality and non-use regarding both Parties' Confidential Information which are substantially the same as those undertaken by the Parties under the License Agreement. In the event that a Party performs one or more of its obligations under this Agreement through any such Affiliate or Approved Co-Development Third Party, then such Party shall at all times be responsible for the performance by such Affiliate or Approved Co-Development Third Party of such Party's obligations hereunder.

2.2.3 All internal Co-Development Personnel of each Party (or its Affiliates) shall be expressed in terms of FTEs. The FTE Rate shall be adjusted on an annual basis, the first adjustment shall be on January 1, 2019 and thereafter each adjustment shall be on January 1 of each succeeding Calendar Year. Each such adjustment shall be calculated by increasing the FTE Rate as of December 31, 2018 by the percentage increase in the CPI as of December 31 of the then most recently ended Calendar Year over the level of the CPI on December 31, 2018.

2.3 Conduct of Clinical Trials. Sanofi shall act as the sponsor of any clinical trial conducted pursuant to the Development Plan, provided that Sanofi shall consider in good faith whether to use Biontech's resources in regions where such internal resources are available [***] and whether in certain circumstances Biontech shall be the co-sponsor or sponsor of selected clinical trials. The Party acting as sponsor (or co-sponsor, as applicable) shall ensure that any such clinical trial (for which it is sponsor (or co-sponsor, as applicable)) is performed in accordance with this Agreement, the applicable protocol and Applicable Law, and the other Party shall provide such Party with any assistance as reasonably requested by such Party, in order for such Party to fulfil its obligations as sponsor (or co-sponsor) of such clinical trial. Each Party shall mention or list the other Party as collaborator (e.g. "in collaboration with BioNTech RNA Pharmaceuticals GmbH" or "in collaboration with Sanofi", as applicable) (and the other Party hereby agrees to such mention or listing) in the relevant clinical trial databases and registers (e.g. clinicaltrials.gov (or equivalent)), in public materials published by such Party in relation to all clinical trials conducted pursuant to the Development Plan and, to the extent reasonably practicable, on labels of vials used in such clinical trials, as well as when either Party formally presents the Development program under this Agreement at conferences, provided that, prior to any such mention, listing or publication the Parties have agreed in writing the form of information that can be used in such mentions, listings or publications, and all mentions, listings and publications of a Party as collaborator under this Section 2.3 shall be made in all cases in a manner and to the extent consistent with Applicable Law and such agreed form of information.

2.4 Biomarker Execution. [***]

2.5 Reporting. Each Party shall keep the other Party reasonably informed as to its progress, results (including the development of any technology or invention), status and plans with respect to the Co-Development Activities performed by or on behalf of such Party through the provision of periodic, informal oral reports to the other Party's Project Manager. Without limiting the foregoing, each Party shall provide to the other Party a [***] written report (the **Co-Development Report**) delivered no later than [***] following the end of each [***] such written report shall set out detailed particulars of the following items: (a) the Co-Development Activities performed by such Party during such [***] (b) the data, results and other Intellectual Property Rights made, conceived and first reduced to practice in the conduct of such Co-Development Activities by or on behalf of such Party; (c) the status of preparation for the planned Co-Development Activities to be performed in the upcoming [***] and the status of such activities; and (d) any other relevant information determined by the Joint Project Team to be included in such report pursuant to Section 6.2(i).

2.6 Maintenance of Records.

2.6.1 During the Term and for a period of at [***] after the Term (or, if longer, a period required by Applicable Law), each Party shall maintain records reflecting the work done and the results achieved in its performance of the Development Plan (the **Co-Development Records**), such records shall be in a reasonable level of detail customary for companies engaged in pharmaceutical research. Without limiting the foregoing, such records shall be in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes in compliance with Applicable Law.

2.6.2 Each Party shall make its Co-Development Records available for inspection by the other Party or its representative, during normal business hours and upon reasonable notice, upon reasonable written request of the other Party. Upon request by each Party, the other Party shall deliver to the requesting Party copies of all its Co-Development Records (which may include copies in an electronic format readily accessible by the requesting Party), provided that the requesting Party shall reimburse the reasonable and documented out-of-pocket costs incurred by the other Party in connection with the preparation and delivery of such copies. Each Party shall not be obliged to: (a) provide the other Party with access to its Co-Development Records or (b) deliver to the other Party copies of its Co-Development Records, in each case (a) and (b), more than [***].

2.7 Ownership of Clinical Data. Sanofi shall exclusively own all Clinical Data [***] Each Party acknowledges and agrees that Section 4.1.2 of the License Agreement shall not apply to such Clinical Data.

2.8 Manufacturing and Clinical Supply of Licensed Product #1.

2.8.1 The Parties' respective responsibilities relating to the Manufacturing and supply of Licensed Product #1 to be used for Phase I Clinical Trials and Phase II Clinical Trials are set forth in the Clinical Supply Agreement and the License Agreement. If the Joint Steering Committee approves any modification to the Licensed Product #1 set out in Schedule B pursuant to Section 6.3.2(d), at Sanofi's request, the Parties shall promptly update Appendix 1 of the Clinical Supply Agreement, such that the Licensed Product #1 incorporating such modification shall constitute a Drug Product under the Clinical Supply Agreement.

2.8.2 Biontech shall: (a) subject to Section 2.8.3, be responsible for the performance of all CMC Activities with respect to Licensed Product #1 under the CMC Development Plan; (b) perform the CMC Activities allocated to Biontech under the CMC Development Plan in accordance with the terms of this Agreement, and (c) contribute and commit the required resources and use Commercially Reasonable Efforts to meet the objectives set forth in the CMC Development Plan.

2.8.3 If either Party wishes Sanofi to perform any CMC Activities with respect to Licensed Product #1, such Party shall propose to the Joint Manufacturing Committee an update to the CMC Development Plan reflecting such CMC Activities to be performed by Sanofi, and Sanofi may perform such CMC Activities if agreed by the Joint Manufacturing Committee or, if the Joint Manufacturing Committee cannot reach agreement on such matter, upon the approval by the Joint Steering Committee pursuant to Section 6.3.2(c) of such update to the CMC Development Plan.

2.8.4 The initial version of the CMC Development Plan is set out in Schedule D. Thereafter, the Joint Manufacturing Committee shall discuss and approve any amendments to the CMC Development Plan proposed by either Party under Section 2.8.5(a) (provided, with respect to any proposed amendments to the CMC Development Plan to provide for Sanofi's performance of any CMC Activities, if the Joint Manufacturing Committee cannot agree on such matters, the Joint Steering Committee shall decide whether Sanofi may perform such CMC Activities pursuant to Section 6.3.2(c)). Biontech shall keep the Joint Manufacturing Committee fully informed as to its progress, results (including the development of any technology or inventions), status and plans for performing and implementing the CMC Development Plan, including by periodic, informal oral reports to the Joint Manufacturing Committee, and by providing a quarterly report to the Joint Manufacturing Committee with respect to CMC Activities performed under the CMC Development Plan delivered no later than [***] following the end of every [***], such written report shall set out detailed particulars of the following items: (a) the CMC Activities performed under the CMC Development Plan during such [***]; (b) the data, results and other Intellectual Property Rights made, conceived and first reduced to practice in the performance of such CMC Activities; (c) the status of preparation for the planned CMC Activities to be performed under the CMC Development Plan in the upcoming [***] and the status of such CMC Activities; and (d) any other relevant information determined by the Joint Manufacturing Committee to be included in such report pursuant to Section 2.8.5(b).

2.8.5 The Joint Manufacturing Committee shall be responsible for discussing and approving: (a) any amendments to the CMC Development Plan as proposed by either Party; and (b) the information to be included in the quarterly written reports described in Section 2.8.4. If the members of the Joint Manufacturing Committee cannot agree on such matters, notwithstanding anything to the contrary in Section 3.3.6 of the License Agreement and Sections 9.4 and 9.5 of the Clinical Supply Agreement: (i) with respect to any proposed amendment or update to the CMC Development Plan to provide for Sanofi's performance of any CMC Activities as described in Section 2.8.4, such matter shall be referred to the Joint Steering Committee for decision under Section 6.3.2(c); and (ii) with respect to any other matter, Sanofi shall have the deciding vote, and the third sentence of Section 9.5 of the Clinical Supply Agreement shall not apply with respect to such matter.

2.8.6 For the avoidance of doubt, the Manufacture and supply of any Licensed Product #1 for use in Phase III Clinical Trials pursuant to the Development Plan are subject to Sections 3.3.3 to 3.3.6 of the License Agreement.

3. Development Costs.

3.1 Development Costs related to the Biontech Territory. All Shared Development Costs shall be shared between the Parties pursuant to the following scheme:

[***]

3.2 Development Costs not related to the Biontech Territory. Sanofi shall remain solely responsible [***].

3.3 Budget.

3.3.1 Annual Development Plan Budget.

(a) The Budget shall include particulars of the Shared Development Costs which each Party is reasonably expected to incur with respect to its Co-Development Activities during [***] period. Each Party acknowledges and agrees that [***] the **Binding Budget**). The initial Binding Budget is set out in Schedule C to this Agreement. Thereafter, the Budget shall be updated in accordance with Section 3.3.1(b).

(b) No later than [***] (or such other period as agreed by the Joint Project Team under Section 6.2(p)) prior to the end of [***], the Parties' respective Joint Project Team representatives shall in good faith discuss the Budget: (i) if such Calendar Year is [***] or [***], for the following [***] Calendar Year period (excluding the Calendar Year(s) comprising the then-current Binding Budget); or (ii) if such Calendar Year is [***] or any Calendar Year thereafter, [***], in each case (i) and (ii), pursuant to Section 6.2(d), and shall submit a proposed Budget to the Joint Financial Committee for review and comments. The Joint Project Team shall consider any comments from Joint Financial Committee with respect to such proposed Budget and may (but shall not be required to) amend such proposed Budget accordingly. Thereafter, the Joint Project Team shall submit the proposed Budget to the Joint Steering Committee for review and approval under Section 6.3.2(b), such that such proposed Budget shall be approved by the Joint Steering Committee no later than [***] prior to the end of such Calendar Year. In addition, the Joint Project Team may discuss any amendment to the Binding Budget pursuant to Section 6.2(d) and propose such amendment to the Joint Steering Committee for approval under Section 6.3.2(c). Notwithstanding the foregoing, from time to time, the Joint Project Team may approve any amendment to the Binding Budget with respect to the then-current Calendar Year under Section 6.2(e) without having to propose such amendment to the Joint Steering Committee, if the proposed amended Binding Budget will not deviate by [***] or more from the Binding Budget for such Calendar Year as of the first day of such Calendar Year.

3.3.2 Overspent Costs.

(a) Each Party shall promptly inform the other Party if it reasonably determines that it will or is likely to incur, or has incurred, any Shared Development Costs during any Calendar Year above [***] of the aggregate Shared Development Costs allocated to such Party in the Binding Budget with respect to such Calendar Year (the **Overspent Costs**), such notice shall set out the amount of estimated or actual Overspent Costs in question (the **Overspent Costs Notice**).

(b) Upon the submission of an Overspent Costs Notice from one Party to the other Party under Section 3.3.2(a), either Party may escalate the matter to the Joint Steering Committee. Upon such escalation, the Joint Steering Committee shall promptly (and in any event, no later than [***] after such escalation) discuss and decide whether the Binding Budget shall be amended.

(c) For the avoidance of doubt, if the Joint Steering Committee has approved an amendment to the Binding Budget for the relevant Calendar Year reflecting the Overspent Costs in question, such Overspent Costs shall continue to constitute Shared Development Costs.

(d) If the Joint Steering Committee has not approved an amendment to the Binding Budget for the relevant Calendar Year reflecting the Overspent Costs in question, then such Overspent Costs shall not be considered Shared Development Costs.

3.3.3 Reporting. Shared Development Costs and the Excluded Clinical Trial Costs shall initially be borne by the Party (or its Affiliate) incurring such cost or expense. Each Party shall report to the other Party [***] the Shared Development Costs and any Excluded Clinical Trial Costs incurred by such Party (or its Affiliate) during [***] Such report shall include the details necessary to enable the receiving Party to compare the reported Shared Development Costs against the applicable Budget, including specifying in reasonable detail all Shared Development Costs and any Excluded Clinical Trial Costs incurred by such Party (or its Affiliate) during such [***] whereby all FTE Costs and out-of-pocket costs or expenses with respect to Shared Development Costs shall be allocated to the extent possible to a specific activity under the Development Plan. The Parties shall seek to resolve any questions related to such reports within [***] following receipt by each Party of the other Party's report hereunder.

3.3.4 Invoicing and Reconciliation of Shared Development Costs. Following the end of each [***] (1) if Sanofi (or its Affiliates), but not Biontech (or its Affiliates), have incurred Shared Development Costs with respect to such [***] then Sanofi may submit an invoice to Biontech with respect to Biontech's share of the Shared Development Costs for such [***] in accordance with the scheme set out in Section 3.1; and (2) otherwise, the Shared Development Costs borne by each Party or its Affiliate with respect to such [***] shall be reported and reconciled as follows:

(a) no later than [***] after the end of such [***] (provided that, Sanofi shall not be obliged to observe such timeframe if Biontech fails to provide the report described in, and within the [***] period set out in, Section 3.3.3), Sanofi shall submit to Biontech a proposed reconciliation report, setting out the particulars with respect to the reconciliation of the Shared Development Costs incurred by each Party or its Affiliate with respect to such [***]. For the purposes of such reconciliation, the Shared Development Costs incurred by each Party or its Affiliate shall be shared between the Parties in accordance with the scheme set out in Section 3.1;

(b) if Biontech disagrees with such reconciliation report, Biontech may, no later than [***] after Sanofi's submission of the proposed reconciliation report to Biontech, request the Joint Financial Committee to review such report under Section 6.5.2(a);

(c) (1) upon any confirmation by Biontech to Sanofi of its acceptance of such reconciliation report; (2) if Biontech has not requested the Joint Financial Committee to review and discuss such reconciliation report within the [***] period described in clause (b) above, upon the expiry of such [***] period; or (3) if Biontech has requested the Joint Financial Committee to review such reconciliation report within such [***] period, upon approval of such reconciliation report by the Joint Financial Committee:

(i) if the Shared Development Costs incurred by Biontech or its Affiliate in such [***] is less than its agreed share of Shared Development Costs during such [***], Sanofi or its Affiliate shall deliver an invoice to Biontech for any amounts due to Sanofi as a result of such reconciliation;

(ii) if the Shared Development Costs incurred by Sanofi or its Affiliate in such [***] is less than its agreed share of Shared Development Costs during such [***] Sanofi shall notify Biontech that Biontech should issue an invoice to Sanofi for any amounts due to Biontech as a result of such reconciliation,

(d) each Party shall pay the relevant reconciliation payment to the respective other Party within [***] days following receipt of the respective invoice from the other Party.

3.4 Records and Audit Rights. Each Party shall keep complete and accurate records for all of its Shared Development Costs, including the details of the FTEs allocated to the performance of its Co-Development Activities based on the actual hours of work spent on such performance. Each Party shall make such records available to the other Party upon request. For the avoidance of doubt, such records shall constitute the records reasonably necessary to verify the accuracy of the costs associated to the applicable Party's Development activities under Section 4.5 of the License Agreement, and the provisions of Section 4.5 of the License Agreement shall apply with respect to such records accordingly.

3.5 Payment. All payments to be made by one Party to the other Party under this Agreement shall be made in Euros by bank wire transfer without deduction for wire transfer fees in immediately available funds to such bank account designated in writing by the receiving Party to the paying Party from time to time.

3.6 Accounting and Currency. Shared Development Costs and Excluded Clinical Trial Costs shall be calculated, recorded and reported under this Agreement in accordance with the last updated IFRS and in Euros. In the case of Shared Development Costs and Excluded Clinical Trial Costs which are initially incurred in a currency other than Euros, exchange conversion of such amounts into Euros shall be made on a [***] basis and shall be made consistent with the incurring Party's normal practices used to prepare its audited financial statements for internal and external reporting purposes, which uses a widely accepted source of published exchange rates.

3.7 Taxes.

3.7.1 Each Party shall be solely responsible for the payment of all Taxes imposed on such Party's income arising directly or indirectly from the activities of the Parties under this Agreement. [***]

3.7.2 [***]

3.7.3 All payments between the Parties under this Agreement are exclusive of applicable statutory value added tax (**VAT**), if any, which shall be listed separately on each invoice. [***]

4. Intellectual Property and Licensed Products.

4.1 Each Party acknowledges and agrees that:

4.1.1 Sanofi shall solely own all Know-how made, conceived or first reduced to practice:

(a) by or on behalf of Biontech (or its Affiliates) or jointly by or on behalf of the Parties (or their Affiliates) in the conduct of the Co-Development Activities, to the extent such Know-how: (i) is necessary or useful for Developing, Commercializing or otherwise using Licensed Product #1; (ii) if patented, would encompass an activity or composition that is necessary or useful for the Development, Commercialization or other use of Licensed Product #1; or (iii) is otherwise related to Licensed Product #1. [***]

(b) by or on behalf of Sanofi (or its Affiliates) in the conduct of the Co-Development Activities; and

(c) by or on behalf of either Party (or its Affiliates) or jointly by or on behalf of the Parties (or their Affiliates) in the conduct of activities in connection with the preparation of the clinical trials with respect to Licensed Product #1 [***] to the extent such activities were conducted before the Effective Date,

together (a), (b) and (c), the **Sanofi Co-Development Know-how**.

4.1.2 Biontech shall solely own:

(a) all Know-how made, conceived or first reduced to practice by or on behalf of Biontech (or its Affiliates) in the conduct of the Co-Development Activities to the extent such Know-how does not constitute Sanofi Co-Development Know-how (the **Biontech Co-Development Know-how**); and

(b) all CMC Know-how.

4.2 As between the Parties:

4.2.1 Sanofi shall: (a) have the exclusive right (but not the obligation), at its sole expense and sole discretion, to control the Prosecution and Maintenance and enforcement of all Patent Rights claiming or otherwise covering any Sanofi Co-Development Know-how (the **Sanofi Co-Development Patents**) and (b) solely own the Sanofi Co-Development Patents; and

4.2.2 Biontech shall: (a) have the exclusive right (but not the obligation), at its sole expense and sole discretion, to control the Prosecution and Maintenance and enforcement of all Patent Rights claiming or otherwise covering any Biontech Co-Development Know-how (the **Biontech Co-Development Patents**) and all Patent Rights claiming or otherwise covering any CMC Know-how (the **CMC Patents**) and (b) solely own the Biontech Co-Development Patents and the CMC Patents.

For the avoidance of doubt, for the purposes of interpretation of Section 1.44(b) and this Section 4.2, Sanofi Co-Development Know-how, Biontech Co-Development Know-how and CMC Know-how shall not cease to be Know-how to the extent it is disclosed or claimed by a Sanofi Co-Development Patent, Biontech Co-Development Patent or CMC Patent (as applicable).

4.3 For the purposes of Section 7.3.2(a)(ii) (*Research license to Biontech*), and Section 7.3.2(b)(ii) (*Co-Development and Co-Commercial License (Biontech Option Product) to Biontech*) of the License Agreement only, Sanofi Co-Development Technology shall constitute Joint Collaboration Technology (and accordingly, Sanofi Co-Development Technology shall constitute Sanofi Technology).

4.4 For the purposes of Section 7.3.1(a) (*Research license to Sanofi*) and Section 7.3.1(b)(iii) (*Co-Development and Co-Commercial License (Sanofi Option Product) to Sanofi*) of the License Agreement, Biontech Co-Development Technology and CMC Technology shall constitute Biontech Technology.

4.5 Sanofi hereby grants to Biontech:

4.5.1 an exclusive, non-transferable (except through assignment of this Agreement pursuant to Section 13.4 of the License Agreement as incorporated into this Agreement under Section 11.4), worldwide license, with the right to sublicense (subject to Section 4.13), under the Sanofi Co-Development Technology to Develop, have Developed, make, have made, Commercialize and have Commercialized Licensed Products outside of the Field and Discarded Mixtures;

4.5.2 a non-exclusive, non-transferable (except through assignment of this Agreement pursuant to Section 13.4 of the License Agreement as incorporated into this Agreement under Section 11.4), worldwide license, with the right to sublicense (subject to Section 4.13), under the Sanofi Co-Development Technology to Develop, have Developed, make, have made, Commercialize and have Commercialized any product in and outside the Field (excluding any Licensed Product and any Discarded Mixture); and

4.5.3 a non-exclusive, non-transferable (except through assignment of this Agreement pursuant to Section 13.4 of the License Agreement as incorporated into this Agreement under Section 11.4), worldwide, royalty-free license, with the right to sublicense (subject to Section 4.13), under the Co-Development Background Technology of Sanofi to the extent required by Biontech for the co-Development and/or the co-Commercialization of Licensed Product #1 in accordance with this Agreement and/or Commercialization agreement concluded in relation to Licensed Product #1 under Section 4.1.3 of the License Agreement.

[***]

4.6 Biontech hereby grants to Sanofi:

4.6.1 an exclusive, non-transferable (except through assignment of this Agreement pursuant to Section 13.4 of the License Agreement as incorporated into this Agreement under Section 11.4), worldwide license, with the right to sublicense (subject to Section 4.13), under the Biontech Co-Development Technology and the CMC Technology to Develop, have Developed, make, have made, Commercialize and have Commercialized Licensed Products in the Field;

4.6.2 a non-exclusive, non-transferable (except through assignment of this Agreement pursuant to Section 13.4 of the License Agreement as incorporated into this Agreement under Section 11.4), worldwide license, with the right to sublicense (subject to Section 4.13), under the Biontech Co-Development Technology to Develop, have Developed, make, have made, Commercialize and have Commercialized any product in and outside the Field (excluding any Licensed Product and any Discarded Mixture);

4.6.3 a non-exclusive, non-transferable (except through assignment of this Agreement pursuant to Section 13.4 of the License Agreement as incorporated into this Agreement under Section 11.4), worldwide license, with the right to sublicense (subject to Section 4.13), under the Sanofi CMC Technology to Develop, have Developed, make, have made, Commercialize and have Commercialized products (other than Licensed Products and Discarded Mixtures) in the field of Intratumoral Administration of any agent for any indication; and

4.6.4 a non-exclusive, non-transferable (except through assignment of this Agreement pursuant to Section 13.4 of the License Agreement as incorporated into this Agreement under Section 11.4), worldwide, royalty-free license, with the right to sublicense (subject to Section 4.13), under the Co-Development Background Technology of Biontech to

the extent required: (a) for the Development and Commercialization of Licensed Product #1 in the Field, and (b) by Sanofi for the co-Development and/or co-Commercialization of any Sanofi Option Product which constitutes Licensed Product #1 in accordance with the Development and/or Commercialization agreement concluded in relation to such Sanofi Option Product under Section 4.2.5 of the License Agreement.

[***]

4.7 For the avoidance of doubt, Background Technology, Joint Collaboration Technology (other than for the purposes set out in Section 4.3) Biontech Collaboration Technology (other than for the purposes set out in Section 4.4), Licensed Product Patents, Sanofi Foreground Technology, Biontech Foreground Technology and Joint Foreground Technology shall exclude any Co-Development Technology and CMC Technology, and Section 7.2.3 and the last sentence of Section 7.1 of the License Agreement shall not apply with respect to any Co-Development Technology or CMC Technology.

4.8 With respect to the Co-Development Patents and CMC Patents, each Party shall (a) provide the other Party with written notice reasonably in advance of: (i) any filing of such Patent Rights for which it controls the Prosecution and Maintenance pursuant to Section 4.2 above; and (ii) any other substantive submissions and correspondence to patent office(s) with respect to the Prosecution and Maintenance of such Patent Rights; (b) provide the other Party with any final drafts of any application for such Patent Right to be filed or such substantive submission or correspondence (such application, submissions and correspondence, the **Patent Documentation**) reasonably in advance of its filing or submission and consider in good faith the incorporation of reasonable comments by the other Party thereon; (c) provide the other Party with a copy of all Patent Documentation once it has been filed or otherwise submitted; (d) provide the other Party with copies of any substantive communications received from patent office(s) with respect to such Patent Rights; (e) notify the other Party of any: [***] and (f) provide the other Party with written notice as early as possible (in any event, no later than [***] prior to abandoning any such Patent Rights. Each Party shall cause its employees, agents or consultants, at its expense, to execute such documents and to take such other actions as reasonably necessary or appropriate to enable the other Party to prepare, file, Prosecute and Maintain such Patent Rights. In the event that either Party provides the other Party with the written notice described in clause (f) prior to abandoning any Patent Rights, then the other Party shall have the option, exercisable by delivery of written notice thereof within [***] thereafter, to assume the right (but not the obligation), at its sole expense and sole discretion, to control the Prosecution and Maintenance of such Patent Right.

4.9 Patent Enforcement

4.9.1 Each Party (**Enforcing Party**) shall have the first right (but not the obligation), at its sole discretion, to control the enforcement or otherwise abate the infringement of any Patent Rights Prosecuted and Maintained by it in accordance with Section 4.2 above. [***]

4.9.2 [***]

4.10 Each Party shall perform such lawful acts and execute such documents as requested by the other Party from time to time in order to reasonably assist the other Party in the Prosecution and Maintenance and enforcement activities described in this Section 4.

4.11 Each Party shall ensure that all employees and other persons acting on its behalf in performing its obligations under this Agreement shall be obligated, either pursuant to Applicable Law or pursuant to a binding written agreement, to assign to it, or as it shall direct, all inventions made or conceived by such employees or other persons.

4.12 No rights or licenses with respect to any Intellectual Property Rights Controlled by either Party are granted or shall be deemed granted hereunder or in connection herewith, other than those rights expressly granted in this Agreement or the License Agreement.

4.13 Each Party acknowledges and agrees, that the licenses and rights set out in Sections 4.5 and 4.6 of this Agreement shall be sublicensable on the same terms of Section 7.3.4(a) of the License Agreement, and in addition, the licenses set out in Sections 4.5.1, 4.5.3, 4.6.1 and 4.6.4 shall be sublicensable under the same terms of Sections 7.3.4(b) and 7.3.4(c) of the License Agreement.

4.14 [***]

4.15 [***]

5. Profit Sharing.

For the avoidance of doubt, the profit sharing within the Biontech Territory pursuant to Section 4.1.6 of the License Agreement as well as the financial terms (e.g. milestone and royalty payments) agreed for countries outside the Biontech Territory pursuant to Section 6 of the License Agreement shall remain unaffected by this Agreement.

6. Governance.

6.1 Project Managers. Each Party shall designate a Development project manager (**Project Manager**) to act as its primary contact for all operational matters related to this Agreement. Each Project Manager shall be responsible for implementing and coordinating activities hereunder and facilitating the exchange of information between the Parties. Either Party may replace its Project Manager at any time by informing the other Party's Project Manager in advance in writing (which may be by email).

6.2 Joint Project Team. The Parties shall establish a joint project team (the **Joint Project Team**) made up of the Project Manager and at least [***] other representatives from each Party, which shall be responsible for coordinating all activities under this Agreement. Each Party may replace any of its Joint Project Team representatives upon prior notice to the other Party. In particular, the Joint Project Team shall be responsible for:

- (a) the review and discussion of the Development Plan and underlying objectives for Licensed Product #1 in the Field, [***]

(b) co-ordinating the implementation of the Development Plan and the associated Budget;

(c) the review and discussion of any proposed amendment or update to the Development Plan, whether during the annual review under Section 2.1.2 or from time to time during the Term, and the proposal of such amendment or update to the Joint Steering Committee for approval;

(d) the review and discussion of: (i) the Budget for the applicable period pursuant to the annual review under Section 3.3.1(b), taking into account of any comments provided by the Joint Financial Committee under Section 6.5.2(b) and the applicable forecast prepared by the Joint Financial Committee under Section 6.5.2(c); and (ii) any other proposed amendment to the Binding Budget, and the proposal of each such amended Budget to the Joint Steering Committee for approval;

(e) the review and approval of any proposed amendment(s) to the Binding Budget with respect to the then-current Calendar Year, provided that such Binding Budget shall not deviate by [***] or more from the Binding Budget for such Calendar Year as of the first day of such Calendar Year;

(f) the review and discussion of the proposal by either Party of any modification to the Licensed Product #1 [***]

(g) discussion and approval of which party should be responsible for the performance of which Co-Development Activities [***].

(h) discussion and approval of any Third Party proposed to be engaged by a Party to perform or assist with its obligations under this Agreement;

(i) review and discussion of any Co-Development Reports, and discuss and agree whether additional information should be included in future Co-Development Reports;

(j) oversight of all clinical and regulatory matters with respect to the Licensed Product #1 in the Field;

(k) the preparation and review of all material Regulatory Documentation with respect to the Licensed Product #1 in the Field;

(l) the coordination with the Joint Manufacturing Committee in relation to the CMC Development Plan and the forecasting of Drug Products for Clinical Trials (as defined in the Clinical Supply Agreement);

(m) discussion and agreement on target product profiles;

(n) periodically update the Joint Steering Committee with respect to Co-Development Activities performed and other relevant matters;

(o) facilitating the sharing of data and information between the Parties in relation to the Development activities under the Development Plan, regulatory filings and regulatory approvals;

(p) discussion and agreement of any alternative timeframe with respect to the discussion of, and submission to the Joint Financial Committee, a proposed Budget by the Joint Project Team as part of the annual review under Section 3.3.1(b); and

(q) any other responsibilities allocated to the Joint Project Team by the Joint Steering Committee.

6.3 Decisions of the Joint Project Team/Escalation/Joint Steering Committee.

6.3.1 The quorum for each Joint Project Team meeting shall be at least one (1) Joint Project Team representative from each Party. Each Party shall have one collective vote in all decisions of the Joint Project Team with respect to matters falling within its responsibility, and shall use good faith efforts to decide such matters unanimously. If consensus cannot be reached by the Joint Project Team, the relevant matter shall be escalated to the Joint Steering Committee for discussion and decision.

6.3.2 Each Party hereby acknowledges and agrees that, notwithstanding the last sentence of Section 11.2.2 of the License Agreement, the Joint Steering Committee shall be responsible for:

(a) the discussion and agreement of any matter escalated by the Joint Project Team or the Joint Financial Committee under Section 6.3.1 or Section 6.5.3 (as applicable) for resolution by the Joint Steering Committee;

(b) the discussion and agreement of updates to the Development Plan as part of the annual review under Section 2.1.2 or updates to the Budget as part of annual review under Section 3.3.1(b) on an annual basis, each such annual update shall be approved no later than [***] prior to the end of the relevant Calendar Year;

(c) the discussion and agreement of any other amendment or update to the Development Plan or the Budget, and any amendment or update of the CMC Development Plan to allocate any CMC Activities for performance by Sanofi as referred by the Joint Manufacturing Committee under Section 2.8.5;

(d) the discussion and agreement of any modification to the Licensed Product #1 set out in Schedule B;

(e) [***]

(f) the discussion and agreement of any alternative timeframe with respect to the review of, and submission to the Joint Steering Committee of, any updates to a Development Plan by the Joint Project Team, as part of an annual review under Section 2.1.2, in the case of (b) to (d), as proposed by the Joint Project Team to the Joint Steering Committee pursuant to Sections 6.2(c) or Section 6.2(d) (as applicable), or, in the case of (c) and with respect to the Budget, as proposed by either Party under Section 3.3.2 to reflect the Overspent Costs in question.

6.3.3 If the Joint Steering Committee cannot agree unanimously on any matter set out in Sections 6.3.2(a) to (d) (inclusive) and (f):

(a) if such matter constitutes an amendment or update to the then-current Binding Budget, which causes an increase of Biontech's aggregate share of budgeted Shared Development Costs with respect to [***] covered by then-current Binding Budget by an amount equal [***] or more, the third and fourth sentences of Section 11.2.4 of the License Agreement and the first two sentences of Section 13.7 of the License Agreement shall apply (but the last two sentences of Section 13.7 of the License Agreement shall not apply). If the Parties' CEOs are unable to settle any dispute with respect to such matter escalated to them within thirty (30) days from the date that the dispute has been escalated to the CEOs, then Sanofi shall have the deciding vote with respect to such matters; and

(b) otherwise, the third and fourth sentences of Section 11.2.4 of the License Agreement and the last three sentences of Section 13.7 of the License Agreement shall not apply with respect to such matters, and Sanofi shall have a deciding vote with respect to such matters (for the avoidance of doubt, without having to escalate such matter to the Parties' CEOs).

For the avoidance of doubt, any matter set out in Section 6.3.3(a) which is so decided by the Parties' CEOs pursuant to Section 13.7 of the License Agreement and any matter set out in Sections 6.3.3(a) and 6.3.3(b) which is so decided by Sanofi through its exercise of its deciding vote, shall be treated as having been agreed or approved by the Joint Steering Committee for the purposes of this Agreement.

6.3.4 If, during each of Calendar Year [***], Sanofi exercises its final decision-making authority to approve any amendment or update to the Binding Budget (covering any such Calendar Year) which causes an increase in Biontech's share of Shared Development Costs with respect to such Calendar Year (compared with its share of Shared Development Costs had such amendment or update to the Binding Budget not been implemented), then Biontech shall not be required to pay to Sanofi the amount of such increase (the **Additional Co-Development Costs**) [***] provided that: (i) Biontech shall not be required to pay more than [***]

6.3.5 The Joint Project Team shall not have the authority to amend or modify the terms and conditions of this Agreement or the License Agreement (save for the amendment of the Development Plan and the Budget in accordance with this Section 6.3) or to waive any obligation of either Party under this Agreement or the License Agreement.

6.4 Meetings of the Joint Project Team. The Joint Project Team shall meet as soon as reasonably practicable after the Signing Date (in any event, no later than [***] after the Signing Date), and thereafter, no less than once every [***], and more often as reasonably considered necessary at the request of either Party, to, among other matters, provide an update on the progress of the Development activities hereunder. The Joint Project Team may meet in person or by means of teleconference, internet conference, videoconference or other similar communications equipment, provided that at least [***] shall be conducted in person in each Calendar Year. Minutes of all meetings of the Joint Project Team shall be prepared by or on behalf of such representative of the Joint Project Team of either Party as the Joint Project Team may from time to time agree and shall be transmitted by such representative of such Party to all members of the Joint Project Team within [***] after the date of the meeting. The minutes shall be deemed to be approved by the other Party if the other Party does not object within [***] receipt.

6.5 Joint Financial Committee.

6.5.1 Each Party shall designate [***] representatives which together shall constitute the joint financial committee (**Joint Financial Committee**), which shall be formed no later than [***] after the Signing Date. Each Party may replace any of its Joint Financial Committee representatives upon prior notice to the other Party.

6.5.2 The Joint Financial Committee shall be responsible for:

- (a) review and approval of any reconciliation report as requested by Biontech under Section 3.3.4(b);
- (b) review of the proposed Budget submitted by the Joint Project Team under Section 3.3.1(b), and submission of any comments to the Joint Project Team with respect to such proposed Budget within [***] of its receipt of the proposed Budget from the Joint Project Team;
- (c) during each Calendar Quarter, preparation of a forecast of Shared Development Costs reasonably expected to be incurred by each Party with respect to the immediately subsequent Calendar Quarter; and
- (d) preparation of necessary documentation to support strategic financial decisions of the Joint Steering Committee in connection with the Development Plan.

6.5.3 The quorum for each Joint Financial Committee meeting shall be at least one (1) representative from each Party. Each Party shall have one collective vote in all decisions of the Joint Financial Committee with respect to matters falling within its responsibility, and shall use good faith efforts to decide all such matters unanimously. If consensus cannot be reached by the Joint Financial Committee, the relevant matter shall be escalated to the Joint Steering Committee for discussion and decision. If the Joint Steering Committee cannot agree on such matter unanimously, the fourth sentence of Section 11.2.4 (and accordingly Section 13.7) of the License Agreement shall apply with respect to such matter accordingly, except that, the reference to "Parties' CEOs" in Section 13.7 shall instead be deemed to be a reference to Biontech's CEO and Sanofi's Chief Financial Officer with respect to such matter, and any such matter to the extent approved or agreed by the Joint Steering Committee or Biontech's CEO and Sanofi's Chief Financial Officer under Section 13.7 of the License Agreement (as applicable) shall be treated as having been agreed or approved by the Joint Financial Committee for the purposes of this Agreement. The Joint Financial Committee shall not have the authority to amend or modify the terms and conditions of this Agreement or the License Agreement or to waive any obligation of either Party under this Agreement or the License Agreement.

7. Pharmacovigilance and Regulatory Matters.

7.1 Regulatory Matters. Sanofi or its Affiliate shall have the exclusive right (but not the obligation) to file, submit and maintain any Regulatory Documentation in its name (and such Regulatory Documentation, to the extent filed by Sanofi or its Affiliate, shall be the sole property of Sanofi (or its Affiliate, as applicable)), unless otherwise agreed between the Parties. Without limiting the foregoing, Sanofi or its Affiliate shall be the holder of the Marketing Approval for any Licensed Product #1 in the Field to the extent the relevant applications have been filed by Sanofi or its Affiliate. Sanofi shall lead all interactions with all Regulatory Authorities in all regions. [***]

Biontech shall have the right (but not the obligation) to participate in and attend with Sanofi (with not less than two representatives from Biontech) all meetings with Regulatory Authorities in the Biontech Territory, to the extent permitted by the relevant Regulatory Authority and Applicable Law.

7.2 Pharmacovigilance. To the extent Sanofi or its Affiliate is the sponsor of a clinical trial with respect to a Licensed Product #1 in the Field, Sanofi or its Affiliate shall be the host of the clinical and pharmacovigilance related databases with respect to such clinical trial and shall be responsible for compliance with all Applicable Laws pertaining to the safety of such Licensed Product #1. Each Party shall comply with its respective obligations under the Safety Data Exchange Agreement entered into between the Parties dated October 4, 2018 (**SDEA**). For the avoidance of doubt, such agreement shall constitute a “SDEA” under Section 3.2.3 of the License Agreement.

8. Confidentiality and Data Privacy.

8.1 For the avoidance of doubt: (a) any information disclosed by one Party to the other Party pursuant to this Agreement (including through any audit or inspection conducted pursuant to this Agreement or during any meeting of the Joint Project Team, Joint Steering Committee, Joint Manufacturing Committee or the Joint Financial Committee) shall constitute information related to the subject matter of the License Agreement for the purposes of the definition of “Confidential Information” under the License Agreement, and the provisions in such definition and Section 8 of the License Agreement shall apply to such information accordingly; and (b) the Sanofi Co-Development Technology, Co-Development Background Technology of Sanofi, Regulatory Documentation filed by Sanofi or its Affiliate and Clinical Data shall constitute Sanofi’s Confidential Information (in respect of which Sanofi is the Disclosing Party and Biontech the Receiving Party) and the Biontech Co-Development Technology, CMC Technology and Co-Development Background Technology of Biontech shall constitute Biontech’s Confidential Information (in respect of which Biontech is the Disclosing Party and Sanofi the Receiving Party).

8.2 Notwithstanding any other term of this Agreement, neither Party shall, or shall be required to, transfer to the other Party, any personal data if either Party, acting reasonably, determines that such transfer or any subsequent processing of such personal data would not comply with any Applicable Laws relating to the transfer and processing of such personal data. Each Party shall ensure that any transfer and subsequent processing of such personal data by it under or in connection with this Agreement is lawful, and if required the Parties shall negotiate in good faith and seek to enter into such agreements as are reasonably required to ensure the same, including, where applicable, entering into the Standard Contractual Clauses published by the European Commission. For the purposes of this Section 8.2, “personal data” and “process” shall be construed in accordance with the EU General Data Protection Regulation 2016/679.

9. Term and Termination.

9.1 Term. This Agreement shall be effective from the Effective Date and shall continue until the completion of all Co-Development Activities and CMC Activities, unless terminated earlier in accordance with Section 9.2 or otherwise agreed between the Parties (the **Term**).

9.2 Termination.

9.2.1 This Agreement shall terminate automatically:

- (a) in the event of any termination or expiry of the License Agreement in its entirety;
- (b) in the event of any termination of the License Agreement on a Licensed Product-by-Licensed Product basis, where such Licensed Product is Licensed Product #1, under Section 12.3.1 or Section 12.3.2 of the License Agreement; or
- (c) in the event of any termination of the Co-Development of an Option Product under Section 12.2.2 or Section 12.3.4 of the License Agreement, where such Option Product is Licensed Product #1.

9.2.2 Either Party may terminate this Agreement with immediate effect by written notice to the other Party:

(a) if the other Party materially breaches any of its material obligations hereunder and fails to cure such breach [***] following its receipt of written notice thereof from the first Party. In the event of a dispute between the Parties as to whether a material breach has occurred, either Party may refer such dispute to the dispute resolution process set out in Section 13.7 of the License Agreement. Any right to terminate under this Section 9.2.2(a) or Section 12.3.4 of the License Agreement and the cure period shall be suspended in the event that, during the cure period, the Party alleged to have been in material breach shall have in good faith initiated dispute resolution in accordance with Section 13.7 of the License Agreement with respect to the alleged breach, which suspension shall continue until such dispute has been resolved in accordance with Section 13.7 of the License Agreement; or

(b) if the other Party breaches its payment obligations under this Agreement with respect to an aggregate outstanding amount of at least [***] and such Party fails to cure such breach within [***] following its receipt of written notice thereof from the first Party.

9.3 Consequences of Termination or Expiry.

9.3.1 *General consequences.*

(a) In the event of any termination or expiry of this Agreement:

(i) within [***] of such termination or expiry, each Party shall return or deliver to the other Party all of the other Party's Confidential Information disclosed to such Party under this Agreement, as well as any of the other Party's materials delivered by the other Party under this Agreement, provided that each Party shall be permitted to retain and use any Confidential Information of the other Party which is necessary or useful for such Party to exercise any remaining rights or perform its remaining obligations under this Agreement or under the License Agreement; and

(ii) within [***] of such termination or expiry, the Parties shall reconcile the Shared Development Costs incurred prior to the date of such termination or expiry (to the extent not previously reconciled under Section 3.3.4), in accordance with the principles set out in Sections 3.1 and 3.2, and shall promptly make any required payments to the other Party as a result of such reconciliation. Except as set forth in Sections 9.3.2(a)(iii) and 9.3.2(c), any Additional Co-Development Costs, to the extent not already paid by Biontech as of the date of such termination or expiry, shall become immediately payable by Biontech.

9.3.2 Specific consequences.

(a) In the event of any termination of this Agreement as a result of Sanofi's termination of the entirety of the License Agreement under Section 12.2.1 (*Termination by Sanofi for convenience*) of the License Agreement, in addition to the termination events set out in Section 12.4.2 of the License Agreement:

(i) at Biontech's written request, Sanofi shall: (1) transfer control to Biontech of any ongoing clinical trial being conducted by or on behalf of Sanofi under the Development Plan as of the effective date of termination and (2) continue to conduct such clinical trial (the costs of which as between the Parties, and the invoicing and reconciliation of such costs, shall continue to be governed by Section 3), for up to [***] to enable such transfer to be completed without interruption of any such clinical trial, whereupon after such transfer Biontech will assume the costs of such clinical trial, provided that, with respect to any such clinical trial for which such transfer is expressly prohibited by the applicable Regulatory Authority, Sanofi shall continue to conduct such clinical trial to completion, at Sanofi's cost and expense;

(ii) the licenses granted to Biontech under Section 4.5 of this Agreement shall survive; and

(iii) for any Additional Co-Development Costs, to the extent not already paid by Biontech as of the date of such termination, the payment schedule pursuant to Section 6.3.4 shall continue to apply.

(b) In the event of any termination of this Agreement as a result of Biontech's termination of co-Development of Licensed Product #1 under Section 12.2.2 (*Termination of co-development by Biontech for convenience*) of the License Agreement, for the avoidance of doubt, (i) the termination consequences set forth in Section 12.4.4 of the License Agreement shall apply; and (ii) the licenses granted to Sanofi under Sections 7.3.1 and 7.3.3(ii) of the License Agreement and under Section 4.6 of this Agreement shall survive.

(c) In the event of any termination of this Agreement as a result of Biontech's termination of the License Agreement under Section 12.3.1 (*Termination for Sanofi's breach*) or Section 12.3.3 (*Termination for Sanofi's insolvency*) of the License Agreement, whether in its entirety or with respect to Licensed Product #1 only, in addition to the termination events set out in Section 12.4.6 of the License Agreement, (1) Section 9.3.2(a)(i) of this Agreement shall apply with respect to any ongoing clinical trial conducted by or on behalf of Sanofi under the Development Plan as of the effective date of such termination; (2) the Clinical Supply Agreement shall automatically terminate with respect to Licensed Product #1 (and such termination shall be treated as a termination by Sanofi pursuant to Section 12.3(c) of the Clinical Supply Agreement); (3) the licenses granted to Biontech under Section 4.5 of this Agreement shall survive; and (4) for any Additional Co-Development Costs, to the extent not already paid by Biontech as of the date of such termination, the payment schedule pursuant to Section 6.3.4 shall continue to apply.

(d) In the event of any termination of this Agreement as a result of Sanofi's termination of the License Agreement under Section 12.3.2 (*termination for Biontech's breach*) or Section 12.3.3 (*termination for Biontech's insolvency*) of the License Agreement (whether in its entirety or with respect to Licensed Product #1 only), in addition to the termination events set out in Section 12.4.8 of the License Agreement:

(i) within [***] after such date of termination, Biontech shall provide to Sanofi a report containing the details set out in Section 2.5(a) to (d) with respect to the Co-Development Activities performed by or on behalf of Biontech prior to the date of such termination, to the extent not previously reported to Sanofi under Section 2.5;

(ii) promptly upon Sanofi's request: (1) Biontech shall assign (or, in the case of agreements relating to Licensed Product #1 and other products being Developed or Commercialized by Biontech, partially assign) to Sanofi, to the extent assignable (or partially assignable, as applicable), Biontech's rights in any or all agreements with Biontech's Approved Co-Development Third Parties to the extent related to the Co-Development Activities; and (2) Biontech shall provide copies of such agreements to Sanofi. To the extent that any such agreement is not assignable (or partially assignable, as applicable) by Biontech, then such agreement shall not be assigned (or partially assigned, as applicable), and upon the request of Sanofi, Biontech shall cooperate with Sanofi in good faith and allow Sanofi to obtain and to enjoy the benefit of such agreement (or, in the case of any agreement relating to Licensed Product #1 and other products being Developed or Commercialized by Biontech, such agreement to the extent relating to Licensed Product #1) in the form of a license or such other rights;

(iii) to the extent the Manufacturing process with respect to Licensed Product #1 has not completely transferred to Sanofi pursuant to Section 3.3.4 of the License Agreement, at Sanofi's request: (1) Biontech shall transfer such Manufacturing process to Sanofi or its designee or (2) continue to supply to Sanofi with clinical quantities of Licensed Product #1 in the Field subject to a supply agreement to be negotiated and agreed in good faith between the Parties, until the earlier of: (i) [***] after the effective date of termination; or (ii) such Manufacturing process having been completely transferred to Sanofi, or establishment by Sanofi of an alternative supply for such Licensed Product on commercially reasonable terms; and

(iv) Biontech shall, at Sanofi's written request, (a) transfer control to Sanofi of any ongoing clinical trial being conducted by or on behalf of Biontech under the Development Plan as of the effective date of termination and (b) continue to conduct such clinical trials, at Biontech's cost in the case of termination of the License Agreement under Section 12.3.2 (*termination for Biontech's breach*) of the License Agreement, and at Sanofi's cost in the case of termination under Section 12.3.3 (*termination for Biontech's insolvency*) of the License Agreement in the case of, for up to [***] to enable such transfer to be completed without interruption of any such clinical trial, whereupon after such transfer Sanofi will assume the costs of such clinical trial, provided that, with respect to any such clinical trial for which such transfer is expressly prohibited by the applicable Regulatory Authority, Biontech shall continue to conduct such clinical trial to completion, at Biontech's cost and expense;

(e) In the event of any termination of this Agreement as a result of Sanofi's termination of the co-Development of Licensed Product #1 under Section 12.3.4 (*termination for Biontech's breach of co-development obligations*) of the License Agreement or any termination by Sanofi of this Agreement under Section 9.2.2, for the avoidance of doubt, Section 12.4.9 of the License Agreement shall apply, and the following provisions shall apply in addition:

(i) Biontech shall grant to Sanofi: (a) an exclusive, transferable, worldwide license, with the right to sublicense (subject to Section 7.3.4 of the License Agreement), under the Biontech Background Technology in Schedule D of the License Agreement, Biontech's interest in the Joint Collaboration Technology (if any), Biontech Co-Development Technology and Biontech Foreground Technology to Develop, have Developed, make, have made, Commercialize and have Commercialized Licensed Product #1 in the Field;

and (b) a non-exclusive, transferable, worldwide license, with the rights to sublicense (subject to Section 7.3.4 of the License Agreement), under the Biontech Background Technology (to the extent not set out in Schedule D of the License Agreement) to Develop, have Developed, make, have made, Commercialize and have Commercialized Licensed Product #1 in the Field. For the avoidance of doubt, the foregoing licenses shall not limit Section 7.3 of the License Agreement, and shall not be affected by any termination of the License Agreement (whether in its entirety or with respect to a product). For the purposes of Section 7.3.4(a) of the License Agreement, the phrase “the rights granted to such Party pursuant to Section 7.3.1 to 7.3.3” shall be deemed to also include the rights granted to Sanofi under this Section 9.3.2(e)(i), and for the purposes of Section 7.3.4(b) of the License Agreement, the phrase “the rights granted to it under Section 7.3.1(b) or 7.3.2(b)” shall be deemed to also include rights granted to Sanofi under this Section 9.3.2(e)(i);

(ii) the licenses granted to Sanofi under Section 4.6 shall survive;

(iii) Biontech shall no longer have the right to co-Develop or co-Commercialize Licensed Product #1;

(iv) any milestones payable by Sanofi pursuant to Section 6 of the License Agreement with respect to Licensed Product #1 shall be reduced by [***] and any royalties payable by Sanofi pursuant to Section 6 of the License Agreement to the extent relating to the Net Sales of Licensed Product #1 shall be reduced by [***] and

(v) the events set out in Section 9.3.2(d)(i) to (iv) shall apply.

9.3.3 Survival. Upon the expiry or termination of this Agreement, the provisions of this Agreement shall no longer be of any force or effect, save for the following provisions which shall survive such expiry or termination: Sections 1, 2.6.1 (for the duration set out therein), 2.7 (first sentence), 4 (in accordance with Sections 4.14 and 9.3.2), 8.1, 9.3, 10 and 11 (including the Sections of the License Agreement as incorporated into this Agreement under Section 11.4).

10. Disclaimer of Warranties; Limitation of Liability

10.1 For the avoidance of doubt, the Co-Development Activities constitute Development to be conducted under the License Agreement, and accordingly the provisions of Section 9.3 of the License Agreement shall apply accordingly.

10.2 For the avoidance of doubt, Section 10.3 of the License Agreement shall also apply with respect to this Agreement.

11. General Provisions.

11.1 This Agreement shall be governed by the laws of Germany without reference to its conflict of laws provision. Any dispute arising out of this Agreement shall be constitute a dispute arising between the Parties in connection with the License Agreement, and accordingly Section 13.7 and the second, third and fourth sentences of Section 13.8 of the License Agreement shall apply to any such dispute, subject to Sections 2.8.5, 6.3 and 6.5.3.

11.2 This Agreement (including the Schedules to this Agreement), together with the License Agreement and the Clinical Supply Agreement, represent the entire understanding between the Parties with respect to the subject matter hereof and supersedes all previous oral or written communication or agreements, and all contemporaneous oral communication and agreements between the Parties. Each Party acknowledges and agrees that, if there is any conflict between any provision of this Agreement and any provision of the License Agreement or the Clinical Supply Agreement, such provision of this Agreement shall prevail to the extent of such conflict.

11.3 This Agreement may only be amended, modified or supplemented by the Parties in writing. The same applies to this Section 11.3.

11.4 Sections 13.1, 13.4, 13.5, 13.6, 13.9 and 13.10 of the License Agreement shall be incorporated by reference into this Agreement (and any reference to "this Agreement" in each such incorporated provision shall be construed as a reference to this Agreement).

[Signatures on the Following Page]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives.

SANOFI

By: _____ [***]

Name: _____ [***]

Title: _____ [***]

Date: _____ December 22, 2018

By: _____ [***]

Name: _____ [***]

Title: _____ [***]

Date: _____ December 22, 2018

BIONTECH RNA PHARMACEUTICALS GMBH

By: _____ [***]

Name: _____ [***]

Title: _____ [***]

Date: _____ December 22, 2018

Schedule A - Approved Co-Development Third Parties

Approved Co-Development Third Parties of Sanofi:

[***]

Approved Co-Development Third Parties of Biontech:

[***]

Schedule B -Licensed Product #1

SAR441000 - A Mixture containing the following:

- mRNA encoding Interferon alpha
- mRNA encoding IL12
- mRNA encoding IL15sushi
- mRNA encoding GM-CSF

Schedule C – Development Plan

[***]

Schedule D – CMC Development Plan

[***]

THE SYMBOL “[*]” DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED**

COLLABORATION AGREEMENT

between

BIONTECH RNA PHARMACEUTICALS GMBH AND BIONTECH AG

and

GENENTECH, INC. AND F. HOFFMANN-LA ROCHE LTD

Dated as of September 20, 2016

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COLLABORATION AGREEMENT

This Collaboration Agreement (the “**Agreement**”) is made and entered into as of September 20, 2016 (the “**Execution Date**”) by and between BioNTech RNA Pharmaceuticals GmbH, a limited liability company organized under the laws of Germany (“**RNP**”) and BioNTech AG, a stock corporation organized under the laws of Germany (“**BNT**”) (RNP and BNT collectively, “**BioNTech**”), and Genentech, Inc., a corporation organized under the laws of the State of Delaware (“**GNE**”) and F. Hoffmann-La Roche Ltd, a corporation organized under the laws of Switzerland (“**Roche**”) (GNE and Roche, collectively, “**Genentech**”). BioNTech and Genentech are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**.”

RECITALS

WHEREAS, BioNTech Controls certain intellectual property rights with respect to Pharmaceutical Products comprising one or more Neopeptide RNA(s) in the Territory;

WHEREAS, BioNTech and Genentech wish to conduct joint research activities, engage in a shared (50%:50%) co-development program, and conduct coordinated manufacturing activities, in each case to enable the commercialization of Collaboration Products in the Territory (each capitalized term as defined herein), and subject to certain exceptions set forth herein, wish to share (50%:50%) the profits and losses associated therewith;

WHEREAS, BioNTech and Genentech wish to enter into the Manufacturing Development and Supply Agreement as described herein and executed on the Execution Date; and

WHEREAS, BioNTech wishes to grant an exclusive license to Genentech, and Genentech wishes to take, an exclusive license under such intellectual property rights to Develop and commercialize Collaboration Products in the Territory, in each case in accordance with the terms and conditions set forth below.

NOW, THEREFORE, in consideration of the premises and the mutual promises and conditions hereinafter set forth, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:

**ARTICLE 1.
DEFINITIONS**

Unless otherwise specifically provided herein, the following terms shall have the following meanings:

1.1 “Accelerated Marketing Authorization” means a Marketing Authorization other than a Non-Accelerated Marketing Authorization.

1.2 “**Accounting Standards**” has the meaning set forth in Schedule 1.8.

1.3 “**Additional Jurisdictions**” has the meaning set forth in Section 10.3.1(c)(ii).

1.4 “**Adverse Ruling**” has the meaning set forth in Section 14.2.

1.5 “**Affiliate**” of a Party means any corporation or other business entity that, during the Term, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with such Party. For purposes of this definition, the term “control” (including, the correlative meanings, “controlled by” and “under common control with”) means (a) the direct or indirect ownership of more than fifty percent (50%) of (i) the stock or other equity interests having the right to vote for directors (supervisory, management or otherwise) thereof or (ii) any general partnership interests or (b) the ability to otherwise control the management and policies of such corporation or other business entity, whether through control of the decisions of the managing directors or of the board of directors, supervisory board or equivalent governing body thereof or otherwise. Notwithstanding the foregoing, for purposes of this Agreement, [***] and all business entities directly or indirectly controlled by [***], shall not be considered Affiliates of Genentech, unless and until GNE elects to include one or more of such business entities as an Affiliate of Genentech, by providing written notice to BioNTech of such election, (B) Ganymed Pharmaceuticals AG and all business entities directly or indirectly controlled by Ganymed shall not be considered an Affiliate of RNP or BNT, and (C) AT Impf GmbH, having its place of business at Rosenheimer Platz 6, 81669 Munich, Germany, and any person or entity that, during the Term, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with AT Impf GmbH (other than BNT or any person or entity that is directly or indirectly controlled by BNT) shall not be considered an Affiliate of BNT.

1.6 “**Agreement**” has the meaning set forth in the preamble hereto.

1.7 “**Alliance Manager**” has the meaning set forth in Section 2.13.

1.8 “**Allowable Expenses**” has the meaning set forth in Schedule 1.8.

1.9 “**Ancillary Agreements**” means (a) the Manufacturing Development and Supply Agreement, the Commercial Manufacturing Agreement and the Quality Agreement(s), and any agreement that is entered into by the Parties or their respective Affiliates pursuant to such agreement, (b) any agreement that is entered into by the Parties or their respective Affiliates pursuant to this Agreement (e.g. the Co-Promotion Agreement or Pharmacovigilance Agreement) and (c) any agreement that is designated in writing by the Parties as an “Ancillary Agreement” to this Agreement.

1.10 “**Applicable Law**” means applicable laws, rules, and regulations, including any rules, regulations, guidelines, or other requirements of the Regulatory Authorities (including Compliance Requirements) that may be in effect from time to time.

1.11 “Applicable Promotional Law” means all Applicable Laws applicable to the marketing, promotion, distribution and sale of Co-Promotion Products, including (if applicable) the FFDCA, the American Medical Association Guidelines on Gifts to Physicians from Industry and the Pharmaceutical Research and Manufacturers of America (“PhRMA”) Code on Interactions with Healthcare Professionals.

1.12 “Arbitrator” has the meaning set forth in Section 8.17.

1.13 “Assignee” has the meaning set forth in Section 10.2.2.

1.14 “Assignor” has the meaning set forth in Section 10.2.2.

1.15 “Batch” has the meaning set forth in the MDSA.

1.16 “BioNTech” has the meaning set forth in the preamble hereto.

1.17 “BioNTech Co-Funding Rejection” has the meaning set forth in Section 2.7.2(c).

1.18 “BioNTech Collaboration Products” means Collaboration Products being Developed by BioNTech in a BioNTech Indication pursuant to Section 4.5 or Commercialized under [***]; provided that Genentech has not paid a BioNTech Indication Opt-In Fee with respect to the applicable Indication. For clarity, in the event that Genentech pays a BioNTech Indication Opt-In Fee with respect to the applicable Indication, Collaboration Products with respect to such Indication shall be GDP Collaboration Products.

1.19 “[*]”** has the meaning set forth in Schedule 1.8.

1.20 “BioNTech Core Patents” means the Patents listed on Schedule 1.20 and all Patents claiming priority thereto or claiming priority to a priority document thereof.

1.21 “BioNTech Development and [*] Activities”** has the meaning set forth in Section 5.3.3.

1.22 “BioNTech [*]”** has the meaning set forth in Section 5.3.1.

1.23 “BioNTech Indication” has the meaning set forth in Section 4.5.1.

1.24 “BioNTech Indication Opt-In Fee” has the meaning set forth in Section 8.3.

1.25 “BioNTech Initial Knowledge Transfer Items” has the meaning set forth in Section 2.19.1(a).

1.26 “BioNTech IP” means, collectively, BioNTech Know-How, BioNTech Patents, and BioNTech Core Patents.

1.27 “BioNTech Know-How” means any Neoepitope Prediction Algorithms, Neoepitope RNAs, any liposome formulations, components of product comprising one or more Neoepitope RNA(s) (including [***]) and all other Know-How, in each case, that (a) is Controlled by BioNTech or any of its Affiliates as of the Execution Date or at any time thereafter until the end of the Term; and (b) is necessary or useful to research, develop, manufacture, commercialize, make, have made, use, offer for [***]; *provided*, however, that BioNTech Know-How specifically excludes Collaboration Know-How.

1.28 “BioNTech Opt-Out Period” means the period commencing as of [***] and ending with [***]

1.29 “BioNTech Patents” means all Patents that (a) are Controlled by BioNTech or any of its Affiliates as of the Execution Date or at any time thereafter until the end of the Term; and (b) are necessary or useful to research, develop, manufacture, commercialize, make, have made, use, offer for sale, sell and import Pharmaceutical Products that comprise (i) one or more Neoepitope RNA(s), [***] *provided*, however, that BioNTech Patents specifically exclude Collaboration Patents and BioNTech Core Patents.

1.30 “BioNTech Platform Product” means any product researched, developed or commercialized by BioNTech (in each case, whether directly or indirectly through a Third Party) that uses BioNTech IP and is substantially similar to any material aspect of the Collaboration Manufacturing Process such that a Regulatory Authority could reasonably require reporting of safety data from such product in connection with Collaboration Product. As of the Effective Date, such BioNTech Platform Products may include products researched, developed or commercialized by BioNTech pursuant to collaboration agreements with Bayer Animal Health GmbH and Sanofi.

1.31 “BioNTech [*]”** has the meaning set forth in Section 5.1.

1.32 “BioNTech Study” has the meaning set forth in Section 4.5.1.

1.33 “BioNTech Study Conduct Requirements” has the meaning set forth in Section 4.5.2.

1.34 “Biosamples” means patient-specific normal (e.g., whole blood or peripheral blood mononuclear cells (PBMC)) and tumor tissue (fresh frozen (FF) or formalin-fixed, paraffin-embedded (FFPE) blocks) which are subsequently processed and sequenced to identify Neoepitopes.

1.35 “BLA” means Biologics License Application and amendments thereto filed pursuant to the requirements of the FDA, as defined in 21 C.F.R. § 600 *et seq.*, for FDA approval of a biological Pharmaceutical Product as well as any foreign equivalent thereof.

1.36 “Board of Directors” has the meaning set forth in the definition of “**Change in Control.**”

1.37 “Breaching Party” has the meaning set forth in Section 14.2.

1.38 “Business Day” means a day, other than a Saturday, Sunday or day on which commercial banks located in the United States or Germany are authorized or required by law or regulation to close.

1.39 “Calendar Quarter” means each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1, except that the first Calendar Quarter of the Term shall commence on the Effective Date and end on the day immediately prior to the first to occur of January 1, April 1, July 1 or October 1 after the Effective Date, and the last Calendar Quarter shall end on the last day of the Term.

1.40 “Calendar Year” means each successive period of twelve (12) calendar months commencing on January 1 and ending on December 31, except that the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the year in which the Effective Date occurs and the last Calendar Year of the Term shall commence on January 1 of the year in which the Term ends and end on the last day of the Term.

1.41 “Capacity” has the meaning set forth in the MDSA.

1.42 “Change in Control” with respect to BNT or RNP, shall be deemed to have occurred if any of the following occurs after the Effective Date:

(a) any “person” or “group” (as such terms are defined below) (a) becomes the “beneficial owner” (as defined below), directly or indirectly, of shares of capital stock or other interests (including partnership interests) of such Party then outstanding and normally entitled (without regard to the occurrence of any contingency) to vote in the election of the directors, managers or similar supervisory positions (“**Voting Stock**”) of such Party representing more than fifty percent (50%) of the total voting power of all outstanding classes of Voting Stock of such Party or (b) has the power, directly or indirectly, to appoint a majority of the Party’s managing directors or to elect a majority of the members of the Party’s board of directors, supervisory board or similar governing body (“**Board of Directors**”); or

(b) such Party enters into a merger, consolidation or similar transaction with another Person (whether or not such Party is the surviving entity) and as a result of such merger, consolidation or similar transaction (a) the managing directors or the members of the Board of Directors of such Party immediately prior to such transaction constitute less than a majority of the managing directors or the members of the Board of Directors of such Party or such surviving Person immediately following such transaction or (b) the Persons that beneficially owned, directly or indirectly, the shares of Voting Stock of such Party immediately prior to such transaction cease to beneficially own, directly or indirectly, shares of Voting Stock of such Party representing a majority of the total voting power of all outstanding classes of Voting Stock of the surviving Person in substantially the same proportions as their ownership of Voting Stock of such Party immediately prior to such transaction; or

(c) such Party sells or transfers to any Third Party, in one or more related transactions, properties or assets representing all or substantially all of such Party's consolidated total assets to which this Agreement relates; or

(d) the managing directors, Board of Directors or the holders of capital stock of such Party approve a plan or proposal for the liquidation or dissolution of such Party.

Notwithstanding the foregoing, the occurrence of neither of the following shall, by itself, be considered a Change in Control, in each case if entered into in the ordinary course of business and not for the purpose or effect of circumventing any other Party's rights hereunder: (a) the sale of capital stock of such Party in an initial public offering on an internationally recognized securities exchange, including the NYSE, NASDAQ, London Stock Exchange and Frankfurt Stock Exchange, and (b) the sale of capital stock of such Party to a Financial Party in a capital-raising financing transaction, e.g. private placement or similar transaction, so long as following such financing transaction no Person other than an existing shareholder of BNT or RNP (as set forth on Schedule 1.42) or a Financial Party (individually or collectively as a member of any "group") has the power, directly or indirectly, to elect a majority of the members of the Board of Directors.

For the purpose of this definition of Change in Control, (x) "person" and "group" have the meanings given such terms under Section 13(d) and 14(d) of the United States Securities Exchange Act of 1934 and the term "group" includes any group acting for the purpose of acquiring, holding or disposing of securities within the meaning of Rule 13d-5(b)(1) under the said Act; (y) a "beneficial owner" shall be determined in accordance with Rule 13d-3 under the aforesaid Act; and (z) the terms "beneficially owned" and "beneficially own" shall have meanings correlative to that of "beneficial owner."

1.43 "Change in Control Firewall" has the meaning set forth in Schedule 1.43.

1.44 [*]**

1.45 [*]**

1.46 [*] Change in Control**" means any Change in Control that [***]

1.47 [*] Firewall**" has the meaning set forth in Schedule 1.43.

1.48 "Class of Agents" means all Pharmaceutical Products that [***]

1.49 "Clinical Data" means with respect to any Collaboration Product and any other drug included in the applicable Clinical Study, all Information that is generated pursuant to a clinical study under this Agreement [***]

1.50 "Clinical Development Decisions" means all clinical Development decisions [***]

1.51 “**Clinical Facility**” has the meaning set forth in the MDSA.

1.52 “**Clinical Manufacture**” has the meaning set forth in the MDSA

1.53 “**Clinical Studies**” means any and all tests and studies in human subjects that are required by Applicable Law, or otherwise requested or recommended by the Regulatory Authorities, to obtain or maintain Regulatory Approvals for a Collaboration Product for an Indication, including Post-Approval Commitments and tests or studies that are intended to expand the Product Labeling for such Collaboration Product with respect to such Indication, together with Marketing Studies.

1.54 “**CMC**” means Chemistry, Manufacturing, and Control.

1.55 “**CMC Development Costs**” has the meaning set forth in Schedule 1.8.

1.56 “**CMC Development Plan**” has the meaning set forth in the Manufacturing Development and Supply Agreement.

1.57 “**Code**” means the Internal Revenue Code of 1986, as amended.

1.58 “**Collaboration IP**” means Collaboration Patents and Collaboration Know-How.

1.59 “**Collaboration Know-How**” means any Know-How that is discovered, generated, conceived or reduced to practice by a Party (or any authorized Third Party acting on a Party’s behalf) solely or jointly in the course of [***] (other than, in each case [***], Genentech Molecule Clinical Study Data).

1.60 “**Collaboration Patents**” means Patents that claim any Collaboration Know-How.

1.61 “**Collaboration Product**” means [***]

1.62 “**Collaboration Product Clinical Study Data**” means all Clinical Data that is related to the use in a Clinical Study of a Collaboration Product alone or in combination with one or more Combination Agents but shall exclude Genentech Molecule Clinical Study Data.

1.63 “**Collaboration Term**” means the period from the Effective Date until such time as there is no Collaboration Product being Developed, Manufactured or Commercialized in the Territory.

1.64 “**Combination Agent**” means a Pharmaceutical Product that is proposed for Development or being Developed, or has received Regulatory Approval (i.e., under this Agreement) for use in combination with a Collaboration Product, whether or not co-formulated.

1.65 “**Commercial Facility**” has the meaning set forth in the MDSA.

1.66 “**Commercial Manufacture**” has the meaning set forth in the MDSA.

1.67 “**Commercial Manufacturing Agreement**” has the meaning set forth in the MDSA.

1.68 “**Commercial Readiness**” means the point in time, prior to [***], at which Genentech seeks to ensure readiness for market launch of such Collaboration Product [***] in accordance with [***]

1.69 “**Commercialization**” means any and all activities directed to the preparation for sale of, offering for sale of, or sale of a Collaboration Product, including activities related to marketing, promoting, distributing, and importing such Collaboration Product. When used as a verb, “**to Commercialize**” and “**Commercializing**” means to engage in Commercialization, and “**Commercialized**” has a corresponding meaning.

1.70 “**Commercialization Plan**” has the meaning set forth in Section 2.9.2(b).

1.71 “**Commercially Reasonable Efforts**” means, with respect to the performance of Development, Commercialization or Manufacturing activities with respect to a Collaboration Product or the performance of activities with respect to the Research Plan, the carrying out of such activities using efforts and resources comparable to the efforts and resources that such Party would typically devote [***]

1.72 “**Commissioning**” has the meaning set forth in the MDSA.

1.73 “**Committees**” has the meaning set forth in Section 2.1.

1.74 “**Committee Co-Chair**” has the meaning set forth in Section 2.2.

1.75 “**Competing Program**” means any program described in clause (a) or clause (b)(i) of the definition of [***]

1.76 “**Competitive Product**” means [***]

1.77 “**Competitive Product Infringement**” has the meaning set forth in Section 10.5.2(b)(ii).

1.78 “**Compliance Requirements**” has the meaning set forth in the MDSA.

1.79 “**Compulsory Sublicense**” means a license or sublicense granted to a Third Party (a “**Compulsory Sublicensee**”) through the order, decree or grant of a governmental authority having competent jurisdiction, authorizing such Third Party to Manufacture, use, sell, offer for sale, import or export a Collaboration Product in any country in the Territory.

1.80 “**Conduct**” means, with respect to any Clinical Study, to (a) sponsor or conduct, directly or indirectly through an Affiliate or Third Party, such Clinical Study; or (b) provide to an Affiliate or Third Party funding for, or clinical supplies for use in, such Clinical Study.

1.81 “Confidential Information” has the meaning set forth in Section 11.1.

1.82 “Confidentiality Agreements” means the following agreements: (a) that certain Non-Disclosure Agreement between BNT and Roche, dated June 1, 2014 and (b) that certain Letter between BNT and GNE, dated March 13, 2015, as amended May 7, 2015.

1.83 “Consensus Clinical Studies” has the meaning set forth in Section 2.7.2.

1.84 “Control” or **“Controlled”** means the (a) with respect to Know-How, Patents and Regulatory Documentation or other intellectual property rights, possession by a Party (whether directly or indirectly and whether by ownership, license or otherwise) (other than by operation of the license and other grants in Article 9) of, (1) with respect to any tangible Know-How, the legal authority or right to physical possession of such tangible Know-How, with the right to provide such tangible Know-How to the other Party on the terms and conditions set forth herein, or (2) with respect to Patents, intangible Know-How, Regulatory Documentation or other intellectual property rights, the legal authority or right to grant a license, sublicense, access or right to use (as applicable) (including the right to reference Regulatory Documentation) under such Patents, intangible Know-How, Regulatory Documentation or other intellectual property rights to the other Party on the terms and conditions set forth herein, in each case of (1) and (2) without breaching the terms of any agreement with a Third Party, or (b) with respect to any product or agent, the exclusive right (whether by ownership or exclusive license) to develop and commercialize such product or agent in any Major Market.

1.85 “Controlling Litigation Party” has the meaning set forth in Section 10.5.4.

1.86 “Controlling Party” has the meaning set forth in Section 10.3.2.

1.87 “Co-Promote” or **“Co-Promotion”** has the meaning set forth in Section 6.5.4.

1.88 “Co-Promotion Agreement” has the meaning set forth in Section 6.5.3.

1.89 “Co-Promotion Candidate Product” means a GDP Collaboration Product (other than a GDP Collaboration Product with respect to which a BioNTech Co-Funding Rejection has occurred) for which [***] there are, at the Effective Date, [***]

1.90 “Co-Promotion Exercise Period” means, with respect to a Co-Promotion Candidate Product [***], the period beginning on [***] and ending [***] in accordance with Section 6.5.2(a).

1.91 “Co-Promotion Option” has the meaning set forth in Section 6.5.1.

1.92 “Co-Promotion Potential Territory” means the Major Markets [***]

1.93 “Co-Promotion Product” has the meaning set forth in Section 6.5.2.

1.94 “Co-Promotion Territory” has the meaning set forth in Section 6.5.1.

1.95 “Copyleft Software” has the meaning set forth in Section 12.2.1(k).

1.96 “Core Facility” has the meaning set forth in the MDSA.

1.97 “Corporate Names” means the Trademarks and logos identified on Schedule 1.97 and such other names and logos as BioNTech or Genentech may designate in writing from time to time.

1.98 “Course of Therapy” means [***]

1.99 “Covered by” or **“Covers,”** or the like, means, with respect to a given product (including a Collaboration Product), that the sale, offer for sale or import of such product (including a Collaboration Product), but for ownership of, or a license granted in this Agreement under, the relevant Patent would infringe a Valid Claim of such Patent in the country of sale on the date of sale.

1.100 “CREATE Act” has the meaning set forth in Section 10.2.4.

1.101 “Declined BioNTech Core Patent” has the meaning set forth in Section 10.5.2(b)(iv).

1.102 “Deemed Opt-Out” has the meaning set forth in Section 8.5.3.

1.103 “Default Notice” has the meaning set forth in Section 14.2.

1.104 “Defend” or **“Defense”** has the meaning set forth in Section 10.5.3.

1.105 “Defending Party” has the meaning set forth in Section 10.5.3.

1.106 “Deferral Period” has the meaning set forth in Section 8.2.2(a).

1.107 “Detail” means, with respect to a Co-Promotion Product in the Co-Promotion Territory, a face-to-face sales call in which the sales representative makes a presentation of such Co-Promotion Product to a physician or other medical professional licensed to prescribe drugs, such that the relevant characteristics of such Co-Promotion Product are described by the sales representative in a fair and balanced manner consistent with the requirements of this Agreement, the Co-Promotion Agreement and Applicable Promotional Law and in a manner that is customary in the industry for the purpose of promoting a prescription Pharmaceutical Product. When used as a verb, **“Detail”** means to engage in a Detail.

1.108 “Development” means all activities related to preclinical and other non-clinical testing, test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, qualification and validation, quality assurance/quality control, clinical studies (including Clinical Studies), manufacturing (including Manufacturing) in support thereof, statistical analysis and report writing, the preparation and submission of Drug Approval Applications, regulatory affairs with respect to the foregoing and all other activities necessary or reasonably useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining or maintaining a Regulatory Approval for a Collaboration Product. When used as a verb, “**Develop**” means to engage in Development.

1.109 “Development Costs” has the meaning set forth in Schedule 1.8.

1.110 “[*] IP”** has the meaning set forth in 10.6.3.

1.111 [*]**

1.112 “Disclosing Party” has the meaning set forth in Section 11.1.

1.113 “Disclosure” has the meaning set forth in Section 11.4.

1.114 “Dispute” or the like, means any controversy, claim or legal proceeding arising out of or relating to this Agreement, or the breach, termination or invalidity thereof. Notwithstanding the foregoing, Disputes shall not include any disagreements solely about decisions for which one Party has final decision-making authority under this Agreement, including under Article 2.

1.115 [*]** has the meaning set forth in Section 5.3.2(a).

1.116 “Dollars” or “\$” means United States Dollars.

1.117 “Drug Approval Application” means a New Drug Application or BLA as defined in the FDCA or PHSA, or any corresponding foreign application in the Territory, including, with respect to the European Union, a Marketing Authorization Application filed with the EMA pursuant to the centralized approval procedure or with the applicable Regulatory Authority of a country in Europe with respect to the mutual recognition or any other national approval procedure.

1.118 “Effective Date” has the meaning set forth in Section 14.1.2.

1.119 “EMA” means the European Medicines Agency and any successor agency thereto.

1.120 “Enforce” or “**Enforcement**” has the meaning set forth in Section 10.5.2(a).

1.121 “Engineering Runs” has the meaning set forth in the MDSA.

1.122 “EUFETS” means EUFETS GmbH.

1.123 “EUFETS Facility” has the meaning set forth in the MDSA.

1.124 “EURIBOR” means the Euro Interbank Offered Rate for deposits in Euros having a maturity of one month published by the European Money Markets Institute, as adjusted from time to time on the first business day of each month.

1.125 “European Union” or “EU” means the economic and political union of the countries of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, the United Kingdom and any additional countries that may subsequently become members thereof (irrespective of whether such countries remain in such union). For purposes of this Agreement, Switzerland, Norway and the United Kingdom shall be deemed included within the definition of “European Union.”

1.126 “Exchange” has the meaning set forth in Section 11.4.

1.127 “Exclusivity Period” has the meaning set forth in Section 9.7.

1.128 “Execution Date” has the meaning set forth in the preamble hereto.

1.129 “Existing BioNTech Product” means a product described in the clinical trial protocols for the Ongoing Clinical Studies identified in Schedule 4.3.1, as such protocols were provided by BioNTech to Genentech prior to the Execution Date.

1.130 “Existing [*] Product”** has the meaning set forth in Section 15.2.2(b).

1.131 “Existing Third Party In-License Agreements” has the meaning set forth in Section 12.2.2(a).

1.132 “Existing Third Party In-License Agreement Royalty Payments” means the royalty payments owed based on the sales of Collaboration Products under the Existing Third Party In-License Agreements set forth in Schedule 1.132.

1.133 “Exploit” means to make, have made, import, use, sell, or offer for sale a Collaboration Product, including to research, Develop, Commercialize, register, Manufacture, have Manufactured, hold, or keep (whether for disposal or otherwise), have used, export, transport, distribute, promote, market, or have sold or otherwise dispose of such Collaboration Product.

1.134 “Exploitation” means the act of Exploiting a Collaboration Product.

1.135 “Ex-U.S. Territory Activities” has the meaning set forth in Section 8.13.2.

1.136 “Facility” has the meaning set forth in the MDSA.

1.137 “**FDA**” means the United States Food and Drug Administration and any successor agency thereto.

1.138 “**FDCA**” means the United States Federal Food, Drug, and Cosmetic Act, as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

1.139 “**Field**” means all uses.

1.140 “**Financial Party**” means a private equity firm, investment fund, pension fund or venture capital fund that in each case does not, directly or indirectly, except through a passive investment interest, operate a business other than the investment or portfolio management business including any venture capital arm of a pharmaceutical or biotechnology company or group provided that such venture capital arm of a pharmaceutical or biotechnology company or group has implemented and continues to maintain and comply with written procedures to prevent disclosure to and use by those parts of the pharmaceutical or biotechnology company or group which are active in the research, development, manufacture or commercialization of Pharmaceutical Products of: (a) Collaboration Product Clinical Study Data, (b) the GDP (other than a high level summary of status and results), (c) the Neoepitope Prediction Algorithm, (d) any Confidential Information of Genentech, or (e) Genentech Know-How.

1.141 “**First Commercial Sale**” means, with respect to a Collaboration Product or Reversion Product and a country (or the Territory, as applicable), the first invoiced sale for monetary value for use or consumption by the end user of such Collaboration Product or Reversion Product in such country (or the Territory) after Regulatory Approval for such Collaboration Product or Reversion Product has been obtained in such country (or the Territory). Sales prior to receipt of Regulatory Approval for such Collaboration Product or Reversion Product, such as so-called “treatment IND sales,” “named patient sales,” and “compassionate use sales,” shall not be construed as a First Commercial Sale.

1.142 [***]

1.143 [***]

1.144 “**Frontline Indication**” means an Indication for use of a Collaboration Product as a first-line therapy or component of such therapy.

1.145 “**FTE**” means the equivalent of the work of one (1) employee full time for one (1) Calendar Year (consisting of at least a total of eighteen hundred (1800) hours per Calendar Year) of work directly related to the applicable activity.

1.146 “**FTE Costs**” means, [***]

1.147 “**FTE Rate**” means [***]

1.148 "Fully-Burdened Manufacturing Cost" has the meaning set forth in Schedule 1.8.

1.149 "Future Acquirer" means the Third Party to any Change in Control transaction and such Third Party's Affiliates immediately prior to the Change in Control.

1.150 "GDP Budget" means the forecasted annual budget for the Development Activities under the GDP, which budget shall be for informational purposes only, and therefore non-binding on the Parties. The current non-binding estimate of the GDP Budget for 2016 and forecasts for the years from 2017 to 2019 are set forth in Schedule 1.150, for informational purposes only.

1.151 "GDP Collaboration Product" means a Collaboration Product Developed under the GDP or with respect to which a BioNTech Indication Opt-In Fee or a Genentech Indication Co-Funding Fee, as applicable, is due or paid.

1.152 "GDP Indication" means any Indication that has been, is being or will be Developed under the GDP.

1.153 "Genentech" has the meaning set forth in the preamble hereto.

1.154 "Genentech Agent" means any Pharmaceutical Product Controlled by Genentech, an Affiliate of Genentech or a Third Party Collaborator (to the extent the collaboration by Genentech or its Affiliates with such Third Party Collaborator relates to such Genentech Agent).

1.155 "Genentech Collaboration Product" has the meaning set forth in Section 2.7.2(c).

1.156 "Genentech Core Patents" means the Patents listed on Schedule 1.156, and all Patents claiming priority thereto or claiming priority to a priority document thereof.

1.157 "Genentech Indication" has the meaning set forth in Section 2.7.2(c).

1.158 "Genentech Indication Co-Funding Fee" has the meaning set forth in Section 8.3.

1.159 "Genentech IP" means, collectively, Genentech Know-How, Genentech Patents, and Genentech Core Patents.

1.160 "Genentech Know-How" means any Neoepitope Prediction Algorithms and any other Know-How, in each case, that is either (a) both (i) Controlled by GNE as of the Execution Date or at any time thereafter until the end of the Term; and (ii) necessary or useful to research, develop, commercialize, make, have made, use, offer for sale, sell and import Pharmaceutical Products that comprise (A) one or more Neoepitope RNA(s), but not any Non-Neoepitope RNA(s) or (B) one or more Permitted Hybrid Neoepitope RNA(s), but not any Non-Neoepitope RNA(s) or (b) Controlled by Roche as of the Effective Date or during the Term and used or disclosed to BioNTech in the performance of the Research Plan, GDP or CMC Development Plan; *provided*, however, that Genentech Know-How specifically excludes Collaboration Know-How.

1.161 “Genentech Marketing Authorization” has the meaning set forth in Section 5.1.

1.162 “Genentech Molecule Clinical Study Data” means all Clinical Data related [***]

1.163 “Genentech Opt-In Period” has meaning set forth in Section 4.5.5(a).

1.164 “Genentech Patents” means all Patents that (a) are Controlled by Genentech as of the Execution Date or at any time thereafter until the end of the Term; (b) [***]; and (c) Cover Genentech Know-How; *provided*, however, that Genentech Patents specifically exclude Collaboration Patents and Genentech Core Patents.

1.165 “Genentech Reversion IP” means Genentech IP other than Diagnostics IP that both (a) was actually used or generated by Genentech with respect to a Termination Product, and (b) is necessary to continue Development, Manufacture or Commercialization without unreasonable delay of such Termination Product.

1.166 “Genentech Study” has the meaning set forth in Section 2.7.2(c).

1.167 “Genentech Tumor Type” means any of the tumor types set forth on Schedule 1.16Z, subject to Section 4.5.3, and subject to any replacement tumor type that Genentech may elect through written notice to BioNTech at any time prior to the Trigger Point (provided that at the time of such replacement notice such replacement tumor type is not part of a BioNTech Indication), to exchange for any then-current Genentech Tumor Type.

1.168 “Global Development Plan” or “**GDP**” means a Development plan setting forth in reasonable detail specific Clinical Studies and other Party Development Activities to be performed with respect to GDP Collaboration Product(s), which plan shall allocate responsibility for such Clinical Studies and Party Development Activities between the Parties.

1.169 “Good Clinical Practices” or “**cGCPs**” has the meaning set forth in the MDSA.

1.170 “Good Laboratory Practices” or “**cGLPs**” has the meaning set forth in the MDSA.

1.171 “Good Manufacturing Practices” or “**cGMPs**” has the meaning set forth in the MDSA.

1.172 “Governmental Authority” means any U.S. federal, state, local, or any non-U.S. government, governmental, regulatory or administrative authority, agency or commission or any court, tribunal, or judicial or arbitral body.

1.173 “**GTT Proposed Study**” has the meaning set forth in Section 4.5.3.

1.174 “**HSR Act**” means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended.

1.175 “**HSR Filing**” has the meaning set forth in Section 14.1.1.

1.176 “[***]”

1.177 “**IFRS**” means International Financial Reporting Standards.

1.178 “**IND**” means (a) in the United States (i) an investigational new drug application filed with the FDA for authorization to conduct Clinical Studies and (ii) all supplements and amendments that may be filed with respect to the foregoing; and (b) any foreign counterpart of the foregoing.

1.179 “**Indemnification Claim Notice**” has the meaning set forth in Section 13.4.

1.180 “**Indemnified Party**” has the meaning set forth in Section 13.4.

1.181 “**Independent Facility**” has the meaning set forth in the MDSA.

1.182 “**Indication**” means the therapeutic indication for use defined in the applicable IND or any Marketing Authorization for a Collaboration Product. [***]

1.183 “**Indication Studies**” has the meaning set forth in Section 4.5.1.

1.184 “**Information**” means all technical, scientific, and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, results and other material, including: biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, preclinical, clinical, safety, manufacturing and quality control data and information, including study designs and protocols; Regulatory Authority documentation, correspondence and communications (oral or written); and analytical assays and test methods; in each case (whether or not confidential, proprietary, patented or patentable) in written, electronic or any other form now known or hereafter developed.

1.185 “**Infringement**” has the meaning set forth in Section 10.5.1(a).

1.186 “**Initiation**” or “**Initiate**” means, with respect to a Clinical Study, the first dosing of the first human subject in such Clinical Study.

1.187 “**IVAC 2.0 Process**” has the meaning set forth in the MDSA.

1.188 “**IVAC 2.1 Process**” has the meaning set forth in the MDSA.

1.189 “IVAC x.y Process” has the meaning set forth in the MDSA.

1.190 “IVAC Trademark” means the mark described in Schedule 1.190.

1.191 “Joint Commercialization Committee” or “JCC” has the meaning set forth in Section 2.1.

1.192 “Joint Confidential Information” has the meaning set forth in Section 11.1.

1.193 “Joint Development Activities” has the meaning set forth in Section 4.4.1.

1.194 “Joint Development Committee” or “JDC” has the meaning set forth in Section 2.1.

1.195 “Joint Manufacturing Committee” or “JMC” has the meaning set forth in Section 2.1.

1.196 “Joint Research Committee” or “JRC” has the meaning set forth in Section 2.1.

1.197 “Key Jurisdictions” has the meaning set forth in Section 10.3.1(c)(i)

1.198 “Know-How” means any Information, ideas, data, inventions, works of authorship, trade secrets, [***], technology, or materials, including formulations [***], molecules (including RNAs), assays, reagents, reference standards, compositions, human or animal tissue, samples or specimens, techniques, methods, procedures, processes, results, model designs and data bases, test data (including pharmacological, toxicological, immune monitoring, sequencing, pharmacokinetic and preclinical and clinical information and test data, and statistical analysis) and components thereof.

1.199 “Licensure” has the meaning set forth in the MDSA.

1.200 “Losses” has the meaning set forth in Section 13.1.

1.201 “Major Markets” means the United States, Germany, the United Kingdom, France, Italy and Spain.

1.202 “Major Regulatory Filing” has the meaning set forth in Section 5.4.3.

1.203 “Major Regulatory Jurisdictions” has the meaning set forth in Section 5.4.3.

1.204 “Manufacture” and “Manufacturing” has the meaning set forth in the MDSA.

1.205 “Manufacturing Development and Supply Agreement” or “MDSA” has the meaning set forth in Section 7.1.

1.206 “**Manufacturing Documentation**” has the meaning set forth in the MDSA.

1.207 “**Manufacturing Network**” has the meaning set forth in the MDSA.

1.208 “**Manufacturing Network Plan**” has the meaning set forth in the MDSA.

1.209 “**Manufacturing Operations Strategy**” has the meaning set forth in the MDSA.

1.210 “**Manufacturing Process**” has the meaning set forth in the MDSA.

1.211 “**Marketing Authorization**” means regulatory approval (whether a Non-Accelerated Marketing Authorization or an Accelerated Marketing Authorization) [***] required to sell one or more Collaboration Products for any Indication in accordance with the Applicable Laws of a given country or territory. [***]

1.212 “**Marketing Study**” means a human clinical study of a Collaboration Product conducted following Initiation of a Pivotal Study for such Collaboration Product that is not required for receipt of Marketing Authorization (whether such human clinical study is conducted prior to or after receipt of such Marketing Authorization) and is not a Post-Approval Commitment, but that may be useful in support of the post-Marketing Authorization Exploitation of such Collaboration Product.

1.213 “**Markings**” has the meaning set forth in Section 6.4.2.

1.214 [***]

1.215 “**Mechanical Completion**” has the meaning set forth in the MDSA.

1.216 “**Medical Affairs Activities**” means, with respect to any country in the Territory, the coordination of medical information requests and field based medical scientific liaisons with respect to Collaboration Products, including activities of medical scientific liaisons, activities involving key opinion leaders, and the provision of medical information services with respect to a Collaboration Product.

1.217 “**Melanoma Follow-Up Study**” has the meaning set forth in Section 4.3.2(a).

1.218 “**Neoepitope(s)**” means an epitope of a polypeptide arising in a tumor cell, where the epitope comprises a polypeptide that reflects: (a) a non-inherited DNA mutation, (b) a tumor specific RNA sequence alteration, or (c) an alternative tumor-specific translation start site in the tumor cell [***]

1.219 “Neopeptide Prediction Algorithm” means a methodology of predicting Neopeptides based on Patient Sequencing, including algorithms, designs, structures, features, functions, processes, and systems, and the underlying software programs (including libraries, databases, scripts, object and source code) (“**Neopeptide Prediction Software**”), and any other related Know-How necessary or useful to use, develop, reproduce, prepare derivative works, distribute, display and perform any of the Neopeptide Prediction Software, and all intellectual property rights other than Patents in any of the foregoing.

1.220 “Neopeptide Prediction Software” has the meaning set forth in Section 1.219.

1.221 “Neopeptide RNA(s)” means a single stranded nucleic acid polymer comprising one or more ribose sugars that is capable of being translated into a polypeptide and encoding one or more Neopeptide(s) [***]

1.222 “Net Profits” and “**Net Losses**” have the meaning set forth in Schedule 1.8.

1.223 “Net Sales” has the meaning set forth in Schedule 1.8.

1.224 “New Partnership Audit Procedures” means the amendments to the Code that were enacted as section 1101 of the Bipartisan Budget Act of 2015, P.L. 114-74.

1.225 “Next Generation Sequencing” or “**NGS**” means non-Sanger-based whole exome high-throughput nucleic acid sequencing technology to be used in the Manufacturing Process to identify Neopeptides.

1.226 “Non-Accelerated Marketing Authorization” means a Marketing Authorization other than one obtained pursuant to an accelerated approval procedure under 21 C.F.R. part 314, subpart H, 21 C.F.R. part 601, subpart E, or FFDCa section 506 or any foreign equivalents thereof.

1.227 “Non-Breaching Party” has the meaning set forth in Section 14.2.

1.228 “Non-Controlling Party” has the meaning set forth in Section 10.3.2.

1.229 [*]**

1.230 [*]**

1.231 [*]**

1.232 “Ongoing Clinical Studies” has the meaning set forth in Section 4.3.1.

1.233 “Ongoing Knowledge Transfer” has the meaning set forth in Section 2.19.2(c).

1.234 “Operational Readiness” has the meaning set forth in the MDSA.

1.235 “Opt-In Right” has the meaning set forth in Section 4.5.5(a).

1.236 “Opt-Out” has the meaning set forth in Section 8.5.1.

1.237 “Opt-Out Commencement Date” has the meaning set forth in Section 8.5.1.

1.238 “Outside Patent Litigation Counsel” has the meaning set forth in Section 10.5.4.

1.239 “Outside Patent Prosecution Counsel” has the meaning set forth in Section 10.3.2.

1.240 “Party” and **“Parties”** has the meaning set forth in the preamble hereto.

1.241 “Party Development Activities” means Development activities conducted in support of obtaining or maintaining Regulatory Approval of a Collaboration Product in a country in the Territory (other than research activities under the Research Plan), including Joint Development Activities, CMC Development Plan activities, Ongoing Clinical Studies, BioNTech Studies, Genentech Studies and any Post-Approval Commitments and Marketing Studies.

1.242 “Patents” means all patents and patent applications in any country in the world, including any continuations, continuations-in-part, divisions, provisionals or any substitute applications, any patent issued with respect to any such patent applications, any reissue, reexamination, renewal or extension (including any supplemental protection certificate) of any such patent, and any confirmation patent or registration patent or patent of addition based on any such patent, and all non-United States counterparts of any of the foregoing.

1.243 “Patient Sequencing” means the identification of nucleotide or amino acid sequence, including through the use of Next Generation Sequencing, based upon a Biosample collected from a patient.

1.244 “Payee” has the meaning set forth in Section 8.11.2.

1.245 “Payor” has the meaning set forth in Section 8.11.2.

1.246 [*]**

1.247 [*]**

1.248 [*]**

1.249 “Person” means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.

1.250 [*]**

1.251 “Pharmaceutical Product” means any medicament that is developed to treat, cure or prevent a disease in humans and is subject to approval by a Regulatory Authority.

1.252 “Pharmacovigilance Agreement” has the meaning set forth in Section 5.8.

1.253 “Phase I Clinical Study” means a Clinical Study, the principal purpose of which is a preliminary determination of safety in healthy individuals or patients or similar Clinical Study prescribed by the Regulatory Authorities, including the trials referred to in 21 C.F.R. §312.21(a), as amended.

1.254 “PHSA” means the United States Public Health Service Act, as amended from time to time.

1.255 “Pilot Facility” has the meaning set forth in the MDSA.

1.256 “Pivotal Study” means a Clinical Study of a Collaboration Product that is designed to demonstrate, along with previously conducted studies, substantial evidence of its effectiveness and provide sufficient information to determine whether it is safe, pure and potent for use under conditions prescribed, recommended, or suggested in proposed labeling to obtain a Marketing Authorization (including an Accelerated Marketing Authorization) of such Collaboration Product, including all tests and studies that are required by the FDA or any other Regulatory Authority from time to time, pursuant to Applicable Law or otherwise.

1.257 “Post-Approval Commitment” means a human Clinical Study for a Collaboration Product conducted after Marketing Authorization of such Collaboration Product has been obtained from an appropriate Regulatory Authority due to a request or requirement of such Regulatory Authority.

1.258 “Post-Term License Notice” has the meaning set forth in Section 14.5.4.

1.259 “Preclinically Developing” means, [***]

1.260 “Product Labeling” means, with respect to a Collaboration Product in a country in the Territory, (a) the Regulatory Authority-approved prescribing information for such Collaboration Product for such country, including any required patient information, and (b) all labels and other written, printed, or graphic matter upon a container, wrapper, or any package insert utilized with or for such Collaboration Product in such country.

1.261 “Product Trademarks” means the Trademark(s) to be used for the Commercialization of Collaboration Products in the Territory and any registrations thereof or any pending applications relating thereto in the Territory (excluding, in any event, the Corporate Names and any trademarks, service marks, names or logos that include any corporate name or logo of the Parties or their Affiliates).

1.262 “Proposed Study(ies)” has the meaning set forth in Section 4.5.1.

1.263 “Prosecution and Maintenance” or **“Prosecute and Maintain,”** with respect to a given Patent, means all activities associated with the preparation, filing, prosecution, and maintenance of such Patent, as well as supplemental examinations, re-examinations, reissues, applications for patent term extensions, calculation and applications for patent term adjustments, supplementary protection certificates, and the like with respect to such Patent. In addition, Prosecute and Maintain shall include any actions associated with obtaining additional patent protection of the disclosure of a given Patent following a notice of allowance of such Patent or keeping a patent application pending for strategic reasons (e.g. through the filing of continuation applications, continuation-in-part applications, divisional applications or other substitute applications). For clarity, Prosecute and Maintain shall not include any such actions with respect to a Patent brought by a Third Party, including any reexaminations, inter partes reviews, and post grant reviews, as well as interferences and derivation proceedings, oppositions and other similar proceedings brought by a Third Party with respect to such Patent.

1.264 “Publication Plan” means a [***] overall scientific communication and publication plan developed each year by the Joint Research Team and the Joint Development Team and approved by the Joint Research Committee and the Joint Development Committee, that sets forth, for such year, [***]

1.265 [*]**

1.266 [*]**

1.267 “Qualification Batch” has the meaning set forth in the MDSA.

1.268 “Quality Agreement” has the meaning set forth in the MDSA.

1.269 “Receiving Party” has the meaning set forth in Section 11.1.

1.270 “Regulatory Approval” means, with respect to a country in the Territory, any and all approvals (including Investigational New Drug Applications (“INDs”) or Drug Approval Applications), licenses, registrations, or authorizations of any Regulatory Authority necessary to Manufacture, use, store, import, transport, commercially distribute, sell, or market in such country a Collaboration Product including, where applicable, (a) pricing or reimbursement approval in such country, (b) post-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto), and (c) labeling approval.

1.271 “Regulatory Authority” means any applicable supra-national, federal, national, regional, state, provincial, or local regulatory agencies, departments, bureaus, commissions, councils, or other government entities regulating or otherwise exercising authority with respect to the research, development, manufacture, commercialization, making, having made, use, offering for sale, sale or importation of Collaboration Products.

1.272 “Regulatory Data” means collectively all non-clinical and Clinical Data, CMC data and Information and other Information, results, and analyses with respect to any Party Development Activities.

1.273 “Regulatory Data Exclusivity” means an exclusive right, other than through the issuance of a patent, lawfully granted by a Governmental Authority, to market, or to rely on certain data in supporting the marketing of, a Collaboration Product or Reversion Product, as applicable, in that country in respect of which that Governmental Authority has jurisdiction conferred on it by Applicable Law, which exclusive right effectively prohibits reliance on the regulatory submissions made with respect to such product, directly or indirectly and in whole or in part, in that country for the relevant time period.

1.274 “Regulatory Documentation” means all (a) applications (including all INDs and Drug Approval Applications and other Major Regulatory Filings), registrations, licenses, authorizations, and approvals (including Regulatory Approvals); (b) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect thereto, including all regulatory drug lists, advertising and promotion documents, adverse event files, and complaint files; and (c) Regulatory Data contained or relied upon in any of the foregoing, in each case ((a), (b), and (c)) relating to a Collaboration Product.

1.275 “Regulatory Expenses” has the meaning set forth in Schedule 1.8.

1.276 “Rejects,” and with correlative meaning **“Rejected”** and **“Rejection,”** has the meaning set forth in Section 4.5.2(d).

1.277 “Research Plan” has the meaning set forth in Section 3.1.1.

1.278 “Research Term” means the period commencing on the Effective Date and, unless earlier terminated in accordance herewith, ending on [***], unless extended by mutual written agreement of GNE and BioNTech.

1.279 “Reversion Product” means any Pharmaceutical Product that [***]

1.280 “Right of Reference or Use” means the right to cross reference, copy, incorporate by reference or rely upon any Regulatory Documentation solely for the purposes of obtaining or maintaining Regulatory Approval or Marketing Authorization for a Collaboration Product, including (1) a “Right of Reference or Use” as that term is defined in 21 C.F.R. §314.3(b) in the United States, (2) any analogous procedures with respect to biologics or BLAs in the United States and (3) any equivalents thereof outside the United States.

1.281 “ROFN” has the meaning set forth in Section 9.6.3.

1.282 “ROFN Election Notice” has the meaning set forth in Section 9.6.3.

1.283 “ROFN Exercise Period” has the meaning set forth in Section 9.6.3.

1.284 “ROFN Licensable Subject Matter” has the meaning set forth in Section 9.6.3.

1.285 “**ROFN License Agreement**” has the meaning set forth in Section 9.6.3.

1.286 “**ROFN Notice**” has the meaning set forth in Section 9.6.3.

1.287 “**Royalty Product**” has the meaning set forth in Schedule 1.8.

1.288 “**Royalty Rate**” has the meaning set forth in Section 8.6.1.

1.289 “**Royalty Term**” has the meaning set forth in Schedule 1.8.

1.290 “**Sales**” has the meaning set forth in Schedule 1.8.

1.291 “**Shared Development Costs**” has the meaning set forth in Schedule 1.8.

1.292 [***].

1.293 [***]

1.294 “**Signatories**” means RNP, BNT, GNE and Roche, each of which is a “**Signatory**”.

1.295 “**Start-up**” has the meaning set forth in the MDSA.

1.296 “**Study Proposal**” has the meaning set forth in Section 4.5.1.

1.297 “**Sublicensee**” means a Person, other than an Affiliate, that is granted a sublicense by either Party (other than through a Compulsory Sublicense) as provided in Section 9.3 (other than any sublicense under Section 9.1.2 or Section 9.2.2).

1.298 [***]

1.299 “**Team**” has the meaning set forth in Section 2.3.

1.300 “**Team Co-Leader**” has the meaning set forth in Section 2.3.

1.301 “**TECENTRIQ®**” means that certain proprietary product of Genentech having as its active ingredient atezolizumab.

1.302 “**Technology Platform**” has the meaning set forth in the MDSA.

1.303 “**Technology Platform Roadmap**” has the meaning set forth in the MDSA.

1.304 “**Technology Platform Strategy**” has the meaning set forth in the MDSA.

1.305 “**Technology Transfer**” has the meaning set forth in the MDSA.

1.306 “**Term**” has the meaning set forth in Section 14.1.2.

1.307 “**Termination Product**” means a [***] as of the effective date of termination of this Agreement.

1.308 “**Territory**” means the entire world.

1.309 “**Third Party**” means any Person other than a Party or any of its Affiliates.

1.310 “**Third Party Claims**” has the meaning set forth in Section 13.1.

1.311 “**Third Party Collaborator**” means a Third Party [***]

1.312 “**Third Party Infringement Claim**” has the meaning set forth in Section 10.5.1(b).

1.313 “**Third Party IP**” has the meaning set forth in Section 10.6.3.

1.314 “**Third Party IP Payments**” has the meaning set forth in Section 10.6.3(b).

1.315 “**Third Party Product**” means a product comprising one or more Neoepitope RNA(s) with respect to which [***]

1.316 “**Trademark**” means any word, name, symbol, color, designation or device or any combination thereof that functions as a source identifier, including any trademark, trade dress, brand mark, service mark, trade name, brand name, logo or business symbol, whether or not registered.

1.317 [***]

1.318 [***]

1.319 [***].

1.320 [***].

1.321 [***]

1.322 [***]

1.323 “**United States**” or “**U.S.**” means the United States of America, its territories and possessions, Guam and the Commonwealth of Puerto Rico.

1.324 [***]

1.325 “**Valid Claim**” means [***]

1.326 “VAT” means within the European Union such Taxes (as defined in Section 8.11.6) as may be levied in accordance with (but subject to derogation from) Council Directive 2006/112/EC and outside the European Union any Taxes levied by reference to added value or sales.

1.327 “Voting Stock” has the meaning set forth in the definition of “Change in Control.”

1.328 “Working Group” has the meaning set forth in Section 2.16.

1.329 [***]

1.330 [***].

ARTICLE 2. GOVERNANCE

2.1 Establishment of Governance Committees. Within [***] days of the Effective Date, or as otherwise specified below, Genentech and BioNTech shall establish the following committees to have strategic oversight of the joint research, Development, regulatory, and Manufacturing activities for Collaboration Products: a Joint Research Committee (“JRC”) with responsibility for overseeing, coordinating and expediting the activities under the Research Plan and the Joint Research Team’s activities related thereto; a Joint Development Committee (“JDC”) with responsibility for overseeing, coordinating and expediting the Global Development Plan and other activities specified below in Section 2.7.1 and the Joint Development Team’s activities related thereto; a Joint Manufacturing Committee (“JMC”) with responsibility for overseeing, coordinating and expediting all clinical and commercial Manufacturing activities, including clinical and commercial NGS and Neoepitope prediction, production planning, supply chain management, and activities to scale and improve existing Manufacturing processes; and within [***], a Joint Commercialization Committee (“JCC”) with responsibility for [***] coordinating any Co-Promotion activities related thereto in accordance with this Agreement and the Co-Promotion Agreement. Each of the JRC, JDC, JMC and JCC is sometimes referred to individually herein as a “Committee” and collectively as the “Committees.”

2.2 Committee Membership. Each of the Committees shall be comprised of at least [***] but no more than [***] representatives designated by each Party (except with respect to the JMC, which shall have no more than [***] representatives per Party) and [***] number of representatives. The representatives shall be appropriate (in terms of their seniority, availability, function in their respective organizations, training and experience) for the tasks then being undertaken and the stage of Development, Manufacturing or Commercialization of Collaboration Products for which joint activities will be performed. Each Party shall designate one of its representatives as its primary contact for Committee matters (such Party’s “Committee Co-Chair”). A Party may replace any or all of its representatives (and designated Committee Co-Chair) at any time by informing the other Party’s Alliance Manager in advance, in writing (which may be by email). The initial members of the Committees are listed in Schedule 2.2.

2.3 Team Membership. Each Committee may establish teams from time-to-time, with a defined scope and duration, to carry out the activities of such Committee. Within [***] days of the Effective Date, a Joint Research Team shall be established to conduct the work being overseen by the JRC, a Joint Development Team shall be established to conduct the work being overseen by the JDC, and a Joint Manufacturing Team shall be established to conduct the work being overseen by the JMC. Each of the JRT, JDT and JMT is sometimes referred to individually herein as a “**Team**” and collectively as the “**Teams**.” Each of the Teams shall be composed of representatives designated by each Party and [***] number of representatives. The Teams shall include individuals with expertise and responsibilities appropriate (in terms of their seniority, availability, function in their respective organizations, training and experience) for the tasks then being undertaken and the stage of Development, Manufacturing or Commercialization of Collaboration Products for which joint activities will be performed. Each Party shall designate one of its representatives as its primary contact for Team matters (such Party’s “**Team Co-Leader**”). A Party may replace any or all of its representatives (and designated Team Co-Leader) at any time by informing the other Team Co-Leader in advance, in writing (which may be by email).

2.4 Meetings; Participation. Once established, a Committee or Team shall meet at least [***] (unless otherwise agreed by the Parties) and at such other times as deemed appropriate by the Committee or Team. The presence of at least [***] shall constitute a quorum at a Committee meeting. The Committee or Team may meet in person or via teleconference, video conference or the like, provided that at least [***] per Calendar Year shall be held in person, unless otherwise agreed by the Parties. Each Party shall bear the expense of its respective representatives’ participation in Committee or Team meetings. If a Party’s representative is unable to attend a given meeting, such Party may designate a knowledgeable alternate to attend such meeting and perform the functions of such representative. Each Party may invite a reasonable number of non-voting employees, consultants or scientific advisors to attend Committee or Team meetings, provided that such invitees are bound by appropriate confidentiality obligations. In addition to formal meetings, the Committee and Team representatives shall communicate as necessary to ensure appropriate progress in their respective areas of accountability.

2.5 Minutes; Other Documentation. Promptly after a Committee or Team is established, it shall hold an organizational meeting to define such procedures and mechanisms as may be reasonably necessary for its operation to assure the efficient conduct of each Party’s obligations under this Agreement. Genentech shall be responsible for keeping minutes of Committee and Team meetings that record in writing all decisions made, action items assigned or completed and other appropriate matters. Meeting minutes shall be sent to both Parties promptly after a meeting for review, comment and approval by each Party. A decision that may be made at a Committee or Team meeting may also be made, without a meeting, if such decision is agreed to in writing (which may be by email) by each Party’s Committee Co-Chair or Team Co-Leader, as the case may be (or its designee), provided that each Party’s writing clearly indicates that such decision is a formal decision by such Party’s Committee Co-Chair or Team Co-Leader. Any modifications to the plans and budgets approved at a Committee meeting shall constitute an amendment to such plan or budget upon approval by both Parties of the meeting minutes related thereto.

2.6 Joint Research Committee.

2.6.1 Responsibilities of the JRC. The Joint Research Committee shall be responsible for performing the following functions:

- (a) review progress reported by the Joint Research Team with respect to activities under the approved Research Plan;
- (b) address and coordinate the resolution of issues that may arise relating to the Initial Knowledge Transfer and the Ongoing Knowledge Transfer in each case to the extent relating to the activities under the approved Research Plan;
- (c) review and approve amendments to the Research Plan as proposed by the Joint Research Team as well as any “Non-Clinical GDP Activities” set forth in the GDP;
- (d) together with the Joint Development Committee, review the annual Publication Plan developed by the Joint Research Team together with the Joint Development Team, and approve the portion of such plan addressed to research publications;
- (e) review and make recommendations to the JDC as to [***]
- (f) ensure that each Party keeps the JRC informed regarding all material activities performed by such Party under this Agreement that are within the purview of the JRC; and
- (g) perform such other functions as specified in this Agreement or as agreed to by the Parties in writing.

2.6.2 Decision-Making Authority. With respect to the responsibilities of the JRC, each Party shall [***], and the Parties shall attempt to make decisions [***]. In the event that agreement on a particular matter cannot be reached by the JRC within [***] Business Days or such longer period as the JRC members agree, after the JRC first meets to consider such matter, then such matter shall be [***]

2.6.3 Term of the JRC Operations. The JRC shall continue to exist until the first to occur of (a) the mutual agreement of the Parties to disband the JRC, (b) disbandment pursuant to Section 15.2, (c) disbandment pursuant to Section 2.18 or (d) the end of the Research Term. Thereafter, the JRC shall cease operations and perform no further functions hereunder and any responsibilities which would have been assigned to the JRC shall be responsibilities of the JDC [***].

2.7 Joint Development Committee.

2.7.1 Responsibilities of the JDC. The Joint Development Committee shall be responsible for performing the following functions:

- (a) review progress of Development and regulatory approval of Collaboration Products as reported by the Joint Development Team;
- (b) address and coordinate the resolution of issues that may arise relating to the Initial Knowledge Transfer and the Ongoing Knowledge Transfer (in each case other than to the extent relating to activities under the Research Plan);
- (c) review and decide [***]
- (d) review and decide whether to (i) approve amendments to the GDP as proposed by the Joint Development Team or (ii) amend the GDP to include any additional Clinical Studies proposed by either Party (including Proposed Studies);
- (e) approve new and amended GDP Budgets as proposed by the Joint Development Team;
- (f) review and decide whether to approve any Proposed Studies as BioNTech Studies based upon the criteria set forth in Section 4.5.2;
- (g) review and decide whether to approve any GTT Proposed Studies as BioNTech Studies based upon the criteria set forth in Section 4.5.3;
- (h) review and decide whether to approve any proposed Melanoma Follow-Up Study based upon the criteria set forth in Section 4.3.2;
- (i) oversee the Conduct and modification of Ongoing Clinical Studies (as set forth in Section 4.3.1), any Melanoma Follow-Up Studies (as set forth in Section 4.3.2) and any BioNTech Studies (as set forth in Section 4.5.4), and to review and decide whether to approve any material deviations from (i) the Ongoing Clinical Studies as such Clinical Studies exist as of the Execution Date (as set forth in Section 4.3.1), (ii) any Melanoma Follow-Up Studies as previously approved by the JDC (as set forth in Section 4.3.2) or (iii) any BioNTech Studies as previously approved by the JDC (as set forth in Section 4.5.4);
- (j) together with the Joint Research Committee, review the annual Publication Plan developed by the Joint Development Team together with the Joint Research Team, and approve [***] the portion of such plan addressed to Development publications;
- (k) ensure that each Party keeps the JDC informed regarding all material activities Conducted or otherwise performed by such Party under this Agreement that are within the purview of the JDC, including status updates of (i) BioNTech's progress toward Developing BioNTech Collaboration Products (including Conducting BioNTech Studies) and (ii) Genentech's progress toward Developing Genentech Collaboration Products (including Conducting Genentech Studies);
- (l) perform such other functions as specified in this Agreement or as agreed to by the Parties in writing; and

(m) oversee all Clinical Studies, comparator studies or investigator-sponsored studies of Collaboration Products Conducted by the Parties, regardless of which Party Conducts the studies or has final decision-making authority in matters related to such studies.

For clarity, all “Non-Clinical GDP Activities” included in the GDP shall not be subject to the decision-making by the JDC, but shall be controlled by the JRC.

2.7.2 Decision-Making Authority.

(a) With respect to the responsibilities of the JDC, each Party shall [***], and the Parties shall attempt to make decisions [***]

2.7.3 Term of the JDC Operations. The JDC shall continue to exist until the first to occur of (a) the mutual agreement of the Parties to disband the JDC, (b) disbandment pursuant to Section 15.2, (c) disbandment pursuant to Section 2.18 or (d) the end of the Term. Thereafter, the JDC shall cease operations and perform no further functions hereunder.

2.8 Joint Manufacturing Committee.

2.8.1 Responsibilities of the JMC. The Joint Manufacturing Committee shall be responsible for performing the following functions:

(a) coordinate with the JDC and JCC to ensure adequate quantity, quality, and timeliness of supply of Collaboration Products to meet clinical and commercial needs worldwide;

(b) review and approve the initial plans (and any subsequent amendments) specified in the MDSA with regard to Manufacturing activities for the Collaboration Product, including the CMC Development Plan, Manufacturing Network Plan, Technology Transfer Plans and any other plan recommended by the JMT and approved by the JMC; in all cases, ensuring that the activities thereunder are performed in accordance with the MDSA, Quality Agreement and JMC-approved performance targets, timelines and budgets;

(c) review progress of, and provide guidance with respect to, CMC development activities and associated costs as reported by the JMT pursuant to the approved CMC Development Plan and annual budget;

(d) approve and oversee the development and implementation of the Manufacturing Process for clinical and commercial supply of Collaboration Product in accordance with the MDSA, applicable Quality Agreement, JMC-approved performance targets, timelines and budgets and [***];

(e) approve and oversee, with respect to clinical and commercial supply of Collaboration Product, the Technology Platform Strategy and Manufacturing Operations Strategy;

(f) oversee and monitor, with respect to Commercial Facilities within the Manufacturing Network, the progress of the activities required for construction, Mechanical Completion, Commissioning, Start-up (including Technology Transfer) and Licensure by the applicable Regulatory Authority;

(g) review and oversee the performance by Third Parties of certain Manufacture or supply obligations in accordance with the MDSA and applicable Quality Agreement;

(h) review and approve business processes for aligning patient demand forecast requirements with Manufacturing supply planning and scheduling requirements, and assess and resolve gaps between demand, and supply and Capacity plans;

(i) investigate and advise on Manufacturing, supply and quality issues;

(j) review, at least semi-annually, the performance under the MDSA by the Parties;

(k) review and recommend for approval by the Parties any changes to the MDSA, applicable Quality Agreement, Commercial Manufacturing Agreement or other subsequent agreement related to Manufacturing of Collaboration Product, each as proposed by the JMT;

(l) coordinate and address the resolution of issues that may arise relating to implementation of the CMC Development Plan Manufacturing and Technology Transfers under the MDSA; and

(m) perform such other functions as specified in this Agreement or the MDSA or as agreed to by the Parties in writing.

For clarity, except for reports as provided in Section 2.2.5(c) of the MDSA, Independent Facilities are outside the scope of the JMC's responsibilities.

2.8.2 Decision-Making Authority. With respect to the responsibilities of the JMC, each Party shall [***], and the Parties shall attempt to make decisions [***]. In the event that agreement on a particular matter cannot be reached by the JMC within [***] Business Days or such longer period as the JMC members agree, after the JMC first meets to consider such matter, then such matter shall be [***]

[***]

2.8.3 Term of the JMC Operations. The JMC shall continue to exist until the first to occur of (a) the mutual agreement of the Parties to disband the JMC, (b) disbandment pursuant to Section 15.2 (if elected by Genentech), (c) disbandment pursuant to Section 2.18 (provided that the JMC shall continue to exist for so long as set forth in Section 2.18) or (d) the expiration or termination of the MDSA. Thereafter, the JMC shall cease operations and perform no further functions hereunder. For the avoidance of doubt, in the case of survival of the MDSA, as specified herein in Section 7.3, 14.5, or 15.2, (i) the JMC shall continue to exist (until otherwise elected by Genentech), (ii) the JMC shall operate and perform its functions solely for the purpose of and in connection with coordinating and overseeing any remaining CMC Development Plan and Technology Transfer activities and any remaining Manufacturing and supply services, [***]

2.9 Joint Commercialization Committee.

2.9.1 Establishment of the Joint Commercialization Committee. Within [***], the Parties shall establish a Joint Commercialization Committee with responsibility for [***] coordinating any Co-Promotion activities related thereto.

2.9.2 Responsibilities of the JCC. Upon establishment, the Joint Commercialization Committee shall be responsible for performing the following functions:

- (a) oversight of [***];
- (b) [***]
- (c) [***], review and approve the co-promotion plan for the Co-Promotion Territory as prepared by Genentech;
- (d) [***], serve as a forum for monitoring and coordinating matters relating to Co-Promotion of Collaboration Products in the Co-Promotion Territory;
- (e) [***], oversee and coordinate the Parties' Detailing activities of GDP Collaboration Products in the Co-Promotion Territory; and
- (f) perform such other functions as specified in this Agreement or as agreed to by the Parties.

Each Party shall share with the other Party upon request, through the JCC, any marketing and sales information developed by such Party, including market research, sales force sizing and targeting information, in each case relating solely to GDP Collaboration Products. In addition, each Party shall provide to the JCC on a [***] basis a summary of all Commercialization activities with respect to GDP Collaboration Products undertaken by such Party.

2.9.3 Decision-Making Authority. With respect to the decision-making responsibilities of the JCC, each Party shall [***], and the Parties shall attempt to make decisions [***]. In the event that agreement on a particular matter cannot be reached in any JCC meeting, Genentech shall have the final decision-making authority with respect to such matter, which it may exercise following such meeting or at any time thereafter.

2.9.4 Term of the JCC Operations. The JCC shall continue to exist until the first to occur of (a) the mutual agreement of the Parties to disband the JCC, (b) disbandment pursuant to Section 15.2, (c) disbandment pursuant to Section 2.18 or (d) the end of the Term. Thereafter, the JCC shall cease operations and perform no further functions hereunder.

2.10 Joint Research Team.

2.10.1 Establishment of the Joint Research Team. The JRC may establish a Joint Research Team ("JRT") to coordinate and implement all activities related to the research activities to be conducted by GNE and BioNTech pursuant to the Research Plan.

2.10.2 Responsibilities of the JRT. The Joint Research Team shall be responsible for performing the following functions:

- timelines;
- (a) implement the Research Plan, ensuring that activities thereunder are performed in accordance with the approved
- approval;
- (b) prepare draft amendments (as needed) to the Research Plan, and submit such amended Research Plan to the JRC for
- Agreement that are within the purview of the JRT;
- (c) ensure that each Party keeps the JRT informed regarding all material activities performed by such Party under this
- the JRC; and
- (d) develop and implement, in collaboration with the Joint Development Team, the annual Publication Plan;
- (e) discuss and attempt to resolve any disputed matters related to the research collaboration before referring such matters to
- (f) perform such other functions as agreed to by the JRC or as specified in this Agreement.

2.10.3 Decision-Making Authority. With respect to the responsibilities of the JRT, each Party shall have [***], and the Parties shall attempt to make decisions [***]. In the event that agreement on a particular matter cannot be reached by the JRT within [***] Business Days or such longer period as the JRT members agree, after the JRT first meets to consider such matter, the matter shall be referred to the JRC, which shall resolve such matter in accordance with Section 2.6.2.

2.10.4 Term of the JRT Operations. The Joint Research Team shall continue to exist until the first to occur of (a) the decision of the JRC to disband the JRT or (b) the disbandment of the JRC or JRT otherwise pursuant to this Agreement. Thereafter, the JRT shall cease operations and perform no further functions hereunder.

2.11 Joint Development Team.

2.11.1 Establishment of the Joint Development Team. The Parties shall establish a Joint Development Team (“**JDT**”) to define, coordinate and implement all activities related to the Development of GDP Collaboration Products, including preclinical Development, clinical Development and regulatory filings (but excluding any research activities within the purview of the JRC (and JRT), any manufacturing activities within the purview of the JMC (and JMT) and any commercial activities within the purview of the JCC).

2.11.2 Responsibilities of the JDT. The Joint Development Team shall be responsible for performing the following functions:

- (a) implement the Global Development Plan, ensuring that activities thereunder are performed in accordance with the approved timelines;
 - (b) prepare draft amendments (as needed) to the Global Development Plan, and submit such amended Global Development Plans to the JDC for approval;
 - (c) prepare draft amendments (as needed) to the annual GDP Budget, and submit such annual GDP Budgets to the JDC for approval;
 - (d) ensure that each Party keeps the JDT informed regarding all material activities performed by such Party under this Agreement that are within the purview of the JDT;
 - (e) develop and implement, in collaboration with the Joint Research Team, the annual Publication Plan;
 - (f) discuss and attempt to resolve any disputed matters related to the collaboration before referring such matters to the JDC;
- and
- (g) perform such other functions as agreed to by the JDC or as specified in this Agreement.

2.11.3 Decision-Making Authority. With respect to the responsibilities of the JDT, each Party shall [***], and the Parties shall attempt to make decisions [***]. In the event that agreement on a particular matter cannot be reached by the JDT within [***] Business Days or such longer period as the JDT members agree, after the JDT first meets to consider such matter, the matter shall be referred to the JDC, which shall resolve such matter in accordance with Section 2.7.2.

2.11.4 Term of the JDT Operations. The Joint Development Team shall continue to exist until the first to occur of the decision of the JDC to disband the JDT or the disbandment of the JDC or JDT otherwise pursuant to this Agreement. Thereafter, the JDT shall cease operations and perform no further functions hereunder.

2.12 Joint Manufacturing Team.

2.12.1 Establishment of the Joint Manufacturing Team. The JMC may establish a Joint Manufacturing Team (“JMT”) to define, coordinate and implement all activities related to the CMC Development Plan and Manufacture of Collaboration Products.

2.12.2 Responsibilities of the JMT. The Joint Manufacturing Team shall be responsible for performing the following functions:

- (a) coordinate with the JDT and JCC to ensure adequate quantity and quality of supply of Collaboration Products to meet clinical and commercial needs worldwide;

(b) keep the JMC informed of all material activities being performed by the JMT;

(c) prepare and draft the following plans and subsequent amendments (as needed) for submission to the JMC for approval: CMC Development Plan, Manufacturing Network Plan, Technology Transfer Plans, Technology Platform Strategy and Manufacturing Operations Strategy;

(d) implement the CMC Development Plan and other approved plans and strategies set forth in clause (c) above; in all cases, ensuring that activities thereunder are performed in accordance with the respective plan or strategy, approved timelines and budgets and guidance provided by the JMC;

(e) prepare and draft amendments (as needed) to the annual Manufacturing budget for activities to be conducted pursuant to the CMC Development Plan and other approved plans and strategies set forth in clause (c) above, and submit such annual budgets to the JMC for approval;

(f) develop and manage (subject to JMC approval) business processes for aligning patient demand forecast requirements with Manufacturing supply planning and scheduling requirements; make assessments of and recommendations to the JMC for resolving gaps between demand and supply and Capacity plans; and conduct, on a [***] basis, the activities set forth under Section 6.3.1 of the MDSA;

(g) manage the performance by Third Parties of Manufacture or supply obligations in accordance with the MDSA and Quality Agreement;

(h) coordinate the activities of the MDSA Parties relating to the Manufacture of the Collaboration Product at a Facility;

(i) draft and recommend to the JMC for approval any changes to the MDSA, Quality Agreement or other subsequent agreement related to Manufacturing of Collaboration Product;

(j) discuss and attempt to resolve any disputed matters related to the Manufacture of Collaboration Product before referring such matters to the JMC; and

(k) perform such other functions as agreed to by the JMC or as specified in this Agreement.

2.12.3 Decision-Making Authority. With respect to the responsibilities of the JMT, each Party shall [***], and the Parties shall attempt to make decisions [***]. In the event that agreement on a particular matter cannot be reached by the JMT within [***] Business Days or such longer period as the JMT members agree, after the JMT first meets to consider such matter, the matter shall be referred to the JMC, which shall resolve such matter in accordance with Section 2.8.2.

2.12.4 Term of the JMT Operations. The Joint Manufacturing Team shall continue to exist until the first to occur of the decision of the JMC to disband the JMT or the disbandment of the JMC or JMT otherwise pursuant to this Agreement. Thereafter, the JMT shall cease operations and perform no further functions hereunder. For the avoidance of doubt, in the case of survival of the MDSA under Section 7.3, 14.5 or 15.2, the JMT shall continue to exist (until otherwise elected by Genentech) and shall operate and perform its functions solely for the purpose of and in connection with coordinating and overseeing any remaining CMC Development Plan and Technology Transfer activities, and any remaining Manufacturing and supply services.

2.13 Alliance Managers. Promptly following the Effective Date, each Party shall designate an individual to act as its primary contact for business matters related to this Agreement (such Party's "**Alliance Manager**"), unless another contact is expressly specified in this Agreement or mutually agreed by the Parties. The Alliance Managers shall promote collaboration between the Parties and attempt to prevent and resolve disputes in a timely manner. Either Party may replace its Alliance Manager at any time by informing the other Party's Alliance Manager in advance, in writing (which may be by email).

2.14 Limitations on Authority. Each Party shall retain the rights, powers, and discretion granted to it under this Agreement, and no such rights, powers, or discretion shall be delegated to or vested in a Committee or Team unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing. No Committee or Team shall have the power to amend, modify or waive compliance with this Agreement, which may only be amended or modified, or compliance with which may only be waived, as provided in Section 15.12.

2.15 Interactions Between Committees, Teams and Internal Teams. The Parties recognize that each Party possesses an internal structure (including various committees, teams and review boards) that will be involved in administering such Party's activities under this Agreement. Nothing contained in this Article shall prevent a Party from making routine day-to-day decisions relating to the conduct of those activities for which it has a performance or other obligations hereunder, in each case in a manner consistent with the then-current applicable plan and the terms and conditions of this Agreement.

2.16 Working Groups. From time to time, a Committee or Team may establish and delegate duties to sub-committees or directed teams (each, a "**Working Group**") on an "as-needed" basis to oversee particular projects or activities (for example, joint finance group, joint regulatory groups or joint medical information group). Each such Working Group shall be constituted and shall operate as the Committee or Team determines; provided that each Working Group shall have [***], unless otherwise mutually agreed. Working Groups may be established on an ad hoc basis for specific purposes and durations. Each Working Group and its activities shall be subject to the oversight, review and approval of, and shall report to, the Committee or Team that formed said Working Group. In no event shall the authority of the Working Group exceed that specified for the Committee or Team that formed the Working Group to this Article. All decisions of a Working Group shall [***]. Any disagreement between the designees of Genentech and BioNTech on a Working Group shall be referred to the Committee or Team that formed the Working Group for resolution. In the event that any Committee or Team is disbanded, then the Working Groups thereunder shall also automatically be disbanded.

2.17 Expenses. Each Party shall be responsible for all travel and related costs and expenses for its members and other representatives to attend meetings of, and otherwise participate on, a Committee, Team or Working Group and such costs and expenses shall not constitute Development Costs or Allowable Expenses.

2.18 Consequences of BioNTech Opt-Out. In the event that, pursuant to Section 8.5, BioNTech exercises its Opt-Out to terminate its obligation to co-fund Development (or a Deemed Opt-Out has occurred pursuant to Section 8.5.3), all Committees or Teams shall automatically be disbanded [***] days (or such longer period as the Parties mutually agree) after the Opt-Out Commencement Date and Genentech shall assume all decision-making authority previously vested in such Committee(s). Notwithstanding the foregoing, Genentech may request in writing that BioNTech continue its participation on an advisory (non-voting) basis in any Committee or Team notwithstanding such disbandment, in which case Genentech shall be responsible for the cost and expense of BioNTech's participation in such Committee or Team based upon BioNTech's then-current FTE Rate. [***]

2.19 Technical and Knowledge Transfer.

2.19.1 Initial Knowledge Transfer.

(a) In order to enable Genentech to fulfil its obligations as set forth in this Agreement and the Ancillary Agreements, respectively, the Parties have agreed to an initial knowledge transfer of documents and other Know-How set forth in Schedule 2.19.1(a) attached hereto ("**BioNTech Initial Knowledge Transfer Items**"). BioNTech shall, and shall cause its Affiliates to, at BioNTech's sole cost and expense, disclose such Know-How and transfer true and complete and accurate copies of all documents within the BioNTech Initial Knowledge Transfer Items to Genentech, within [***] days, as applicable in accordance with Schedule 2.19.1(a), of the Effective Date. BioNTech shall provide the documents and other Know-How specified in Schedule 2.19.1(a) via a mutually agreed secure document management or project collaboration software platform (e.g., Sharepoint) in an electronic format editable and readable by generally available Third Party software (e.g. PDF or Microsoft Word documents) or as otherwise reasonably requested by Genentech. [***]

(b) In addition to the provision of the BioNTech Initial Knowledge Transfer Items, BioNTech, at its sole cost and expense, shall provide Genentech with reasonable access to employees and Third Party service providers with relevant subject matter expertise to answer questions and assist Genentech in understanding the BioNTech Initial Knowledge Transfer Items. Such access and assistance may occur through the Committees and Teams, on-site visits at BioNTech's or Genentech's offices or facilities or telephonic or other meetings with personnel of BioNTech and its Third Party service providers.

(c) GNE shall at Genentech's sole cost and expense, disclose to BioNTech the Genentech Know-How set forth on Schedule 2.19.1(c). GNE shall provide such Genentech Know-How via a mutually agreed secure document management or project collaboration software platform (e.g., Sharepoint) in an electronic format editable and readable by generally available Third Party software (e.g., PDF or Microsoft Word documents) or as otherwise reasonably requested by BioNTech. In addition, Genentech, at its sole cost and expense, shall provide BioNTech with reasonable access to employees with relevant subject matter expertise to answer questions and assist BioNTech in understanding such Genentech Know-How. Such access and assistance may occur through the Committees and Teams, on-site visits at BioNTech's or Genentech's offices or facilities or telephonic or other meetings with personnel of Genentech.

2.19.2 Ongoing Transfer of Technical Information.

(a) Until [***] or such other date as mutually agreed by the Parties, on a [***] basis, or such other frequency as mutually agreed by the Parties through the applicable Committee, BioNTech shall provide to such Committee or Joint Research Team, Joint Development Team, Joint Manufacturing Team or such other team or working group appointed by a Committee, the following: (i) BioNTech Know-How, to the extent not previously disclosed, Genentech requires to perform its obligations under this Agreement or the Ancillary Agreements and (ii) Collaboration Know-How made or developed by or on behalf of BioNTech pursuant to this Agreement or the Ancillary Agreements. BioNTech shall respond to subsequent requests for such Know-How and make appropriate personnel available to Genentech at reasonable times and places and upon reasonable prior notice for the purpose of assisting Genentech to understand and use the BioNTech Know-How and Collaboration Know-How in connection with the Research Plan, CMC Development Plan, GDP or other plan as requested and approved by the respective Committee.

(b) Until [***] or such other date as mutually agreed by the Parties, on a [***] basis, or such other frequency as mutually agreed by the Parties through the applicable Committee, Genentech shall provide to such Committee or Joint Research Team, Joint Development Team, Joint Manufacturing Team or such other team or working group appointed by a Committee, the following: (i) Genentech Know-How described in clause (a) of the definition of Genentech Know-How, to the extent not previously disclosed, that BioNTech requires to perform its obligations under this Agreement or the Ancillary Agreements, (ii) Genentech Know-How described in clause (b) of the definition of Genentech Know-How upon Genentech's decision to include such Genentech Know-How in the performance of the Research Plan, GDP or CMC Development Plan and (iii) Collaboration Know-How made or developed by or on behalf of Genentech pursuant to this Agreement or the Ancillary Agreements. Genentech shall respond to subsequent requests for such Know-How and make appropriate personnel available to BioNTech at reasonable times and places and upon reasonable prior notice for the purpose of providing reasonable assistance to BioNTech to understand and use such Genentech Know-How and Collaboration Know-How in connection with performing the activities for which BioNTech is responsible under the Research Plan, CMC Development Plan, GDP or other plan as requested and approved by the respective Committee.

(c) The ongoing knowledge transfer obligation described in clause (a) above for BioNTech and the ongoing knowledge transfer obligation described in clause (b) above for Genentech shall each be referenced herein as the (“**Ongoing Knowledge Transfer**”).

2.19.3 Transfer of Materials. Without limiting any specific transfer of materials set forth in the MDSA, BioNTech shall provide Genentech with sufficient quantities of the physical specimens and materials set forth in Schedule 2.19.3 within [***] days of the Effective Date as specified in Schedule 2.19.3 or as otherwise may be extended as mutually agreed upon by the Parties pursuant to Section 10.9. In addition, BioNTech shall provide Genentech with sufficient quantities of any other materials deemed appropriate by the applicable Committee or as set forth in the CMC Development Plan, solely for the purposes of enabling Genentech to fulfill its obligations under this Agreement and the Ancillary Agreements. BioNTech represents and warrants that it, to its’ and its Affiliates’ knowledge, has sufficient rights to transfer such materials to Genentech and to grant Genentech and its Affiliates and Sublicensees the right to use such materials in the exercise of its rights or performance of its obligations under this Agreement and the Ancillary Agreements (including use of such materials in or for the Exploitation of Collaboration Products) without restriction or payment. Notwithstanding the foregoing, each Party shall otherwise be responsible for procuring any materials required for it to conduct its activities under the Research Plan.

2.20 [***] Activities

2.20.1 Subject to the provisions of this Section 2.20, and notwithstanding any other provisions of subcontracting under this Agreement or any of the Ancillary Agreements, BioNTech may use [***] as a subcontractor to perform activities on its behalf, including under the Research Plan, under this Agreement or the Ancillary Agreements but only pursuant to the terms of the [***] Agreement, [***] Agreement and the [***] Agreement (collectively, the “[***] Agreements”); provided that (a) BioNTech shall negotiate in good faith with [***], in consultation with Genentech, and enter into an amendment to the [***] Agreement or similar agreement to obtain rights to any [***] developed by [***], and any such amendment or agreement shall be reviewed and approved by Genentech prior to execution, and (b) during the Term, BioNTech shall not enter into any amendments to the [***] Agreements and shall not terminate any of the [***] Agreements without Genentech’s prior written consent. If BioNTech has not entered into an amendment to the [***] Agreement or similar agreement to obtain rights to improvements to the [***] by January 1, 2017, then, at Genentech’s discretion and written notice, BioNTech shall cease using, and thereafter may no longer use, [***] as a subcontractor to perform activities on its behalf under this Agreement or any Ancillary Agreement. BioNTech shall be responsible for ensuring that [***] performs any activities subcontracted to [***] hereunder in a timely manner and in accordance with the terms of this Agreement applicable to the performance by BioNTech of such activities. In no event shall BioNTech permit [***] to subcontract any of its activities to be performed on behalf of BioNTech without the prior written consent of Genentech. [***].

2.20.2 [***]

ARTICLE 3.
RESEARCH PROGRAM

3.1 Research Plan and Activities.

3.1.1 Research Program. During the Research Term, GNE and BioNTech shall conduct a research collaboration oriented to improving the Technology Platform relating to the Collaboration Products, pursuant to a research plan, which shall set forth each of Genentech's and BioNTech's respective activities under the plan, and the number of FTEs (which may be a range) to be devoted by each Party, [***] ("**Research Plan**"). Each Party shall be responsible for funding its own FTEs and out-of-pocket costs and expenses under the Research Plan.

3.1.2 Initial Research Plan and Activities. Attached hereto as Schedule 3.1.2 is the initial Research Plan, which plan assigns responsibility for research activities between the Parties. Each Party shall use Commercially Reasonable Efforts to perform the activities assigned to it under the Research Plan. Each Party shall conduct its activities under the Research Plan in accordance with the terms and conditions of this Agreement. Each Party shall use Commercially Reasonable Efforts to devote to its activities under the Research Plan those FTEs specified in the Research Plan.

3.1.3 Amendments. During the Research Term, the JRC shall review the Research Plan from time to time as necessary for the purpose of considering appropriate amendments thereto. In addition, either Party, through its representatives on the JRC, may propose amendments to the Research Plan at any time. In connection with amending the Research Plan, the Parties shall determine the FTEs and other resources and out-of-pocket expenditures required for implementation of the Research Plan for the applicable Calendar Year and for each Calendar Quarter within such Calendar Year.

3.2 Subcontracting.

3.2.1 Genentech shall have the right to subcontract any of its activities under the Research Plan to a Third Party. Genentech shall keep the JRC informed of such subcontracting activities.

3.2.2 Each Party shall be responsible (and liable) to the other Party for the performance of its subcontractors and for any failure by its subcontractors to comply with the restrictions, limitations and obligations set forth in this Agreement as if such performance or failure of such subcontractors were the performance or failure of the subcontracting Party under this Agreement.

3.2.3 Subject to Section 2.20, any subcontracting by either Party of any of its activities under the Research Plan shall be conducted pursuant to a written subcontract specifying the work to be subcontracted, and containing provisions that are compliant with the applicable terms and conditions of this Agreement and any Ancillary Agreements, including provisions with respect to intellectual property and confidential information, and that as between the subcontracting Party or its Affiliates and its subcontractor, any intellectual property arising out of the performance of such activities shall be Controlled by the subcontracting Party or its Affiliates. [***].

3.2.4 Subject to Section 2.20, BioNTech shall have the right to subcontract any of its activities under the Research Plan to a Third Party; provided that [***]

3.3 Records and Results.

3.3.1 Without limiting Section 10.1, each Party shall use reasonable efforts to keep the other Party informed of its activities under the Research Plan and [***] per Calendar Year, at mutually agreed meetings of the JRC, shall provide to the JRC a reasonably detailed written report, in English, describing activities performed and results obtained under the Research Plan since the prior written report, in a form determined by the JRC. In the event that either Party requests further information regarding any such report, including a request for data or other primary research results, the Parties shall cooperate to achieve such data exchange in a timely and efficient manner. Neither Party shall be required to generate additional data or prepare additional reports to comply with the foregoing obligation. Notwithstanding the foregoing, the JRC may determine what reports shall be generated in respect of Research Plan activities, including the content and timing thereof, including by authorizing or requiring reports other than as provided in this Section 3.3.1. The Parties shall promptly share all such reports with the JRC.

3.3.2 In addition to Section 3.3.1, in the event a Party identifies, as part of the Research Plan or otherwise in connection with its activities with respect to the Collaboration Products, an improvement [***], then such Party shall provide to the JRC, if such results have not already been so provided under Section 3.3.1, a reasonably detailed written report, in English, describing the activities performed and results obtained and [***]. The JRC shall review such report, and may request further information regarding any such report, including a request for data or other primary research results, that may be reasonably useful to evaluate [***]; provided that such Party shall not be required to generate additional data or prepare additional reports to comply with the foregoing obligation. Within [***] days of the receipt of such report, the JRC shall [***]

3.3.3 Each Party shall, and shall ensure that any Third Parties contracted pursuant to Section 3.2, maintain records in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, and in compliance with Applicable Law, which shall be complete and accurate and shall properly reflect all work done and results achieved in the performance of its designated activities under a Research Plan and which shall record only such activities and shall not include or be commingled with records of activities other than those conducted pursuant to the Research Plan. Such records shall be retained by the applicable Party for the longer of (a) ten (10) years from its creation or (b) such period as may be required by Applicable Law.

**ARTICLE 4.
DEVELOPMENT**

4.1 Generally. The Parties shall use Commercially Reasonable Efforts to Develop one or more Collaboration Products for Commercialization in the Major Markets.

4.2 GDP. Genentech and BioNTech shall pursue the Global Development Plan as set forth herein. Except as set forth in this Article 4, neither Party nor its Affiliates shall (a) Conduct any Clinical Studies of a Collaboration Product that is not set forth in the GDP or (b) use any BioNTech IP, that does not fall within any of the exceptions under Section 11.1.4 and is disclosed to Genentech under this Agreement or the Ancillary Agreements, to conduct any clinical studies of any Pharmaceutical Product that (i) comprises one or more Neoepitope RNA(s), but not any Non-Neoepitope RNA(s) or (ii) one or more Permitted Hybrid Neoepitope RNA(s), [***] that is not set forth in the GDP.

4.3 BioNTech Ongoing Clinical Studies and Related Follow-Up Studies.

4.3.1 Conduct of Ongoing Clinical Studies. Notwithstanding [***], BioNTech may complete its ongoing Clinical Study in triple negative breast cancer along with its ongoing Clinical Study in melanoma, each as described in, and in accordance with, the protocols identified in Schedule 4.3.1, as such protocols were provided by BioNTech to Genentech prior to the Execution Date (“**Ongoing Clinical Studies**”), including, upon notification to the JDC, reasonable amendments thereto within the ordinary course of business that are not material deviations. Any amendments proposed by BioNTech to such protocols that are material deviations shall require the approval of the JDC.

4.3.2 Other Clinical Studies in Melanoma.

(a) If, in BioNTech’s reasonable judgment, the results of BioNTech’s Ongoing Clinical Study in melanoma demonstrate sufficient evidence of activity to warrant a subsequent Clinical Study, then prior to [***], BioNTech may propose to the JDC one non-registrational subsequent Clinical Study in melanoma that BioNTech would conduct at its sole cost and expense under a BioNTech IND (“**Melanoma Follow-Up Study**”). In connection with such proposal, BioNTech shall provide to the JDC the draft protocol for the proposed study. The JDC shall approve such Melanoma Follow-Up Study if [***]. If the JDC approves such Melanoma Follow-Up Study, BioNTech may Conduct such Melanoma Follow-Up Study, at BioNTech’s sole cost and expense, provided that BioNTech provides updates to the JDC regarding the status of such Melanoma Follow-Up Study and obtains the prior written approval of the JDC for any modifications to the protocol to such Melanoma Follow-Up Study that would (individually or collectively) constitute material deviations from the protocol that was presented to the JDC at the time of its initial approval. The JDC shall approve such material deviations from the protocol if the criteria for approval of the Melanoma Follow-Up Study set forth in this Section 4.3.2(a) continue to be fulfilled.

(b) Any additional clinical Development by BioNTech shall be solely as permitted under Sections 4.4 and 4.5.

4.3.3 Genentech's Use of Ongoing Clinical Study Data. Genentech may access and use any data generated in connection with the Ongoing Clinical Studies and, if applicable, the Melanoma Follow-Up Study. [***]

4.4 Development Under the Global Development Plan.

4.4.1 GDP. The initial GDP for the Development of the Collaboration Products hereunder, which assigns responsibility for Party Development Activities between the Parties in relation to GDP Collaboration Products (such activities, "**Joint Development Activities**"), is attached hereto as Schedule 4.4.1. Each Party shall Conduct Joint Development Activities assigned to it with reasonable care and diligence and in accordance with the terms and conditions of this Agreement and the GDP. Except as otherwise expressly provided in the GDP, the CMC Development Plan or otherwise specified herein, all Development under the GDP shall be conducted by Genentech.

4.4.2 Amendments. The JDC shall review the GDP from time to time as necessary for the purpose of considering appropriate amendments thereto. In addition, either Party, through its representatives on the JDT, may propose amendments to the GDP for Joint Development Activities at any time. Following [***], if Genentech proposes to amend the GDP to include a Clinical Study for Development of a Collaboration Product in an Indication that is not then included in the GDP, it shall provide the JDC with a written clinical Development plan from proof of concept through Regulatory Approval for such Indication consisting of [***] As part of the process of amending the GDP, the Parties shall determine the internal personnel and other resources and out-of-pocket expenditures required for the Joint Development Activities for the applicable Calendar Year and for each Calendar Quarter within such Calendar Year, to be reflected in the GDP Budget.

4.4.3 Conduct of Clinical Studies Under the GDP. Except as otherwise agreed by the Parties in writing, Genentech shall Conduct all Clinical Studies prior to [***] under the GDP, and thereafter all Clinical Studies under the GDP with respect to which Genentech has final decision-making authority as set forth in Section 2.7.2(g)(i). [***]. Except as otherwise agreed by the Parties in writing, BioNTech shall Conduct all Clinical Studies with respect to which BioNTech has [***]; *provided* that (a) BioNTech shall Conduct any applicable Clinical Studies under the GDP in a timely, effective and cost-efficient manner according to Applicable Law (including Compliance Requirements), and (b) BioNTech may only Conduct a Clinical Study under the GDP if BioNTech possesses safety reporting and other applicable infrastructure and personnel adequate to support such Clinical Study and share safety data with Genentech in a manner that enables Genentech's compliance with any Regulatory Authority reporting requirements per Genentech's standard processes [***]

4.4.4 Subcontracting.

(a) Genentech shall have the right to subcontract any of its activities under the GDP or in connection with a Genentech Study to a Third Party. Genentech shall keep the JDC informed of such subcontracting activities.

(b) BioNTech shall have the right to subcontract any of its activities under the GDP or in connection with an Ongoing Clinical Study, Melanoma Follow-Up Study or BioNTech Study to a Third Party; provided that [***]

(c) Subject to Section 2.20, any subcontracting by either Party of any of its activities under the GDP or in connection with an Ongoing Clinical Study, Melanoma Follow-Up Study, Genentech Study or BioNTech Study shall be conducted pursuant to a written subcontract specifying the work to be subcontracted, and containing provisions that are compliant with the applicable terms and conditions of this Agreement and any Ancillary Agreements, including provisions with respect to intellectual property and confidential information, and that as between the subcontracting Party or its Affiliates and its subcontractor, any intellectual property arising out of the performance of such activities by such subcontractor shall be Controlled by the subcontracting Party or its Affiliates. In the event that such intellectual property would, if it were made by a Party, be Collaboration IP, then such intellectual property shall be Collaboration IP and in the event that such intellectual property would, if it were made by a Party, be BioNTech IP or Genentech IP, then such intellectual property is hereby licensed to the other Party subject to Section 9.1 or 9.2, as applicable.

(d) Each Party shall be responsible (and liable) to the other Party for the performance of its subcontractors and for any failure by its subcontractors to comply with the restrictions, limitations and obligations set forth in this Agreement as if such performance or failure of such subcontractors were the performance or failure of the subcontracting Party under this Agreement.

4.5 BioNTech Proposed New Indications; BioNTech Studies.

4.5.1 Proposed Additional Indication. BioNTech may, at any time during the Term, based upon sound scientific rationale, provide the JDC with a written proposal meeting the requirements of this Section 4.5.1 (“**Study Proposal**”) to amend the GDP to include a Clinical Study (“**Proposed Study**”) for Development of a Collaboration Product in an Indication that is not then included in the GDP. Each such Study Proposal shall include [***]. BioNTech shall present such Study Proposal to the JDC at its next regularly scheduled meeting. The JDC shall decide whether to approve such Proposed Study and whether to add the relevant Indication to the GDP, which decision shall be reflected in the minutes of the JDC. Each Study Proposal shall contain reasonably sufficient detail to enable the JDC to assess whether to approve such Proposed Study and whether to add the relevant Indication to the GDP. If the JDC decides to add the Indication covered by the Study Proposal to the GDP, the GDP shall be amended to include the Proposed Study (together with any modifications agreed upon by the JDC), such Indication shall become a GDP Indication, and the Conduct of such Proposed Study (as modified by the JDC) and any additional Clinical Studies in such Indication shall be a Joint Development Activity, pursuant to Section 4.4. In the event that the JDC declines to add a new Indication presented by BioNTech to the GDP pursuant to this Section 4.5.1, then BioNTech may have the right to Conduct the Proposed Study to the extent permitted pursuant to Section 4.5.2 as a “**BioNTech Study**”, and upon Initiation by BioNTech of the Proposed Study and subject to Section 4.5.5(c), such Indication, shall be a “**BioNTech Indication**” and such Collaboration Product shall be a “**BioNTech Collaboration Product**”.

4.5.2 BioNTech's Right to Conduct a BioNTech Study. Subject to Section 4.5.5, BioNTech shall have the rights set forth in this Section 4.5.2 to Conduct a Proposed Study that the JDC declines to include in the GDP solely if [***], the “**BioNTech Study Conduct Requirements**”), and (5) the applicable conditions in subsections (a)-(d) below are satisfied. In the event that BioNTech fails to Initiate a Proposed Study that the JDC has declined to include in the GDP within [***] of the JDC decision to not include the study in the GDP, then if BioNTech wishes to Conduct the study at a later time, it must re-submit the Study Proposal for such study to the JDC for consideration in accordance with Section 4.5.1 as if the study were a new Proposed Study.

[***]

4.5.3 Preservation of Genentech Tumor Types. Following [***], if at a given time, the then-current GDP does not provide for a Clinical Study for a tumor type listed on Schedule 1.167 as Genentech Tumor Types, then BioNTech may propose a Clinical Study in such tumor type (a “**GTT Proposed Study**”) by presenting a Study Proposal to the JDC pursuant to Section 4.5.1; provided that a GTT Proposed Study may not be in a Genentech Indication. The JDC shall decide whether to add such GTT Proposed Study to the GDP with Genentech having the right to cast the deciding vote. In the event that the JDC determines to add the GTT Proposed Study to the GDP, the applicable tumor type shall remain a Genentech Tumor Type and the applicable Indication shall become a GDP Indication. In the event the JDC determines not to add such GTT Proposed Study to the GDP, then BioNTech may pursue the GTT Proposed Study in accordance with the Study Proposal if all of the following conditions are met: [***]. In such case, upon BioNTech's timely (within the [***] timeframe described in the preceding sentence) Initiation of the GTT Proposed Study and so long as BioNTech is using Commercially Reasonable Efforts to Conduct such GTT Proposed Study, the GTT Proposed Study will be a BioNTech Study, the proposed Indication will be a BioNTech Indication and the applicable tumor type will cease to be a Genentech Tumor Type.

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4.5.4 BioNTech's Conduct of BioNTech Studies. For any BioNTech Study (including [***] Conducted by BioNTech), the following shall apply:

(a) Each BioNTech Study shall be Conducted by BioNTech at BioNTech's sole cost and expense, which costs and expenses shall not be included in Shared Development Costs, unless otherwise agreed by the Parties. Notwithstanding the foregoing, in the event the JMC determines that the Manufacture and supply of Collaboration Product for such BioNTech Study can be supported within the Manufacturing Network in accordance with patient demand forecasting pursuant to the MDSA, the cost for Manufacturing the Collaboration Product at Commercial Facilities of Genentech within the Manufacturing Network will be charged to BioNTech [***]. BioNTech may contract with a contract research organization to conduct such study, *provided* that the terms of Section 4.4.4 shall also apply with respect to BioNTech's Conduct of BioNTech Studies.

(b) BioNTech shall not Initiate any BioNTech Study until after execution of the Pharmacovigilance Agreement by both Parties. BioNTech shall Conduct any BioNTech Clinical Study under [***] in accordance with Section 5.3. For clarity, subject to Genentech's rights and BioNTech's obligations as set forth in this Section 4.5, BioNTech may conduct a subsequent Clinical Study, including a Pivotal Study to the extent permitted under Section 4.5.2(b) or Section 4.5.2(c).

(c) All BioNTech Studies will be subject to oversight by the JDC and BioNTech shall (i) provide regular updates on the status and results of each such BioNTech Study to the JDC, including reporting the achievement of key Clinical Study and Development milestones to be determined by the JDC, and (ii) inform the JDC of any changes to the Study Proposal (including study designs and protocols) for each BioNTech Study. Genentech, through the JDC, shall be permitted to provide BioNTech with comments on the Development plans for BioNTech Studies and on the conduct of the BioNTech Studies, and BioNTech shall [***]. Notwithstanding the foregoing, any modifications to the protocol for a BioNTech Study that would (individually or collectively) constitute material deviations from the protocol in the Study Proposal originally presented to the JDC shall require the prior approval of the JDC, [***].

(d) BioNTech will use Commercially Reasonable Efforts to ensure careful and diligent execution of the Development program for each BioNTech Indication reflected in the initial Study Proposal therefor, and shall Conduct each BioNTech Study according to Applicable Law including Compliance Requirements. BioNTech shall fully and adequately fund and be responsible for any BioNTech Studies permitted pursuant to Section 4.5.2 (including Manufacturing at BioNTech's cost and expense adequate supply of Collaboration Product for such studies, which supply shall not prejudice the supply of Collaboration Product for activities under the Research Plan or the GDP or activities relating to Genentech Indications).

(e) In the event a BioNTech Study is in a Genentech Tumor Type, Genentech shall [***], in accordance with Section 2.7.2(g) (i). For clarity, (i) such [***] shall not apply in relation to Ongoing Clinical Studies or the Melanoma Follow-up Study and (ii) BioNTech shall [***] regarding any BioNTech Study that was proposed as a GTT Proposed Study in accordance with Section 4.5.3.

(f) Unless otherwise agreed by the Parties, a BioNTech Study may only involve [***]

(g) [***]

4.5.5 Genentech's Opt-In Right for BioNTech Studies.

(a) For each BioNTech Study (including [***] that has been or is being conducted by BioNTech in a particular Indication, Genentech shall have the option (“**Opt-In Right**”), exercisable at any time prior to the first filing for the first application for Marketing Authorization for such Indication (“**Genentech Opt-In Period**”), to convert the Indication to a GDP Indication by providing written notice to BioNTech and paying the BioNTech Indication Opt-In Fee pursuant to Section 8.3. Upon written request of Genentech, BioNTech shall inform Genentech (in writing within [***] days of Genentech's written request) in reasonable detail of all Development Costs incurred for such BioNTech Indication which would form the basis for the calculation of the BioNTech Indication Opt-In Fee pursuant to Section 8.3. Any disputes in relation to such Development Costs shall be settled in accordance with Sections 8.16 and 8.17.

(b) In the event that the Genentech Opt-In Period expires with respect to a BioNTech Indication without exercise by Genentech of its Opt-In Right, and BioNTech's [***], the Parties may amend this Agreement to address further details of the transition including with respect to Product Trademarks, branding, NDC numbers and commercial launch activities.

(c) Following Genentech's exercise of its Opt-In Right with respect to a BioNTech Study [***], (i) the relevant Indication shall become a GDP Indication, and (ii) the relevant Collaboration Product shall cease to be a BioNTech Collaboration Product and shall become a GDP Collaboration Product. In addition, following Genentech's exercise of its Opt-In Right [***] with respect to a BioNTech Study (A) BioNTech shall complete any applicable Clinical Study (if such Clinical Study is still ongoing) under the GDP unless otherwise agreed by the Parties, (B) all Development Costs for such study incurred thereafter shall constitute Shared Development Costs and (C) BioNTech shall [***]. If, at the time of Genentech's exercise of its Opt-In Right [***], BioNTech has incurred costs or entered into non-cancellable financial commitments, in each case, relating to the construction, Commissioning, licensing, operation and/or maintenance of an Independent Facility, the Parties shall enter into good faith negotiations to determine whether it is feasible to continue to have such Independent Facility support the Manufacturing of such Collaboration Product or to find alternative ways to compensate BioNTech for the investments already made to the extent that such costs and non-cancellable financial commitments were specific to the Manufacture of the relevant BioNTech Collaboration Product and cannot be used for other purposes by BioNTech.

(d) In the event that the Genentech Opt-In Period with respect to a BioNTech Indication expires without exercise by Genentech of its Opt-In Right, then BioNTech shall notify Genentech [***].

4.6 Genentech's Conduct of Genentech Studies; [*] for Genentech Collaboration Products.** In the event that BioNTech exercises its BioNTech Co-Funding Rejection right pursuant to Section 2.7.2(c), the following shall apply:

4.6.1 Each Genentech Study shall be Conducted by Genentech at Genentech's sole cost and expense, which costs and expenses shall not be included in Shared Development Costs, unless otherwise agreed by the Parties. The cost for Manufacturing the Collaboration Product at Clinical Facilities will be charged to Genentech [***].

4.6.2 In the event that a Regulatory Authority accepts a Drug Approval Application for a Genentech Collaboration Product in a Genentech Indication, then upon the first such acceptance by a Regulatory Authority, BioNTech shall be required to pay the Genentech Indication Co-Funding Fee (as set forth in Section 8.3.2) with respect to the applicable Genentech Indication. Following the first acceptance by a Regulatory Authority of an application for Marketing Authorization of a Genentech Collaboration Product, (a) the relevant Indication shall become a GDP Indication, and (b) the relevant Collaboration Product shall cease to be a Genentech Collaboration Product and shall become a GDP Collaboration Product.

4.7 [*]**

4.8 Records and Reports; Study Data.

4.8.1 Each Party shall, and shall ensure that any of its Affiliates, subcontractors and Sublicensees performing Development activities with respect to the Collaboration Products and any Third Parties contracted pursuant to Section 4.4.4, maintain records in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, and in compliance with Applicable Law, which shall be complete and accurate and shall properly reflect all work done and results achieved in the performance of its designated Party Development Activities which shall record only such activities and shall not include or be commingled with records of activities other than Party Development Activities. Such records shall be retained by the applicable Party for the longer of (a) ten (10) years from its creation or (b) such period as may be required by Applicable Law.

4.8.2 Without limiting Sections 5.8 or 10.1, each Party shall use reasonable efforts to keep the other Party informed of its Party Development Activities and [***] per Calendar Year, at mutually agreed meetings of the JDC, shall provide to the JDC a reasonably detailed written report, in English, describing Party Development Activities performed and results obtained since the prior written report, in a form determined by the JDC. In the event that either Party requests further information regarding any such report,

including a request for Clinical Data, the Parties shall cooperate to achieve such data exchange in a thorough, timely and efficient manner. Neither Party shall be required to generate additional data or prepare additional reports to comply with the foregoing obligation. Notwithstanding the foregoing, the JDC may determine what reports shall be generated in respect of Party Development Activities, including the content and timing thereof, including by authorizing or requiring reports other than as provided in this Section 4.8.2. The Parties shall promptly share all such reports with the JDC.

4.8.3 Genentech shall own all right, title and interest in and to Genentech Molecule Clinical Study Data; provided that BioNTech shall have the right to use such Genentech Molecule Clinical Study Data, subject to Section 11.1, solely to perform its obligations under this Agreement.

4.9 Investigator-Sponsored Studies. Investigator-sponsored studies of the Collaboration Product with respect to which a Party or its Affiliate or its Sublicensee is providing funding or clinical supplies of Collaboration Product shall be treated as a Clinical Study Conducted by such Party for all purposes (including JDC review and approval, cost allocation and intellectual property). [***].

4.10 Compliance. Each Party shall perform or cause to be performed, any and all of its Party Development Activities in good scientific manner and in compliance with all Applicable Laws, including Compliance Requirements.

ARTICLE 5. REGULATORY

5.1 General. For the purposes of this Agreement, the Parties agree that all GDP Indications for all Collaboration Products in a given jurisdiction will be governed by one or more Marketing Authorization(s) owned by Genentech or its Affiliate or Sublicensee (such Marketing Authorization(s) and any additional Marketing Authorizations owned by Genentech or its Affiliate or Sublicensee, each hereinafter a “**Genentech Marketing Authorization**”).

5.2 Lead Regulatory Parties. “**Lead Regulatory Party**” means the Party so assigned pursuant to this Section 5.2, with the rights and responsibilities set forth under Section 5.4. The Party that is not the Lead Regulatory Party shall be the “**Supporting Regulatory Party**”. Genentech shall be the Lead Regulatory Party with respect to all Collaboration Products for all Indications, other than with respect to (a) the Ongoing Clinical Studies, any Melanoma Follow-Up Study permitted pursuant to Section 4.3.2(a), and (b) any BioNTech Study Conducted under [***]

5.3 BioNTech Study under [*]**

5.3.1 If the JDC declines to include a Proposed Study from BioNTech in the GDP after [***] (or at such earlier time permitted pursuant to Section 4.5.2), and BioNTech has right to Conduct such Proposed Study pursuant to Section 4.5.2, then BioNTech may Conduct such Proposed Study as a BioNTech Study under [***].

5.3.2 Subject to Genentech's rights and BioNTech's obligations as set forth in Section 4.5 and provided that [***]

5.3.3 BioNTech shall prioritize Development and Manufacturing activities it is conducting in support of the GDP and GDP Collaboration Products and any Genentech Indications and Genentech Products over any development and manufacturing activities it is conducting in support of [***]. In particular, BioNTech agrees that:

(a) In any communications and interactions with a Regulatory Authority that are undertaken [***]

(b) BioNTech shall ensure that BioNTech Development and [***] Activities do not distract or divert resources from activities conducted under or in support of the GDP or GDP Collaboration Products or any Genentech Indications or Genentech Collaboration Products; and

(c) [***]

5.3.4 The Parties acknowledge and agree that this Agreement has been drafted primarily in view of the Genentech Marketing Authorization for GDP Collaboration Products. No later than [***] days following the request of Genentech, and in any event prior to [***], the Parties agree to amend this Agreement to reflect [***].

5.4 Regulatory Activities.

5.4.1 As between the Parties, the Lead Regulatory Party shall have the sole right and responsibility to prepare and submit Regulatory Documentation and to file for, obtain, and maintain Regulatory Approvals (including the setting of the overall regulatory strategy therefor). With respect to GDP Collaboration Products and Genentech Collaboration Products, the Supporting Regulatory Party shall support the Lead Regulatory Party, as may be reasonably necessary, in obtaining such Regulatory Approvals for the Collaboration Products, and in the activities in support thereof, including providing information, documents or other materials required by Applicable Law for inclusion in or in support of Regulatory Documentation, in each case in accordance with the terms and conditions of this Agreement and the GDP.

5.4.2 All Regulatory Documentation (including all Regulatory Approvals and Product Labeling) (except for Clinical Data which shall be owned pursuant to Section 4.8.3 or Section 11.1) relating to the Collaboration Products with respect to the Territory shall be owned by, and shall be the sole property and held in the name of, the Lead Regulatory Party or its designated Affiliate, Sublicensee or designee.

5.4.3 The Lead Regulatory Party pursuant to Section 5.2 with respect to [***] shall provide the other Party with an opportunity to review and comment on [***] The Lead Regulatory Party shall provide the Supporting Regulatory Party access to [***]

5.4.4 The Lead Regulatory Party pursuant to Section 5.2 [***] shall provide the Supporting Regulatory Party with prior written notice, to the extent the Lead Regulatory Party has advance knowledge, of any material scheduled meeting, conference, or discussion (including any advisory committee meeting) with a Regulatory Authority [***]

5.4.5 The Lead Regulatory Party shall make every reasonable effort to notify the Supporting Regulatory Party promptly following its determination that any event, incident, or circumstance has occurred that may result in the need for a recall, market suspension, or market withdrawal of a Collaboration Product in the Territory, and shall include in such notice the reasoning behind such determination, and any supporting facts. The Lead Regulatory Party shall have the right to make the final determination whether to voluntarily implement any such recall, market suspension, or market withdrawal in the Territory. If a recall, market suspension, or market withdrawal is mandated by a Regulatory Authority in the Territory, the Lead Regulatory Party shall initiate such a recall, market suspension, or market withdrawal in compliance with Applicable Law. For all recalls, market suspensions or market withdrawals undertaken pursuant to this Section 5.4.5, the Lead Regulatory Party responsible for the recall, market suspension, or market withdrawal shall be solely responsible for the execution thereof, and the Supporting Regulatory Party shall reasonably cooperate in all such recall efforts. [***]

5.5 CMC Regulatory Support.

5.5.1 For Clinical Manufacture and Commercial Manufacture of GDP Collaboration Products and Genentech Collaboration Products, BioNTech shall consult with Genentech, and provide to Genentech all CMC-related documents and input as required by Genentech (or its Affiliate) or any applicable Regulatory Authority in connection with any Regulatory Documentation to be submitted to any applicable Regulatory Authority by Genentech (or its Affiliate) in order to obtain any required Regulatory Approvals in the Territory. In addition, for clinical supply of GDP Collaboration Products and Genentech Collaboration Products, BioNTech shall provide Genentech in a timely manner with a copy of any BioNTech Manufacturing and control records for Existing BioNTech Product and Collaboration Product which may be required for any Regulatory Documentation to be submitted by Genentech with respect to Collaboration Product, which records shall be in BioNTech's standard formats unless otherwise agreed upon by the Parties.

5.5.2 For GDP Collaboration Products and Genentech Collaboration Products that will be Manufactured by Genentech, BioNTech shall (a) consult with and otherwise provide support to Genentech on CMC-related regulatory matters, as requested by Genentech and (b) assist Genentech (or its Affiliate) in responding to requests and inquiries from Regulatory Authorities prior to, during and after regulatory review periods, and attending meetings with Regulatory Authorities to the extent Genentech requests BioNTech to participate given its unique knowledge or its status as manufacturer of the Collaboration Product for clinical supply.

5.6 Regulatory Correspondence.

5.6.1 Each Party shall immediately and within [***] notify the other Party in writing of, and shall provide the other Party with copies of, any correspondence and other documentation received or prepared by such Party in connection with any of the following events: (a) receipt of a regulatory letter, warning letter, Form 483 (Inspectional Observations) or similar item, from the FDA or any other Regulatory Authority directed to the Manufacture or distribution of Collaboration Product by BioNTech or in connection with any general cGMP inspections applicable to the Facility; (b) any recall, market withdrawal or correction of any Collaboration Product Manufactured, tested, packaged, stored or distributed hereunder, where the recall, market withdrawal or correction is attributable to any Manufacturing or distribution activities by or on behalf of BioNTech; and (c) receipt of a regulatory letter, warning letter or similar item from the FDA or any other Regulatory Authority directed to or any regulatory comments related to Collaboration Product Manufactured or distributed hereunder where the comments relate or are attributable to any Manufacturing, testing, packaging, storage or distribution activities by or on behalf of BioNTech.

5.6.2 In the event Genentech receives any regulatory letter or comments from any Regulatory Authority in the Territory related to the Manufacture of Collaboration Product, including receipt of a Form 483 (Inspectional Observations) or a warning letter, BioNTech will, to the extent within its control or possession, promptly provide Genentech with relevant data or information related to the Manufacture of Collaboration Product sufficient for Genentech to prepare any response related to the Manufacture or distribution of Collaboration Product and will cooperate fully with Genentech in preparing such response. Genentech shall provide BioNTech with a copy of each such response (redacted to remove information not related to the Manufacture or distribution of Collaboration Product or Genentech's obligations under this Agreement) for BioNTech's review and comment prior to Genentech's submission of its detailed written response. Genentech shall give all due consideration to any BioNTech comments to each such proposed Genentech response provided that BioNTech conveys its comments to Genentech in a timely manner.

5.6.3 In the event BioNTech receives any regulatory letter or comments from any Regulatory Authority in the Territory directed to its Manufacture or distribution of Collaboration Product, including receipt of a Form 483 (Inspectional Observations) or a warning letter, Genentech will, to the extent within its control or possession, promptly provide BioNTech with all Information related to the Manufacture of Collaboration Product sufficient for BioNTech to prepare any response related to the Manufacture or distribution of Collaboration Product and will cooperate fully with BioNTech in preparing such response. BioNTech shall provide Genentech with a copy of each such response (redacted to remove information not related to the Manufacture or distribution of Collaboration Product or BioNTech's obligations under this Agreement) for Genentech's review and comment prior to BioNTech's submission of its detailed written response. BioNTech shall give all due consideration to any Genentech comments to each such proposed BioNTech response provided that Genentech conveys its comments to BioNTech in a timely manner.

5.7 Regulatory Data; Annual Report.

5.7.1 Each Party shall promptly provide to the other Party summaries of [***]

5.7.2 BioNTech shall support Genentech, as may be reasonably necessary or appropriate, in obtaining Regulatory Approval for the Collaboration Products, including providing necessary documents or other materials required by Applicable Law to obtain Regulatory Approvals, in each case in accordance with the terms and conditions of this Agreement and the GDP.

5.7.3 BioNTech shall provide Genentech within [***] days after the end of each annual reporting period for each applicable Collaboration Product (as calculated consistent with appropriate regulations and guidelines) with such information as is reasonably requested in writing by Genentech for the preparation of the annual report with respect to the Manufacturing and control of such Collaboration Product for such annual reporting period. Thereafter, Genentech shall provide to BioNTech at least [***] Business Days prior to Genentech's filing with the respective Regulatory Authorities a copy of such Genentech annual report, and Genentech shall take into consideration any BioNTech comments to such annual report with respect to the Manufacture of Collaboration Product.

5.8 Pharmacovigilance. Prior to [***], the Parties shall execute a separate pharmacovigilance agreement setting forth the Parties' responsibilities and obligations with respect to the procedures and timeframes for compliance with Applicable Law pertaining to safety reporting of the Collaboration Products ("**Pharmacovigilance Agreement**").

5.9 BioNTech Platform Product. During the Term and to the extent permissible under relevant agreements concluded with Third Parties, BioNTech shall provide a high level safety report in connection with the development of BioNTech Platform Products in order for Genentech to determine whether such development could impact the Development of Collaboration Products and whether a Regulatory Authority may require the reporting of certain safety data and related Information for such applicable BioNTech Platform Products. The contents and frequency of such report shall be determined by the JDC. In the event that Genentech determines that it may need to inform or report certain safety data and related Information for one or more BioNTech Platform Products, the Parties, through the JDC, shall discuss in good faith a path for providing such safety data and related Information for such BioNTech Platform Products to a Regulatory Authority and BioNTech shall provide reasonable assistance to Genentech in order for Genentech to report such safety data and related Information. In the event that BioNTech may not disclose such safety data and related Information to Genentech under relevant agreements concluded with Third Parties, BioNTech shall use reasonable efforts to enable Genentech to comply with its obligations under Applicable Law (e.g., if requested by Genentech, through a direct communication with the Regulatory Authority requesting such safety data and related Information or by obtaining the consent from the relevant Third Party, if possible). Genentech shall provide to BioNTech copies of all correspondence submitted to or received from any Regulatory Authority to the extent related to such safety data or related Information provided to Genentech under this Section 5.9.

ARTICLE 6.
COMMERCIALIZATION AND MEDICAL AFFAIRS

6.1 Generally.

6.1.1 Commercialization of GDP Collaboration Products, Royalty Products and BioNTech Collaboration Products. Except as otherwise provided in this Agreement or any Co-Promotion Agreement, Genentech (itself or through its Affiliates or Sublicensees) shall have the sole right to Commercialize each GDP Collaboration Product (including any Royalty Product) in the Territory and shall use Commercially Reasonable Efforts to Commercialize each GDP Collaboration Product (including any Royalty Product) in the Major Markets and in each other market in the Territory in which it has obtained Marketing Authorization for such GDP Collaboration Product. Except as otherwise provided in this Agreement, BioNTech shall have the right to Commercialize any BioNTech Collaboration Product under [***] Authorization, provided that [***]

6.1.2 Marketing of BioNTech Collaboration Products under [*].** In the event BioNTech has the right to Commercialize a BioNTech Collaboration Product under [***] in accordance with Section 5.1 and Section 6.1.1, BioNTech shall have the sole right to conduct, at its sole cost and expense, marketing activities in connection with such Commercialization, as addressed further in Schedule 5.3.

6.1.3 Value Creation. [*]**

6.2 Booking of Sales; Distribution. Genentech shall have the sole right to (a) invoice and book sales, establish all terms of sale (including pricing and discounts), warehouse, and distribute GDP Collaboration Products (including Royalty Products) in the Territory and to perform or cause to be performed all related services and other Commercialization activities, (b) handle all order processing, invoicing, collection, distribution, reimbursement services, and inventory management with respect to such GDP Collaboration Products (including Royalty Products) in the Territory, (c) handle all returns, recalls, or withdrawals with respect to any GDP Collaboration Product (including any Royalty Product) in the Territory, (d) handle all payer/distributor account management with respect to any GDP Collaboration Product (including any Royalty Product) in the Territory, and (e) manage all aspects of contracting with providers, distributors, managed care vendors or payers with respect to any GDP Collaboration Product (including any Royalty Product) in the Territory. BioNTech shall have the sole right to do any of the above in relation to BioNTech Collaboration Products.

6.3 Product Trademarks. Genentech shall have the sole right and responsibility to determine the Product Trademarks to be used with respect to the Exploitation of the GDP Collaboration Products (including Royalty Products) on a worldwide basis, and to own any such Product Trademarks other than (in the event that Genentech determines that the IVAC Trademark shall be a Product Trademark) the IVAC Trademark. BioNTech shall not, and shall not permit its Affiliates to (a) use in their respective businesses, any Trademark that is confusingly similar to, misleading or deceptive with respect to or that dilutes any (or any part) of the Product Trademarks, or (b) do any act which endangers, destroys, or similarly affects, in any material respect, the value of the goodwill pertaining to the Product Trademarks. BioNTech agrees, and shall cause its Affiliates, to conform (x) to the customary industry standards for the protection of Product Trademarks for Pharmaceutical Products and such guidelines of Genentech with respect to manner of use (as provided in writing by Genentech) of the Product Trademarks, and (y) to maintain the quality standards of Genentech with respect to the goods sold and services provided in connection with such Product Trademarks. BioNTech shall not do any act which endangers, destroys, or similarly affects, in any material respect, the value of the goodwill pertaining to the Product Trademarks. BioNTech shall not, and shall not permit its Affiliates to, attack, dispute, or contest the validity of or ownership of such Product Trademark anywhere in the Territory or any registrations issued or issuing with respect thereto. The JCC shall approve any Product Trademarks to be used by BioNTech in connection with BioNTech Collaboration Products Commercialized under [***] pursuant to Section 6.1.1, and shall decline to approve any such Product Trademarks that the JCC determines may be confusingly similar to the Product Trademarks being used to Commercialize GDP Collaboration Products.

6.4 Product Labeling; Markings and Co-Branding.

6.4.1 Genentech shall own and be responsible for all Product Labeling for all GDP Collaboration Products (including Royalty Products), and BioNTech shall be responsible for all Product Labeling for all BioNTech Collaboration Products under [***]

6.4.2 To the extent permitted and appropriate, and except as otherwise required by Applicable Law, and subject to obtaining necessary Regulatory Approvals in a country in the Territory, the packaging, and Product Labeling for any GDP Collaboration Product (including any Royalty Product) and any promotional materials dedicated solely to a GDP Collaboration Product (including a Royalty Product) used by either Party or its Affiliates in connection with any GDP Collaboration Product (including any Royalty Product) in such country shall contain, [***] (collectively, the “**Markings**”). The manner in which the Markings are to be presented on such promotional materials, packaging, and Product Labeling for GDP Collaboration Products (including Royalty Products) shall be [***], subject to Sections 9.4 and 10.7. [***]

6.5 Co-Promotion Option.

6.5.1 Option. For each Co-Promotion Candidate Product, [***], during the applicable Co-Promotion Exercise Period, subject to the requirements of this Section 6.5, BioNTech shall have the right to assume [***] of the total sales force [***] measured in terms of FTEs (at a percentage within such range to be determined by Genentech), [***] in the Co-Promotion Potential Territory, [***], the “**Co-Promotion Territory**”) (the “**Co-Promotion Option**”).

6.5.2 Notice and Exercise.

(a) No later than [***], BioNTech shall notify Genentech that BioNTech has an interest in exercising its Co-Promotion Option [***]. Following receipt of such notice, Genentech shall (i) conduct a sales force sizing analysis for the applicable Co-Promotion Candidate Product [***], and (ii) provide the results of such analysis, as soon as reasonably practicable, but in any event no later than [***] months before the anticipated date of Commercial Readiness, to BioNTech for review and comment along with the percentage of such sales force for which BioNTech may exercise its Co-Promotion Option; provided that, following the first such BioNTech notice to Genentech that specifies countries other than or in addition to the U.S., Genentech shall provide the results of such sales force sizing analysis for any such countries that are European Union countries no later than [***] months before the anticipated date of Commercial Readiness.

(b) To exercise the Co-Promotion Option, BioNTech must provide Genentech with written notice of its election to exercise the Co-Promotion Option for the offered percentage with respect to the applicable Co-Promotion Candidate Product (hereafter, a “**Co-Promotion Product**”), [***] within [***] days following receipt of Genentech’s sales force analysis and percentage pursuant to Section 6.5.2(a).

(c) Notwithstanding the foregoing, if after the end of the Co-Promotion Exercise Period, Genentech exercises its Opt-In Right or a [***] occurs pursuant to Section 4.5.5, BioNTech shall automatically be deemed to have exercised its Co-Promotion Option with respect to the applicable GDP Collaboration Products [***] in all of the countries in the Co-Promotion Potential Territory unless and to the extent BioNTech rejects such deemed exercise in writing within [***] days of Genentech’s payment of the applicable BioNTech Indication Opt-In Fee. Any such deemed exercise of BioNTech’s Co-Promotion Option shall become effective upon the earlier of the expiration of the [***]-day rejection period or BioNTech’s written notice to Genentech confirming its acceptance of such deemed exercise.

(d) Except as set forth in subsection (c) above, if BioNTech does not provide the election notice described in subsection (b) prior to expiration of the applicable Co-Promotion Exercise Period, BioNTech shall be deemed to have irrevocably waived its right to Co-Promote such Co-Promotion Candidate Product [***]

6.5.3 Co-Promotion Agreement. Promptly after BioNTech’s first exercise of its Co-Promotion Option (or the effective date of a deemed exercise of BioNTech’s Co-Promotion Option), the Parties shall commence negotiations in good faith and enter into a separate co-promotion agreement (the “**Co-Promotion Agreement**”) setting forth the terms of BioNTech’s and Genentech’s Co-Promotion rights and obligations in accordance with the terms and conditions in this Section 6.5 and those set forth in Schedule 6.5.3 attached hereto. The Parties shall negotiate with such diligence as is required to enter into and execute the Co-Promotion Agreement within [***] months following BioNTech’s first exercise (including any deemed exercise) of its Co-Promotion Option, or such other date as the Parties may agree in writing. The Parties shall promptly amend the Co-Promotion Agreement upon each subsequent exercise or deemed exercise by BioNTech of its Co-Promotion Option (e.g., [***]).

6.5.4 General Requirements for Co-Promotion Activities. BioNTech shall not engage in any Detailing until the Co-Promotion Agreement has been executed. BioNTech may not use a contract sales force to fulfill its Co-Promote obligations. Any BioNTech sales representatives involved in promoting a Co-Promotion Product shall devote [***] Under the Co-Promotion Agreement, Genentech shall have the sole right to control all decisions with respect to the co-promotion arrangement, including the call plans and assigned territories of BioNTech's sales representatives, the promotional materials to be used, the training and testing applicable to such sales representatives, and restrictions with respect to the ability of such sales representatives to Detail other products; provided that [***] **“Co-Promote”** or **“Co-Promotion”** means the Detailing and such other activities assigned to BioNTech in the Co-Promotion Agreement, and shall not include any Medical Affairs Activities, sale or distribution of such Co-Promotion Product [***] by BioNTech or its Affiliates. At least [***] months prior to the anticipated launch of each Co-Promotion Candidate Product, BioNTech must have a qualified sales force in place (representing the percentage of the total sales force assigned to BioNTech pursuant to Section 6.5.2(a)) with prior experience promoting products to prescribing oncologists in each relevant country. If BioNTech cannot demonstrate that it has such a qualified internal sales force [***] at least [***] months prior to the launch of the applicable Co-Promotion Candidate Product [***], BioNTech shall be deemed to have irrevocably waived its right to Co-Promote such Co-Promotion Candidate Product in such Indications in such country(ies).

6.5.5 Effect of Opt-Out. BioNTech's rights and obligations under this Section 6.5, including its Co-Promotion Option and any Co-Promotion Agreement, shall terminate immediately upon exercise of BioNTech's Opt-Out.

6.6 Medical Affairs.

6.6.1 General. Medical Affairs Activities are not intended to market or promote Collaboration Products.

6.6.2 GDP Collaboration Products. Genentech shall have the sole right and responsibility to conduct and make decisions regarding Medical Affairs Activities with respect to any GDP Collaboration Product. For clarity, Genentech shall retain such sole right and responsibility in the event that BioNTech exercises its Co-Promotion Option, including under the Co-Promotion Agreement.

6.6.3 BioNTech Indications. For each BioNTech Indication under [***], BioNTech shall have the sole right and obligation to conduct Medical Affairs Activities in relation to such BioNTech Indication, at BioNTech's sole cost and expense.

ARTICLE 7.
MANUFACTURING

7.1 Manufacturing Development and Supply Agreement. That certain Manufacturing Development and Supply Agreement entered into by and among RNP, BNT, GNE and Roche as of even date herewith and effective as of the Effective Date (the “**Manufacturing Development and Supply Agreement**”) shall govern the Parties’ respective responsibilities for and obligations with respect to Development of the Manufacturing Process and Technology Platform for Collaboration Product, Clinical Manufacture and Commercial Manufacture and supply of Collaboration Product and the Manufacturing Network for Collaboration Product, including Clinical Facilities and Commercial Facilities and the Manufacturing Operations Strategy; all of which shall be conducted under the oversight of the JMC.

7.2 Conflicts Between MDSA and Current Agreement. In the event of a conflict between this Agreement and the MDSA, the following principles shall apply: (a) this Agreement controls with respect to governance, decision-making and financial matters, and (b) the MDSA governs with regard to matters not falling within the categories specified in clause (a).

7.3 Effect of Opt-Out. In the event BioNTech exercises its Opt-Out right, or a Deemed Opt-Out occurs pursuant to Section 8.5.3, the following provisions shall apply upon the Opt-Out Commencement Date in respect of Development of the Manufacturing Process and Technology Platform and Manufacture of Collaboration Product.

7.3.1 Development Services. During a transitional period until the earlier of (i) [***] and (ii) [***], BioNTech shall continue to (a) develop the Manufacturing Process and the Technology Platform in accordance with the Technology Platform Strategy and Technology Platform Roadmap, each as may be amended from time to time; (b) conduct and support respective Technology Transfers to the Facilities of Genentech and (c) provide technical support for the Manufacturing Process in the Facilities of Genentech. In addition, and without limiting the foregoing, Genentech may request that BioNTech (including EUFETS) perform, to the extent not already completed and to enable Genentech to continue to develop the Manufacturing Process and Technology Platform, a Technology Transfer of the Manufacturing Process from the Clinical Facilities or the Pilot Facility to Genentech, including the Development of the Manufacturing Process, Manufacturing Documentation and BioNTech Know-How and any other reasonable activities, including any such activities that may be on-going in support of the Technology Platform Strategy and Technology Platform Roadmap. The following shall apply in respect of any activities performed by BioNTech (including EUFETS) under this Section 7.3.1:

(a) Genentech shall compensate BioNTech for the performance of such Development and Technology Transfer services at a rate equal to BioNTech’s FTE Costs and consumables multiplied by one hundred fifteen percent (115%).

(b) Genentech may, at any time after the Opt-Out Commencement Date, terminate such Development and Technology Transfer services under this Section 7.3.1 upon [***] days’ written notice.

(c) BioNTech shall perform the Development and Technology Transfer services in accordance with the requirements of the MDSA and the Quality Agreement.

7.3.2 Clinical Manufacture and Supply. During a transitional period until the earlier of (i) [***] or (ii) [***], BioNTech shall perform Clinical Manufacture and supply the quantities of Collaboration Products for Clinical Studies contemplated by the GDP (as amended until the Opt-Out Commencement Date) or for Genentech Studies pursuant to the patient demand forecasting provisions of the MDSA. The following shall apply in respect of any activities performed by BioNTech (including EUFETS) under this Section 7.3.2:

(a) Genentech shall pay BioNTech a supply price for Collaboration Product equal to [***]

(b) Genentech may at any time after the Opt-Out Commencement Date, terminate the clinical supply of Collaboration Products under this Section 7.3.2 upon [***] written notice.

(c) During such time as BioNTech is obligated to provide clinical supply of Collaboration Products, it shall perform the Clinical Manufacture of Collaboration Product in accordance with the requirements of the MDSA (including for the avoidance of doubt with respect to Capacities and forecasting) and the Quality Agreement.

7.3.3 BioNTech Rights to Build Manufacturing Facilities and JMC Decision-Making Rights. BioNTech's rights to build any Commercial Facilities for inclusion in the Manufacturing Network pursuant to Section 2.2.2 of the MDSA and any Independent Facilities outside of the Manufacturing Network (including the Manufacture of BioNTech Indications under [***]) pursuant to Section 2.2.5 of the MDSA, respectively, shall terminate upon the Opt-Out Commencement Date. In addition, BioNTech's JMC decision-making rights as set forth in Section 2.8.2 shall terminate and become Genentech decision-making rights upon the Opt-Out Commencement Date. Notwithstanding the foregoing, in the event that BioNTech has completed Commissioning or obtained Licensure for a BioNTech Commercial Facility(ies) upon the Opt-Out Commencement Date, then [***]

7.3.4 Survival. The MDSA, the Commercial Manufacturing Agreement and the respective Quality Agreement(s) shall survive solely to the extent that, and as long as, BioNTech provides Development services or Manufacturing and supply services under this Section 7.3, and shall terminate thereafter except for those provisions specified in the MDSA, the Commercial Manufacturing Agreement and the respective Quality Agreement(s) which expressly survive termination.

ARTICLE 8. PAYMENTS AND RECORDS

8.1 Upfront Payments. No later than [***] days following the Effective Date, Genentech shall pay BioNTech an irrevocable upfront amount equal to [***] of which:

[***]

Upon completion of the transfer of all documents, Know-How and materials set forth on Schedule 2.19.1(a) and Schedule 2.19.3 in accordance with the terms of Sections 2.19.1(a) and 2.19.3, BioNTech shall provide written notice to Genentech of such completion. No later than [***] Business Days from such notice, Genentech shall request any missing or incomplete documents, Know-How or materials set forth on Schedule 2.19.1(a) or Schedule 2.19.3. Subject to Section 10.9, no later than [***] days following (a) Genentech's confirmation that such transfer is complete and the transferred items are reasonably acceptable to Genentech in terms of content that would be reasonably expected for a transfer of this type, or (b) the expiration of such [***] Business Day period without any Genentech request for missing or incomplete documents, Know-How or materials, Genentech shall pay BioNTech an additional amount equal to [***]. In the initial BioNTech press release permitted under Section 11.4.2, BioNTech may describe the two payments under this Section 8.1 as "\$310,000,000 in upfront and near term milestone payments". [***].

8.2 Development Costs.

8.2.1 Development Costs Relating to Ongoing Clinical Studies. BioNTech shall be solely responsible for and shall bear all Development Costs incurred by it and its Affiliates in connection with the performance of the Ongoing Clinical Studies and any Melanoma Follow-Up Study conducted pursuant to Section 4.3.2.

8.2.2 Development Costs Relating to Joint Development Activities (i.e., Shared Development Costs). Except as otherwise provided herein, each Party shall bear fifty percent (50%) of all Shared Development Costs.

(a) [***]

(b) [***]

(c) Genentech shall be solely responsible for and bear 100% of all Shared Development Costs incurred after the Opt-Out Commencement Date in the event of an Opt-Out by BioNTech or a Deemed Opt-Out pursuant to Section 8.5.3.

8.2.3 Forecasting of Development Costs.

(a) Genentech shall provide to BioNTech consolidated non-binding forecasts of Shared Development Costs in accordance with its regular internal forecasting processes for informational purposes only. This shall include forecasting of the GDP Budget for a given Calendar Year, regular variance updates to the then current Calendar Year forecast, and multi-year outlooks. The forecasting process shall commence with the first forecast cycle at Genentech following the Effective Date and shall continue as long as there are forecasted Shared Development Costs. Genentech shall provide notice to BioNTech [***] days prior to each forecast to request BioNTech's forecast of Shared Development Costs that BioNTech expects to incur in connection with Joint Development Activities assigned to BioNTech in accordance with the relevant forecast period. BioNTech will provide the appropriate data within [***] days of receipt of any such notice.

(b) In addition, BioNTech shall inform Genentech if it determines that the Development Costs relating to any BioNTech Study or any Ongoing Clinical Study which are expected to be incurred by BioNTech will likely exceed, in each case, the originally forecasted BioNTech budget by more than [***].

8.2.4 Shared Development Cost Overruns. [***]

8.2.5 Development Costs Relating to BioNTech Studies. BioNTech shall bear one hundred percent (100%) of all Development Costs incurred in connection with the performance of BioNTech Studies, subject to Section 4.5.5. In the event that Genentech incurs Development Costs in connection with a BioNTech Study, then such costs shall be reported to BioNTech within [***] days after the end of each Calendar Quarter and reimbursed by BioNTech with [***] days after the end of such Calendar Quarter, and Genentech may offset the amounts of any such unpaid invoices from any payments due to BioNTech pursuant to Sections 8.2.7, 8.4.1, and 8.7. The preceding sentence shall apply *mutatis mutandis* if BioNTech incurs Development Costs in connection with any Genentech Study.

8.2.6 Development Costs and Reconciliation. Each Party shall report to the other Party, within [***] days after the end of each Calendar Quarter, the Development Costs incurred by such Party during such Calendar Quarter for Joint Development Activities (unless the other Party has no obligation to reimburse such Development Costs). Such report shall specify in reasonable detail all amounts included in such Development Costs during such Calendar Quarter (broken down by activity), and any FTE Costs and out-of-pocket costs shall be allocated to the extent possible to a specific activity in the applicable GDP. Each such report shall enable the receiving Party to compare the reported Development Costs against the applicable GDP Budget previously approved by the JDC, on both a quarterly basis and a cumulative basis for each activity. With respect to Shared Development Costs under the GDP (other than those following the effective date of an Opt-Out by BioNTech), the Parties shall seek to resolve any questions related to such accounting statements within [***] days following receipt by each Party of the other Party's report hereunder. Following such resolution, Genentech shall prepare a reconciliation report for the Shared Development Costs under the GDP for such Calendar Quarter and shall either (a) deliver an invoice to BioNTech for any amounts due to Genentech as a result of reconciliation or (b) notify BioNTech that it should issue an invoice to Genentech, if BioNTech is assigned activities under the GDP and its Shared Development Costs under the GDP exceed Genentech's Shared Development Costs under the GDP for such Calendar Quarter.

8.2.7 Shared Development Cost Reconciliation Payments. Shared Development Costs shall initially be borne by the Party (or its Affiliates) incurring the cost or expense and thereafter shall be subject to reimbursement, if applicable, in accordance with Section 8.2.2, Section 8.2.6 and this Section 8.2.7. Within [***] days after the end of each Calendar Quarter, following receipt of an invoice therefor from the other Party, the Party that has paid less than its share of Shared Development Costs during such Calendar Quarter shall make a reconciling payment to the other Party to achieve the appropriate allocation of Shared Development Costs provided in Section 8.2.2.

8.3 BioNTech Indication Opt-In Fee; Genentech Indication Co-Funding Fee.

8.3.1 BioNTech Indication Opt-In Fee. Upon Genentech's exercise of its Opt-In Right or occurrence of a [***] with respect to a BioNTech Indication pursuant to Section 4.5.5, BioNTech shall submit a written invoice to Genentech for the BioNTech Indication Opt-In Fee which shall set forth in reasonable detail all Development Costs incurred by BioNTech prior to the date of the invoice for such BioNTech Indication. Genentech shall pay such invoice within [***] days following receipt thereof except in the event of a dispute regarding the invoiced amount, in which case the dispute shall be resolved pursuant to Sections 8.16 and 8.17, and Genentech shall pay such invoice within [***] days following the resolution of such dispute. The opt-in fee for a given BioNTech Indication shall be a one-time fee equal to [***] (such amount, a "**BioNTech Indication Opt-In Fee**"). Following Genentech's exercise of its Opt-In Right with respect to a BioNTech Indication, any future Development Costs for such Indication shall be considered Shared Development Costs and the applicable Collaboration Product shall thereafter be deemed a GDP Collaboration Product (and no longer a BioNTech Collaboration Product).

8.3.2 Genentech Indication Co-Funding Fee. In the event BioNTech is required pursuant to Section 4.6.2 to pay a Genentech Indication Co-Funding Fee, then Genentech shall submit a written invoice to BioNTech for such fee which shall set forth in reasonable detail all Development Costs incurred by Genentech prior to the date of the invoice for such Genentech Indication as to which BioNTech exercised the BioNTech Co-Funding Rejection plus [***] ("**Genentech Indication Co-Funding Fee**"). BioNTech shall pay such invoice within [***] days following receipt thereof except in the event of a dispute regarding the invoiced amount, in which case the dispute shall be resolved pursuant to Sections 8.16 and 8.17, and BioNTech shall pay such invoice within [***] days following the resolution of such dispute. After the date of such invoice, any future Development Costs for such Indication shall be considered Shared Development Costs.

8.4 Profit or Loss Share. Commencing as of the First Commercial Sale in the Territory of a GDP Collaboration Product, in the event that BioNTech has not exercised its Opt-Out pursuant to Section 8.5, the terms and conditions of this Section 8.4 shall govern each Party's rights and obligations with respect to Net Profits and Net Losses relating to GDP Collaboration Products. Subject to this Section 8.4, (a) BioNTech shall receive fifty percent (50%) of all Net Profits, and bear fifty percent (50%) of all Net Losses, as applicable, with respect to GDP Collaboration Products and (b) Genentech shall receive fifty percent (50%) of all Net Profits, and bear fifty percent (50%) of all Net Losses. An example of a calculation of Net Profit/Loss and related settlement calculations is set forth on Schedule 8.4. This example is for illustration only and reflects only one possible scenario.

8.4.1 Profit/Loss Split Reports and Payments. In the event that this Section 8.4 applies, each Party shall report to the other Party within [***] days after the end of each Calendar Quarter commencing with the Calendar Quarter in which the First Commercial Sale in the Territory of a GDP Collaboration Product occurs, the elements of the Net Profit/Net Loss calculation, including Net Sales and Allowable Expenses (including Fully-Burdened Manufacturing Cost) incurred by such Party during such Calendar Quarter.

Such report shall specify in reasonable detail all deductions allowed and taken in the calculation of Net Sales and all expenses included in Allowable Expenses. [***]. Within [***] days after receipt of such reports, Genentech shall provide a consolidated financial statement setting forth the Net Profit or Net Loss for the Calendar Quarter. The following remittances shall be paid within [***] days after Genentech has provided the consolidated financial statement:

(a) If there is a Net Profit for such Calendar Quarter, then Genentech shall pay to BioNTech an amount equal to (i) fifty percent (50%) of the Net Profit for such Calendar Quarter, plus (ii) the Allowable Expense, if any, incurred by BioNTech in such Calendar Quarter; or

(b) Subject to Section 8.4.1(d) below, if there is a Net Loss for such Calendar Quarter, then the Party that has borne less than fifty percent (50%) of the Net Losses in such Calendar Quarter shall make a reconciling payment to the other Party so that each Party bears a fifty percent (50%) share of the Net Losses during such Calendar Quarter.

(c) [***]

(d) [***]

(e) [***]

8.4.2 FTE Records and Calculations. Each Party shall record and account for its FTE effort to the extent that such FTE efforts are included in Development Costs or Allowable Expenses that are, or may in the future be, shared (or the basis for determining a BioNTech Indication Opt-In Fee or a Genentech Indication Co-Funding Fee) under this Agreement. Each Party shall calculate and maintain records of FTE effort incurred by it in the same manner as used for other products Developed by such Party, unless other procedures are set forth in the Co-Promotion Agreement, in which case such other procedures shall be applied equally to both Parties to the extent set forth in the Co-Promotion Agreement.

8.5 BioNTech Opt-Out Right.

8.5.1 Exercise of Opt-Out by BioNTech. During the BioNTech Opt-Out Period, by written notice to Genentech, BioNTech shall have the right to opt-out of its obligation to pay fifty percent (50%) of all future Shared Development Costs (“**Opt-Out**”) incurred after the Opt-Out commencement date set forth in the table below, or such later date in the table below as may be specified in BioNTech’s notice (“**Opt-Out Commencement Date**”). In no event shall BioNTech shall have the right to Opt-Out if a notice of termination of this Agreement has been delivered by either Party. For clarity, BioNTech shall continue to co-fund the GDP during the period between the exercise of its Opt-Out and the Opt-Out Commencement Date.

[***]

8.5.2 Consequences of Opt-Out. In the event BioNTech exercises its Opt-Out (or a Deemed Opt-Out occurs pursuant to Section 8.5.3), then starting with the Opt-Out Commencement Date, (a) Net Profits/Net Losses shall no longer be shared by the Parties pursuant to Section 8.4, and (b) Shared Development Costs shall no longer be shared by the Parties pursuant to Section 8.2.2, Section 8.2.6 and Section 8.2.7. Instead, BioNTech shall receive as its sole future financial consideration, royalty payments on Net Sales of Royalty Products pursuant to Section 8.6. In addition, effective as of the Opt-Out Commencement Date, the consequences set forth in Sections 2.18, 6.5.5 and 7.3 shall become effective immediately, and BioNTech shall become solely responsible for any Existing Third Party In-License Agreement Royalty Payments, and, unless otherwise agreed in writing between the Parties, BioNTech shall cease all its activities under the Research Plan and all its Party Development Activities (to the extent permitted by Applicable Law) and transfer to Genentech all data and other Know-How created in connection with the Party Development Activities and activities under the Research Plan or the CMC Development Plan in BioNTech's possession and not previously transferred to Genentech pursuant to Section 2.19.

8.5.3 Deemed Opt-Out. At any time during the Term, if BioNTech is either (i) unable to pay or is late in paying (by [***] days or more with respect to any invoice) BioNTech's portion of its Development Costs shared under Section 8.2.2 [***], Genentech may provide BioNTech with written notice that an Opt-Out by BioNTech has been deemed to have occurred ("**Deemed Opt-Out**"), which notice shall state the applicable Opt-Out Commencement Date, which shall be the first day of the Calendar Quarter following such default in payment.

8.6 Royalties.

8.6.1 Royalty Rates. In lieu of sharing Net Profit/Net Loss, in the event of an Opt-Out by BioNTech pursuant to Section 8.5 or a Deemed Opt-Out pursuant to Section 8.5.3, during the Royalty Term, and subject to Section 8.6.3, Genentech shall pay to BioNTech [***] (the "**Royalty Rate**") on annual worldwide Net Sales of each Royalty Product which, at the time of sale, is Covered by a Valid Claim included in the [***]

8.6.2 Royalty Term. Genentech shall have no obligation to pay any royalty with respect to Net Sales of any Royalty Product in any country after the Royalty Term for such Royalty Product in such country has expired. Upon expiry of Genentech's payment obligation under this Section 8.6 with respect to a Royalty Product in a country, the license in Section 9.1.1 shall be fully paid-up, royalty-free and irrevocable in respect of that Royalty Product in that country.

8.6.3 Reductions. Notwithstanding the foregoing:

(a) in the event that [***] during the Royalty Term for a Royalty Product, one or more Competitive Products are sold [***], then the Royalty Rate applicable to Net Sales of Royalty Products [***] shall be reduced to [***] for the remainder of the Royalty Term, [***];

(b) in the event that Genentech obtains rights or licenses from a Third Party under Third Party IP pursuant to Section 10.6, Genentech shall be entitled to deduct [***];

(c) [***]; and

(d) at Genentech's election, Genentech shall have the right to offset from future royalties under this Section 8.6 any unpaid deferred Development Costs that have come due under Section 8.2.2.

8.7 Royalty Payments and Reports. Genentech shall calculate all amounts payable to BioNTech pursuant to Section 8.6 at the end of each Calendar Quarter, which amounts shall be converted to Dollars, in accordance with Section 8.9. Genentech shall pay to BioNTech the royalty amounts due with respect to a given Calendar Quarter within [***] days after the end of such Calendar Quarter. Each payment of royalties due to BioNTech shall be accompanied by a statement of the amount of Net Sales of each Royalty Product in the Territory during the applicable Calendar Quarter converted to Dollars and a calculation of the amount of royalty payment due on such Net Sales for such Calendar Quarter. Without limiting the generality of the foregoing, Genentech shall require its Affiliates and Sublicensees to account for their Net Sales and to provide such reports with respect thereto as if such sales were made by Genentech.

8.8 Apportionment of Compulsory Sublicensee Consideration.

[***].

8.9 Mode of Payment; Offsets. All payments to either Party under this Agreement shall be made by deposit of Dollars in the requisite amount to such bank account as the receiving Party may from time to time designate by notice to the paying Party. As of the Execution Date, that applicable bank account for payments to each Party is set forth in Schedule 8.9. For the purpose of calculating any sums due under, or otherwise reimbursable pursuant to, this Agreement (including the calculation of Net Sales expressed in currencies other than Dollars), a Party shall convert any amount expressed in a foreign currency into Dollar equivalents using the then-current internal foreign currency translation method actually used by such Party on a consistent basis in preparing its audited financial statements. Either Party shall have the right to offset any expense that is owed by the other Party but not paid against any payments owed by either Party, if any, under this Agreement.

8.10 Accounting Procedures. For purposes of determining Development Costs and Allowable Expenses, any expense allocated by either Party to a particular expense category of Development Costs or Allowable Expenses shall not also be allocated to another category under Development Costs or Allowable Expenses. Each Party shall determine Development Costs and Allowable Expenses using its standard accounting procedures, consistently applied, to the maximum extent practicable as if the Collaboration Product were a solely-owned product of the Party (provided that the application of such procedures results, on balance, in outcomes that are fair and equitable to both Parties taking into consideration the interests of both Parties as reflected in this Agreement). The Parties also recognize that such procedures may change from time to time and that any such changes may affect the calculation of Development Costs, Allowable Expenses, and such other expenses. Where the change is or would be material to the other Party, the Party proposing to make the change shall provide the other Party with an explanation of the proposed change and an estimation of the effect of the change on the relevant cost or expense category. The Parties shall use good faith efforts to negotiate any resulting changes to this Agreement so as to preserve as closely as reasonably possible the Parties' respective economic interests under this Agreement. Transfers between a Party and its Affiliates (or between such Affiliates) shall not have any effect for purposes of calculating Development Costs, Allowable Expenses, or other payments or expenses under this Agreement.

8.11 Taxes.

8.11.1 Each Party will make all payments to the other Party under this Agreement without deduction or withholding for Taxes except to the extent that any such deduction or withholding is required by law in effect at the time of payment.

8.11.2 Any Tax required to be withheld on amounts payable under this Agreement will promptly be paid by the Party making the payment (the "Payor") on behalf of the Party receiving the payment (the "Payee") to the appropriate Governmental Authority, and Payor will furnish Payee with proof of payment of such Tax.

8.11.3 Each Party agrees to use commercially reasonable efforts to assist the other Party in claiming exemption from such deductions or withholdings under double taxation or any similar agreement or treaty from time to time in force and in minimizing the amount required to be so withheld or deducted.

8.11.4 All amounts payable under or provided for in this Agreement shall be exclusive of any amount in respect of VAT. If VAT is applicable on any amount payable under this Agreement and the reverse charge procedure does not apply, then the Payor shall pay an additional amount equal to VAT on that amount; provided it has first received a valid invoice for the supply, save when the reverse charge procedure applies. Valid invoices must include all relevant information as stated in any applicable guideline or as defined by other local rules and regulations as the case may be.

8.11.5 To the extent the activities of the Parties under this Agreement result in the recognition of a partnership for non-U.S. Tax purposes, the Parties agree that any non-U.S. Tax imposed at the level of the partnership on its profit (not including Tax required to be withheld to satisfy a Party's own income tax obligation) shall be allocated and borne by the Parties according to the partnership profit allocation under the respective applicable tax law.

8.11.6 In the event of a conflict between this Agreement and any Ancillary Agreement, this Agreement shall control with respect to Tax matters. Solely for purposes of this Section 8.11, “**Tax**” or “**Taxes**” means any present or future taxes, levies, imposts duties, charges, assessments or fees of any nature (including interest, penalties and additions thereto).

8.12 Interest on Late Payments. If any payment due to either Party under this Agreement is not paid when due, then such paying Party shall pay interest thereon (before and after any judgment) at an annual rate (but with interest accruing on a daily basis) of [***], such interest to run from the date on which payment of such sum became due until payment thereof in full together with such interest.

8.13 Tax Returns.

[***]

8.14 Financial Records. Each Party shall, and shall cause its Affiliates to, keep complete and accurate books and records pertaining to Development Costs, Net Sales, Fully-Burdened Manufacturing Costs, Allowable Expenses and, with limiting the foregoing, elements in the calculation of Net Profits/Net Losses, as applicable, and Development of Collaboration Products in sufficient detail to calculate all amounts payable hereunder and to verify compliance with its obligations under this Agreement. Such books and records shall be retained by such Party and its Affiliates until the later of (a) [***] after the end of the period to which such books and records pertain, and (b) the expiration of the applicable tax statute of limitations (or any extensions thereof), or for such longer period as may be required by Applicable Law.

8.15 Invoices. Each invoice issued pursuant to this Article 8 shall refer to this Agreement and identify the trigger for the payment obligation. Unless otherwise requested by Genentech in writing, BioNTech shall send invoices to Genentech at the address for GNE in the preamble of this Agreement, to the attention of [***]. With respect to invoices issued by Genentech, Genentech shall send invoices to BioNTech at:

Biontech RNA Pharmaceuticals GmbH
Attn: [***]
An der Goldgrube 12
55131 Mainz, Germany.

8.16 Audit. At the request of the other Party, each Party shall, and shall cause its Affiliates to, permit an independent auditor designated by the other Party and reasonably acceptable to the audited Party, at reasonable times and upon reasonable notice, to audit the books and records maintained pursuant to Section 8.14 to ensure the accuracy of all reports and payments made hereunder. Such examinations may not (a) be conducted for any Calendar Quarter more than [***] after the end of such quarter, (b) [***] or (c) [***]. Except as provided below, the cost of this audit shall be borne by the auditing Party, unless the audit reveals a variance of more than [***] from the reported amounts, in which case the audited Party shall bear the cost of the audit. Unless disputed pursuant to Section 8.17 below, if such audit concludes that (i) additional amounts were owed by the audited Party, the audited Party shall pay the additional amounts, with interest from the date originally due as provided in Section 8.12, or (ii) excess payments were made by the audited Party, the auditing Party shall reimburse such excess payments, in either case ((i) or (ii)), within [***] days after the date on which such audit is completed by the auditing Party.

8.17 Audit Dispute. In the event of a dispute with respect to any audit under Section 8.16, BioNTech and Genentech shall work in good faith to resolve the disagreement. If the Parties are unable to reach a mutually acceptable resolution of any such dispute within [***] days, either Party may submit the dispute for resolution to a certified public accounting firm jointly selected by each Party's certified public accountants or to such other Person as the Parties shall mutually agree (the "**Arbitrator**"). The decision of the Arbitrator shall be final and the costs of such arbitration as well as the initial audit shall be borne between the Parties in such manner as the Arbitrator shall determine. Not later than [***] days after such decision and in accordance with such decision, the audited Party shall pay the additional amounts, with interest from the date originally due as provided in Section 8.12, or the auditing Party shall reimburse the excess payments, as applicable.

8.18 Confidentiality. The receiving Party shall treat all information subject to review under this Article 8 in accordance with the confidentiality provisions of Article 11 and the Parties shall cause the Arbitrator to enter into a reasonably acceptable confidentiality agreement with the audited Party obligating such firm to retain all such financial information in confidence pursuant to such confidentiality agreement.

ARTICLE 9. GRANT OF RIGHTS

9.1 Licenses to Genentech.

9.1.1 Exclusive License. BioNTech hereby grants to Genentech an exclusive (subject to [***], non-transferable (other than in connection with a permitted assignment of this Agreement), sublicensable (only in accordance with Section 9.3) license, under the BioNTech IP (including the Know-How and Patents related to the Manufacturing Process which includes the IVAC 2.0 Process, the IVAC 2.1 Process, any IVAC x.y Process and the Commercial Manufacturing Process) and BioNTech's interest in the Collaboration IP (subject in the case of [***] subject to [***], to (a) research, develop, make, have made, use, offer for sale, sell and import Pharmaceutical Products that comprise (i) one or more Neoepitope RNA(s), [***] in the Field in the Territory and (b) otherwise perform its obligations under this Agreement and the Ancillary Agreements, *provided that* [***]

9.1.2 Non-Exclusive License. [***]

9.1.3 No License. Notwithstanding the license granted in Section 9.1.1, nothing in this Agreement shall be deemed to grant to Genentech any license or other rights under the BioNTech IP to [***]

9.1.4 Notice Rights. [***]**9.2 Licenses to BioNTech.****9.2.1 License; Grant Back License.**

(a) Genentech hereby grants to BioNTech an exclusive (subject to Genentech's rights under Section 4.5.5 and Genentech's obligations under MDSA), non-transferable (other than in connection with a permitted assignment of this Agreement), sublicensable (only in accordance with Section 9.3) license, under the Genentech IP, the BioNTech IP (to the extent exclusively licensed to Genentech under Section 9.1.1) and Genentech's interest in the Collaboration IP (to the extent exclusively licensed to Genentech under Section 9.1.1) (in the case of Collaboration Product Clinical Study Data, subject to Section 11.6), to (a) research, develop, make, have made, use, and import BioNTech Collaboration Products solely in connection with the Conduct of the BioNTech Studies and (b) Conduct the Ongoing Clinical Studies in accordance with Section 4.3.1 and any related follow-up clinical study to the extent permitted under and in accordance with Section 4.3.2; provided that, [***].

(b) Genentech hereby grants to BioNTech a non-exclusive, non-transferable (other than in connection with a permitted assignment of this Agreement), sublicensable (only in accordance with Section 9.3) license, under the Genentech IP (excluding any Neoepitope Prediction Algorithm within the Genentech IP which is the subject of the license set forth in Section 9.2.2), the BioNTech IP (to the extent licensed to Genentech under Section 9.1.1) and the Collaboration IP (but in the case of Collaboration Product Clinical Study Data, subject to Section 11.6) (i) to perform its obligations under this Agreement and the Ancillary Agreements (including any Co-Promotion Agreement) and (ii) to construct and use Commercial Facilities as set forth in Section 2.2.4 of the MDSA.

(c) Subject to, and effective only upon expiration of, Genentech's Opt-In Rights and [***] pursuant to Section 4.5.5, Genentech hereby grants to BioNTech an exclusive, non-transferable (other than in connection with a permitted assignment of this Agreement), sublicensable (only in accordance with Section 9.3) license, under the Genentech IP, the BioNTech IP (to the extent exclusively licensed to Genentech under Section 9.1.1) and Genentech's interest in the Collaboration IP (to the extent exclusively licensed to Genentech under Section 9.1.1) (in the case of Collaboration Product Clinical Study Data, subject to Section 11.6), to offer for sale, sell or import BioNTech Collaboration Products.

9.2.2 Non-Exclusive License. [***].

9.2.3 No License. Notwithstanding the licenses granted in Section 9.2.1, nothing in this Agreement shall be deemed to grant to BioNTech any license or other rights under the Genentech IP to [***].

9.3 Sublicenses; Exercise of Licensed Rights by Third Parties or Affiliates. Either Party may sublicense the rights under the licenses granted to it under Sections 9.1.1, 9.2.1, 9.4 and 9.5 to its permitted subcontractors hereunder (subject to Sections 3.2 and 4.4.4) or under any Ancillary Agreement (or in the case of Genentech, [***] without the other Party's consent, provided that such Party (1) shall remain directly responsible for all of its obligations under this Agreement that have been, so subcontracted or sublicensed and (2) shall ensure that such subcontractors and sublicensees comply with the terms and conditions of this Agreement, including the intellectual property provisions and confidentiality provisions of this Agreement. Subject to Sections 3.2 and 4.4.4, the rights under the licenses granted in Sections 9.1.1 and 9.1.2 and Sections 9.2.1 and 9.2.2 may be exercised by a Third Party on behalf of a Party (or a permitted sublicensee) without the grant of a sublicense of such rights. Either Party may exercise its rights and perform its obligations under this Agreement by itself or through the engagement of any of its Affiliates. Any other sublicensing under Section 9.1.1 or 9.2.1 shall require the other Party's prior written consent. For the avoidance of doubt, any sublicenses granted hereunder shall terminate automatically upon the termination of the relevant main license granted hereunder. As between the sublicensing Party and its Sublicensee, any intellectual property made as a result of the performance of such activities by such Sublicensee shall be Controlled by the sublicensing Party. In the event that such intellectual property would, if it were made by a Party, be Collaboration IP, then such intellectual property shall be Collaboration IP. In the event that such intellectual property would, if it were made by a Party, be BioNTech IP or Genentech IP, then such intellectual property is hereby licensed to the other Party subject to Section 9.1 or 9.2, as applicable.

9.4 Trademark and Corporate Names Licenses. BioNTech hereby grants to Genentech a worldwide, fully-paid, non-exclusive license, with the right to grant sublicenses solely as provided in Section 9.3 and subject to Section 10.7.1, to use the Corporate Names of BioNTech, solely in connection with the exercise of Genentech's rights and fulfillment of Genentech's obligations under Section 6.4. BioNTech hereby grants to Genentech a worldwide, fully-paid, exclusive license, with the right to grant sublicenses solely as provided in Section 9.3, and subject to Section 10.7, to use the IVAC Trademark as a Product Trademark in connection with the exercise of Genentech's rights and obligations under this Agreement if Genentech sees fit to also use the IVAC Trademark as a Product Trademark. In the event that the Parties enter into a Co-Promotion Agreement, Genentech shall grant to BioNTech a non-exclusive license to use the Corporate Names of Genentech and any Product Trademarks in connection with BioNTech's activities under such agreement.

9.5 Rights of Reference or Use.

9.5.1 In the event that BioNTech [***] pursuant to Sections 4.5 and 5.3, effective as of the date of filing, Genentech hereby grants (and shall cause its Affiliates and Sublicensees under the license granted in Section 9.1.1 to grant) to BioNTech during the Term a non-exclusive, non-transferable (other than in connection with a permitted assignment of this Agreement but not in connection with a Change in Control except as otherwise provided in Section 15.2) Right of Reference or Use (with the right to grant further rights of reference to Affiliates, Sublicensees and any exclusive distributor in any country in which BioNTech uses an exclusive distributor for its products) to [***]. Genentech will provide a letter to FDA or the applicable Regulatory Authority confirming such Right of Reference or Use in support of a [***]. For clarity, notwithstanding any grant to BioNTech of a Right of Reference or Use pursuant to this Section 9.5, BioNTech shall have no rights to any Genentech Molecule Clinical Trial Data, any Genentech IP (except as licensed pursuant to Section 9.2) or any other intellectual property Controlled by Genentech or any of its Affiliates or sublicensees.

9.5.2 BioNTech hereby grants (and shall cause its Affiliates and Sublicensees under the license granted in Section 9.2.1 to grant) to Genentech during the Term a non-exclusive, non-transferable Right of Reference or Use to [***]. BioNTech will provide a letter to FDA or the applicable Regulatory Authority confirming such Right of Reference or Use in support of a Genentech IND or Genentech Marketing Authorization. For clarity, notwithstanding any grant to Genentech of a Right of Reference or Use pursuant to this Section 9.5, Genentech shall have no rights to any Clinical Data or other intellectual property, in both cases, that is solely related to any Combination Agent Controlled by BioNTech or any of its Affiliates or sublicensees.

9.6 Genentech Rights of First Negotiation. Genentech shall have rights to engage in exclusive negotiations with BioNTech and certain other related rights as set forth in this Section 9.6.

9.6.1 [***]

9.6.2 [***]

9.6.3 ROFN Procedures. “ROFN Licensable Subject Matter” means each combination of products under Section 9.6.1 or each [***] under Section 9.6.2, as with respect to which Genentech has a right of first negotiation under such Section. “ROFN” means, with respect to each ROFN Licensable Subject Matter, Genentech’s right to engage in exclusive negotiations for such ROFN Licensable Subject Matter before BioNTech licenses, grants, or otherwise transfers, including by option or sale, to any Third Party any rights to develop manufacture, commercialize, make, have made, use, offer for sale, sell and import (or any exclusive rights to research), in whole or in part, such ROFN Licensable Subject Matter in the Field in the Territory as set forth in this Section 9.6.

(a) **Notice.** At any time during the Term (with respect to ROFN Licensable Subject Matter under Section 9.6.1) prior to [***] or at any time during the Term prior to the [***] (with respect to ROFN Licensable Subject Matter under Section 9.6.2), in the event that BioNTech intends to license, grant, or otherwise transfer, including by option or sale, to any Third Party any rights to develop, manufacture, commercialize, make, have made, use, offer for sale, sell and import (or any exclusive rights to research), in whole or in part, any ROFN Licensable Subject Matter, BioNTech shall so notify Genentech in writing and [***] “ROFN Notice”).

(b) **ROFN Exercise.** Genentech may exercise a ROFN with respect to a ROFN Licensable Subject Matter by providing written notice to BioNTech (a “**ROFN Election Notice**”) at any time during the period commencing on the first date on which Genentech has received the ROFN Notice and ending [***] days thereafter (the “**ROFN Exercise Period**”) with respect to such ROFN.

(c) **ROFN License Agreement.** If Genentech exercises a ROFN with respect to a ROFN Licensable Subject Matter during the ROFN Exercise Period, then during the period beginning on the date Genentech provides the ROFN Election Notice to BioNTech and ending [***] thereafter (or such later date as may be mutually agreed by the Parties) (the “**ROFN Negotiation Period**”), the Parties shall negotiate in good faith the terms and conditions of an agreement pursuant to which Genentech or an Affiliate of Genentech would obtain the exclusive rights to develop, manufacture, commercialize, make, have made, use, offer for sale, sell and import (and the non-exclusive right to research) such ROFN Licensable Subject Matter in the Field in the Territory (a “**ROFN License Agreement**”).

(d) **Genentech Failure to Exercise.** If (i) Genentech does not deliver a ROFN Election Notice to BioNTech with respect to the applicable ROFN Licensable Subject Matter during the applicable ROFN Exercise Period or (ii) Genentech and BioNTech do not agree on the terms of a ROFN License Agreement despite good faith negotiations with respect to the applicable ROFN Licensable Subject Matter during the applicable ROFN Negotiation Period, then, in either case (i) or (ii), BioNTech shall be free to grant to a Third Party rights to research, develop, manufacture, commercialize, make, have made, use, offer for sale, sell and import, in whole or in part, such ROFN Licensable Subject Matter in the Field in the Territory; *provided that*, in the case of (ii) above, during the [***], BioNTech shall not grant to a Third Party rights to research, develop, manufacture, commercialize, make, have made, use, offer for sale, sell and import, in whole or in part, such ROFN Licensable Subject Matter in the Field in the Territory on terms and conditions [***]

9.7 Exclusivity. For a period of [***] years after the Effective Date (such period, the “**Exclusivity Period**”), none of (a) [***], and (b) BioNTech and its Affiliates shall carry out, conduct or engage in any activity, by itself or with or through any Third Party, directly or indirectly, to research, develop, manufacture, commercialize, make, have made, use, offer for sale, sell and import any Pharmaceutical Products comprising one or more Neoepitope RNA(s) in the Field other than pursuant to and in accordance with this Agreement; *provided, however* that such restriction does not restrict any of the foregoing Persons from conducting internal research and preclinical development for benchmarking purposes on Pharmaceutical Products comprising one or more Neoepitope RNA(s) that are Third Party Products at the time of such research or preclinical development. [***]

ARTICLE 10.
INTELLECTUAL PROPERTY

10.1 Disclosure. During the Term, without limiting Section 2.19.2, each Party shall promptly disclose to the other Party [***]

10.2 Ownership; Assignment and Cooperation; Inventorship.

10.2.1 Ownership of Intellectual Property. As between the Parties:

- (a) BNT or RNP (as applicable) shall solely own the BioNTech IP,
- (b) [***]
- (c) [***]

10.2.2 Assignment and Cooperation. The assignments necessary to accomplish the ownership provisions set forth in this Article 10 are hereby made, and each Party shall execute such further documentation as may be necessary or appropriate, and provide reasonable assistance and cooperation to implement the provisions of this Article 10. Accordingly, each Party (“**Assignor**”) hereby irrevocably assigns to the other Party (“**Assignee**”) an equal, undivided interest in and to all right, title, and interest in and to Collaboration IP. Assignor agrees to execute such documents, render such assistance, and take such other action as an Assignee may reasonably request, to apply for, register, perfect, confirm, and protect Assignee’s rights in all Collaboration IP. Each Party shall require, to the extent legally possible under relevant national or local laws, all of its employees, Affiliates and any Third Parties working pursuant to this Agreement on its behalf, to assign (or otherwise convey rights) to such Party its right, title and interests in any Patents and Know-How conceived, reduced to practice, created or otherwise made by such employee, Affiliate or Third Party, and to cooperate with such Party in connection with obtaining patent protection therefor.

10.2.3 Inventorship and Authorship. Inventorship and authorship shall be determined in accordance with the Applicable Laws of the United States regarding patents and copyrights, respectively; *provided*, however, that in the event that determining inventorship or authorship in accordance with such Applicable Laws would be in violation of the Applicable Laws of the country or jurisdiction in which such invention or creation was made or created, inventorship or authorship, as applicable, shall be determined in accordance with the Applicable Laws of such country or jurisdiction.

10.2.4 CREATE Act. This Agreement shall be deemed a joint research agreement under the Cooperative Research and Technology Enhancement Act of 2004, 35 U.S.C. §102(c) (the “**CREATE Act**”), and any foreign counterparts thereto, entered into for the purpose of researching, identifying and developing products comprising one or more Neoepitope RNA(s) including Collaboration Products and under the terms set forth herein.

10.3 Patent Prosecution and Maintenance.**10.3.1 Patent Prosecution and Maintenance Control.** As between the Parties:

[***]

10.3.2 Patent Prosecution and Maintenance Cooperation. Solely with respect to the rights and obligations described in this Section 10.3, the Party that has the right to Prosecute and Maintain the BioNTech Patents, BioNTech Core Patents, Genentech Patents, Genentech Core Patents or Collaboration Patents, as applicable, will be referred to as the “**Controlling Party**” and the other Party will be referred to as the “**Non-Controlling Party**”. During the Term, the Parties agree to cooperate fully in the preparation, filing, prosecution, and maintenance of the BioNTech Patents, BioNTech Core Patents, Genentech Patents, Genentech Core Patents and Collaboration Patents in the Territory. Notwithstanding which Party is the Controlling Party, the Parties shall agree, on a country by country basis, on preferably the same outside patent counsel firms to be responsible for the Prosecution and Maintenance of the BioNTech Core Patents, Genentech Core Patents and Collaboration Patents on behalf of each Party as the Controlling Party (each, an “**Outside Patent Prosecution Counsel**”); [***] Cooperation shall include:

(a) The Non-Controlling Party shall, at the Controlling Party’s reasonable request, assist and cooperate in the Prosecution and Maintenance of the BioNTech Patents, BioNTech Core Patents, Genentech Patents, Genentech Core Patents or Collaboration Patents, including making its relevant scientists and scientific records reasonably available to the Controlling Party, executing all papers and instruments (including assignment of invention agreements and powers of attorney) and requiring its employees or contractors to execute such papers and instruments.

(b) [***]

(c) [***]

(d) [***]

10.4 [*]**

10.5 Enforcement and Defense of Patents; Defense of Claims by Third Parties .

10.5.1 Notice. Each Party shall promptly notify, in writing, the other Party upon learning of:

(a) any actual, alleged, or suspected infringement, misappropriation or misuse by a Third Party of a BioNTech Core Patent, Genentech Core Patent, Collaboration Patent or any Know-How or Patent related to the Neoepitope Prediction Algorithm (within the BioNTech IP, Genentech IP or Collaboration IP) or any reexaminations, inter partes reviews, and post grant reviews as well as interferences and derivation proceedings, oppositions and other similar proceedings or claim of declaratory judgment brought by a Third Party alleging the invalidity, unpatentability, unenforceability, or non-infringement of any such BioNTech Core Patent, Genentech Core Patent or Collaboration Patent (including receipt of a copy or knowledge of a Biosimilar Application under Section 351(l)(1)(B)(iii) or Section 351(l)(8)(A) of the PHSA (or other Applicable Law in the relevant jurisdiction) or alleging misappropriation or misuse of any Know-How or Patent related to the Neoepitope Prediction Algorithm (within the BioNTech IP, Genentech IP or Collaboration IP)) (each an “**Infringement**”), and

(b) any notice, allegation, suit, or other proceeding against BioNTech or Genentech, or any of their respective Affiliates or licensees or customers, of infringement, misappropriation or misuse of any intellectual property rights as a result of the Exploitation of any Collaboration Product or any Neoepitope Prediction Algorithm (“**Third Party Infringement Claim**”).

In each case ((a) or (b)), the Party providing notice shall promptly notify the other Party and use commercially reasonable efforts to provide all evidence in its possession pertaining to the Infringement, claim or suit that it can disclose without breach of pre-existing obligations to a Third Party or waiver of privilege. [***]

10.5.2 Enforcement and Defense Actions Against Infringements.

(a) [***]

(b) [***]

(c) [***]

(d) [***] Collaboration Patents in the Territory or to Enforce against any misappropriation or misuse of any Know-How or Patent related to the Neoepitope Prediction Algorithm within the Collaboration IP (including any Genentech IP or BioNTech IP (other than BioNTech Core Patents) incorporated therein). If Genentech declines to Enforce against an Infringement that constitutes a substantial risk to the overall value of such Collaboration Patent in the applicable country within the Territory or any misappropriation or misuse of any Know-How or Patent related to the Neoepitope Prediction Algorithm within the Collaboration IP, then: (i) Genentech shall provide BioNTech with reasonable advanced written notice of such decision [***]

10.5.3 Third Party Infringement Defense Actions. Notwithstanding Section 13.5, for any Third Party Infringement Claim, Genentech (with respect to any Third Party Infringement Claim as to (a) GDP Collaboration Product(s) or Genentech Collaboration Product(s) alone, (b) at least one GDP Collaboration Product or Genentech Collaboration Product, on the one hand, and at least one BioNTech Collaboration Product, on the other hand, or (c) as to any Know-How or Patent related to the Neoepitope Prediction Algorithm within the Collaboration IP (including any Genentech IP or BioNTech IP incorporated therein) and BioNTech (with respect to any Third Party Infringement Claim that does not include any GDP Collaboration Product or Genentech Collaboration Product but includes a BioNTech Collaboration Product) shall have the right, but not the obligation, to defend and control the defense of any such Third Party Infringement Claim, including directing all aspects, stages, motions, and proceedings of litigation (“**Defend**” or “**Defense**”). In the event the Party with the right to defend against a Third Party Infringement Claim under this Section 10.5.3 does not elect to assume the defense of such Third Party Infringement Claim (“**Non-Defending Party**”) and the other Party (“**Defending Party**”) has the obligation to assume the defense of such Third Party Infringement Claim under Section 13.5 or the other Party is the defendant against which the Third Party Infringement Claim was made, then the Non-Defending Party shall provide to the Defending Party with reasonable advanced written notice of such decision so as to permit the Defending Party to take appropriate action in accordance with this Agreement, [***]

10.5.4 Cooperation. Solely with respect to the rights and obligations described in this Section 10.4, the Party that has the right to Enforce against the Infringement or Defend against the Third Party Infringement Claim, will be referred to as the “**Controlling Litigation Party**” and the other Party will be referred to as the “**Non-Controlling Litigation Party**”. Notwithstanding which Party is the Controlling Litigation Party, the Parties shall agree on an outside patent counsel firm to be responsible for the Enforcement against an Infringement and Defense of a Third Party Infringement Claim on behalf of the Controlling Litigation Party (“**Outside Patent Litigation Counsel**”). Cooperation shall include:

(a) The Non-Controlling Litigation Party shall cooperate with the Controlling Litigation Party in any such action to Enforce against any Infringement or Defend against any Third Party Infringement Claim or raising of any counter claim in connection with the Enforcement or Defense as described in this Section 10.4, including, if necessary, by being joined as a party, provided the Non-Controlling Litigation Party shall have the right to be represented by their own counsel at their own expense (notwithstanding any other cost allocation provision of this Agreement). The Outside Patent Litigation Counsel shall lead the Enforcement against the Infringement or Defense against the Third Party Infringement Claim with respect to any other counsel participation in the Enforcement or Defense.

(b) The Controlling Litigation Party shall, through Outside Patent Litigation Counsel, keep the other Party reasonably informed of all material developments in connection with any such Infringement or Third Party Infringement Claim, including providing the other Party with copies of draft and filed filings, motions, pleadings and other material submissions and communications (including oral communications) with the relevant judicial authority relating to such Infringement or Third Party Infringement Claim, sufficiently in advance, where reasonable, for the Non-Controlling Litigation Party to comment, through Outside Patent Litigation Counsel, on the Enforcement against or Defense of such Infringement or Third Party Infringement Claim. The Controlling Litigation Party shall give due consideration to the Non-Controlling Litigation Party's comments with respect to the Enforcement against or Defense of such Infringement or Third Party Infringement Claim under this Section 10.4. Notwithstanding the foregoing, BioNTech shall Enforce against or Defend of such Infringement or Third Party Infringement Claim consistent with Genentech's comments as required under this Section 10.4.

(c) **Settlement.** The Controlling Litigation Party shall, at its sole discretion, have the right to settle such claim; provided that the Controlling Litigation Party may not settle or consent to an adverse judgment without the expressed written consent of the Non-Controlling Party (such consent not to be unreasonably withheld or delayed).

(d) **Third Party Payments.** [***]

(e) **Recoveries.** Any recovery realized as a result of any action described in this Section 10.4 (whether by way of settlement or otherwise) shall be [***]

10.6 Third Party Licenses. Existing Third Party In-License Agreement Royalty Payments for any GDP Collaboration Product shall be shared equally by the Parties as an "Allowable Expense" in the Net Profit/Net Loss calculation pursuant to Section 8.4 or in the case of a Royalty Product, shall be borne solely by BioNTech in accordance with the terms and conditions of this Agreement, including Section 12.2.2(d). For all other payments or other consideration payable to any Third Party for rights or licenses under BioNTech IP or Genentech IP or intellectual property rights that are reasonably necessary for the Exploitation of any Collaboration Product, the following shall apply:

10.6.1 BioNTech IP. BioNTech shall be responsible for and bear the following:

(a) all costs for any payments or other consideration payable to any Third Party (i) for the rights and licenses (including the right to grant sublicenses) under the BioNTech IP as such BioNTech IP exists as of the Effective Date; (ii) for the rights and licenses (including the right to grant sublicenses) under [***]; or (iii) as a result of the Exploitation of Collaboration Products under any agreement between BioNTech or its Affiliates and a Third Party existing as of the Effective Date, including any Existing Third Party In-License Agreements (except for Existing Third Party In-License Agreement Royalty Payments which shall be allocated as described above in Section 10.6);

(b) any compensation payable by BioNTech or its Affiliates under statute, contract or otherwise to inventors that have contributed or will contribute to BioNTech IP or (subject to any sharing as an Allowable Expense) any Collaboration IP created, conceived or reduced to practice by or on behalf of BioNTech; and

(c) any costs for any payments or other consideration payable to any Third Party for the rights or licenses under intellectual property rights necessary or reasonably useful for BioNTech to perform its research activities in relation to the Neoepitope Prediction Algorithm under the Research Plan, including any such rights or licenses under the software disclosed in Schedule 12.2.1(i) and Schedule 12.3.1(h).

For clarity, except for Existing Third Party In-License Agreement Royalty Payments which shall be allocated as described above in Section 10.6, BioNTech shall be responsible for and bear the costs for any payments or other consideration to a Third Party as listed under Schedule 12.2.1(a). Notwithstanding the foregoing, any additional rights or licenses that may be obtained for the Exploitation of Collaboration Products (other than for research activities under the Research Plan) under any agreement with a Third Party existing as of the Effective Date shall be considered "Third Party IP" as defined under Section 10.6.3 and the Parties shall [***]

10.6.2 Genentech IP. Other than in connection with (a) an amendment of this Agreement pursuant to Section 5.3.4 or (b) grant of a post-termination license to BioNTech pursuant to Section 14.5.4, Genentech shall be responsible and bear the following:

(a) all costs for any payments or other consideration due to any Third Party (i) for the rights and licenses (including the right to grant sublicenses) under the Genentech IP as such Genentech IP exists as of the Effective Date or (ii) as a result of the Exploitation of Collaboration Products under any agreement of Genentech or its Affiliates with a Third Party existing as of the Effective Date;

(b) any compensation payable by Genentech or its Affiliates under statute, contract or otherwise to inventors that have contributed or will contribute to Genentech IP (subject to any sharing as an Allowable Expense); and

(c) any costs for any payments or other consideration payable to any Third Party for the rights or licenses under intellectual property rights necessary or reasonably useful for Genentech to perform its research activities in relation to the Neoepitope Prediction Algorithm under the Research Plan, including any such rights or licenses under the software disclosed in Schedule 12.2.1(i) and Schedule 12.3.1(h).

Notwithstanding the foregoing, any additional rights or licenses that may be obtained for the Exploitation of Collaboration Products (other than for research activities under the Research Plan) under any agreement with a Third Party existing as of the Effective Date shall be considered "Third Party IP" as defined under Section 10.6.3 and the Parties shall [***]

10.6.3 Other Third Party IP. With respect to (a) all intellectual property rights owned or controlled by a Third Party (including any improvements by the inventors that have contributed to the BioNTech IP) and that are reasonably necessary for the Exploitation of any Collaboration Product (other than for research activities under the Research Plan), including the clinical Development of the Neoepitope Prediction Algorithm for such Collaboration Product ("Third Party IP") or [***]

(a) [***]

(b) [***]

(c) In all other cases [***], Genentech shall have the first right to negotiate and obtain rights or licenses under any Third Party IP [***] that is reasonably necessary for the Exploitation of the Collaboration Products. [***]

10.7 Corporate Names and Product Trademarks.

10.7.1 Ownership of Corporate Names. Subject to Section 9.4, as between the Parties, BioNTech shall retain all right, title and interest in and to its Corporate Names, and Genentech shall retain all right, title and interest in and to its Corporate Names.

10.7.2 Ownership and Prosecution of Product Trademarks. Subject to Section 9.4, Genentech shall own all right, title, and interest to the Product Trademarks (other than the IVAC Trademark) in the Territory for use with GDP Collaboration Product(s) or Genentech Collaboration Product(s), and shall be responsible for the registration, prosecution, and maintenance thereof. BioNTech shall provide all assistance and documents reasonably requested by Genentech in support of its prosecution, registration, and maintenance of the Product Trademarks. BioNTech shall own the IVAC Trademark and any Product Trademarks exclusively used in connection with BioNTech Collaboration Products, and the terms of this Section 10.7.2 shall apply with respect to the IVAC Trademark and such Product Trademarks exclusively used in connection with BioNTech Collaboration Products, *mutatis mutandis*.

10.7.3 Enforcement of Product Trademarks. Genentech shall have the sole right and responsibility for taking such action as Genentech, after consultation with BioNTech, deems necessary against a Third Party based on any alleged, threatened, or actual infringement, dilution, misappropriation, or other violation of, or unfair trade practices or any other like offense relating to, the Product Trademarks by a Third Party in the Territory. All costs of enforcing the Product Trademarks shall be shared equally (50%:50%) by the Parties.

10.7.4 [*]**

10.7.5 Notice and Cooperation. Each Party shall provide to the other Party prompt written notice of any actual or threatened infringement of the Product Trademarks in the Territory and of any actual or threatened claim that the use of the Product Trademarks in the Territory violates the rights of any Third Party. Each Party agrees to cooperate fully with the other Party with respect to any enforcement action or defense commenced pursuant to this Section 10.7.

10.8 [*]**

10.9 [*]**

10.10 Attorney-Client Privilege. Neither Party is waiving, nor shall be deemed to have waived or diminished, any of its attorney work product protections, attorney-client privileges or similar protections and privileges or the like as a result of disclosing information pursuant to this Agreement, or any of its Confidential Information (including Confidential Information related to pending or threatened litigation) to the receiving Party, regardless of whether the disclosing Party has asserted, or is or may be entitled to assert, such privileges and protections. The Parties: (a) share a common legal and commercial interest in such disclosure that is subject to such privileges and protections; (b) are or may become joint defendants in proceedings to which the information covered by such protections and privileges relates; (c) intend that such privileges and protections remain intact should either Party become subject to any actual or threatened proceeding to which the disclosing Party's Confidential Information covered by such protections and privileges relates; and (d) intend that after the Effective Date both the receiving Party and the disclosing Party shall have the right to assert such protections and privileges.

ARTICLE 11.

CONFIDENTIALITY AND NON-DISCLOSURE

11.1 Disclosure and Use of Confidential Information.

11.1.1 Continuing Obligation. This Article 11 shall survive the expiration or termination of this Agreement for a period of [***] years, except for [***]

11.1.2 Rights and Obligations. Except to the extent expressly authorized by this Agreement, each Party (in context, the "**Receiving Party**") in possession of the Confidential Information of the other Party (in context, the "**Disclosing Party**") or Joint Confidential Information agrees to: (a) hold in confidence and not disclose the Disclosing

Party's Confidential Information or Joint Confidential Information to any Affiliate or Third Party (other than, subject to Section 15.2, by a Party to an Affiliate under an obligation of confidentiality), (b) use commercially reasonable efforts to protect the Confidential Information of the other Party or Joint Confidential Information (including commercially reasonable efforts a Party employs with respect to its own confidential information of a similar nature and commercially reasonable efforts to assure that no unauthorized use or disclosure is made by others to whom access to the Confidential Information of the other Party (or Joint Confidential Information) is granted) and (c) only use (or permit the use of) the Disclosing Party's Confidential Information or Joint Confidential Information in connection with activities contemplated by, the exercise of rights permitted by, or in order to further the purposes of, this Agreement. [***]

11.1.3 "Confidential Information" means any and all Information (a) provided by or on behalf of one Party to the other Party in connection with this Agreement, whether prior to, on, or after the Effective Date and (b) owned solely by a Party or jointly by the Parties; in all cases, including information relating to the following: [***] Notwithstanding the foregoing, the following shall be deemed to be "**Joint Confidential Information**" for purposes of this Article 11: [***]

11.1.4 Exceptions. The obligations of the Receiving Party set forth in Section 11.1.2, shall not apply to the Disclosing Party's Confidential Information or Joint Confidential Information to the extent that such Confidential Information:

(a) can be demonstrated by documentation or other competent proof to have been in the Receiving Party's possession prior to disclosure by the Disclosing Party without any obligation of confidentiality with respect to such information; *provided* that the foregoing exception shall not apply with respect to Joint Confidential Information;

(b) is subsequently received by the Receiving Party from a Third Party which is not bound by any obligation of confidentiality with respect to such information;

(c) has been published by a Third Party or otherwise enters the public domain through no fault of the Receiving Party in breach of this Agreement;

(d) can be demonstrated by documentation or other competent evidence to have been independently developed by or for the Receiving Party without reference to the Disclosing Party's Confidential Information; *provided* that the foregoing exception shall not apply with respect to Joint Confidential Information; or

(e) is no longer subject to the provisions of this Section 11.1 by the prior written consent of the Disclosing Party.

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the Receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the Receiving Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of the Receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the Receiving Party unless the combination and its principles are in the public domain or in the possession of the Receiving Party.

11.2 Permitted Disclosures.

11.2.1 Legal Compliance. A Party may disclose the other Party's Confidential Information or Joint Confidential Information if such disclosure is required by law, rule or regulation (including to comply with the order of a court or governmental regulations), but only to the extent such disclosure is reasonably necessary for such compliance; provided, however, except for disclosures otherwise permitted under Section 11.2, or as otherwise required or necessitated by law, such Party shall provide prompt notice of such disclosure requirement to the other Party and provide reasonable assistance to enable such other Party to seek a protective order or otherwise prevent such disclosure.

11.2.2 Regulatory Authorities. A Party may disclose the other Party's Confidential Information or Joint Confidential Information to the extent such disclosure is required to comply with applicable governmental regulations, to conduct preclinical or Clinical Studies related to Collaboration Products in accordance with the terms of this Agreement, or, with respect to any Lead Regulatory Party, to obtain Regulatory Approval of Collaboration Products in accordance with the terms of this Agreement.

11.2.3 Patent Prosecution. A Party may disclose the other Party's Confidential Information or Joint Confidential Information to the extent such disclosure is reasonably necessary for the filing, publication or Prosecution and Maintenance of any patent application or patent on inventions, subject to the provisions of Section 10.3.

11.2.4 Permitted Third Parties. Subject to Sections 4.8.3, 11.6 and 11.7, the Receiving Party may disclose and grant use of particular Confidential Information of the Disclosing Party or Joint Confidential Information to the Receiving Party's permitted sublicensees, agents, consultants, clinical investigators, or subcontractors as the Receiving Party reasonably determines is necessary to fulfill its obligations or exercise its rights under this Agreement; provided, however, that (a) any such permitted sublicensees, agents, consultants, clinical investigators or subcontractors must be contractually bound in writing by obligations substantially similar to those set forth in Section 11.1 and (b) in no event may BioNTech disclose or grant use of any such Information to any Class A Competitor or an Affiliate thereof (or an employee or consultant of such Class A Competitor or Affiliate thereof) without Genentech's prior written consent. [***]

11.2.5 Scientific Publications. The Receiving Party may disclose the Disclosing Party's Confidential Information or Joint Confidential Information as expressly permitted pursuant to Section 11.5.

11.2.6 Genentech Molecule Clinical Trial Data. Genentech Molecule Clinical Trial Data is the Confidential Information of Genentech. Notwithstanding any other provision of this Section 11.2, BioNTech may not disclose Genentech Molecule Clinical Trial Data without Genentech's prior written consent, other than pursuant to Section 11.2.1.

11.3 Use of Name. Except as expressly provided herein, neither Party shall (and no right, express or implied, is granted to) mention or otherwise use the name, logo, or Trademark of the other Party or any of its Affiliates (or any abbreviation or adaptation thereof) in any publication, press release, marketing and promotional material or other form of publicity, or in any other manner in connection with the performance of this Agreement, without the prior written approval of such other Party in each instance. The restrictions imposed by this Section 11.3 shall not prohibit either Party from making any disclosure identifying the other Party that is required by Applicable Law.

11.4 Press Releases and Other Public Disclosures.

11.4.1 Generally. For purposes of Section 11.4 a “**Disclosure**” means a press release or other public disclosure concerning this Agreement or the subject matter hereof, including (a) the existence and terms and conditions of this Agreement; (b) information arising from the conduct of activities under this Agreement; and (c) Collaboration Products, and any information specifically related to such Collaboration Products (including any Collaboration Product Clinical Study Data). Disclosures include public communications that contain previously disclosed information. The provisions of Section 11.4 are in addition to the other provisions of Article 11.

11.4.2 Disclosures. If one Party desires to make a Disclosure, it shall obtain the other Party’s prior written approval for the proposed Disclosure, which approval shall not unreasonably be withheld or delayed. Each Party hereby agrees that the other Party may issue the applicable press release set forth in Schedule 11.4.2, following the Execution Date by both Parties.

11.4.3 Disclosure Required by Law. In the event that one Party reasonably concludes that a Disclosure is required by law, rule or regulation (including the disclosure requirements of the Securities and Exchange Commission or the securities exchange or other stock market on which such Party’s securities are traded (for purposes of Section 11.4, collectively, an “**Exchange**”)), it shall notify the other Party at least [***] Business Days in advance and if the other Party notifies the disclosing Party that it would prefer not to make such Disclosure, the Party seeking such Disclosure shall either (a) limit such Disclosure to address the concerns of the other Party or (b) provide a written opinion from counsel stating that such limited Disclosure is not sufficient to comply with the applicable law, rule or regulation before making such Disclosure. Each Party agrees that it shall obtain its own legal advice with regard to its compliance with securities laws, rules and regulations, and will not rely on any statements made by the other Party relating to such securities laws, rules and regulations.

11.4.4 Filing of Agreement. Without limiting Section 11.4.3, with respect to complying with the disclosure requirements of an Exchange, in connection with any required filing of this Agreement with such Exchange, the filing Party shall, at the request of the other Party, seek confidential treatment for portions of this Agreement from such

Exchange and shall provide such other Party with the opportunity, for no less than [***] Business Days (before the date of the proposed filing), to review and comment on any such proposed filing, and shall thereafter provide reasonable advance notice and opportunity for comment on any subsequent changes to such filing. BioNTech shall, whether or not requested by Genentech, redact and request confidential treatment for [***], and the information in the Schedules to this Agreement.

11.5 Scientific Publications. Notwithstanding Section 11.4, in the event a Party wishes to publish in a peer review journal or present at a scientific conference (a) Information relating to or arising from this Agreement (including relating to or arising from activities performed by a Third Party subcontractor on behalf of a Party, [***]) consistent with the then-current Publication Plan, if any, or if no Publication Plan is in effect, as otherwise approved by the JRC, with respect to research publications, or the JDC, with respect to Development publications, or (b) Information solely made, collected or otherwise generated by or on behalf of it or its Affiliates [***] prior to the Effective Date, such Party shall provide to the other Party the proposed publication or presentation (including, without limitation, abstracts and manuscripts) at least [***] days ([***] days for posters, slides and written descriptions of oral presentations only) for publications under clause (a) and [***] days for publications under clause (b) prior to the date of submission for publication or the date of presentation, whichever is earlier, of any of such submitted materials. The other Party shall review such submitted materials and respond to the submitting Party as soon as reasonably possible, but in any case (i) within [***] days for the proposed publication or presentation (including but not limited to abstracts and manuscripts) and [***] days for posters, slides and written descriptions or oral presentations only, of receipt thereof for publications under clause (a) and (ii) within [***] days for the proposed publications under clause (b). At the option of the reviewing Party, the submitting Party shall (1) take into due consideration any comments made by the reviewing Party, (2) delete from such proposed publication or presentation any Confidential Information of the reviewing Party and [***]; and (3) delay the date of such submission for publication or the date of such presentation for a period of time sufficiently long (but in no event longer than [***] days for publications under clause (a) and [***] days for publications under clause (b)) to permit the reviewing Party to seek appropriate patent protection. In the event the reviewing Party does not respond within the period specified above, the submitting Party will be free to make such proposed publication or presentation.

11.6 Restriction on Disclosure of [*]**

11.7 Restriction on Disclosure of [*]**

ARTICLE 12. REPRESENTATIONS AND WARRANTIES

12.1 Mutual Representations and Warranties. As a condition and an inducement to the Parties to enter into this Agreement, each of RNP and BNT on the one hand, and GNE and Roche on the other, represents and warrants to the other, as of the Execution Date, and covenants, as follows:

12.1.1 Organization. It is duly organized, validly existing, and in good standing under the laws of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver, and perform this Agreement and the Ancillary Agreements.

12.1.2 Authorization. The execution and delivery of this Agreement and the Ancillary Agreements and the performance of this Agreement and the Ancillary Agreements by it have been duly authorized by all necessary corporate action, and do not and will not (a) conflict with such Signatory's charter documents, bylaws, or other organizational documents, (b) conflict with, or result in a breach or constitute default under, or give rise to any payment obligations or right of termination, cancellation, modification or acceleration of any obligation or loss of any benefit under any agreement, instrument, or contractual obligation to which such Signatory is bound, (c) violate any requirement of any Applicable Law, or (d) violate any order, writ, judgment, injunction, decree, determination, or award of any court or governmental agency presently in effect applicable to such Signatory.

12.1.3 Binding Agreement. This Agreement is a legal, valid, and binding obligation of such Signatory enforceable against it in accordance with its terms and conditions. It is not under any obligation to any Person, contractual or otherwise, that is conflicting or inconsistent in any respect with the terms of this Agreement or any Ancillary Agreement or that would impede the diligent and complete fulfillment of its obligations of this Agreement or any Ancillary Agreement.

12.2 Additional Representations and Warranties of BioNTech. BioNTech further represents and warrants to Genentech, as of the Execution Date, and covenants, as follows:

12.2.1 Intellectual Property.

(a) **Title.** All Patents Controlled by BioNTech or its Affiliates that are to the knowledge of BioNTech and its Affiliates necessary to research, develop, manufacture, commercialize, make, have made, use, offer for sale, sell and import Pharmaceutical Products that comprise (i) one or more Neoepitope RNA(s), [***] are listed on Schedule 1.20. BioNTech is (a) the sole and exclusive owner of the entire right, title and interest in the BioNTech Core Patents listed on Schedule 1.20 as "Owned BioNTech Core Patents"; (b) the sole and exclusive licensee of the BioNTech Core Patents indicated on Schedule 1.20 as "In-Licensed BioNTech Core Patents"; and (c) entitled to grant the rights and licenses (or sublicenses) specified in this Agreement and the Ancillary Agreements, including the rights of Prosecution and Maintenance specified in this Agreement, in each case of (a), (b), and (c), free of any encumbrance, lien, or claim of ownership by any Third Party or Affiliate and except as disclosed in Schedule 12.2.1(a), without payment of any royalties, license fees or other amounts to any Person.

(b) **Valid and Enforceable.** To the knowledge of BioNTech and its Affiliates, all BioNTech Core Patents are subsisting, and all necessary Prosecution and Maintenance fees in connection with such BioNTech Core Patents have been paid, and all necessary documents and certificates in connection with such BioNTech Core

Patents have been filed with the relevant Governmental Authorities for the purposes of Prosecuting and Maintaining such BioNTech Core Patents and BioNTech has complied with its duty to disclose material information to the U.S. Patent and Trademark Office and other foreign patent authorities in connection with such BioNTech Core Patents. To the knowledge of BioNTech and its Affiliates and except as may be disclosed from BioNTech to Genentech or Genentech to BioNTech through their respective outside counsel, the BioNTech Core Patents are not invalid or unenforceable.

(c) **Rights of Prosecution and Enforcement.** To the knowledge of BioNTech and its Affiliates and except as otherwise disclosed on Schedule 12.2.1(c), neither BioNTech nor any of its Affiliates has (i) granted any Person the right to control the Prosecution and Maintenance of any of the BioNTech Core Patents, (ii) granted any Person the right to bring infringement actions with respect to, or otherwise to enforce rights with respect to, any of the BioNTech Core Patents, or (iii) expressly agreed not to sue or to indemnify any Person against any charge of infringement of any of BioNTech Core Patents.

(d) **No Infringement of BioNTech IP.** To the knowledge of BioNTech and its Affiliates, no Person is infringing or threatening to infringe or misappropriating or threatening to misappropriate the BioNTech Core Patents (including pending applications and registrations therefor as if such applications or registrations were to issue or become registered), any Neoepitope Prediction Algorithm within the BioNTech IP or the Regulatory Documentation.

(e) **No Infringement of Third Party IP.** To the knowledge of BioNTech and its Affiliates and except as may be disclosed from BioNTech to Genentech or Genentech to BioNTech through their respective outside counsel, (i) the conception, reduction to practice or creation of the BioNTech Core Patents, any Neoepitope Prediction Algorithm within the BioNTech IP and Regulatory Documentation and the Exploitation of Collaboration Products based upon the BioNTech Core Patents, any Neoepitope Prediction Algorithm within the BioNTech IP and Regulatory Documentation do not and will not infringe or misappropriate any intellectual property right (including pending applications and registrations therefor as if such applications or registrations were to issue or become registered) of any Person, or otherwise violate any intellectual property right of any Person under the Applicable Laws of any jurisdiction, and (ii) the BioNTech Core Patents are not dominated by any Patent (including pending applications and registrations therefor as if such applications or registrations were to issue or become registered) of any Person and not Controlled by BioNTech.

(f) **German Employees' Inventions Act.** In accordance with the German Employees' Inventions Act, BioNTech agrees to claim the unlimited use of any Invention conceived, reduced to practice, developed, made or created in the performance of, or as a result of the Research Plan, CMC Development Plan or Joint Development Activities by employees of any German Affiliates. For the avoidance of doubt, each Party is responsible for fulfilling the obligations towards their employees under the German Employee's Inventions Act.

(g) **Assignments.** To the extent the assignment of inventions to BioNTech or its Affiliates is not effected by statutory law (e.g. the German Employees' Inventions Act), all current and former officers, employees, agents and consultants of BioNTech or any of its Affiliates or, to the knowledge of BioNTech and its Affiliates, their respective subcontractors [***] who are inventors of or have otherwise contributed in a material manner to the creation or development of any BioNTech IP have, directly or indirectly, agreed to protect such BioNTech IP as proprietary information and assign any and all rights in and to such BioNTech IP to BioNTech or such Affiliate or such subcontractor (as applicable), by execution and delivery to BioNTech or such Affiliate or subcontractor of an assignment or other agreement or otherwise. To the knowledge of BioNTech and its Affiliates, no current officer, employee, agent, or consultant of BioNTech or any of its Affiliates or their respective subcontractors [***] is in violation of any term of any assignment or other agreement regarding the protection of Patents or other intellectual property or proprietary information of BioNTech or such Affiliate or of any employment contract or any other contractual obligation relating to the relationship of any such Person with BioNTech. To the knowledge of BioNTech, all inventions relating to any Pharmaceutical Products that comprise (i) one or more Neopeptide RNA(s), [***] made as of the Effective Date by inventors who are employed by or in any other way legally related to BioNTech or its Affiliates have been disclosed by such inventors to BioNTech or its Affiliates, as applicable.

(h) **Confidentiality of BioNTech Know-How.** Except as disclosed in scientific publications made generally available to the public, BioNTech and its Affiliates have maintained the BioNTech Know-How at all times as confidential and only disclosed the BioNTech Know-How to Third Parties, [***] under obligations of confidentiality. To the knowledge of BioNTech and its Affiliates, no such Third Party has used or disclosed BioNTech Know-How in breach of its confidentiality obligations.

(i) **Neopeptide Prediction Algorithm.** To the knowledge of BioNTech and its Affiliates [***] (i) BioNTech owns or has sufficient rights in any Neopeptide Prediction Algorithm within the BioNTech IP as of the Execution Date to transfer such Neopeptide Prediction Algorithm and grant the rights and licenses (and sublicenses) to Genentech under this Agreement, free of any encumbrance, lien, or claim of ownership by any Third Party or Affiliate and without payment of any royalties, license fees or other amounts to any Person, and (ii) the use and other exploitation of such Neopeptide Prediction Algorithm in the Exploitation of Collaboration Products will not depend on the acquisition of rights from any Third Party.

(j) **No Viruses.** To the knowledge of BioNTech and its Affiliates, any Neopeptide Prediction Algorithm within the BioNTech IP as of the Execution Date does not contain or incorporate any code, lock, authorization key, disabling code, or similar device or code that is intended to impair, disable or otherwise impede the operation of software or hardware or any "back door," "time bomb," "Trojan horse," "drop-dead device," "virus" or other software routines or code or hardware components designed to permit unauthorized access, to send information to any Third Party without the user's consent, to disable or erase software, hardware or data, or to contaminate, corrupt, or damage information technology systems or architecture or to perform any other similar actions.

(k) **No Copyleft.** To the knowledge of BioNTech and its Affiliates, any Neoepitope Prediction Algorithm within the BioNTech IP and the Neoepitope Prediction Software used by BioNTech in its Neoepitope Prediction Algorithm as of the Execution Date are not, do not contain or incorporate, and are not bundled, combined, or linked with, any software or other materials in a form or manner which creates, or purports to create, obligations (i) for a licensee to license its own intellectual property rights, including Patents, to any Third Parties or (ii) that a licensee's software or other materials must: (A) be disclosed or distributed in source code form; (B) be licensed for the purpose of making derivative works; or (C) be redistributable at no charge (such software or other materials collectively, "**Copyleft Software**"). Without limiting the foregoing:

(i) To the knowledge of BioNTech and its Affiliates and to the extent that, at any time prior to the Execution Date, any mechanism was used to facilitate communication between (x) the Neoepitope Prediction Software owned by BioNTech within the BioNTech IP and (y) any Copyleft Software, or other software disclosed on Schedule 12.2.1(i), the mechanism that was used was a command line argument and the semantics of the communication did not involve the exchange of complex data structures.

(ii) To the knowledge of BioNTech and its Affiliates, the Neoepitope Prediction Software used by BioNTech in its Neoepitope Prediction Algorithm as of the Execution Date has not [***]

(iii) In the development of the Neoepitope Prediction Software used by BioNTech in its Neoepitope Prediction Algorithm as of the Execution Date, BioNTech has followed standard operating procedures with respect to software development that control and document the use of Copyleft Software. During the Term, BioNTech will maintain and enforce standard operating procedures with respect to the use of Copyleft Software in association with the development of the Neoepitope Prediction Software used in the development of Collaboration Products under this Agreement. Such standard operating procedures shall require that the Committee Co-Chairs of the JRC and the JDC be notified of any anticipated use or transfer of Copyleft Software and that to the extent that any communication mechanism is implemented between (x) the Neoepitope Prediction Software owned by BioNTech within the BioNTech IP and (y) any Copyleft Software, including any software disclosed on Schedule 12.2.1(i), that mechanism shall be a command line argument and the semantics of the communication shall not involve the exchange of complex data structures. Any variation from these standard operating procedures must be approved in writing by the JRC and the JDC.

(l) **No Other Claims.** To the knowledge of BioNTech and its Affiliates, there are no claims, judgments, or settlements against, or amounts with respect thereto owed by, BioNTech or any of its Affiliates relating to (i) the BioNTech Core Patents, any Neoepitope Prediction Algorithm within the BioNTech IP or the Regulatory Documentation or (ii) the research, development, manufacture, commercialization, making, having made, using, offering for sale, selling and importing Pharmaceutical Products that comprise (i) one or more Neoepitope RNA(s), [***].

12.2.2 Existing Third Party In-License Agreements.

(a) **Disclosure.** Except for those agreements listed on Schedule 12.2.2(a) (collectively, “**Existing Third Party In-License Agreements**”), there are no agreements between BioNTech or any of its Affiliates with any Third Parties (i) pursuant to which BioNTech or its Affiliate has obtained, or has a right to obtain, a license under or rights to use BioNTech Core Patents (other than any Neoepitope Prediction Algorithm) that is relevant to this Agreement or the Ancillary Agreements or (ii) pursuant to which BioNTech or its Affiliate otherwise owes, or would otherwise owe, payments to a Third Party as a result of the Exploitation of Collaboration Products based upon the BioNTech Core Patents (other than any Neoepitope Prediction Algorithm) or other activities conducted hereunder or under any Ancillary Agreement (whether by BioNTech or Genentech or their respective (sub)licensees), including the grant of rights and licenses under the BioNTech Core Patents (other than any Neoepitope Prediction Algorithm) to Genentech;

(b) **Existing Third Party In-License Agreements.** (i) BioNTech has provided Genentech true and complete and accurate copies of the Existing Third Party In-License Agreements (as may be redacted to remove confidential information) as the same is in effect; (ii) each Existing Third Party In-License Agreement is in full force and effect and BioNTech has the rights under each such Existing Third Party In-License Agreement to disclose and provide the BioNTech IP to Genentech and to grant Genentech the licenses under, and right to use, such BioNTech IP (other than any Neoepitope Prediction Algorithm) in the Exploitation of the Collaboration Products without restriction in accordance with the terms of this Agreement; (iii) BioNTech shall maintain each Existing Third Party In-License Agreement in full force and effect during the Term, in each case in accordance with its terms and conditions, but subject to BioNTech’s rights to terminate, amend, waive or otherwise modify any such agreement as provided in Section 12.2.2(c) below; (iv) no written notice of default or termination has been received or given by BioNTech or any of its Affiliates under any Existing Third Party In-License Agreement; and (v) to BioNTech’s and its Affiliates’ knowledge, there is no act or omission by BioNTech or any of its Affiliates that would give the counterparty thereto a right to terminate any Existing Third Party In-License Agreement;

(c) **Maintenance of Existing Third Party In-License Agreements.** During the Term, neither BioNTech nor any of its Affiliates shall terminate, amend, waive or otherwise modify (or provide consent with respect to any termination, amendment, waiver or modification of) the rights under any Existing Third Party In-License Agreement in any manner that materially diminishes the licenses or rights granted to Genentech hereunder, materially impairs Genentech’s ability to perform its obligations hereunder or otherwise materially adversely affects, or is likely to materially adversely affect, Genentech’s rights hereunder; in all cases, without the prior written consent of Genentech. In the event of any notice of breach or notice of termination received by BioNTech or any of its Affiliates, as applicable, under the provisions of any Existing Third Party In-License Agreement, BioNTech shall immediately notify Genentech in writing and if BioNTech or its Affiliate fails to cure such breach, Genentech shall have the right, but not the obligation, to cure such breach on behalf of BioNTech or its Affiliates, as applicable, and to offset any reasonable amounts incurred or paid by Genentech in connection with the cure of such breach against any amounts otherwise payable by Genentech to BioNTech under this Agreement until fully offset.

(d) **Enforcement of Existing Third Party In-License Agreements.** In the event that BioNTech is of the opinion that the other party of any applicable Existing Third Party In-License Agreement has breached its obligations under such agreement, BioNTech shall notify Genentech in writing, and the Parties shall promptly discuss and agree on such actions as may be necessary or useful to enforce such Existing Third Party In-License Agreement, including injunctive or other equitable relief with respect to breach of obligations related to confidentiality or exclusivity. Without limiting the foregoing, in the event an Existing Third Party In-License Agreement expires or terminates during the Term, any sublicense(s) granted from BioNTech to Genentech under any such Existing Third Party In-License Agreement hereunder shall survive (to the extent permitted under the Existing Third Party In-License Agreements). Any Existing Third Party In-License Agreement Royalty Payment that Genentech shall pay to such Third Party under such sublicense(s) for activities performed in accordance with this Agreement shall constitute an "Allowable Expense" in the Net Profit/Net Loss calculation pursuant to Section 8.4 or in the event of an Opt-Out by BioNTech pursuant to Section 8.5 or a Deemed Opt-Out pursuant to Section 8.5.3, shall be offset against any amounts otherwise payable by Genentech to BioNTech under this Agreement until fully offset, and any other amounts that Genentech shall pay to such Third Party under such sublicense shall be offset against any amounts otherwise payable by Genentech to BioNTech under this Agreement until fully offset.

12.2.3 Regulatory.

(a) **Regulatory Documentation.** BioNTech and its Affiliates have generated, prepared, maintained, and retained all Regulatory Documentation that is required to be maintained or retained pursuant to and in accordance with cGLPs and cGCPs and in compliance with Applicable Law, and all such information is true and complete and accurate and what it purports to be.

(b) **No Misrepresentation to Regulatory Authority.** Neither BioNTech nor any of its Affiliates, nor any of its or their respective officers, employees, or agents has made an untrue statement of material fact or fraudulent statement to the FDA or any other Regulatory Authority with respect to the Development or Manufacture of the Collaboration Products, failed to disclose a material fact required to be disclosed to the FDA or any other Regulatory Authority with respect to the Development or Manufacture of the Collaboration Products, or committed an act, made a statement, or failed to make a statement with respect to the Development or Manufacture of the Collaboration Products that could reasonably be expected to provide a basis for the FDA to invoke its policy respecting "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities", set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto or any analogous laws or policies in the Territory.

(c) **No Debarment.** Neither BioNTech nor any of its Affiliates has been debarred or is subject to debarment and neither BioNTech nor any of its Affiliates will use in any capacity, in connection with the services to be performed under this Agreement, any Person who has been debarred pursuant to Section 306 of the FFDCA, or who is the subject of a conviction described in such section. BioNTech agrees to inform Genentech in writing immediately if it or any Person who is performing services hereunder is debarred or is the subject of a conviction described in Section 306, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the knowledge of BioNTech and its Affiliates, is threatened, relating to the debarment or conviction of BioNTech or any Person performing services hereunder.

(d) **Development of Collaboration Product.** BioNTech and its Affiliates have at all times conducted and will conduct, and their respective subcontractors and consultants have at all times conducted and will conduct, all Development of the Collaboration Products (i) in accordance with cGLP and cGCP (to the extent applicable, and it being understood that Development of Collaboration Product has as of the Effective Date solely been conducted in accordance with respective European standards) and in compliance with Applicable Law including applicable Compliance Requirements, (ii) in accordance with the applicable protocol and good scientific practices and (iii) maintaining standard operating procedures with respect to clauses (i) and (ii). BioNTech has at all times conducted and will conduct, and has caused and will cause its subcontractors and consultants to conduct at all times, any and all preclinical and Clinical Studies related to the Collaboration Products in accordance with cGLP and cGCP (to the extent applicable, and it being understood that preclinical and Clinical Studies related to the Collaboration Products have as of the Effective Date solely been conducted in accordance with respective European standards) and in compliance with Applicable Law including applicable Compliance Requirements, (ii) in accordance with the applicable protocol and good scientific practices and (iii) maintaining standard operating procedures with respect to clauses (i) and (ii). BioNTech and its Affiliates have employed (and, with respect to such tests and studies that BioNTech will perform, will employ) Persons with appropriate education, knowledge and experience to conduct and to oversee the conduct of the preclinical and Clinical Studies with respect to the Collaboration Products.

(e) **Safety Reporting.** BioNTech and its Affiliates are, and at all times have been, in compliance with all adverse event reporting requirements applicable to the Collaboration Products. Schedule 12.2.3(e) sets forth a complete and accurate list of all (i) adverse drug experience information; (ii) material events and matters concerning or affecting safety or lack of efficacy; and (iii) medical inquiries and complaints, in each case, relating to the Collaboration Products. Neither BioNTech nor any of its Affiliates has any knowledge of any scientific or technical facts or circumstances that would adversely affect the scientific, therapeutic, or commercial potential of Collaboration Products. Neither BioNTech nor any of its Affiliates is aware of anything that could adversely affect the acceptance, or the subsequent approval, by any Regulatory Authority of any filing, application or request for Regulatory Approval.

(f) **Manufacture of Collaboration Product.** BioNTech and its Affiliates have at all times conducted, and their respective subcontractors and consultants have at all times conducted, all Manufacture of the Collaboration Products in accordance with the applicable Compliance Requirements. The processes used to Manufacture the Collaboration Products are adequate to ensure that the Collaboration Products meet the specifications established therefor.

(g) **Manufacturing Facility.** Unless otherwise disclosed in Schedule 12.2.3(g), neither BioNTech nor its Affiliates have received: (i) (A) any FDA Form 483 Notice of Observation, or similar notice from any other Regulatory Authority, relating to the Collaboration Products or the facilities in which the Collaboration Products are Manufactured; (B) any FDA “Notices of Adverse Findings,” or similar notice from any other Regulatory Authority, with respect to the Collaboration Products; or (C) any “warning letters,” or “untitled letters,” or other similar Regulatory Authority notice of inspectional observations or deficiencies or other written correspondence from the FDA or any other Regulatory Authority concerning the Collaboration Products or the facilities in which the Collaboration Products are Manufactured; and (ii) there has not been a recall or withdrawal or replacement of any Collaboration Product by, or on behalf of, BioNTech or any of its Affiliates, whether voluntary or involuntary.

12.2.4 Accuracy of Information. The representations and warranties of BioNTech in this Agreement, and the information, documents and materials furnished to Genentech in connection with its period of diligence prior to the Execution Date, do not, taken as a whole, (a) contain any untrue statement of a material fact, or (b) omit to state any material fact necessary to make the statements or facts contained therein, in light of the circumstances under which they were made, not misleading.

12.2.5 Effective Date. During the period from the Execution Date until the Effective Date, BioNTech shall promptly inform Genentech in writing if and when BioNTech or any of its Affiliates becomes aware that the representations and warranties made by BioNTech pursuant to Sections 12.1 and 12.2 as of the Execution Date are no longer true and correct in any material respects if made on and as of the date of such notice. Upon receipt of such notice, Genentech shall have the right, on written notice to BioNTech, to terminate this Agreement, and upon receipt of such notice by BioNTech, this Agreement shall be null and void and have no further force and effect; provided, however, Sections 9.6, 11.7 and 14.1 and Article 13 (other than Section 13.7) shall survive with respect any rights that accrued to the benefit of a Party prior to such termination.

12.3 Additional Representations and Warranties by Genentech. Genentech further represents and warrants to BioNTech, as of the Execution Date, and covenants, as follows:

12.3.1 Intellectual Property.

(a) **Title.** All Patents Controlled by Genentech that are to the knowledge of Genentech necessary to research, develop, manufacture, commercialize, make, have made, use, offer for sale, sell and import Pharmaceutical Products comprising one or more Neoepitope RNA(s) [***] are listed on Schedule 1.156. Genentech is the sole and exclusive owner of the entire right, title and interest in the Genentech Core Patent listed on Schedule 1.156; and Genentech is entitled to grant the rights and licenses (or sublicenses) specified in this Agreement and the Ancillary Agreements, including the rights of Prosecution and Maintenance specified in this Agreement, in each case, free of any encumbrance, lien, or claim of ownership by any Third Party or Affiliate and, without payment of any royalties, license fees or other amounts to any person.

(b) **Valid and Enforceable.** To the knowledge of Genentech, all Genentech Core Patents are subsisting, and all necessary Prosecution and Maintenance fees in connection with such Genentech Core Patents have been paid, and all necessary documents and certificates in connection with such Genentech Core Patents have been filed with the relevant Governmental Authorities for the purposes of Prosecuting and Maintaining such Genentech Core Patents and Genentech has complied with its duty to disclose material information to the U.S. Patent and Trademark Office and other foreign patent authorities in connection with such Genentech Core Patents. To the knowledge of Genentech and except as may be disclosed from Genentech to BioNTech or BioNTech to Genentech through their respective outside counsel, the Genentech Core Patents owned by Genentech are not invalid or unenforceable.

(c) **Rights of Prosecution and Enforcement.** To the knowledge of Genentech, Genentech has not (i) granted any Person the right to control the Prosecution and Maintenance of any of the Genentech Core Patents, (ii) granted any Person the right to bring infringement actions with respect to, or otherwise to enforce rights with respect to, any of the Genentech Core Patents, or (iii) expressly agreed not to sue or to indemnify any Person against any charge of infringement of any of Genentech Core Patents.

(d) **No Infringement of Genentech IP.** To the knowledge of Genentech, no Person is infringing or threatening to infringe or misappropriating or threatening to misappropriate the Genentech Core Patents (including pending applications and registrations therefor as if such applications or registrations were to issue or become registered) or any Neoepitope Prediction Algorithm within the Genentech IP.

(e) **No Infringement of Third Party IP.** To the knowledge of Genentech and except as may be disclosed from Genentech to BioNTech or BioNTech to Genentech through their respective outside counsel, (i) the conception, reduction to practice or creation of the Genentech Core Patents, any Neoepitope Prediction Algorithm within the Genentech IP and the Exploitation of Collaboration Products based upon the Genentech Core Patents, any Neoepitope Prediction Algorithm within the Genentech IP do not and will not infringe or misappropriate any intellectual property right (including pending applications and registrations thereof as if such applications or registrations were to issue or become registered) of any Person or otherwise violate any intellectual property right of any Person under the Applicable Laws of any jurisdictions, and (ii) the Genentech Core Patents are not dominated by any Patent (including pending applications and registrations therefor as if such applications or registrations were to issue or become registered) of any Person and not Controlled by Genentech.

(f) **Assignments.** To the extent the assignment of inventions to Genentech or its Affiliates is not effected by statutory law (e.g. the Statute of German Employees' Inventions Act), all current and former officers, employees, agents and consultants of Genentech or any of its Affiliates or, to the knowledge of Genentech and its Affiliates, their respective subcontractors who are inventors of or have otherwise contributed in a material manner to the creation or development of any Genentech IP have, directly or indirectly, agreed to protect such Genentech IP as proprietary information and assign any and all rights in and to such Genentech IP to Genentech or such Affiliate or such subcontractor (as

applicable), by execution and delivery to Genentech or such Affiliate or subcontractor of an assignment or other agreement or otherwise. To the knowledge of Genentech and its Affiliates, no current officer, employee, agent, or consultant of Genentech or any of its Affiliates or their respective subcontractors is in violation of any term of any assignment or other agreement regarding the protection of Patents or other intellectual property or proprietary information of Genentech or such Affiliate or of any employment contract or any other contractual obligation relating to the relationship of any such Person with Genentech.

(g) **Confidentiality of Genentech Know-How.** Except as disclosed in scientific publications generally made available to the public, Genentech and its Affiliates have maintained the Genentech Know-How at all times as confidential and only disclosed the Genentech Know-How to Third Parties under obligations of confidentiality. To the knowledge of Genentech, no such Third Party has used or disclosed Genentech Know-How in breach of its confidentiality obligations.

(h) **Neopeptide Prediction Algorithm.** To the knowledge of Genentech and except as disclosed on Schedule 12.3.1(h), (i) Genentech owns or has sufficient rights in any Neopeptide Prediction Algorithm within the Genentech IP as of the Execution Date to disclose and provide copies of such Neopeptide Prediction Algorithm and grant the rights and licenses (and sublicenses) provided to BioNTech under this Agreement, free of any encumbrance, lien, or claim of ownership by any Third Party or Affiliate and without payment of any royalties, license fees or other amounts to any Person, and (ii) the use and other exploitation of such Neopeptide Prediction Algorithm in the Exploitation of Collaboration Products will not depend on the acquisition of rights from any Third Party.

(i) **No Viruses.** To the knowledge of Genentech and its Affiliates, any Neopeptide Prediction Algorithm within the Genentech IP as of the Execution Date does not contain or incorporate any code, lock, authorization key, disabling code, or similar device or code that is intended to impair, disable or otherwise impede the operation of software or hardware or any “back door,” “time bomb,” “Trojan horse,” “drop-dead device,” “virus” or other software routines or code or hardware components designed to permit unauthorized access, to send information to a Third Party(ies) without the user’s consent, to disable or erase software, hardware or data, or to contaminate, corrupt, or damage information technology systems or architecture or to perform any other similar actions.

(j) **No Copyleft.** To the knowledge of Genentech and its Affiliates, any Neopeptide Prediction Algorithm within the Genentech IP and the Neopeptide Prediction Software used by Genentech in its Neopeptide Prediction Algorithm as of the Execution Date are not, do not contain or incorporate, and are not bundled, combined, or linked with, any software or other materials in a form or manner which creates, or purports to create, obligations (i) for a licensee to license its own intellectual property rights, including Patents, to any Third Parties or (ii) that a licensee’s software or other materials must: (A) be disclosed or distributed in source code form; (B) be licensed for the purpose of making derivative works; or (C) be redistributable at no charge. Without limiting the foregoing:

(i) To the knowledge of Genentech and its Affiliates and to the extent that, at any time prior to the Execution Date, any mechanism was used to facilitate communication between (i) the Neopeptide Prediction Software owned by Genentech within the Genentech IP and (ii) any Copyleft Software, or other software disclosed on Schedule 12.3.1(h), the mechanism that was used was a command line argument and the semantics of the communication did not involve the exchange of complex data structures.

(ii) To the knowledge of Genentech, the Neoepitope Prediction Software used by Genentech in its Neoepitope Prediction Algorithm as of the Execution Date has not been transferred from one location to another location.

(iii) In the development of the Neoepitope Prediction Software used by Genentech in its Neoepitope Prediction Algorithm as of the Execution Date, Genentech has followed standard operating procedures with respect to software development that control and document the use of Copyleft Software. During the Term, Genentech will maintain and enforce standard operating procedures with respect to the use of Copyleft Software in association with the development of the Neoepitope Prediction Software used in the development of Collaboration Products under this Agreement. Such standard operating procedures shall require that the Committee Co-Chairs of the JRC and the JDC be notified of any anticipated use or transfer of Copyleft Software and that to the extent that any communication mechanism is implemented between (x) the Neoepitope Prediction Software owned by Genentech within the Genentech IP and (y) any Copyleft Software or other software disclosed on Schedule 12.3.1(h), that mechanism shall be a command line argument and the semantics of the communication shall not involve the exchange of complex data structures. Any variation from these standard operating procedures must be approved in writing by the JRC and the JDC.

(k) **No Other Claims.** To the knowledge of Genentech, there are no claims, judgments, or settlements against, or amounts with respect thereto, owed by Genentech or any of its Affiliates relating to the Genentech Core Patents, any Neoepitope Prediction Algorithm within the Genentech IP or the Regulatory Documentation or the Exploitation of Collaboration Products.

(l) **Disclosure.** There are no agreements between Genentech or any of its Affiliates with any Third Parties (i) pursuant to which Genentech or its Affiliate has obtained, or has a right to obtain, a license under or rights to use the Genentech Core Patents that is relevant to this Agreement or the Ancillary Agreements or (ii) pursuant to which Genentech or its Affiliate otherwise owes, or would otherwise owe, payments to a Third Party as a result of the Exploitation of Collaboration Products or other activities conducted hereunder (whether by BioNTech or Genentech or their respective (sub)licensees), including the grant of rights and licenses under the Genentech Core Patents to BioNTech.

12.4 DISCLAIMER OF WARRANTIES. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATIONS OR GRANTS ANY WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND EACH PARTY SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER

WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR USE OR PURPOSE OR ANY WARRANTY AS TO THE VALIDITY OF ANY PATENTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

EACH PARTY FURTHER DISCLAIMS ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, WITH RESPECT TO EACH OF THEIR RESEARCH, DEVELOPMENT AND COMMERCIALIZATION EFFORTS HEREUNDER, INCLUDING, WITHOUT LIMITATION, WHETHER THE COLLABORATION PRODUCTS CAN BE SUCCESSFULLY DEVELOPED OR MARKETED, THE ACCURACY, PERFORMANCE, UTILITY, RELIABILITY, TECHNOLOGICAL OR COMMERCIAL VALUE, COMPREHENSIVENESS, MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE WHATSOEVER OF THE COLLABORATION PRODUCTS.

12.5 Disclosures. The inclusion of, or reference to, any item or information in any schedule referenced in this Article 12 herein, or otherwise disclosed through outside counsel, does not and shall not (a) constitute an admission or (b) otherwise imply that such item or information (i) is material or (ii) meets all criteria set forth in the applicable section in this Article 12 for inclusion in such section.

ARTICLE 13. INDEMNITY AND INSURANCE

13.1 Indemnification of BioNTech. Genentech shall indemnify BioNTech, its Affiliates and their respective directors, officers, employees, and agents, and defend and save each of them harmless, from and against any and all losses, damages, liabilities, costs, and expenses (including reasonable attorneys' fees and expenses) (collectively, "**Losses**") in connection with any and all suits, investigations, claims, or demands of Third Parties (collectively, "**Third Party Claims**") arising from or occurring as a result of:

(a) the breach by Genentech of its obligations under this Agreement or any Ancillary Agreement;

(b) the breach of any of the warranties or representations made by Genentech to BioNTech under this Agreement or any Ancillary Agreement;

(c) the negligence or willful misconduct on the part of Genentech or its Affiliates or their respective directors, officers, employees, and agents in performing its or their obligations under this Agreement or any Ancillary Agreement; or

(d) the use of any Product Trademarks (including the IVAC Trademark to the extent Genentech uses it as a Product Trademark hereunder) by Genentech or BioNTech in accordance with this Agreement and the Ancillary Agreements; and

(e) (i) the use by BioNTech or its Affiliate of a Combination Agent Controlled by Genentech or its Affiliates in a Clinical Study of a Collaboration Product hereunder, or [***]

except in the case of clauses (a) through (e) above, for those Losses for which BioNTech has an obligation to indemnify Genentech pursuant to Section 13.2, as to which Losses each Party shall indemnify the other to the extent of their respective liability for the Losses.

13.2 Indemnification of Genentech. BioNTech shall indemnify Genentech, its Affiliates and their respective directors, officers, employees, and agents, and defend and save each of them harmless, from and against any and all Losses in connection with any and all Third Party Claims arising from or occurring as a result of:

(a) the breach by BioNTech of its obligations under this Agreement or any Ancillary Agreement;

(b) the breach of any of the warranties or representations made by BNT or RNP to Genentech under this Agreement or any Ancillary Agreement; or

(c) the negligence or willful misconduct on the part of BioNTech or its Affiliates or its or their respective directors, officers, employees, and agents in performing its obligations under this Agreement or any Ancillary Agreement;

(d) (i) the use by Genentech or its Affiliate of a Combination Agent Controlled by BioNTech or its Affiliates in a Clinical Study of a Collaboration Product hereunder, or [***];

except, in the case of clauses (a) through (d) above, for those Losses for which Genentech has an obligation to indemnify BioNTech pursuant to Section 13.1, as to which Losses each Party shall indemnify the other to the extent of their respective liability for the Losses.

13.3 Certain Losses. Any Losses, other than those Losses for which indemnification is provided in Section 13.1 or Section 13.2, in connection with any Third Party Claim brought against either Party resulting directly or indirectly from (a) the performance of the Joint Development Activities by either Party (or its Affiliates, employees, or agents) in accordance with the GDP shall be included as a Shared Development Cost or (b) the Commercialization of a GDP Collaboration Product, or the Manufacture of a GDP Collaboration Product in support of such Commercialization shall be included as an Allowable Expense. If either Party learns of any Third Party Claim with respect to Losses covered by this Section 13.3, such Party shall provide the other Party with prompt written notice thereof. The Parties shall confer with respect to how to respond to such Third Party Claim and how to handle such Third Party Claim in an efficient manner. In the absence of such an agreement, each Party shall have the right to take such action as it deems appropriate.

13.4 Notice of Claim. All indemnification claims in respect of a Party, its Affiliates, or their respective directors, officers, employees and agents shall be made solely by such Party to this Agreement (the "**Indemnified Party**"). The Indemnified Party shall give the indemnifying Party prompt written notice (an "**Indemnification Claim Notice**") of any

Losses or discovery of fact upon which such indemnified Party intends to base a request for indemnification under this Article 13, but in no event shall the indemnifying Party be liable for any Losses that result from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss is known at such time). The Indemnified Party shall furnish promptly to the indemnifying Party copies of all papers and official documents received in respect of any Losses and Third Party Claims.

13.5 Control of Defense.

13.5.1 In General. At its option, the indemnifying Party may assume the defense of any Third Party Claim by giving written notice to the Indemnified Party within [***] days after the indemnifying Party's receipt of an Indemnification Claim Notice. The assumption of the defense of a Third Party Claim by the indemnifying Party shall not be construed as an acknowledgment that the indemnifying Party is liable to indemnify the Indemnified Party in respect of the Third Party Claim, nor shall it constitute a waiver by the indemnifying Party of any defenses it may assert against the Indemnified Party's claim for indemnification. Upon assuming the defense of a Third Party Claim, the indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the indemnifying Party. In the event the indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party shall immediately deliver to the indemnifying Party all original notices and documents (including court papers) received by the Indemnified Party in connection with the Third Party Claim. Should the indemnifying Party assume the defense of a Third Party Claim, except as provided in Section 13.5.2, the indemnifying Party shall not be liable to the Indemnified Party for any legal expenses subsequently incurred by such Indemnified Party in connection with the analysis, defense or settlement of the Third Party Claim unless specifically requested in writing by the indemnifying Party. In the event that it is ultimately determined that the indemnifying Party is not obligated to indemnify, defend or hold harmless the Indemnified Party from and against the Third Party Claim, the Indemnified Party shall reimburse the indemnifying Party for any and all costs and expenses (including attorneys' fees and costs of suit) and any Losses incurred by the indemnifying Party in its defense of the Third Party Claim.

13.5.2 Right to Participate in Defense. Without limiting Section 13.5.1, any Indemnified Party shall be entitled to participate in, but not control, the defense of such Third Party Claim and to employ counsel of its choice for such purpose; *provided, however*, that such employment shall be at the Indemnified Party's own expense unless (a) the employment thereof has been specifically authorized by the indemnifying Party in writing, (b) the indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 13.5.1 (in which case the Indemnified Party shall control the defense), or (c) the interests of the indemnitee and the indemnifying Party with respect to such Third Party Claim are sufficiently adverse to prohibit the representation by the same counsel of both Parties under Applicable Law, ethical rules or equitable principles.

13.5.3 Settlement. With respect to any Losses relating solely to the payment of money damages in connection with a Third Party Claim and that shall not result in the Indemnified Party's becoming subject to injunctive or other relief, and as to which the indemnifying Party shall have acknowledged in writing the obligation to indemnify the Indemnified Party hereunder, the indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the indemnifying Party, in its sole discretion, shall deem appropriate; provided that the judgment, settlement or other disposition does not and will not (a) result in a finding or admission of any violation of any Applicable Law or any violation of the rights of any person, or (b) result in the Indemnified Party's rights under this Agreement being adversely affected. In all other cases, where the indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 13.5.1, the indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Third Party Claim; *provided* it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld or delayed). If the indemnifying Party does not assume and conduct the defense of a Third Party Claim as provided above, the Indemnified Party may defend against such Third Party Claim; *provided* that the Indemnified Party shall not settle any Third Party Claim without the prior written consent of the indemnifying Party, not to be unreasonably withheld or delayed.

13.5.4 Cooperation. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party shall, and shall cause each indemnitee to, cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to the indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making Indemnified Parties and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the indemnifying Party shall reimburse the Indemnified Party for all its reasonable out-of-pocket expenses in connection therewith.

13.5.5 Expenses. Except as provided above, the costs and expenses, including fees and disbursements of counsel, incurred by the Indemnified Party in connection with any claim shall be reimbursed on a Calendar Quarter basis by the indemnifying Party, without prejudice to the indemnifying Party's right to contest the Indemnified Party's right to indemnification and subject to refund in the event the indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party.

13.6 Limitation of Liability. IN NO EVENT SHALL EITHER BIONTECH OR GENENTECH BE LIABLE FOR INDIRECT DAMAGES (INDIREKTE SCHÄDEN/MITTELBARE SCHÄDEN/WEITERE SCHÄDEN ALS SCHÄDEN MIT LANGEM KAUSALZUSAMMENHANG) OR CONSEQUENTIAL DAMAGES (MANGELFOLGESCHÄDEN, SEKUNDÄRE SCHÄDEN, FOLGESCHÄDEN UND SCHÄDEN, DIE SICH AUS EINEM DIREKTEN SCHADEN/UNMITTELBAREN SCHADEN ERGEBEN) INCLUDING LOST PROFIT (ENTGANGENER GEWINN) ARISING FROM OR RELATED TO BREACH OF THIS AGREEMENT, WHETHER BASED ON CONTRACT, TORT OR ANY OTHER LEGAL THEORY, EXCEPT TO THE EXTENT SUCH DAMAGES OR LOST PROFIT ARE DUE TO THE GROSS NEGLIGENCE OR WILLFUL MISCONDUCT OF THE OTHER PARTY; PROVIDED, HOWEVER, THAT NOTHING IN THIS SECTION 13.6 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY UNDER SECTIONS 13.1, 13.2, 13.3, 13.4 and 13.5.

13.7 Insurance.

13.7.1 Each Party shall maintain insurance coverage as set forth in this Section 13.7 at its own cost; provided, however, Genentech has the right, in its sole discretion, to self-insure, in part or in whole, for any such coverage. The following provisions of this Section 13.7 shall not apply with respect to BioNTech's Conduct of any Ongoing Clinical Study.

(a) Each Party shall maintain commercial general liability ("CGL") insurance, including contractual liability, combined single limit for bodily injury and property damage liability, in the minimum amount per occurrence of: (i) [***] with respect to Genentech and [***] with respect to BioNTech, commencing as of the Effective Date; (ii) [***] with respect to Genentech and [***] with respect to BioNTech, commencing at least [***] days prior to any period during which a Party (or its Sublicensees or permitted subcontractors) is conducting a clinical trial with any Collaboration Product; and (iii) [***] with respect to Genentech and [***] with respect to BioNTech, commencing at least [***] prior to any period during which a Party (or its Sublicensees) is selling any Collaboration Product, *provided*, however, that, in each case, the total amount of insurance coverage to be maintained by either Party for all occurrences per Calendar Year shall be limited to [***] of the minimum amounts per occurrence set forth above.

(b) Each Party shall maintain products liability insurance, including contractual liability, combined single limit for bodily injury and property damage liability, for all occurrences per Calendar Year in the minimum amount of: (i) [***] with respect to Genentech and [***] with respect to BioNTech commencing at least [***] days prior to any period during which a Party (or its Sublicensees or permitted subcontractors) is conducting a clinical trial with any Collaboration Product and (ii) [***] with respect to Genentech and [***] Euro with respect to BioNTech commencing at least [***] prior to any period during which a Party (or its Sublicensees) is selling any Collaboration Product; provided, however, the JDC may, via mutual agreement, upon [***] days' notice to the Parties, increase such minimum amount, taking into account the particular Collaboration Products then being Developed under the GDP and the methods of administration, Indications in clinical trials and projected sales thereof and, in the event the Parties enter into a Co-Promotion Agreement, the JCC may, via mutual agreement, upon [***] days' notice to the Parties, increase such minimum amount, taking into account the particular Collaboration Products then being co-promoted under a Co-Promotion Agreement and the methods of administration, Indications approved and projected sales thereof.

(c) **Workers' Compensation and Employers' Liability Insurance.** Each Party shall maintain (i) to the extent not covered by applicable statutory law (e.g. in Germany), workers' compensation insurance in accordance with Applicable Law and (ii) employers' liability insurance, in the minimum amount of [***] or [***]. Each Party agrees to waive its right of subrogation with respect to workers' compensation claim.

13.7.2 Additional Requirements. Except to the extent that a Party self-insures, the following provisions shall apply.

(a) All insurance coverage shall be primary insurance with respect to each Party's own participation under this Agreement and shall be maintained with an insurance company or companies having an A.M. Best's rating (or its equivalent) of A XII.

(b) The insurance policies shall be under an occurrence form, but if only a claims made form is available to a Party, such Party shall maintain the insurance coverage for at least [***] years after such Party completes performance of its obligations under this Agreement.

(c) Each Party's aggregate deductibles under its CGL and Products Liability and insurance policies shall be satisfactory to the other Party.

(d) On request, each Party shall provide to the other Party certificates of insurance evidencing the insurance coverage required under this Section 13.7. Each Party shall provide to the other Party at least [***] days' prior written notice of any cancellation, nonrenewal or material change in any of the required insurance coverages.

ARTICLE 14. TERM AND TERMINATION

14.1 Term.

14.1.1 HSR and Other Governmental Filings. The Parties shall each, as promptly as practicable after the Execution Date, file or cause to be filed with the U.S. Federal Trade Commission and the U.S. Department of Justice and any relevant foreign governmental authority any notifications required to be filed under the HSR Act (the "**HSR Filing**") or any similar applicable foreign law or regulation with respect to the transactions contemplated hereby; *provided* that the Parties shall each make the HSR Filing within [***] Business Days after the Execution Date and shall each file any notifications or filings required to be filed under any competition, antitrust or similar applicable foreign laws and regulations as promptly as reasonably practicable. The Parties shall use commercially reasonable efforts to respond promptly to any requests for additional information made by such agencies, and to cause the waiting period (and any extension thereof) under the HSR Act to terminate or expire at the earliest possible date and obtain any required authorization or clearance under any competition, antitrust or similar applicable foreign law or regulation ("**Required Clearances**") after the date of filing. [***] In addition, each Party is responsible for the costs and expenses of its own legal and other advice in preparing and conducting the HSR Filing or any equivalent foreign filing.

14.1.2 Term. Notwithstanding anything in this Agreement to the contrary, this Agreement (other than this Section 14.1, and Sections 9.6, 11.4.2 and 11.7, and Article 13 (other than Section 13.7) which are binding and effective as of the Execution Date) shall not become effective until the later of (a) the expiration or earlier termination of the waiting period (or any extension thereof) under the HSR Act in the United States and the receipt of any Required Clearances and (b) the date on which each of the closing conditions set forth on Schedule 14.1.2 are met or waived in writing by Genentech (the date when (a) and (b) are first both satisfied, the “**Effective Date**”), and upon the Effective Date the full Agreement and all its terms and provisions shall be automatically effective and binding on both Parties. If, on the [***]day after the date of the HSR Filing, the waiting period required thereunder has not expired or any Required Clearances shall not have been obtained, either Party shall have the right, on written notice to the other Party, to terminate this Agreement, and upon receipt of such notice by such other Party, this Agreement shall be null and void and have no further force and effect; provided, however, the aforesaid Sections and Article shall survive with respect any rights that accrued to the benefit of a Party prior to such termination. If, by [***]days after the Execution Date, each of the closing conditions set forth on Schedule 14.1.2 have not been met or waived in writing, then at any time prior to each such closing condition having been met or waived in writing, Genentech shall have the right by delivery of written notice to BioNTech to terminate this Agreement effective immediately, and upon receipt of such notice by BioNTech, this Agreement shall be null and void and have no further force and effect; provided, however, the aforesaid Sections and Article shall survive with respect any rights that accrued to the benefit of a Party prior to such termination. This Agreement shall commence on the Effective Date (other than the provisions effective as of the Execution Date as designated above) and, unless earlier terminated in accordance herewith, shall continue in force and effect until the date of expiration of the Collaboration Term (or the date of expiration of the last Royalty Term for a Royalty Product, if BioNTech has exercised its Opt-Out (or a Deemed Opt-Out has occurred pursuant to Section 8.5.3)) (such period, the “**Term**”).

14.1.3 Effect of Expiration of the Term. Following the expiration of the Term, the grants in Article 9 shall become fully-paid, royalty-free and irrevocable.

14.2 Termination by Either Party for Material Breach. If either Party (the “**Non-Breaching Party**”) believes that the other Party (or any of its Affiliates or permitted subcontractors or sublicensees) (the “**Breaching Party**”) has materially breached one or more of its material obligations under this Agreement (a “**Material Breach**”), then the Non-Breaching Party may deliver notice of a Material Breach to the Breaching Party (a “**Default Notice**”). If the Breaching Party does not dispute that it has committed a Material Breach, then if the Breaching Party fails to cure such Material Breach, or fails to take steps as would be considered reasonable to effectively cure such Material Breach, within [***] days after receipt of the Default Notice or such other period as mutually agreed by the Parties, the Non-Breaching Party may terminate this Agreement upon written notice to the Breaching Party. If the Breaching Party disputes that it has committed a Material Breach, the dispute shall be resolved in good faith pursuant to Section 15.7.1, or pursuant to Section 15.7.2(g), if necessary. If, as a result of the application of such dispute resolution procedures, the Breaching Party is determined to be in Material Breach (an “**Adverse Ruling**”), then the Non-Breaching Party may terminate this Agreement upon written notice to the Breaching Party.

14.3 Additional Termination Rights by Genentech.

14.3.1 For Non-Achievement of Targets. Genentech may terminate this Agreement in its entirety upon [***] days' prior written notice to BioNTech in the event that (a) the Core Facility and the EUFETS Facility have not achieved Operational Readiness with respect to the IVAC 2.0 Process by October 31, 2017, (b) the Clinical Facilities have not achieved Operational Readiness with respect to the IVAC 2.1 Process by May 31, 2018, (c) BioNTech fails to achieve [***], or (d) Genentech in good faith believes that [***]

14.3.2 For Convenience. At any time [***], Genentech may terminate this Agreement in its entirety for any or no reason, upon [***] days' prior written notice to BioNTech.

14.4 Termination for Insolvency. In the event that either entity included within a Party (a) files for protection under bankruptcy or insolvency laws, (b) makes an assignment for the benefit of creditors, (c) appoints or suffers appointment of a receiver or trustee over substantially all of its property that is not discharged within [***] days after such filing, (d) proposes a written agreement of composition or extension of its debts, (e) proposes or is a party to any dissolution or liquidation, or (f) files a petition under any bankruptcy or insolvency act or has any such petition filed against that is not discharged within [***] days of the filing thereof, then the other Party may terminate this Agreement in its entirety effective immediately upon written notice to such Party.

14.5 Effects of Termination. In the event of a termination of this Agreement after the Effective Date for any reason, then, from and after the effective date of termination, the provisions of this Section 14.5 shall apply.

14.5.1 Termination of Licenses and Rights of Reference. As of the effective date of such termination, (a) all licenses and Rights of Reference granted by BioNTech hereunder shall immediately terminate other than the license set forth in Section 9.1.2, and (b) all licenses and Rights of Reference granted by Genentech hereunder shall immediately terminate other than the license set forth in Section 9.2.2; except to the extent reasonably necessary for the licensee Party to fulfill its post-termination obligations under this Section 14.5.

14.5.2 Wind-Down of Clinical Studies. Subject to Sections 14.5.3 and 14.5.5, except as may be otherwise agreed in writing by the Parties, each Party will be responsible for an orderly wind-down of any ongoing Clinical Studies it is Conducting as of the date of termination of this Agreement (other than those that may be transferred under Section 14.5.3) (and, in the case of a GDP Collaboration Product, any wind-down costs associated therewith shall be included as Shared Development Costs, unless an Opt-Out has occurred), in accordance with accepted pharmaceutical industry norms and ethical practices, including with respect to any on-going Clinical Studies hereunder. In connection with such wind-down, if one Party is then supplying the other Party with clinical supplies for such Clinical Studies, then such supplying Party shall supply the other Party under such agreement with continued quantities of clinical supplies to fulfill demand for such clinical supplies until [***] (and in the case of a GDP Collaboration Product if an Opt-Out has not occurred the Fully-Burdened Manufacturing Costs with respect thereto shall be included as Shared Development Costs).

14.5.3 Transfer of Clinical Studies. In the event of a termination of this Agreement by Genentech pursuant to Sections 14.3.1 or 14.3.2 or by BioNTech pursuant to Section 14.2, then, provided that [***] and except as may be otherwise agreed in writing by the Parties, upon written request of BioNTech to be delivered no later than [***] days following the delivery of relevant termination notice, Genentech shall [***] Any transfer costs associated with such Clinical Studies shall be included as Shared Development Costs.

14.5.4 Post-Term License.

(a) In the event of a termination of this Agreement by Genentech pursuant to Sections 14.3.1 or 14.3.2 or by BioNTech pursuant to Section 14.2, provided that the termination is not due to the demonstration of an unfavorable safety profile of Collaboration Product(s), then upon BioNTech's written request to be delivered no later than [***] days following the delivery of a notice of termination by Genentech under Section 14.3.1 or 14.3.2 or by BioNTech under Section 14.2 ("**Post-Term License Notice**"), Genentech shall grant to BioNTech pursuant to a separate written agreement [***] If Genentech and BioNTech have not entered into such agreement until the effective date of termination, [***]

(b) In the event a timely-delivered Post-Term License Notice requests a license under [***] In the event the Parties are unable to agree on such reasonable economic terms, the dispute shall be resolved in accordance with Section 15.7; provided that in the event the dispute is arbitrated, the Arbitrators shall be required to adopt the economic terms proposed by one Party or the other Party, without modification, that best reflect commercially reasonable terms (i.e., baseball-style arbitration). [***]

(c) Pursuant to mutual, good faith discussions, Genentech will transfer to BioNTech or grant a royalty-free license to BioNTech under the trademark(s) Controlled by Genentech and solely relating to the Terminated Product(s) that has been approved by the applicable Regulatory Authority (where approval is required) and used in connection with the Commercialization of any Terminated Product.

14.5.5 Transfer of Data and Regulatory Rights. In the event of a termination of this Agreement by Genentech pursuant to Sections 14.3.1 or 14.3.2 or by BioNTech pursuant to Section 14.2, then, if prior to the effective date of termination, any IND has been filed by Genentech and provided that the termination [***], then upon written request of BioNTech to be delivered no later than [***] days following the delivery of relevant termination notice (a) subject to Section 14.5.11, to the extent permitted by Applicable Law, such INDs and any Regulatory Approvals solely related to the applicable Termination Products held by Genentech or its Affiliates or Sublicensees shall be transferred to BioNTech or its designee, and [***]

14.5.6 Collaboration Patent Prosecution and Maintenance and Enforcement Rights. [***]

14.5.7 Clinical Supply. In the event of a termination of this Agreement by Genentech pursuant to Sections 14.3.1 and 14.3.2 or by BioNTech pursuant to Section 14.2 and provided that (i) Genentech has been performing Clinical Manufacture and supply of a Termination Product before the effective date of termination of this Agreement and (ii) [***], then at BioNTech's written request, Genentech shall, [***], continue to perform such Clinical Manufacture and supply of Termination Product, subject to any applicable surviving provisions of the Ancillary Agreements (pursuant to Section 14.5.12) including the patient demand forecasting provisions of the MDSA. The following shall apply in respect of any activities performed by Genentech under this Section 14.5.7:

(a) BioNTech shall pay Genentech a supply price for Collaboration Product equal to [***]

(b) BioNTech may at any time after the effective date of termination of this Agreement, terminate the clinical supply of Collaboration Products under this Section 14.5.7 upon [***] months' written notice.

(c) During such time as Genentech is obligated to provide clinical supply of Termination Products, it shall perform the Clinical Manufacture of Termination Product in accordance with the requirements of the MDSA (including for the avoidance of doubt with respect to Capacities and forecasting) and the Quality Agreement.

14.5.8 Commercial Supply. In the event of a termination of this Agreement by Genentech pursuant to Sections 14.3.1 and 14.3.2 or by BioNTech pursuant to Section 14.2 and provided that (i) Genentech has established one or more Manufacturing Facilities that have received Licensure to provide commercial supply of a Termination Product and BioNTech has not established any Manufacturing Facilities that have received Licensure and have sufficient Capacities for commercial supply of such Termination Product and (ii) [***], then, subject to any applicable surviving provisions of the Ancillary Agreements (pursuant to Section 14.5.12) including the patient demand forecasting provisions of the MDSA, at BioNTech's written request, Genentech shall:

[***]

14.5.9 [***]

14.5.10 Confidential Information. Except as otherwise necessary to continue exercising any ongoing licenses under this Agreement or any ongoing license mutually agreed upon pursuant to Section 14.5.4, each Party will return (or destroy, as directed by the other Party) all data, files, records and other materials containing or comprising the other Party's Confidential Information. Notwithstanding the foregoing, (a) in respect of physical embodiments of information, the Parties will be permitted to retain one copy of such data, files, records, and other materials for non-commercial archival purposes, and (b) in respect of any information stored electronically or in other non-physical media, it will be sufficient for such Party to procure that access to such information is restricted to non-commercial archiving purposes only.

14.5.11 Limitation. For clarity, Genentech's obligations pursuant to Sections 14.5.2 through 14.5.10, including the licenses contemplated by Section 14.5.4 (and including Genentech's obligation with respect to Regulatory Approvals and Regulatory Documentation pursuant to Section 14.5.5, and Genentech's supply obligations set forth in Sections 14.5.7 and 14.5.8), shall apply with respect to Terminated Products (or, solely to the extent expressly provided pursuant to this Section 14.5, Reversion Products) only, and shall not, for clarity, impose any obligation on Genentech or grant any rights to BioNTech with respect to any Combination Agent except as [***] expressly and mutually agreed by the Parties in connection with a termination of this Agreement.

14.5.12 Effect on Ancillary Agreements. In the case of termination of this Agreement for any reason, all other Ancillary Agreements shall terminate as of the effective date of the termination of this Agreement (or such longer period as may be required to allow the Parties to comply with their obligations under Applicable Law), except that the Manufacturing Development and Supply Agreement, the Commercial Manufacturing Agreement and the Quality Agreement(s), shall survive termination of this Agreement solely to the extent that, and as long as, BioNTech or Genentech is obliged to Manufacture and supply (clinical or commercial) Collaboration Products pursuant to Sections 14.5.2, 14.5.7 or 14.5.8, and shall terminate thereafter.

14.6 Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by Genentech or BioNTech are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that the Parties, as licensees of such rights under this Agreement, shall retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, the Party hereto that is not a Party to such proceeding shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in the non-subject Party's possession, shall be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon the non-subject Party's written request therefor, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement, or (b) if not delivered under clause (a) above, following the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefor by the non-subject Party. The Parties acknowledge and agree that only payments under Section 8.6, royalty payments with respect to BioNTech Collaboration Product [***] pursuant to Section 5.3 and [***] shall (i) constitute royalties within the meaning of Section 365(n) of the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction or (ii) relate to licenses of intellectual property hereunder. To the extent permitted by applicable law, the non-subject Party shall have the right but not the obligation to take over the entire ownership of the Collaboration IP in consideration for a fair compensation.

14.7 Remedies. Except as otherwise expressly provided herein, termination of this Agreement (either in its entirety or with respect to one or more country(ies)) in accordance with the provisions hereof shall not limit remedies that may otherwise be available in law or equity.

14.8 Accrued Rights; Surviving Obligations. Termination or expiration of this Agreement (either in its entirety or with respect to one or more country(ies)) for any reason shall be without prejudice to any rights that shall have accrued to the benefit of a Party prior to such termination or expiration. Such termination or expiration shall not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement. Without limiting the foregoing, [***]

ARTICLE 15. MISCELLANEOUS

15.1 Force Majeure. Neither Party shall be deemed to have breached this Agreement for failure to perform its obligations under this Agreement to the extent such failure results from causes beyond the reasonable control of the affected Party, such causes including acts of God, earthquakes, fires, floods, embargoes, wars, acts of terrorism, insurrections, riots, civil commotions, omissions or delays in action by any governmental authority, acts of a government or agency thereof and judicial orders or decrees. If a force majeure event occurs, the Party unable to perform shall promptly notify the other Party of the occurrence of such event, and the Parties shall meet (in person or telephonically) promptly thereafter to discuss the circumstances relating thereto. The Party unable to perform shall (a) provide reasonable status updates to the other Party from time to time; (b) use commercially reasonable efforts to mitigate any adverse consequences arising out of its failure to perform; and (c) resume performance as promptly as possible.

15.2 Change in Control of BioNTech.

15.2.1 Notice.

(a) BioNTech (or its successor) shall provide Genentech with written notice of any [***] Change in Control within [***] following [***]

(b) The Parties shall agree on a process to have mutually agreed outside counsel assist in making a determination as to whether [***]

15.2.2 [*] Change in Control.** In the event of any [***] Change in Control, then notwithstanding anything to the contrary contained in this Agreement, each of the following consequences shall apply effective as of the closing date of such Change in Control, or such later date as applicable pursuant to Section 15.2.2(k):

(a) BioNTech shall not have the right to Initiate any BioNTech Study without the prior written consent of Genentech. BioNTech may Conduct BioNTech Study(ies), subject to all applicable provisions of this Agreement (including Section 4.5) and any Ancillary Agreements, solely in the event that any such BioNTech Study was Initiated prior to the closing date of such Change in Control.

(b) BioNTech shall no longer have the right to [***].

(c) BioNTech's rights under Section 6.5, including its Co-Promotion Option for all Indications, shall terminate, all Co-Promotion Agreements already executed shall terminate and BioNTech shall have no further Co-Promotion Option rights for any Indication under Section 6.5.

(d) BioNTech's rights to build any Commercial Facilities for inclusion in the Manufacturing Network pursuant to Section 2.2.2 of the MDSA and any Independent Facilities outside of the Manufacturing Network (including for the Manufacture of BioNTech Collaboration Products under [***] pursuant to Section 2.2.5 of the MDSA, respectively, shall terminate upon the closing date of a [***] Change in Control, [***]

(e) Each of the provisions of this Agreement providing for any delivery by Genentech to BioNTech of Information relating to activities contemplated by this Agreement (including Sections 2.19.2(a) and 2.19.2(b)), save only for the provisions of Sections 5.8 and 5.9, shall terminate.

(f) Genentech may request that BioNTech (including EUFETS) perform, to the extent not already completed and to enable Genentech to perform the Clinical Manufacture of Collaboration Product at a facility to be designed, constructed, Commissioned, and Qualified by Genentech and to continue to develop the Manufacturing Process and Technology Platform, a Technology Transfer of the Manufacturing Process from the Clinical Facilities or the Pilot Facility to Genentech, including the Development of the Manufacturing Process, Manufacturing Documentation and BioNTech Know-How and any other reasonable activities, including any such activities that may be on-going in support of the Technology Platform Strategy and Technology Platform Roadmap. Such activities shall be included within Shared Development Costs (except in the case of an Opt-Out, in which case the financial provisions of Section 7.3 shall apply). Genentech may, at any time, terminate such Technology Transfer activities under this Section 15.2.2(f) upon [***] days' written notice. BioNTech shall perform such activities in accordance with the requirements of the MDSA and the Quality Agreement.

(g) BioNTech shall perform Clinical Manufacture and supply the quantities of Collaboration Products for Clinical Studies contemplated by the GDP (as amended until the closing date of a Class A Competitor Change in Control) or for Genentech Studies pursuant to the applicable provisions (including patient demand forecasting provisions) of the MDSA; provided that, in the event Genentech requests Technology Transfer, BioNTech may cease such Clinical Manufacture and supply [***] years following the first commercial launch of a Collaboration Product other than a BioNTech Collaboration Product. The following shall apply in respect of any activities performed by BioNTech (including EUFETS) under this Section 15.2.2(g):

(i) Genentech shall pay BioNTech a supply price for Collaboration Product equal to [***]

(ii) Genentech may at any time after the closing date of the Class A Competitor Change in Control terminate the clinical supply of Collaboration Product upon [***] written notice.

(iii) During such time as BioNTech is obligated to provide clinical supply of Collaboration Products, it shall perform Clinical Manufacture of Collaboration Product in accordance with the requirements of the MDSA (including for the avoidance of doubt with respect to Capacities and forecasting) and the Quality Agreement.

(h) The MDSA, the Commercial Manufacturing Agreement (to the extent a BioNTech Commercial Facility within the Manufacturing Network has been Commissioned or received Licensure) and the respective Quality Agreement(s) shall survive solely to the extent that, and as long as, BioNTech provides Technology Transfer services or Manufacturing and supply services under this Section 15.2.2, and shall terminate thereafter except for those provisions specified in the MDSA, the Commercial Manufacturing Agreement and the respective Quality Agreement(s) which expressly survive termination.

(i) Subject to Section 15.2.2(d), each of the Committees and Teams (other than the JMT and the JMC) shall be disbanded and their activities terminated. Genentech shall have the sole right to make the decisions assigned to the disbanded Committees and Teams and the JMC and JMT solely and exclusively by itself. Notwithstanding the foregoing, Genentech may request in writing that BioNTech continue its participation in any Committee or Team scheduled for automatic disbandment. In such a case, Genentech shall be responsible for the cost and expense of BioNTech's participation in such Committee or Team based on BioNTech's then current FTE Rate. The JMT and JMC shall remain in effect for so long as Technology Transfer or supply of Collaboration Product by BioNTech to Genentech is ongoing or has not been completed. Thereafter, the applicable provisions of Section 2.8.2(g) shall apply.

(j) BioNTech shall, and shall cause the Change in Control party to, promptly adopt and implement and subsequently maintain and comply with written [***] Firewall procedures reasonably acceptable to Genentech.

(k) [***]

15.2.3 Change in Control [***] In the event of any Change in Control other than a Class A Competitor [***], then notwithstanding anything to the contrary contained in this Agreement, each of the following consequences shall apply effective as of the closing date of such Change in Control, subject to Section 15.2.2(k):

(a) BioNTech shall not have the right to Initiate any BioNTech Study without the prior written consent of Genentech. BioNTech may Conduct BioNTech Study(ies), subject to all applicable provisions of this Agreement (including Section 4.5) and any Ancillary Agreements, solely in the event that any such BioNTech Study was Initiated prior to the closing date of such Change in Control.

(b) BioNTech shall no longer have the right to seek a [***]

(c) BioNTech's rights to build any Commercial Facilities for inclusion in the Manufacturing Network pursuant to Section 2.2.2 of the MDSA and any Independent Facilities outside of the Manufacturing Network (including for the Manufacture of BioNTech Indications under [***] pursuant to Section 2.2.5 of the MDSA, respectively, shall terminate upon the closing date of such Change in Control, [***] Section 2.2.5(e) of the MDSA regarding support by Genentech with respect to Independent Facilities shall terminate upon the closing date of such Change in Control. [***] In addition, BioNTech's JMC decision-making rights as set forth in Section 2.8.2 shall terminate and become Genentech decision-making rights (other than with respect to [***])

(d) [***]

(e) Genentech may request that BioNTech (including EUFETS) perform, to the extent not already completed and to enable Genentech to perform the Clinical Manufacture of Collaboration Product at a facility to be designed, constructed, Commissioned, and Qualified by Genentech and to continue to develop the Manufacturing Process and Technology Platform, a Technology Transfer of the Manufacturing Process from the Clinical Facilities or the Pilot Facility to Genentech, including the Development of the Manufacturing Process, Manufacturing Documentation and BioNTech Know-How and any other reasonable activities, including any such activities that may be on-going in support of the Technology Platform Strategy and Technology Platform Roadmap. Such activities shall be included within Shared Development Costs (except in the case of an Opt-Out, in which case the financial provisions of Section 7.3 shall apply). Genentech may, at any time, terminate such Technology Transfer activities under this Section 15.2.3(e) upon [***] days' written notice. BioNTech shall perform such activities in accordance with the requirements of the MDSA and the Quality Agreement.

(f) BioNTech shall perform Clinical Manufacture and supply the quantities of Collaboration Products for Clinical Studies contemplated by the GDP (as amended until the closing date of a non-Class A Competitor Change in Control) or for Genentech Studies pursuant to the applicable provisions (including patient demand forecasting provisions) of the MDSA; provided that, in the event Genentech requests Technology Transfer, BioNTech may cease such Clinical Manufacture and supply [***] following the first commercial launch of a Collaboration Product other than a BioNTech Collaboration Product. The following shall apply in respect of any activities performed by BioNTech (including EUFETS) under this Section 15.2.3(f):

(i) Genentech shall pay BioNTech a supply price for Collaboration Product equal to [***]

(ii) Genentech may at any time after the closing date of the Class A Competitor Change in Control terminate the clinical supply of Collaboration Product upon [***] written notice.

(iii) During such time as BioNTech is obligated to provide clinical supply of Collaboration Products, it shall perform Clinical Manufacture of Collaboration Product in accordance with the requirements of the MDSA (including for the avoidance of doubt with respect to Capacities and forecasting) and the Quality Agreement.

(g) The JCC shall disband, except to the extent relating to Co-Promotion by the Parties as set forth in Section 6.5 or under any Co-Promotion Agreement. The JMT and JMC shall remain in effect for so long as Technology Transfer or supply of Collaboration Product by BioNTech to Genentech is ongoing or has not been completed. Thereafter, the applicable provisions of Section 2.8.2(g) shall apply.

(h) In the event of a Change in Control that occurs prior to [***], BioNTech shall, and shall cause the Change in Control party to, promptly adopt and implement and subsequently maintain and comply with written Change in Control Firewall procedures reasonably acceptable to Genentech.

15.2.4 [***]

15.2.5 [***]

15.3 Export Control. This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States or other countries that may be imposed on the Parties from time to time. Each Party agrees that it will not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate agency or other governmental entity in accordance with Applicable Law.

15.4 Assignment. Except as otherwise expressly provided in this Agreement, neither Party may assign any of its rights or obligations under this Agreement without the prior written consent of the other Party, such consent not to be unreasonably withheld or delayed. Either Party may assign this Agreement, in its entirety, to an acquirer of all its capital stock (by reverse triangular merger or otherwise) or all or substantially all its assets relating to the subject matter of this Agreement and the MDSA, provided, in each case, that the party to which this Agreement is assigned expressly agrees in writing to assume and be bound by the obligations of the assigning Party under this Agreement and is also assigned the MDSA in its entirety in accordance with the terms of Section 10.3 of the MDSA. A copy of such writing shall be provided to the non-assigning Party within [***] days of the assignment. Subject to the foregoing, this Agreement will inure to the benefit of and bind the Parties' successors and assigns. Any assignment or delegation in contravention of the foregoing shall be null and void. For clarity, Section 15.2 applies in the event of a Change in Control.

15.5 Severability. If any of the provisions of this Agreement are held to be illegal, invalid or unenforceable, such illegal, invalid or unenforceable provisions shall be replaced by legal, valid and enforceable provisions that will achieve to the maximum extent possible the intent of the Parties, and the other provisions of this Agreement shall remain in full force and effect.

15.6 Governing Law and Service.

15.6.1 Governing Law. This Agreement shall be governed by and construed under the laws of Switzerland, without regard to conflict of laws principles. For the avoidance of doubt, the joint ownership in the Collaboration IP, as a property right, shall be governed by the laws of Switzerland. The Parties hereby exclude from this Agreement the application of the United Nations Convention on Contracts for the International Sale of Goods.

15.6.2 Service. Each Party further agrees that service of any process, summons, notice or document by registered mail to its address set forth in Section 15.8.2 shall be effective service of process for any action, suit, or proceeding brought against it under this Agreement in any such court.

15.7 Dispute Resolution.

15.7.1 Internal Resolution. Except as otherwise expressly provided in this Agreement (including as otherwise expressly provided with respect to audit disputes in Section 8.17, and Committee, Team or Working Group disputes as set forth in Article 2), any Disputes shall be first referred to a [***] for resolution, prior to proceeding under the other provisions of Section 15.7. A Dispute shall be referred to such executives upon one Party providing the other Party with notice that such Dispute exists, and such executives (or their designees) shall attempt to resolve such Dispute through good faith discussions. In the event that such Dispute is not resolved within [***] days of such other Party's receipt of such notice, subject to Section 15.7.3, either Party may initiate the Dispute resolution provisions in Section 15.7.2.

15.7.2 Arbitration.

(a) **Rules.** Except as otherwise expressly provided in this Agreement (including under Section 15.7.3), the Parties agree that any Dispute not resolved internally by the Parties pursuant to Section 15.7.1 shall be finally resolved through binding arbitration according to the International Chamber of Commerce (ICC) Rules of Arbitration, as applicable on the date of commencement of the arbitration proceedings. Place of arbitration shall be Zurich, Switzerland. Exclusive language of the proceedings shall be English. In addition to the ICC Rules of Arbitration, the procedural law in force at the seat of arbitration shall apply.

(b) **Arbitrators; Language.** Each Party shall select [***], and the [***] so selected shall choose a [***]. All [***] arbitrators shall serve as neutrals and have at least ten (10) years of (i) dispute resolution experience (which may include judicial experience) or (ii) legal or business experience in the biotechnology or pharmaceutical industry. In any event, at least one (1) arbitrator shall satisfy the foregoing experience requirement under clause (ii). If a Party fails to nominate its arbitrator, or if the Parties' arbitrators cannot agree on the [***], the necessary appointments shall be made in accordance

with the Rules. Once an arbitrator is appointed by a Party, such Party shall have no ex parte communication with its appointed arbitrator. The arbitration proceedings and all pleadings and written evidence shall be in the English language. Any written evidence originally in another language shall be submitted in English translation accompanied by the original or a true copy thereof.

(c) **Procedures; Awards.** Each Party agrees to use reasonable efforts to make all of its current employees available, if reasonably needed, and agrees that the arbitrators may deem any party as “necessary.” The arbitrators shall be instructed and required to render a written, binding, non-appealable resolution and award on each issue that clearly states the basis upon which such resolution and award is made. The written resolution and award shall be delivered to the Parties as expeditiously as possible, but in no event more than [***] days after conclusion of the hearing, unless otherwise agreed by the Parties. Judgment upon such award may be entered in any competent court or application may be made to any competent court for judicial acceptance of such an award and order for enforcement. Each Party agrees that, notwithstanding any provision of applicable law or of this Agreement, it will not request, and the arbitrators shall have no authority to award any damages for which a Party may not be liable to the other Party under Section 13.6.

(d) **Costs.** The “prevailing” Party, as determined by the arbitrators, shall be entitled to (i) its share of fees and expenses of the arbitrators and (ii) its attorneys’ fees and associated costs and expenses. In determining which Party “prevailed,” the arbitrators shall consider (A) the significance, including the financial impact, of the claims prevailed upon and (B) the scope of claims prevailed upon, in comparison to the total scope of the claims at issue. If the arbitrators determine that, given the scope of the arbitration, neither Party “prevailed,” the arbitrators shall order that the Parties (x) share equally the fees and expenses of the arbitrators and (y) bear their own attorneys’ fees and associated costs and expenses.

(e) **Interim Equitable Relief.** Notwithstanding anything to the contrary in this Section 15.7.2, in the event that a Party reasonably requires relief on a more expedited basis than would be possible pursuant to the procedure set forth in Article 15, such Party may seek a temporary injunction or other interim equitable relief in a court of competent jurisdiction pending the opportunity of the arbitrators to review the decision under this Section 15.7.2. Such court shall have no jurisdiction or ability to resolve Disputes beyond the specific issue of temporary injunction or other interim equitable relief.

(f) **Protective Orders; Arbitrability.** At the request of either Party, the arbitrators shall enter an appropriate protective order to maintain the confidentiality of information produced or exchanged in the course of the arbitration proceedings. The arbitrators shall have the power to decide all questions of arbitrability.

(g) **Expedited Dispute Resolution Procedure.** In the event that a Breaching Party under Section 14.2 disputes that it has committed a Material Breach or a dispute arises under Section 4.5.4(g), and such dispute is not resolved pursuant to Section 15.7.1, then non-breaching Party under Section 14.2 or the objecting Party under Section 15.7.2(g) may invoke the expedited dispute resolution procedure set forth in Schedule

15.7.2(g). In such a case, the expedited dispute resolution shall be limited to the issues, as applicable, of (i) whether a Material Breach was committed, whether a cure is possible and what actions the Breaching Party must complete to effect such cure or (ii) compliance with Applicable Law in connection with a Clinical Study Conducted by BioNTech. In such a case, any other issues may be resolved through the standard arbitration provisions set forth herein.

15.7.3 Subject Matter Exclusions. Notwithstanding the provisions of Section 15.7.2, any Dispute not resolved internally by the Parties pursuant to Section 15.7.1 that involves the validity, infringement or enforceability of a Patent included in a license granted in this Agreement (a) that is issued in the United States shall be subject to actions before the United States Patent and Trademark Office or submitted exclusively to the federal court located in the jurisdiction of the district where any of the defendants reside and (b) that is issued in any other country (or region) shall be brought before an appropriate regulatory or administrative body or court in that country (or region), and in all cases, the Parties hereby consent to the jurisdiction and venue of such courts and bodies.

15.8 Notices.

15.8.1 Notice Requirements. Except as otherwise expressly provided in this Agreement, any notice required under this Agreement shall be in writing, shall specifically refer to this Agreement and shall be sent in accordance with the provisions of this Section 15.8. Notices shall be sent via one of the following means and will be effective (a) on the date of delivery, if delivered in person; (b) on the date of receipt, if sent by a facsimile (including a PDF image delivered via email); or (c) on the date of receipt, if sent by private express courier or by first class certified mail, return receipt requested (or its equivalent). Any notice sent via facsimile shall be followed by a copy of such notice by private express courier or by first class mail. Notices shall be sent to the other Party at the addresses set forth below. Either Party may change its addresses for purposes of this Section 15.8 by sending written notice to the other Party. For clarity, notice to Genentech shall require notice to both GNE and Roche, and notice to BioNTech shall require notice to both BNT and RNP.

15.8.2 Addresses for Notices.

If to RNP, to:

BioNTech RNA Pharmaceuticals GmbH
An der Goldgrube 12
55131 Mainz
Attention: Managing Director
Facsimile: [***]

If to BNT, to:

BioNTech AG
An der Goldgrube 12
55131 Mainz
Attention: [***]
Facsimile: [***]

If to GNE, to:

Genentech, Inc.
1 DNA Way
South San Francisco, CA 94080
Attn: [***]
Fax: [***]

with a copy (which shall not constitute notice) to:

Genentech, Inc.
1 DNA Way
South San Francisco, CA 94080
Attn: [***]
Fax: [***]

If to Roche, to:

F. Hoffmann-La Roche Ltd
[***]
[***]
[***]
Attn: [***]
Fax: [***]

with a copy (which shall not constitute notice) to:

F. Hoffmann-La Roche Ltd
[***]
[***]
Attention: [***]
Fax: [***]

15.9 Entire Agreement. This Agreement (including the Schedules hereto), together with the Ancillary Agreements, constitute the entire understanding between the Parties with respect to the subject matter hereof and supersede and terminate all prior agreements, understandings and arrangements between the Parties with respect to such subject matter, whether written or oral. The Parties agree that, effective as of the Effective Date, the Confidentiality Agreements shall be superseded by this Agreement, and that disclosures made prior to the Effective Date pursuant to the Confidentiality Agreements shall be subject to the confidentiality and non-use provisions of this Agreement. [***]

15.10 English Language. This Agreement shall be written and executed in, and all other documents or communications issued or created under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

15.11 Equitable Relief. Each Party acknowledges and agrees that the restrictions set forth in Article 10 and Article 11 are reasonable and necessary to protect the legitimate interests of the other Party and that such other Party would not have entered into this Agreement in the absence of such restrictions, and that any breach or threatened breach of any provision of such Articles may result in irreparable injury to such other Party for which there will be no adequate remedy at law. In the event of a breach or threatened breach of any provision of such Articles, the non-breaching Party shall be authorized and entitled to seek from any court of competent jurisdiction injunctive relief, whether preliminary or permanent, specific performance, and an equitable accounting of all earnings, profits, and other benefits arising from such breach, which rights shall be cumulative and in addition to any other rights or remedies to which such non-breaching Party may be entitled in law or equity. Both Parties agree to waive any requirement that the other (a) post a bond or other security as a condition for obtaining any such relief, and (b) show irreparable harm, balancing of harms, consideration of the public interest, or inadequacy of monetary damages as a remedy. Nothing in this Section 15.11 is intended, or should be construed, to limit either Party's right to equitable relief or any other remedy for a breach of any other provision of this Agreement.

15.12 Amendment; Waiver. Except as otherwise expressly provided in this Agreement, no amendment to this Agreement, including this Section 15.12, shall be effective unless made in writing and executed by an authorized representative of each Party. A Party's failure to exercise, or delay in exercising, any right, power, privilege or remedy under this Agreement shall not (a) operate as a waiver thereof or (b) operate as a waiver of any other right, power, privilege or remedy. A waiver will be effective only upon the written consent of the Party granting such waiver.

15.13 No Benefit to Third Parties. Except as provided in Article 13, covenants and agreements set forth in this Agreement are for the sole benefit of the Parties hereto and their successors and permitted assigns, and they shall not be construed as conferring any rights on any other Persons.

15.14 Further Assurance. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

15.15 Relationship of the Parties. Except as provided in Section 8.13.4, it is expressly agreed that BioNTech, on the one hand, and Genentech, on the other hand, shall be independent contractors and that the relationship between BioNTech and Genentech shall not constitute a partnership, joint venture, or agency. Neither BioNTech, on the one hand, nor Genentech, on the other hand, shall have the authority to make any statements, representations, or commitments of any kind, or to take any action, which shall be binding on the other, without the prior written consent of the other Party to do so. It is expressly agreed that each Party shall solely act in its own name when dealing with any Third Party. All persons employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.

15.16 Counterparts; Facsimile Execution. This Agreement may be executed in two (2) or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. A facsimile (including a PDF image delivered via email) of this Agreement, including the signature pages hereto, will be deemed to be an original. Notwithstanding the foregoing, the Parties shall deliver original execution copies of this Agreement to one another as soon as practicable following execution thereof.

15.17 References. Unless otherwise specified, (a) references in this Agreement to any Article, Section or Schedule shall mean references to such Article, Section or Schedule of this Agreement, (b) references in any Section to any clause are references to such clause of such Section, and (c) references to any agreement, instrument, or other document in this Agreement refer to such agreement, instrument, or other document as originally executed or, if subsequently amended, replaced, or supplemented from time to time, as so amended, replaced, or supplemented and in effect at the relevant time of reference thereto.

15.18 Schedules. In the event of any inconsistencies between this Agreement and any schedules or other attachments hereto, the terms of this Agreement shall control.

15.19 Construction. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word “or” is used in the inclusive sense (and/or). Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend, or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term “including,” “include,” or “includes” as used herein shall mean including, without limiting the generality of any description preceding such term. The term “comprising” (or “comprise,” or “comprises” as used herein) shall mean “comprising, without limitation”. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party hereto. The phrase “by or on behalf” of a Party is not intended to include activities conducted by the other Party or its Affiliates or Sublicensees hereunder or under any Ancillary Agreement. The term “incurred” includes “accrued”. Where a provision refers to the consent or agreement of a Party, then the consent of either entity included within such Party shall be deemed consent of both entities included within such Party.

15.20 Actions of Affiliates. Genentech may exercise its rights or perform its obligations under this Agreement personally or through one or more Affiliates, provided that Genentech shall nonetheless be primarily liable for the performance of its Affiliates and for any failure by its Affiliates to comply with the restrictions, limitations and obligations set forth in this Agreement.

[SIGNATURE PAGE FOLLOWS.]

IN WITNESS WHEREOF, the Parties have caused their duly authorized officers to execute and acknowledge this Agreement as of the date first written above.

GENENTECH, INC.

By: [***]

Name: [***]

Title: [***]

F. HOFFMANN-LA ROCHE LTD

By: [***]

Name: [***]

Title: [***]

F. HOFFMANN-LA ROCHE LTD

By: [***]

Name: [***]

Title: [***]

**BIONTECH RNA
PHARMACEUTICALS GMBH**

By: [***]

Name: [***]

Title: [***]

BIONTECH AG

By: [***]

Name: [***]

Title: [***]

[SIGNATURE PAGE TO COLLABORATION AGREEMENT]

Schedule 1.8

Financial Terms

1.8-1

Schedule 1.20

[***]

Schedule 1.42

BNT and RNP Existing Shareholders

<u>Person</u>	<u>Percentage</u>
Medine GmbH	25.0% of BNT
C.Huber2008 GmbH	1.5% of BNT
AT Impf GmbH	62.8% of BNT
MIG GmbH & Co. Fonds 7	3.3% of BNT
Helmut Jeggle	0.2% of BNT
Klaus—J. Krauth	0.0% of BNT
MIG GmbH & Co. Fonds 8	1.1% of BNT
MIG GmbH & Co. Fonds 9	3.8% of BNT
RLG GmbH	0.6% of BNT
Salvia GmbH	1.4% of BNT
Tofino GmbH	0.4% of BNT
BNT	100% of RNP

Schedule 1.43

[***]

Schedule 1.97

Corporate Names

For GNE:

“Genentech, a member of the Roche Group”

“Genentech, Inc.”

For Roche:

“Roche”

“F. Hoffmann-La Roche Ltd”

For RNP:

“BioNTech RNA Pharmaceuticals GmbH”

For BNT:

“BioNTech AG

Schedule 1.132

Existing Third Party In-License Agreement Royalty Payments

Schedule 1.150

[***]

Schedule 1.156

[***]

Schedule 1.167

Schedule 1.190

IVAC Trademark

<u>Trademark</u>	<u>Country</u>	<u>Application Number</u>	<u>Application Date</u>	<u>Registration Number</u>	<u>Registration Date</u>	<u>Owner</u>	<u>Designated Countries</u>
IVAC	WO	1 103 583	10.10.2011	1 103 583	10.10.2011	BioNTech RNA Pharmaceuticals GmbH	CN, CH, EM, JP, US (US 4,797,141);
IVAC	DE	30 2011 020 675.9 / 05	11.04.2011	30 2011 020 675	21.06.2011	BioNTech RNA Pharmaceuticals GmbH	

[**]

Schedule 1.248

[**]

Schedule 2.2

[***]

Schedule 2.19.1(a)

BioNTech Initial Knowledge Transfer Items

No.	Document to be transferred:	Request by Genentech	Document in German	30d transfer target	60d transfer target	90d transfer target
	A Preclinical and Clinical Data / D Regulatory and Clinical Items / F Non Clinical Items					
1	NGS Data	(1) All whole exome sequence data from tumor and matched normal sample-clinical (raw fast files and alignment files (bam)). (2) All whole exome sequence data from preclinical tumor models (raw fastq files and alignment files (bam)). (3) Mutation calls for all samples with tumor and normal exome-seq data. (4) All whole transcriptome RNA sequence data from tumor – clinical and preclinical tumor models (raw fastq files and alignment files (bam))		X (2; 3, 4)	X (1)	
2	Bioinformatics software and source code	All source code, objects, scripts and executables underlying the Neopeptide Prediction Algorithm within BioNTech IP, including the following software packages (but excluding any Third Party software programs as disclosed on Schedule 12.2.1(i)): [***]		X (or as otherwise may be extended as mutually agreed upon by the Parties pursuant to Section 10.9)		
3	IVAC-B16-129 B16-M30 ELISpot Mut vs WT peptide, B16-M30 ELISpot of truncated variants	All relevant preclinical Antigen Immunogenicity data		X		
4	IVAC-B16-160 B16-M30 therapeutic vaccination (RNA, B16F10-WT, s.c.) including depletion of CD4/8 T cells	All relevant preclinical Antigen Immunogenicity data		X		
5	IVAC-B16-220 Spontaneous induction T-cell responses against B16F10 mutations	All relevant preclinical Antigen Immunogenicity data		X		
6	IVAC-B16-193 B16-M30 TIL ELISpot after therapeutic vaccination (RNA, B16F10-WT)	All relevant preclinical Antigen Immunogenicity data		X		
7	IVAC-B16-198 B16-M30 tumor FACS after therapeutic vaccination (RNA, B16F10-WT)	All relevant preclinical Antigen Immunogenicity data		X		
8	IVAC-CT26-027 CT26 pentatope RNA vs. mixed monotope ELISpot	All relevant preclinical Antigen Immunogenicity data		X		

93	GA-RB-007-01B_Prüfablaufprotokoll IFNg-ELISPOT-hu	BioNTech's expertise to enable GNE to perform the immune monitoring assays			X
94	SOP-030-012-V.01, Auftauen von humanen PBMCs	BioNTech's expertise to enable GNE to perform the immune monitoring assays			X
95	SOP-030-033-V.01, Elektroporation	BioNTech's expertise to enable GNE to perform the immune monitoring assays			X
96	LA-50-234-000	BioNTech's expertise to enable GNE to perform the immune monitoring assays			X
97	LA-50-236-000	BioNTech's expertise to enable GNE to perform the immune monitoring assays			X
98	SOP-030-008	BioNTech's expertise to enable GNE to perform the immune monitoring assays			X
99	LA-50-229-000	BioNTech's expertise to enable GNE to perform the immune monitoring assays			X
100	Will be provided	Preclinical tumor lines for which neoantigens have been identified for preclinical studies			X
C RNA Platform/Liposome for Pre-Clinical Studies					
100	Fluid_Path_FD.ppt	Relevant information of how to manufacturing liposomal-based mRNA vaccine for preclinical use			X
101	Material_List.doc	Relevant information of how to manufacturing liposomal-based mRNA vaccine for preclinical use			X
102	Fluid_Path_FD.ppt	Know-how including documents and materials to enable synthesis of mRNA vaccines at GNE for pre-clinical assessment Protocol of the lipoplex formulation			X
103	Lipo_IVAC_Data_FD.ppt	Know-how including documents and materials to enable synthesis of mRNA vaccines at GNE for pre-clinical assessment Protocol of the lipoplex formulation		X	
104	SOP_RB_F&E_033_de Codonoptimierung von Nukleinsäuren: - procedure for codon optimization of epitope-encoding region	Procedure for mRNA optimization	X		X

105	pIVAC001_Dummy_Cassette	Promoter nucleotide sequences necessary for in vitro transcription of the IVAC from a DNA template 5' and 3' UTR nucleotide sequences Nucleotide sequences appended to IVACs Linker element nucleotide sequences, which will separate the neoepitopes within a given IVAC	X
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[***]

[***]

137	SOP_RB_FuE_046 - PCR-basierte Amplifikation mit pEX-Primer - SOP PCR-based amplification using pEX primers	DNA template is linearized plasmid - protocols and reagent summary reports to be provided	X	X
138	P_BM_11_05 Amplification & purification of plasmid DNA used as template in GMP process	DNA template is linearized plasmid - protocols and reagent summary reports to be provided		X
139	P_BM_11_06 Linearization & purification of plasmid DNA used as template in GMP process at Eufets	DNA template is linearized plasmid - protocols and reagent summary reports to be provided		X

140	Ribonucleotide summary report	Ribonucleotides summary report		X
141	5'-Cap Summary Report	5' cap summary report		X
142	Description of manufacturing process	In vitro transcription synthesis kit summary report and step-by-step protocol for in vitro mRNA synthesis		X
143	HAN-31-04 - EUFETS SOP for RNA manufacturing	In vitro transcription synthesis kit summary report and step-by-step protocol for in vitro mRNA synthesis	X	X
144	FOR_RB_FuE_003A-T7 Transcription BioNTech - Form for R&D RNA manufacturing	In vitro transcription synthesis kit summary report and step-by-step protocol for in vitro mRNA synthesis	X	X
145	RNA purification synthesis and purification_raw materials_reagents	In vitro transcription synthesis kit summary report and step-by-step protocol for in vitro mRNA synthesis		X
146	FOR_RB_FuE_007E-magnetic bead purification_BioNTech	In vitro synthesized mRNA purification system summary report and step-by-step protocol for mRNA purification and quality control of the final product.		X
D	Regulatory and Clinical Items			
147	IMPD initial version and all amended versions RB_0003; RB_0004; BN_0002; RB_0001 (only final valid version)	IMPDs of relevant clinical trials CTA for RB_0003-01/Lipo-MERIT, RB_0004-01/IVAC, BN_0002-01/TNBC-MERIT Selected Trial Master File documents for relevant studies		X
148	IB initial version and all amended versions RB_0003; RB_0004; BN_0002; RB_0001 (only final valid version)	CTA for RB_0003-01/Lipo-MERIT, RB_0004-01/IVAC, BN_0002-01/TNBC-MERIT IBs for all relevant studies Selected Trial Master File documents for relevant studies		X
149	Clinical Study Protocol and Appendix initial version and all amended versions RB_0003; RB_0004; BN_0002; RB_0001 (only final valid version)	CTA for RB_0003-01/Lipo-MERIT, RB_0004-01/IVAC, BN_0002-01/TNBC-MERIT Protocols and amendments for all relevant RNA vaccine clinical studies Selected Trial Master File documents for relevant studies		X

173	Questions and Company's Position RB_0004; BN_0002	Health authority meeting briefing material and meeting minutes		X
174	Presentation for Scientific Advice RB_0004; BN_0002	Health authority meeting briefing material and meeting minutes		X
175	Minutes of Scientific Advice RB_0004; BN_0002	Health authority meeting briefing material and meeting minutes		X
176	IMGM No. RS-220VS Validation of a quantitative Real-time PCR method for the determination of RBL001 and RBL002 in mouse blood and organs	Bioanalytical reports and validation reports included in the CTA		X
177	CSR draft version RB_0001	CSR draft for RB_0001/MERIT		X
178	Periodic Update Report DSUR current version RB_0001; RB_0003; RB_0004	Underlying data of current IB and any completed CSRs		X
179	SAE reports (not related to IMP) RB_0001; RB_0004	Selected Trial Master File documents for relevant studies Safety database-safety reports, safety correspondence	(only applicabel for item 24: safety correspondance might be in german)	X
CMC documents for the end-to-end process for clinical manufacturing				
180	Current status of process UMLs can be provided	Current process UML diagrams		X
181	Forms and Templates mentioned for Item 43 for patients uID004, uID005 and uID010 - as indicated for the blank documents for item 43, many of these are in German - with the translated individual blank forms, the process can be easily followed	Clinical manufacturing protocols or batch records for each step of the end-to-end IVAC1.0 manufacturing process In-process tests including protocols and specifications for the end-to-end IVAC1.0 manufacturing process Completed batch records for example clinical IVAC1.0 drug substance and drug product lots	X (partly)	X

182	RB_0004 In process controls DS and DP	In-process tests including protocols and specifications for the end-to-end IVAC1.0 manufacturing process	X
183	RB_0004_Release_tests_RNA_DS_DP	Release tests including protocols and specifications for the IVAC1.0 drug substance and drug product Analytical methods and protocols used for the characterization of IVAC1.0 drug substance/drug product lots	X

[***]

Schedule 2.19.1(c)

Schedule 3.1.2

Research Plan

Introduction

Research Collaboration Objectives

[***]

Key Components of the Research Collaboration and Associated Activities

[***]

I. [***] for [***] and Prioritization

Background

[***]

Proposed areas for potential improvement

[***]

Proposed Initial Studies/Activities

[***]

II. Preclinical Research

Background

[***]

Proposed Initial Research Studies/Activities

[***]

Schedule 4.3.1

Ongoing Clinical Studies

	<u>RB_0004-01</u>	<u>BN_0002-01</u>
Study Number		
Study Name	IVAC MUTANOME	TNBC-MERIT
EudraCT Number	2013-001645-13	2014-002274-37
Study Title	Clinical first-in-human study evaluating the safety, tolerability and immunogenicity of intra-nodal administration of a personalized vaccination with IVAC MUTANOME vaccine with or without initial treatment with RBL001/RBL002 vaccine in patients with advanced melanoma	First-in-human clinical study with RNA-Immunotherapy combination of IVAC_W_bre1_uID and IVAC_M_uID for Individualized Tumor Therapy in Triple Negative Breast Cancer Patients
Phase	I	I
Investigational Medical Product(s)	RBL0001/RBL0002 IVAC MUTANOME (RBMv1.0_uID_A/RBMv1.0_uID_B)	IVAC_W_bre1_uID IVAC_M_uID

Note:

For study BN_0002-01/TNBC-MERIT the following amended versions of CTA documents are being drafted and do not require additional approval of the JDC.

1. CSP: **V6.0** First-in-human clinical study with RNA-Immunotherapy combination of IVAC_W_bre1_uID and IVAC_M_uID for Individualized Tumor Therapy in Triple Negative Breast Cancer Patients
2. CSP: **V7.0** First-in-human clinical study with RNA-Immunotherapy combination of IVAC_W_bre1_uID and IVAC_M_uID for Individualized Tumor Therapy in Triple Negative Breast Cancer Patients
3. IMPD: **V8.0** BN_0002-01/TNBC-MERIT Mutanome Engineered RNA Immuno-Therapy IVAC_W_bre1_uID IVAC_M_uID
4. IB: **V6.0** BN_0002-01/TNBC-MERIT

For study RB_0004-01/IVAC-MUTANOME, the following amended versions of CTA documents are being drafted and do not require additional approval of the JDC.

[***]

Schedule 4.4.1

Initial GDP

Draft Global Development Plan and Estimated Timelines

[***]

Non-Clinical GDP Activities

[***]

Introduction

Key Components of the Non-Clinical Development Plan and Associated Activities

[***]

I. [***]

[***]

II. Clinical [***]

Background

[***]

Proposed Initial Studies/Activities

[***]

III. Non-Clinical Research

Non-Clinical [***] studies

Background

[***]

Proposed Initial Non-Clinical Studies/Activities

[***]

Appendix 4.4.1(I)

[***]

Schedule 5.3

Key Terms for the Amendment of the Agreement in the event of a BioNTech [***]

[***]

Schedule 6.5.3**Key Terms of Co-Promotion Agreement**

This Exhibit sets forth material terms and conditions that, together with the terms of Section 6.5.4 of the Agreement, shall be incorporated into a Co-Promotion Agreement to be negotiated and entered into by the Parties regarding each Collaboration Product and each Indication for which BioNTech exercises its option to Co-Promote in accordance with Section 6.5 of the Agreement (each such Collaboration Product and Indication, the “Co-Promotion Product”).

1. **Sales Force**
 - i. **Establishment** [***]
 - ii. **Qualification** [***]
 - iii. **Product-Specific Training** [***]
2. **Commercialization Activities** [***]
3. **Sales Activity Tracking** [***]
4. **Promotional Materials and Standards** [***]
5. **Sales Information Integration** [***]
6. **[***]Commercialization Responsibilities** [***]
7. **Miscellaneous** [***]

Schedule 8.4

[***]

Schedule 8.4.1

[***]

Schedule 8.9

Bank Accounts

Schedule 9.1.4

[***]

Schedule 10.3.1(c)(i)

Schedule 11.2.4

Schedule 11.4.2**Form of Press Release****BioNTech to enter into worldwide strategic collaboration with Genentech to develop individualized mRNA cancer therapies*****Collaboration will draw upon Genentech's leading position in cancer immunotherapy and BioNTech's premier clinical mRNA vaccine platform***

Mainz, Germany September 21, 2016: BioNTech AG, a fully integrated private biotechnology company developing personalized cancer immunotherapies, today announced that it will enter into a worldwide strategic collaboration with Genentech, a member of the Roche Group, to develop, manufacture and commercialize novel messenger RNA (mRNA)-based, individualized cancer vaccines. The collaboration will combine Genentech's leading cancer immunotherapy portfolio and research program with BioNTech's proprietary mRNA cancer vaccine technology platform, and personalized medicine expertise. Together, the two companies will develop individually tailored cancer immunotherapies against a broad range of cancers to potentially provide a new treatment paradigm for cancer patients.

The collaboration will focus on the development of mRNA cancer vaccines targeting neoantigens, based upon BioNTech's Individualized Vaccines Against Cancer (IVAC®) MUTANOME clinical platform for the potential treatment of multiple cancers. A patient's cancer genome can be rapidly sequenced with next generation technology to define a spectrum of unique mutations known as "neoantigens" or "neoepitopes" present in a particular patient's tumor (the "mutanome"). An mRNA vaccine encoding selected neoepitopes can be manufactured for each individual tumor's mutanome signature, which may trigger an immune response highly specific to the tumor resulting in precisely targeted cancer cell death.

Initial clinical development will focus on combination studies using IVAC® MUTANOME in a variety of cancer types.

Under the terms of the agreement Genentech will pay BioNTech \$310 million in upfront and near-term milestone payments. The two companies will equally share all development costs and any potential profits for certain programs under the agreement. BioNTech has the right to co-promote certain products that arise from the agreement in the United States and certain countries, including Germany and other major European markets. Under certain circumstances, BioNTech may have sole commercialization rights for other products that Genentech elects not to commercialize. BioNTech will manufacture mRNA cancer vaccines for clinical studies. Genentech will manufacture mRNA cancer vaccines for commercial supply and BioNTech will have the right to manufacture commercial product as part of the global supply network.

Professor Dr. Ugur Sahin, CEO of BioNTech AG commented: “We are delighted to collaborate with a leading cancer immunotherapy company such as Genentech. Supported by its extensive tumor immunology understanding, BioNTech has been building clinical experience with its proprietary mRNA vaccines in a number of cancer types over several years. Combining BioNTech’s broad proprietary capabilities in the design, formulation, manufacturing and clinical testing of individualized neoantigens-based mRNA vaccines with Genentech’s eminent cancer immunotherapy, diagnostic, manufacturing and commercial expertise, will allow us, on a global scale, to drive forward the development of individualized vaccines to the market to treat a broad range of cancers. **Sean Marett, COO of BioNTech added:** ”This alliance underpins BioNTech’s strategy of collaborating with companies that are committed to developing truly disruptive immunotherapies and its long term ambitions of bringing its own products to market .”

“Unlike any medicine we have ever developed, virtually all cancer patients may potentially benefit from a custom built cancer vaccine,” said **James Sabry, M.D., Ph.D., Senior Vice President and Global Head of Genentech Partnering.** “By collaborating with BioNTech on this cutting edge approach, we hope to truly advance cancer treatments by using a common molecular backbone – mRNA – that is uniquely tailored to an individual patient.”

BioNTech will continue to develop its non-neopeptide mRNA cancer vaccines outside of the collaboration.

The completion of the agreement is subject to customary closing conditions, including clearance under the Hart-Scott-Rodino Antitrust Improvements Act, and is expected to occur in the fourth quarter of 2016.

For more information, please contact:

BioNTech AG

Regina Jehle

Tel: +49 (0) 6131 9084 1273

Email: Regina.Jehle@biontech.de

Hume Brophy, for BioNTech AG

Mary Clark, Eva Haas, Alexia Faure

Tel: +44 (0) 20 7862 6381

Email: biontech@humbrophy.com

About BioNTech AG

BioNTech AG is an immunotherapy leader with bench-to-market capabilities, developing truly personalized, well-tolerated and potent treatments for cancer and other diseases. Established by clinicians and scientists the Group is pioneering disruptive technologies ranging from individualized mRNA based medicines through innovative Chimeric Antigen Receptors /T-cell Receptor-based products and novel antibody checkpoint immunomodulators. BioNTech’s clinical programs are supported by an in-house molecular diagnostics unit whose products include MammaTyper® a molecular in-vitro diagnostic kit, marketed under CE and IVD marking in Europe and certain other countries. Founded in 2008, BioNTech is privately held and shareholders include the MIG Fonds, Salvia, and the Strüngmann Family Office, with the Strüngmann Family Office as the majority shareholder.

Information about BioNTech is available at www.biontech.de.

Schedule 12.2.1(a)

[***]

Schedule 12.2.1(c)

[***]

Schedule 12.2.1(i)

Schedule 12.2.2(a)

Existing Third Party In-License Agreements

Schedule 12.2.3(e)

Safety Reporting

[***]

Schedule 12.2.3(g)

[***]

Schedule 12.3.1(h)

Schedule 14.1.2

Closing Conditions

Schedule 14.3.1

[***]

Schedule 14.5.4

[***]

Schedule 15.7.2(g)

Expedited Arbitration

[***]

THE SYMBOL “[*]” DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED**

Patent Sublicense Agreement

This Patent Sublicense Agreement (“**Agreement**”) is between CELLSRIPT, LLC, a Wisconsin limited liability company having a place of business at 726 Post Road, Madison, WI 53713, USA, a Wisconsin limited liability company having a place of business at 726 Post Road, Madison, WI 53713, USA (“**Cellscript**”) and BioNTech AG, a German corporation having its principal place of business at An der Goldgrube 12, 55131 Mainz, Germany (“**Company**”). This Agreement is effective as of July 14, 2017 (the “**Effective Date**”). Each of Company and Cellscript are referred to herein as a “**Party**” and collectively as the “**Parties**”.

BACKGROUND

WHEREAS, mRNA RiboTherapeutics, Inc. (“**mRNA RiboTherapeutics**”) has an exclusive license from the Trustees of the University of Pennsylvania, a Pennsylvania nonprofit corporation (“**Penn**”) for certain intellectual property comprising patents, patent applications and technology relating to [***] and certain other intellectual property comprising patents, patent applications and technology relating to [***], as stated in the second amended and restated patent license agreement which became effective December 20, 2016 (the “**Penn License Agreement**”), under which, Cellscript has a sublicense from mRNA RiboTherapeutics in certain fields of use as stated in the amended and restated patent sublicense agreement which became effective December 20, 2016 (the “**Cellscript Sublicense Agreement**”) as amended on June 25, 2017, under which Cellscript has the right to further sublicense all or any part of the rights granted to Cellscript to other parties; and

WHEREAS, Company desires a sublicense from Cellscript under Patents Rights (as defined below) for *in vivo* uses in humans and non-human animals and certain other uses pertaining thereto and Cellscript is willing to grant to Company a sublicense under Patents Rights for such uses under the terms and conditions herein;

NOW, THEREFORE, in consideration of the mutual obligations contained in this Agreement, and intending to be legally bound, the Parties agree as follows:

1 SUBLICENSE

1.1 **Sublicense Grant.** Cellscript hereby grants to Company and Company hereby accepts from Cellscript a worldwide, non-exclusive sublicense under the Patent Rights during the Term to make, have made, import, use, offer for sale, sell and/or have sold Licensed Products according to the terms and conditions herein: (1) in Field of Use B for all uses in the *In Vivo* Field of Use, including: (a) all therapeutic and prophylactic uses in humans; (b) all non-therapeutic and non-prophylactic uses in humans; and (c) all uses, including therapeutic and prophylactic uses (e.g., Veterinary Products), in non-human animals; and (2) in Field of Use A for: research and screening uses, including pre-clinical research and screening comprising *ex vivo* uses in human or non-human animal cells and *in vivo* uses in animals that pertain to and support research, development, manufacture, regulatory approval and commercialization of Licensed Products for use in humans and non-human animals in the *In Vivo* Field of Use in (1)(a) through (1)(c), as all Fields of Use in (1) and (2) (collectively, the “**Sublicensed Fields of Use**”) and as said other terms which are not defined in this Section 1.1 are defined in Sections 1.2 and 6.1 herein (the “**Sublicense**”). The Sublicense includes the right for Company to grant sublicenses to its affiliates and Third Parties for all or any part of the rights and fields of use granted to Company, under terms that are consistent with this Agreement. No other rights or licenses are granted to Company hereunder by Cellscript. [***]

1.2 Related Definitions.

Whenever the words or terms “comprising,” “containing,” “having,” “include,” “includes,” “including,” “such as,” “for example,” “an example,” “examples,” “e.g.,” “for further clarification” or the like are used in this Agreement, they shall be understood to be followed by the words “without limitation” or “but without limitation”. The terms “a,” “an,” and “the” and the use of such terms or nouns in definitions in either the singular or the plural are to be construed to cover both the singular and the plural unless otherwise noted.

“**Licensed Products**” means products that are made, made for, used, imported, offered for sale or sold by Company or its Affiliates or Third Party sublicensees and that, in the absence of a license to Patent Rights, (i) would infringe (or, in the case of pending patent applications, upon issuance, would infringe) at least one claim of the Patent Rights or (ii) use a process or machine covered by a claim of Patent Rights, whether the claim is issued or pending. For clarity, Licensed Products includes any method, procedure or process, the use of which by Company or its Affiliates or Third Party sublicensees, in the absence of a license to Patent Rights by the user, would infringe, induce to infringe or contribute to infringing one or more claims of Patent Rights whether the claim is issued or pending.

“**Exhibit A-1 Patent Rights**” means [***]

“**Exhibit A-2 Patent Rights**” means [***]

“**Patent Rights**” means Exhibit A-1 Patent Rights and/or Exhibit A-2 Patent Rights.

“**Exhibit D Patents**” means all of Penn’s patent rights represented by or issuing from: (a) the United States patents and patent applications listed in Exhibit D; (b) any continuation, divisional, reexamination, and re-issue applications of (a); and (c) any extensions (a) or (b).

“**Affiliate**” means a legal entity that is controlling, controlled by or under common control with Company and that has executed either this Agreement, a sublicense for at least a portion of the rights granted to Company under this Agreement, or a written joinder agreement agreeing to be bound by all of the terms and conditions of this Agreement. The uncapitalized term “**affiliate**” means, with respect to a first legal entity, any other legal entity that is controlling, controlled by or under common control with said first legal entity. For purposes of the definitions of “Affiliate” and “affiliate” herein, the word “**control**” means (x) the direct or indirect ownership of fifty percent (50%) or more of the outstanding voting securities of a legal entity, (y) the right to receive fifty percent (50%) or more of the profits or earnings of a legal entity, or (z) the right to determine the policy decisions of a legal entity.

“**Field of Use A**” means and is limited to internal laboratory research or screening [***] For clarity, Field of Use A includes laboratory research use in animals or human or animal cells, living or dead, from any source, including for pre-clinical laboratory research in laboratory animals or cultured human or non-human animal cells for the purpose of generating data and information prior to use in clinical trials for a use that requires approval by the FDA or another regulatory organization. For further clarity, a party that has a sublicense in Field of Use A pertaining to a sublicensed therapeutic or prophylactic or diagnostic or prognostic use in Field of Use B shall have the right to perform pre-clinical research in Field of Use A comprising *in vivo* uses in non-human animals or *ex vivo* uses in human or non-human animal cells in order to obtain data and information to support pre-clinical development of such therapeutic, prophylactic, diagnostic or prognostic products.

[***]

“**Field of Use B**” means the field other than Field of Use A and includes but is not limited to therapeutic, prophylactic, diagnostic, prognostic and cosmetic uses in humans and agricultural, animal improvement and veterinary uses in animals. For clarity, Field of Use B includes any and all fields of use, including the *In Vivo* Field of Use and *Ex Vivo* Field of Use, other than for Field of Use A.

“**Fields of Use**” means Field of Use A and Field of Use B.

“**Ex Vivo Field of Use**” is a subfield of Field of Use A or Field of Use B wherein a product or method that is covered by Patent Rights (or Exhibit D Patents) is used in cells, tissues or organs that are *ex vivo* or outside of a living human or animal body or organism, whether those cells, tissues or organs are subsequently used only *ex vivo*, such as in culture, or are subsequently introduced into, used in or administered or applied to or on a living body or organism. [***]

“**In Vivo Field of Use**” is a subfield of Field of Use A or Field of Use B wherein a product or method that is covered by Patent Rights (or Exhibit D Patents) is used *in vivo*, [***]

“**Diagnostic and Prognostic Field of Use**” is a subfield of use within Field of Use B wherein a product or service covered by Patent Rights (or Exhibit D Patents) is used for diagnosis, prognosis or testing of a human or non-human animal or a sample therefrom in order to detect, identify, determine a cause, evaluate, analyze, understand, predict, rule in, or rule out a medical condition or disease or to predict an effect or response to treatment, and/or to monitor the effect of a treatment of such medical condition or disease. For clarity, a party that has a sublicense to make, have made, import, use, offer to sell and/or sell a Licensed Product for the Diagnostic and Prognostic Field of Use in conjunction with or pertaining to a product covered by Patent Rights (or Exhibit D Patents) for the *In Vivo* Field of Use in Field of Use B shall have the right to use said Licensed Product for diagnosis, prognosis or testing of a human or non-human animal or a sample therefrom, whether said diagnosis, prognosis or testing is performed *in vitro*, *in vivo* and/or *ex vivo*.

“**Veterinary Product**” means a product that is covered by Patent Rights (or Exhibit D Patents) which is used for the care, treatment, breeding or use of livestock or companion animals.

“**Third Party**” means any person, corporation, partnership, association, consortium or business, legal or governmental entity other than Penn, Cellscript, Company or any of their respective affiliates.

“**Infectious Disease Vaccine Subfield**” is a subfield of Field of Use B wherein a product that is covered by Patent Rights is used as a vaccine for prevention or treatment of one or more infectious disease(s) caused by an infectious agent or agents consisting of viruses, bacteria, fungi, protozoa or parasites. For clarity, the Infectious Disease Vaccine Subfield does not include the right to use Patent Rights to make, have made, import, use, offer for sale, sell and/or have sold any product that is covered by Patent Rights for prevention or treatment of any cancer (e.g., as a therapeutic or prophylactic cancer vaccine) in humans or animals.

1.3 Reservation of Rights by Penn. Penn reserves the right to use, and to permit other non-commercial entities to use, the Patent Rights for educational and non-commercial research purposes.

[Remainder of page left blank]

1.4 U.S. Government Rights. The Parties acknowledge that the United States government retains rights in intellectual property funded under any grant or similar contract with a Federal agency. The License is expressly subject to all applicable United States government rights, including, but not limited to, any applicable requirement that products, which result from such intellectual property and are sold in the United States, must be substantially manufactured in the United States. To the extent any such U.S. manufacturing requirements apply, Cellscript shall, upon request of Company, use commercially reasonable efforts to cause Penn to seek a waiver from the United States government for Company in respect of such U.S. manufacturing requirements.

1.5 Sublicense Conditions. Company's right to extend any or all of the rights granted to Company by Cellscript via a sublicense to affiliates or Third Parties is subject to each of the following conditions:

1.5.1 Company will have the right to grant further sublicenses to its affiliates and to Third Parties ("**sub-sublicensees**") that permit multiple levels of sublicensing, including in Third Party sub-sublicenses that permit further levels of sublicensing (e.g., to "sub-sub-sublicensees"). In each further sub-sublicense agreement to an affiliate or Third Party, Company will require the sub-sublicensee to comply with terms and conditions that are consistent with this Agreement, and in each agreement for further sublicensing (e.g., by a sub-sublicensee of Company to a sub-sub-sublicensee), the party granting the further sublicense will require the party receiving the further sublicense to comply with terms and conditions that are consistent with its sub-sublicense agreement from Company. Except when used to clarify the meaning of the different terms in this Section 1.5.1, the term sublicense in this Agreement includes any permitted sub-sublicense, sub-sub-sublicense, etc. and the term sublicensee includes any permitted sub-sublicensee, sub-sub-sublicensee, etc.

1.5.2 Within [***] days after Company enters into a sublicense agreement, Company will deliver to Cellscript a complete and accurate copy of the entire sublicense agreement written in the English language, provided that Company will have the right to redact the terms and conditions of such sublicense agreement that are not necessary for Cellscript to confirm compliance with all terms and conditions required under this Sublicense, including Section 1.5 hereof. Cellscript's receipt of the sublicense agreement will not constitute a waiver of any right or obligation of Cellscript or of Company under this Agreement.

1.5.3 In the event that Company causes or experiences a Trigger Event (as defined in Section 6.4), to the extent permissible by law, all payments due to Company from its direct sublicensees pursuant to a sublicense to this Agreement that are payable by Company to Cellscript hereunder, including milestone payments and royalty payments, will, upon notice from Cellscript to such sublicensees, become payable directly to Cellscript for the account of Company. Upon receipt of any such funds, Cellscript will remit to mRNA RiboTherapeutics the amounts owed to mRNA RiboTherapeutics and will remit to Company the amount (if any) by which such payments from such sublicensees exceed the amounts owed by Company to Cellscript hereunder. Still

further, in the event that mRNA RiboTherapeutics causes or experiences a trigger event according to the terms of the Penn License Agreement, Cellscript agrees that, upon notification from Penn, Cellscript will remit to Penn all amounts payable by Cellscript to mRNA RiboTherapeutics under the Cellscript Sublicense Agreement (including but not limited to all milestone payments and royalty payments) for the account of mRNA RiboTherapeutics.

1.5.4 Company's execution of a sublicense agreement will not relieve Company of any of its obligations under this Agreement. Company is primarily liable to Cellscript for any act or omission of a sublicensee that would be a breach of this Agreement if performed or omitted by Company, and Company will be deemed to be in breach of this Agreement as a result of such act or omission. Upon learning of any such breach of this Agreement due to an act or omission of a sublicensee of Company, Company will immediately take appropriate actions to stop such act or omission, including termination of the sublicense by Company. Provided that Company takes such appropriate actions and stops such act or omission, a breach by said sublicensee shall not be considered a breach by Company that will be considered a cause for termination of this Agreement under Section 6.3.

1.5.5 A sublicense granted by the Company or a further sublicensee thereof will not be assignable or transferable by said sublicensee or further sublicensee thereof without the prior written consent of Cellscript, except to an affiliate of the sublicensee of Company or an affiliate of said further sublicensee thereof, or to a Third Party company that: (i) can demonstrate based on reliable financial information that it has all technical knowledge, capabilities and/or financial resources needed to perform in all respects in the place and stead of said sublicensee or further sublicensee thereof; (ii) agrees to assume all duties and responsibilities under the sublicense; (iii) warrants that it will invest an amount of money that Company agrees is sufficient to develop and/or commercialize the sublicensed Licensed Product(s); (iv) purchases more than fifty percent (50%) of all of the sublicensee's or the further sublicensee's shares or assets to which the sublicense pertains; and (v) agrees in writing to be bound by all of the terms and conditions of the sublicense and a copy of such written undertaking is promptly provided to Company, which will provide a copy to Cellscript, which, in turn, will provide a copy to mRNA RiboTherapeutics.

1.6 No License by Implication. Nothing in this Agreement confers by estoppel implication or otherwise, any license or rights under any Penn patent other than rights granted under patents included in the Patent Rights and Exhibit D Patents, regardless whether such patents are dominant or subordinate to the Patent Rights and Exhibit D Patents.

1.7 License to the Exhibit D Patents. Whereas Cellscript has an exclusive license from Penn for certain other U.S. patents and patent applications listed in Exhibit D attached hereto, including any continuation, divisional, reexamination, and re-issue applications and any patents or extensions of any of the foregoing (collectively referred to as "**Exhibit D Patents**" herein), which Exhibit D Patents are not included in Patent Rights herein; and whereas, Company desires a sublicense to Exhibit D Patents in the Sublicensed Fields of Use during the Term and Cellscript is willing to grant such a sublicense in the Sublicensed Fields of Use according to the terms and conditions herein, now, therefore, Cellscript hereby grants to Company and Company hereby accepts from Cellscript a limited worldwide, non-exclusive sublicense under Exhibit D Patents during the Term to make, have made, import, use, offer for sale, sell and/or have sold products comprising mRNA containing pseudouridine solely in the Sublicensed Fields of Use, and according to the terms and conditions herein. The sublicense includes the right for Company to grant sublicenses to its Affiliates and Third Parties for all or any part of the rights granted to Company in the Sublicensed Fields of Use, under terms that are consistent with this Agreement.

No other rights or licenses pertaining to Exhibit D Patents are granted by Cellscript to Company under this Agreement. For clarity, no rights or licenses are granted by Cellscript to Company: (x) in Field of Use A for the Research Products Field of Use; or (y) in Field of Use B for any use in humans or non-human animals for (i) the *Ex Vivo* Field of Use, or (ii) the Diagnostic and Prognostic Field of Use, or (iii) to make, have made, import, use, offer for sale, sell and/or have sold any product covered by Exhibit D Patents which does not comprise or use mRNA comprising pseudouridine. Company understands and agrees that, since the products sublicensed to Company pursuant to this Section 1.7 comprise or use mRNA comprising pseudouridine (which products are also covered by Patent Rights), Company shall pay to Cellscript the same milestone and other fees and royalties owed by Company pursuant to Article 3 of this Agreement; however, Company shall not owe any additional milestone or other fees or royalties for products covered by Exhibit D Patents in addition to the amounts owed by Company pursuant to Article 3 of this Agreement.

1.8 Relation of this Agreement to mRNA RiboTherapeutics Sublicense Agreement. Concurrent with the execution of this Agreement, Company is entering into a separate sublicense agreement with mRNA RiboTherapeutics (the “**mRNA RiboTherapeutics Sublicense Agreement**”), pursuant to which mRNA RiboTherapeutics is granting Company a sublicense under Patent Rights with respect to certain fields of use that are different from and are not included within the scope of the Sublicense granted to Company in this Agreement.

2 DILIGENCE

2.1 Development Plan and Sublicense Disclosure Report. By [***] and by [***] of every calendar year thereafter that encompasses the Term, Company will deliver to Cellscript: (1) a copy of an annual development plan, including a projected timeline, for the Patent Rights and a summary of material development efforts for Licensed Products since the last development plan (“**Development Plan**”); and [***] certified as correct by the accounting services manager or chief financial officer, that includes all additional information as listed on Exhibit B for the period since the last SDR.

2.2 Company’s Efforts. Company will use commercially reasonable efforts to develop, commercialize, market and sell Licensed Products in the Sublicensed Fields of Use in a manner consistent with the Development Plan. In addition to Company’s own efforts to develop, commercialize, market and sell Licensed Products, the efforts of other parties, including Affiliates, Third Party sublicensees, contractors, Third Parties funded by Company under a research or service agreement, and distributors, will also be deemed as efforts of Company.

2.3 Diligence Events. Company, whether itself, or through its Affiliates, Third Party sublicensees, contractors, or Third Parties funded by Company under a research or service agreement, will use commercially reasonable efforts to achieve each of the milestone diligence events by the applicable completion date listed in the table below for the first Licensed Product for human therapeutic or prophylactic use in Field of Use B. Company will provide Cellscript with written notice within [***] days of first completion of each milestone diligence event for a Licensed Product for human therapeutic or prophylactic use in Field of Use B by Company or an Affiliate or Third Party sublicensee.

[Remainder of page left blank]

[***]

2.4 Diligence Resources. Until the first Sale of the first Licensed Product in Field of Use B, Company will expend financial resources for the development and commercialization of the Licensed Products in amounts not less than the diligence minimums specified in the table below (“**Development Expenditures**”) in each [***] month period following the Effective Date. Development Expenditures shall include all research and development expenditures directly relating to Licensed Products, including salaries, overhead, sponsored research payments, contract research, regulatory expenses, and documented external consulting payments. Company’s expenditures of financial resources for the development and commercialization of Licensed Products in Field of Use B in amounts not less than the specified Development Expenditures will be deemed commercially reasonable efforts to develop, commercialize, market and sell Licensed Products in Field of Use B. If Company’s total expenditures for development and commercialization of Licensed Products in any [***] month period ending on an anniversary of the Effective Date do not meet or exceed the applicable diligence minimum, then Company will pay to Cellscript the amount of the shortfall. Company will make any payments of the shortfall to Cellscript together with the next Development Plan due to Cellscript under Section 2.1.

[***]

3 FEES AND ROYALTIES

3.1 Sublicense Grant Fees. In partial consideration for the Sublicense, Company will pay to Cellscript: (i) [***]; and (ii) [***] and (iii) [***]

[Remainder of page left blank]

3.2 Sublicense Maintenance Fees. In partial consideration of the Sublicense, Company will pay to Cellscript [***] on each anniversary of the Effective Date during the Term until the date of first Sale of the first Licensed Product in Field of Use B, regardless of whether the Sale is achieved by Company, Cellscript, or an affiliate or sublicensee of any of the foregoing. For clarity, the next annual sublicense maintenance fee under this Agreement is payable to Cellscript on [***] if no Sale of a Licensed Product in Field of Use B occurs prior to [***]

3.3 Milestone Payments. In partial consideration of the Sublicense, Company will pay to Cellscript any milestone payment that is applicable to a Licensed Product developed by the Company under any of the tables in this Section 3.3 the first time after achieving each milestone event for each said Licensed Product in Field of Use B, regardless of whether the milestone is achieved by Company, an Affiliate or a Third Party sublicensee. Company will provide Cellscript with written notice within [***] days after each milestone is achieved by Company or a sublicensee and Company will pay to Cellscript all applicable milestone payments owed therefor within [***] days of the end of the calendar quarter in which the milestone event is achieved. For clarity, each time a milestone is achieved with respect to a Licensed Product, then any other milestone payments with respect to earlier milestones that have not yet been paid will be due and payable together with the milestone payment that is actually achieved. For clarity, if a Licensed Product being developed by Company or its sublicensees does not fall into one of the categories in the tables below, Company will notify Cellscript promptly after identifying the Licensed Product and the Parties will negotiate in good faith appropriate milestones based on the relative value of the product category and the development pathway.

Section 3.3 Table A
MILESTONES for each Licensed Product for
human therapeutic or prophylactic use in the *In Vivo* Field of Use

[***]

Section 3.3 Table C
MILESTONES for each Licensed Product that is a Veterinary Product

[***]

3.4 Earned Royalties. In partial consideration of the Sublicense, Company will pay to Cellscrip royalties on Net Sales of Licensed Products in the Sublicensed Fields of Use as stated below.

3.4.1 Earned Royalties on Licensed Products in Field of Use A. In partial consideration of the Sublicense, Company will pay to Cellscrip a [***] royalty on Net Sales of Licensed Products by Company or its Affiliates or Third Party sublicensees for use in the Sublicensed Fields of Use in Field of Use A during the Quarter. For the avoidance of doubt, if Company or any Affiliate or Third Party sublicensee sells or is reimbursed for the costs of providing a Licensed Product for use in Field of Use A to another party with which it has a contract to collaborate or work together on researching, developing or screening related to a product for human therapeutic or prophylactic use in the *In Vivo* Field of Use, then Company will pay to Cellscrip a [***] royalty on all such Net Sales of Licensed Products for use in Field of Use A by Company or by said sublicensees. For clarity, Company and its Affiliates or Third Party sublicensees shall only have the right to sell Licensed Products for use in Field of Use A to Third Parties that have either a sublicense from or a contract with Company or an Affiliate or Third Party sublicensee to research, develop, test, evaluate, screen, manufacture and/or commercialize a Licensed Product for use in the *In Vivo* Field of Use in Field of Use B.

3.4.2 Earned Royalties on Licensed Products Field of Use B. In partial consideration of the Sublicense, Company will pay to Cellscrip a [***] royalty on Net Sales of Licensed Products in Field of Use B for all uses in the *In Vivo* Field of Use, including: (a) all therapeutic or prophylactic uses in humans; (b) all non-therapeutic or non-prophylactic uses in humans; and (c) all uses, including therapeutic and prophylactic uses (e.g., Veterinary Products), in non-human animals during the Quarter. For the avoidance of doubt, if Company or its Affiliates or Third Party sublicensees grant sublicenses to sell Licensed Products for any such uses in Field of Use B, Company will pay to Cellscrip a [***] royalty on Net Sales of all such Licensed Products sold by said sublicensees. For clarity, no royalties are due under this Agreement for Sales of Licensed Products in the Diagnostic and Prognostic Field of Use, which are sublicensed to Company in the Sublicense Agreement from mRNA RiboTherapeutics.

3.4.3 Royalty Reduction. If Company or an Affiliate or Third Party sublicensee of Company is obligated to pay Third Party Royalties (defined below) for a Licensed Product in Field of Use B, then Company may deduct [***] of such Third Party Royalties from any royalties on Net Sales in Field of Use B due to Cellscrip under Section 3.4.2 of this Agreement, provided that:

(a) On an ongoing basis and prior to reduction of any royalty on Net Sales for a given calendar quarter, Company first provides written evidence to Cellscrip of Company's or applicable sublicensee's obligation to pay such Third Party Royalties; and

(b) In no event shall royalties on Net Sales due to Cellscript in any reporting period be so reduced to less than [***] for Licensed Products for use in the *In Vivo* Field of Use in Field of Use B.

“**Third Party Royalties**” means any royalty obligation in excess of [***] that Company or an Affiliate or a Third Party sublicensee owes to one or more other parties pursuant to one or more licenses for patent rights comprising [***] and that are determined to be necessary to avoid infringement-related litigation with respect to the manufacture, use or sale of any Licensed Product.

3.5 Related Definitions.

3.5.1 The term “**Sale**” means any bona fide transaction for which consideration is received or expected by Company or its Affiliates or Third Party sublicensees for the sale, use, lease, transfer or other disposition of a Licensed Product to a Third Party. A Sale is deemed completed at the time that Company or an Affiliate or Third Party sublicensee invoices, ships or receives payment for a Licensed Product, whichever occurs first.

3.5.2 The term “**Quarter**” means each three-month period beginning on the first day of January, April, July or October.

3.5.3 The term “**Net Sales**” means the consideration received or expected from, or the fair market value attributable to, each Sale, less Qualifying Costs that are directly attributable to a Sale, specifically identified on an invoice or other documentation and actually borne by Company or its Affiliates or Third Party sublicensees. For purposes of determining Net Sales, the words “**fair market value**” mean the cash consideration that Company or its Affiliates or Third Party sublicensees would realize from an unrelated buyer in an arm’s length sale of an identical item sold in the same quantity and at the time and place of the transaction.

3.5.4 The term “**Qualifying Costs**” means: (a) credits or refunds for claims or returns that do not exceed the original invoice amount; (b) prepaid outbound transportation expenses and transportation insurance premiums; and (c) sales and use taxes and other fees imposed by and indefeasibly paid to a governmental agency.

3.6 Minimum Royalties. In partial consideration of the Sublicense, [***] Company will pay to Cellscript the amount, if any, by which the applicable minimum royalties listed in the tables below exceed Company’s or its Affiliates’ or Third Party sublicensees’ actual earned royalties under Section 3.4 for each Quarter after the first Sale of a Licensed Product by Company or its Affiliates or Third Party sublicensees in the applicable Categories. The minimum royalties are divided into two Categories and outlined in the tables below and are tiered, cumulative and individually payable after first Sale of Licensed Product in each of the three respective Categories. For clarity, the highest minimum royalty owed by Company to Cellscript under this Agreement would be [***] For additional clarification, Company is not obligated to pay minimum royalties to Cellscript for Licensed Products in Category 1 until after the first Sale of a Licensed Product in Field of Use A by Company or its Affiliates or Third Party sublicensees; Company is not obligated to pay minimum royalties to Cellscript for Licensed Products in Category 2 until after the first Sale of a Licensed Product in Field of Use B for human therapeutic or prophylactic use in the *In Vivo* Field of Use by Company or its Affiliates or Third Party sublicensees; and Company is not obligated to pay minimum royalties to Cellscript for Licensed Products in a Category 3 until after the first Sale of Licensed Product in Field of Use B that is not a humans therapeutic or prophylactic by Company or its Affiliates or Third Party sublicensees.

Category 1 - Licensed Products in Field of Use A

QUARTER:	First Four Quarters	All Subsequent Quarters
MINIMUM:	[***]	[***]

**Category 2 - Licensed Products in Field of Use B
For Therapeutic or Prophylactic Use in Humans**

QUARTER:	First Four Quarters	All Subsequent Quarters
MINIMUM:	[***]	[***]

**Category 3 - Licensed Products in Field of Use B
That Are NOT
For Therapeutic or Prophylactic Use in Humans**

QUARTER:	First Four Quarters	All Subsequent Quarters
MINIMUM:	[***]	[***]

4 REPORTS AND PAYMENTS

4.1 Royalty Reports. Within [***] days after the end of each Quarter following the first Sale, Company will deliver to Cellscript a report, certified as accurate by the accounting services manager or chief financial officer of Company, detailing the calculation of all royalties, fees and other payments due to Cellscript for such Quarter. The report will include, at a minimum, the following information for the Quarter, each listed by product, by country: [***]

[Remainder of page left blank]

4.2 Payments. Company will pay all royalties, fees and other payments due to Cellscript under Sections 3.3, 3.4 and 3.6 within [***] days after the end of the Quarter in which the royalties, fees or other payments accrued. Cellscript agrees that it will pay all such amounts to mRNA RiboTherapeutics according to and within the time periods required by the Cellscript Sublicense Agreement, and mRNA RiboTherapeutics will pay to Penn all royalties, fees and other payments due to Penn according to and within the time periods required by the Penn License Agreement. For clarity, only one royalty will be due with respect to the Sale of the same unit of Licensed Product.

4.3 Records. Company will maintain, and will cause its Affiliates and Third Party sublicensees to maintain, complete and accurate books, records and related background information to verify Sales, Net Sales, and all of the royalties, fees, and other payments due or paid under this Agreement, as well as the various computations reported under Section 4.1. The records for each Quarter will be maintained for at least [***] years after submission of the applicable report required for Section 4.1.

4.4 Audit Rights. Upon reasonable prior written notice to Company, Company and its Affiliates and Third Party sublicensees will provide Penn and its accountants (or Cellscript and its accountants in the event that Cellscript is Penn's designated auditor) with access to all of the books, records, key personnel and related background information required by Section 4.3 to conduct a review or audit of Sales, Net Sales, and all of the royalties, fees, and other payments payable under this Agreement. Access will be made available: (a) during normal business hours; (b) in a manner reasonably designed to facilitate such accountant's review or audit without unreasonable disruption to Company's business; and (c) no more than once each calendar year during the Term (as defined below) and for a period of [***] years thereafter. Company will promptly pay to Cellscript the amount of any underpayment determined by the review or audit, plus accrued interest. If the review or audit determines that Company has underpaid any payment by [***] or more, then Company will also promptly pay the costs and expenses of the auditing party's accountants in connection with the review or audit. In addition, once annual Sales of Licensed Products exceed [***] Company will conduct, at least once every [***] years at its own expense, an independent audit of Sales, Net Sales, and all of the royalties, fees, and other payments due or paid under this Agreement for the period since the last such audit. Promptly after completion of the audit, Company will provide to Cellscript a copy of the report of the independent auditors along with any underpayments and interest thereon.

4.5 Currency. All dollar amounts referred to in this Agreement are expressed in United States dollars. All payments will be made in United States dollars. If Company receives payment from a sublicensee in a currency other than United States dollars for which a royalty or fee is owed under this Agreement, then (a) the payment will be converted into United States dollars at the conversion rate for the foreign currency as published in the eastern edition of the Wall Street Journal as of the last business day of the Quarter in which the payment was received by Company, and (b) the conversion computation will be documented by Company in the applicable report delivered to Cellscript under Section 4.1.

[Remainder of page left blank]

4.6 Place of Payment. All payments by Company to CELLSRIPT, LLC and will be made to the following addresses:

[***]

4.7 Interest. All amounts that are not paid by Company when due will accrue interest from the date due until paid at a rate equal to [***] (or the maximum allowed by law, if less).

5 CONFIDENTIALITY AND USE OF NAMES

5.1 Confidentiality. Each Party agrees that it will not, under this Agreement, provide to the other Party or its affiliates any Confidential Information of such Party unless (i) such Party has first identified the general nature of such Confidential Information to such other Party in writing and such other Party has affirmatively agreed in writing to receive such Confidential Information, or (ii) such other Party has specifically requested such Confidential Information in writing. For clarity, any such consent or request issued by email or other written electronic means shall satisfy the foregoing “writing” requirements. Any Confidential Information disclosed by a Party to the other Party other than in accordance with this Section 5.1 will be deemed not to be Confidential Information of such Party. Notwithstanding the foregoing, Cellscript is obligated to accept and treat as confidential any Confidential Information disclosed by Company in the reports or notices required by Sections 2.1, 2.3, 3.3, 3.4.3(a), 4.1, 4.4, 4.5, 4.6 and 6.6, which information Company agrees Cellscript may disclose to mRNA RiboTherapeutics or Penn without the prior written consent of Company.

5.2 Confidential Information. Each Party (“**Disclosing Party**”) may disclose to the other Party (“**Receiving Party**”), and Receiving Party may acquire during the course and conduct of activities under the Agreement, certain proprietary or confidential information of Disclosing Party in connection with this Agreement. The term “**Confidential Information**” shall mean all ideas and information of any kind, whether in written, oral, graphical, machine-readable or other form, whether or not marked as confidential or proprietary, which are transferred, disclosed or made available by Disclosing Party in accordance with Section 5.1.

5.3 Restrictions. During the Term and for [***] years thereafter, Receiving Party shall keep all Disclosing Party’s Confidential Information in confidence with the same degree of care with which Receiving Party holds its own confidential information. Receiving Party shall not use Disclosing Party’s Confidential Information except in connection with the performance of its obligations and exercise of its rights under this Agreement. Receiving Party has the right to disclose Disclosing Party’s Confidential Information without Disclosing Party’s prior written consent, to the extent and only to the extent reasonably necessary, to Receiving Party’s affiliates and their employees, subcontractors, consultants or agents who have a need to know such Confidential Information in order to perform Receiving Party’s obligations or exercise Receiving

Party's rights under this Agreement, provided said affiliates and their employees, subcontractors, consultants or agents are required to comply with a written confidentiality agreement having restrictions on use and disclosure of Disclosing Party's Confidential Information which are no less stringent than those in this Section 5.3. Receiving Party assumes responsibility for compliance with such restrictions by its affiliates and their employees, subcontractors, consultants or agents.

5.4 Exceptions. Receiving Party's obligation of nondisclosure and the limitations upon the right to use the Disclosing Party's Confidential Information shall not apply to the extent that Receiving Party can demonstrate, as evidenced by contemporaneous written records, that the Disclosing Party's information: (i) was known to Receiving Party or any of its affiliates prior to the time of disclosure; (ii) is or becomes public knowledge through no fault or omission of Receiving Party or any of its affiliates; (iii) is obtained by Receiving Party or any of its affiliates from a Third Party under no obligation of confidentiality to Disclosing Party; (iv) has been independently developed by employees, subcontractors, consultants or agents of Receiving Party or any of its affiliates without the aid, application or use of Disclosing Party's Confidential Information or (v) is not Confidential Information under Section 5.1.

5.5 Permitted Disclosures. Receiving Party may disclose Disclosing Party's Confidential Information to the extent (and only to the extent) such disclosure is reasonably necessary in the following instances:

5.5.1 in order to comply with applicable law (including any securities law or regulation or the rules of a securities exchange) or with a legal or administrative proceeding;

5.5.2 in connection with prosecuting or defending litigation, regulatory approvals and other regulatory filings and communications, and filing, prosecuting and enforcing Patents in connection with Receiving Party's rights and obligations pursuant to this Agreement; and

5.5.3 in connection with exercising its rights hereunder, to its affiliates; to potential and future collaborators and sublicensees; permitted acquirers or assignees; and investment bankers, investors and lenders, except that Cellscript will obtain the prior written consent of Company before disclosing any information disclosed to Cellscript pursuant to Sections 2.1, 2.3, 3.3, 3.4.3(a), 4.1, 4.4, 4.6 and 6.6;

provided that (1) with respect to Sections 5.5.1 or 5.5.2, where reasonably possible, Receiving Party shall notify Disclosing Party of Receiving Party's intent to make any disclosure pursuant thereto sufficiently prior to making such disclosure so as to allow Disclosing Party adequate time to take whatever action it may deem appropriate to protect the confidentiality of the information to be disclosed, and (2) with respect to Section 5.5.3, each of those named people and entities are required to comply with the restrictions on use and disclosure in Section 5.3 (other than investment bankers, investors and lenders, which must be bound prior to disclosure by commercially reasonable obligations of confidentiality).

5.6 Terms of this Agreement. The Parties agree that the terms of this Agreement shall be treated as Confidential Information of both Parties, and thus may be disclosed only as permitted by Section 5.5. Each Party agrees not to issue any press release or public statement disclosing information relating to this Agreement or the terms hereof without the prior written consent of the other Party not to be unreasonably withheld.

5.7 Relationship to the Confidentiality Agreement. This Agreement is in addition to certain “**Confidentiality Agreements**” between the Parties dated the 1st of January, 2014, and the 4th of January, 2017, and (a) all “Confidential Information” as defined therein that is disclosed or received by the Parties prior to the Effective Date shall continue to be subject to the terms and conditions of the Confidentiality Agreement and (b) all Confidential Information disclosed or received by the Parties following the Effective Date shall be subject to the terms and conditions of this Agreement. For the avoidance of doubt, all other confidentiality agreements concluded between Cellscript and Company prior to the Effective Date of this Agreement shall be superseded by this Agreement.

5.8 Use of Penn’s, Cellscript’s or Company’s Name. Company and its Affiliates, Third Party sublicensees, employees, and agents are not granted any rights hereunder to use the name, logo, seal, trademark, or service mark (including any adaptation of them) of Penn or any Penn school, or their respective organizations, employees, students or representatives, without the prior written consent of Penn. Except to the extent permitted pursuant to this Article 5, neither Party shall have any right, express or implied, to use in any manner the name or other designation of the other Party or any other trade name or trademark of the other Party for any Purpose, except as may be required by applicable law or regulation.

6 TERM AND TERMINATION

6.1 Term. This Agreement will commence on the Effective Date and terminate upon the expiration or abandonment of the last patent to expire or become abandoned of the Patent Rights and Exhibit D Patents (the “**Term**”).

6.2 Early Termination by Company. Company may terminate this Agreement at any time effective upon completion of each of the following conditions: (a) providing at least [***] days prior written notice to Cellscript of such intention to terminate; (b) ceasing to make, have made, use, import, offer for sale and sell all Licensed Products under the Sublicense; (c) providing documentation stating that all sublicenses granted by Company which are still in force at the date of termination can be assigned to Cellscript and working with Cellscript to assign or terminate such sublicenses based on the specific circumstances related thereto; and (d) paying all amounts owed to Cellscript under this Agreement through the effective date of termination. For clarity, Company may individually terminate either the Sublicense to Exhibit A-1 Patent Rights or the Sublicense to Exhibit A-2 Patent Rights or the Sublicense to Exhibit D Patents provided that each of the conditions stipulated in Section 6.2 is met with respect to the Patent Rights and Exhibit D Patents terminated from the Sublicense. [***]

6.3 Early Termination by Cellscript. Cellscript may, to the extent permissible by law, terminate this Agreement if: (a) Company is more than [***] late in paying to Cellscript any amounts owed under this Agreement and does not pay Cellscript in full, including accrued interest, within [***] after receiving written notice of the breach from Cellscript (a “**Payment Default**”); or (b) other than a Payment Default, Company materially breaches this Agreement and Company does not cure the breach within [***] after receiving written notice of the breach from Cellscript; or (c) Company causes or experiences a Trigger Event, or an Affiliate or Third Party sublicensee of Company commences or causes a Patent Challenge (as defined Section in 6.4 below) and Company does not terminate the sublicense or cause the Patent Challenge to be terminated prior to or promptly upon learning of said Patent Challenge. It is understood that, with respect to both of (a) and (b), Company is also responsible for its Affiliates and Third Parties sublicensees.

6.4 **Trigger Event.** The term “**Trigger Event**” means any of the following: (a) Company (i) becomes insolvent, bankrupt or generally fails to pay its debts as such debts become due, (ii) is adjudicated insolvent or bankrupt, (iii) admits in writing its inability to pay its debts, (iv) suffers the appointment of a custodian, receiver or trustee for its assets and, if appointed without its consent, not discharged [***], (v) makes an assignment of its assets for the benefit of creditors, or (vi) suffers proceedings being instituted against it under any law related to bankruptcy, insolvency, dissolution, liquidation or the reorganization, readjustment or release of multiple debtors and, if contested by it, not dismissed or stayed within [***]; (b) the institution or commencement by Company of any proceeding under any law related to bankruptcy, insolvency, liquidation or the reorganization, readjustment or release of multiple debtors; (c) the entering of any order for relief relating to any of the proceedings described in Section 6.4(a) or (b) above; (d) the calling by Company of a meeting of multiple creditors with a view to arranging a composition of adjustment of its debts; (e) the act or failure to act by Company that results in its consent to, approval of, or acquiescence in any of the proceedings described in Section 6.4(a) - (d) above; or (f) the commencement by Company or an Affiliate or Third Party sublicensee of Company of any action against Penn to declare or render invalid or unenforceable the Patent Rights or Exhibit D Patents or any claim thereof, including but not limited to an action for declaratory judgment (a “**Patent Challenge**”).

6.5 **Effect of Termination.**

6.5.1 **Effect of Termination Except under Section 6.2.** Upon the termination of this Agreement prior to expiration of the Term for any reason except pursuant to Section 6.2: (a) the Sublicense to the Patent Rights and Exhibit D Patents will terminate; (b) Company and all its Affiliates will cease all making, having made, using, importing, offering for sale and selling of all Licensed Products with respect to Patent Rights and Exhibit D Patents under the Sublicense, except to the extent permitted by Section 6.5.1(f) and Section 6.6; (c) Company will pay to Cellscript all amounts, including accrued interest, owed to Cellscript under this Agreement through the date of termination, including royalties on Licensed Products invoiced or shipped through the date of termination and any sell off period permitted by Section 6.6, whether or not payment is received prior to termination or expiration of the sell off period permitted by Section 6.6; (d) Company will, at Cellscript’s request, return to Cellscript all Confidential Information of Cellscript (if any) related to exploitation of Patent Rights and Exhibit D Patents and provide to Cellscript one summary of all work related thereto for Licensed Products generated by Company during the Term in order to facilitate the further development of the technology licensed under this Agreement; (e) in the case of termination under Section 6.3, all duties of Cellscript and all rights (but not duties) of Company under this Agreement immediately terminate without further action required by either Cellscript or Company; and (f) all outstanding Third Party sublicenses, to the extent each is not in default, will be assigned by Company to Cellscript, such assignment will be accepted by Cellscript, and each Third Party sublicense agreement will remain in full force and effect with Cellscript as the sublicensor instead of Company, but the duties and obligations of Cellscript under the assigned sublicense agreements will not be greater than the duties of Cellscript under this Agreement and the rights of Cellscript under the assigned sublicenses will not be less than those of Cellscript under this Agreement, including all financial consideration and other rights of Cellscript, and Cellscript may, at its sole discretion, amend such assigned agreements to contain terms and conditions found in this Agreement. [***]

6.5.2 Effect of Termination under Section 6.2. Upon the termination of this Agreement under Section 6.2: (a) the Sublicense to Company and all further sublicenses to Affiliates and Third Parties terminate (except to the extent that said Third Party sublicenses become direct sublicenses of Cellscript pursuant to Section 6.5.2(e)); (b) Company, its Affiliates and Third Party sublicensees will cease all making, having made, using, importing, offering for sale and selling all Licensed Products under the Sublicense, except to the extent permitted pursuant to Section 6.5.2(e) and Section 6.6; (c) Company will pay to Cellscript all amounts, including accrued interest, owed to Cellscript under this Agreement through the date of termination, including royalties on Licensed Products invoiced or shipped through the date of termination and any sell off period permitted by Section 6.6, whether or not payment is received prior to termination or expiration of the sell off period permitted by Section 6.6, and (d) Company will, at Cellscript's request, return to Cellscript all confidential information of Cellscript; and (e) all outstanding sublicenses of Company to Third Parties and all outstanding sublicenses of Company's Affiliates to Third Parties, to the extent each is not in default, will be assigned by Company or its Affiliates to Cellscript (and Company will contractually obligate its Affiliates to make or cause such assignments and work with Cellscript to effect such assignments), and each such assigned sublicense agreement will remain in full force and effect (including for sublicensed Exhibit A-1 Patent Rights and Exhibit A-2 Patent Rights and Exhibit D Patents) with Cellscript as the sublicensor instead of Company, but the duties and obligations of Cellscript under the assigned sublicense agreements will not be greater than the duties and obligations of Company under this Agreement, and the rights of Cellscript under the assigned sublicense agreements will not be less than the rights of Company under this Agreement, including all financial consideration and other rights of Company, and Cellscript may, at its sole discretion, amend such assigned sublicense agreements to contain financial or other terms and conditions found in this Agreement (excluding payment obligations which have already been satisfied by Company).

[Remainder of page left blank]

6.6 Inventory & Sell Off. Subject to the remainder of this Section 6.6, upon the termination of this Agreement for any reason, Company will: (1) cause physical inventories to be taken immediately of: (a) all completed Licensed Products on hand under the control of Company and its Affiliates and Third Party sublicensees and (b) such Licensed Products as are in the process of manufacture and any component parts on the date of termination of this Agreement; (2) deliver promptly to Cellscript a copy of said written inventory, certified by an officer of Company; (3) promptly remove, efface or destroy or require or cause to be removed, effaced or destroyed all references to Penn and Cellscript from any advertising, labels, web sites or other materials used in the promotion of the business of Company or its Affiliates or Third Party sublicensees; and (4) not represent in any manner that it has rights in or to the Patent Rights or Exhibit D Patents or the Licensed Products under this Sublicense and cause its Affiliates and Third Party sublicensees not to represent that they have any rights in or to the Patent Rights or Exhibit D Patents or the Licensed Products. Subject to this Section 6.6, Company and its Affiliates and Third Party sublicensees may sell off its inventory of Licensed Products existing on the date of termination for a period of [***] months and pay Cellscript royalties on Sales of such inventory within [***] days following the expiration of such [***] month period. Notwithstanding the foregoing: (i) Company's obligations under this Section 6.6 will not apply to the Sublicense or to Company's sublicense agreements if the Sublicense is assigned to mRNA RiboTherapeutics pursuant to Section 6.5.1; and (ii) the obligations of each of Company's sublicensees pursuant to this Section 6.6 will not apply to Company's or its Affiliates' or Third Party sublicensees' sublicense agreements that are assigned to Cellscript pursuant to Sections 6.5.1(f) or 6.5.2(e); and, (iii) Company's and its Affiliates' and Third Party sublicensees' obligations under this Section 6.6 will not apply with respect to any Licensed Product that is for use in a Field of Use for which Company (and its Affiliates or Third Party sublicensees) has a different sublicense agreement (e.g., under the mRNA RiboTherapeutics Sublicense Agreement).

6.7 Survival. Company's obligation to pay all amounts, including accrued interest, owed to Cellscript under this Agreement will survive the termination of this Agreement for any reason. Articles 5, 6, 11, 12 and 13 and Sections 4.1 (until all Licensed Products which have been manufactured during the Term have been Sold), 4.2, 4.3 (for the time period set forth therein for all Sales of Licensed Products which have been manufactured during the Term), 4.4 (for the time period set forth therein) and 4.5-4.7, 9.1.1, 9.1.4 (for all amounts paid by Company to Cellscript following termination that are payable to mRNA RiboTherapeutics), 9.2.2, 9.2.4 (for all amounts that are payable to Penn which are paid by Company and received by mRNA Therapeutics from Cellscript following termination), and 9.1.8, 9.2.7, 9.3.3, and 9.7 will survive the termination of this Agreement in accordance with their respective terms. The Parties acknowledge and agree that the Sublicense is, for the purposes of section 365(n) of the U.S. Bankruptcy Code, a license to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties intend that all payments under Article 3 of this Agreement constitute "royalties" within the meaning of section 365(n) of the U.S. Bankruptcy Code.

7 PATENT PROSECUTION AND MAINTENANCE

7.1 Patent Control for Patent Rights. Penn and mRNA RiboTherapeutics control the preparation, prosecution and maintenance of the Patent Rights and the selection of patent counsel, subject to the remainder of this Section 7.1. For purposes of this Section 7.1, the word "maintenance" includes any interference negotiations, claims, or proceedings, in any forum, brought by Penn, or its exclusive licensee, mRNA RiboTherapeutics (if so authorized by Penn), a Third Party, or the United States Patent and Trademark Office or any foreign equivalent pertaining to Patent Rights, and any requests by Penn or mRNA RiboTherapeutics (if so authorized by Penn)

that the United States Patent and Trademark Office or any foreign equivalent reexamine or reissue any patent in the Patent Rights. Notwithstanding the foregoing, Cellscript will provide Company and its counsel with reasonable opportunities to consult with Cellscript regarding prosecution and maintenance of Patent Rights.

7.2 Patent Control for Exhibit D Patents. Penn and Cellscript control the preparation, prosecution and maintenance of the Exhibit D Patents and the selection of patent counsel, subject to the remainder of this Section 7.2. For purposes of this Section 7.2, the word “maintenance” includes any interference negotiations, claims, or proceedings, in any forum, brought by Penn, or its exclusive licensee, Cellscript (if so authorized by Penn), a Third Party, or the United States Patent and Trademark Office pertaining to Exhibit D Patents, and any requests by Penn or Cellscript (if so authorized by Penn) that the United States Patent and Trademark Office reexamine or reissue any patent in the Exhibit D Patents. Notwithstanding the foregoing, Cellscript will provide Company and its counsel with reasonable opportunities to consult with Cellscript regarding prosecution and maintenance of Exhibit D Patents.

8 INFRINGEMENT

8.1 Control. Company shall not have any right to initiate litigation with respect to infringement of the Patent Rights or Exhibit D Patents.

8.2 Cooperation. In any litigation under this Article 8, each Party, at the reasonable request and sole expense of the other Party, will provide reasonable cooperation to such other Party. This Article 8 will not be construed to require either Party to undertake any activities, including legal discovery, at the request of any Third Party, except as may be required by lawful process of a court of competent jurisdiction.

9 COVENANTS, REPRESENTATIONS, WARRANTIES AND DISCLAIMER OF WARRANTIES

9.1 Covenants of Cellscript. Cellscript covenants to Company that, during the Term:

9.1.1 Cellscript will take all reasonable actions necessary to maintain Cellscript’s rights under the Cellscript Sublicense Agreement and, to the extent within its power, will ensure that the rights granted to Company herein are maintained. In the event of termination of the Cellscript Sublicense Agreement, this Agreement will be assigned to mRNA RiboTherapeutics without any further action by the Parties, and the sublicenses granted hereunder, to the extent they are not in breach or default, will remain in full force and effect with respect to the sublicensed Exhibit A-1 Patent Rights, Exhibit A-2 Patent Rights.

9.1.2 Cellscript will use diligent efforts not to breach the Cellscript Sublicense Agreement in any manner that could result in mRNA RiboTherapeutics having the right to terminate the Cellscript Sublicense Agreement, and, in the event of any such breach, Cellscript will use diligent efforts to expeditiously cure Cellscript’s breach of the Cellscript Sublicense Agreement.

9.1.3 Upon Cellscript learning of any breach of a sublicense agreement by any sublicensee of Cellscript or any of its further sublicensees in any manner that could result in mRNA RiboTherapeutics having the right to terminate the Cellscript Sublicense Agreement, Cellscript will expeditiously take appropriate actions to stop such act or omission, up to and including termination of the applicable sublicense, as stated in Section 1.5.4 of the Cellscript Sublicense Agreement.

9.1.4 Cellscript will make all payments due under the Cellscript Sublicense Agreement, and will make all required disclosures to mRNA RiboTherapeutics in connection therewith, in each case in a timely manner in accordance with the terms thereof.

9.1.5 Promptly following Cellscript's receipt of any material written notice or correspondence pertaining to the Sublicense that could reasonably be expected to adversely affect Company's rights under this Agreement, Cellscript will, to the extent permissible, furnish a copy of such notice or correspondence to Company, provided that Cellscript may redact portions of any such written notice or correspondence that does not relate to or impact Company's rights hereunder.

9.1.6 Cellscript acknowledges and agrees that, to the extent that Company reasonably and in good faith requests that the Parties engage with mRNA RiboTherapeutics to seek a reasonable amendment or modification to a provision of the Cellscript Sublicense Agreement that is applicable to Company, the Parties will engage with mRNA RiboTherapeutics to discuss such amendment or modification.

9.1.7 To the extent permissible, Cellscript will promptly notify Company if Cellscript receives a notice from mRNA RiboTherapeutics of intent to terminate the Penn License Agreement

9.1.8 Cellscript agrees that it will not sue, bring an action against, or otherwise assert any claim against Company or its Affiliates or Third Party sublicensees, or their successors in ownership (to which this Agreement or a sublicense under this Agreement is assigned according to terms and conditions for assignment pursuant to Section 15.5 or Section 1.5.5 herein) for infringement of or misappropriation of Patent Rights or Exhibit D Patents that are used by Company or its Affiliates or Third Party sublicensees or their successors in ownership solely in and for the Sublicensed Fields of Use under this Agreement, as Fields of Use are defined in Section 1.2, or the fields of use sublicensed to Company under the mRNA RiboTherapeutics Sublicense Agreement. [***] This covenant shall terminate with the termination of this Agreement unless the termination is: (a) made under Section 6.3, and (b) within [***] days following receipt of notice by Cellscript of termination under Section 6.3, is either: (i) resolved by Company and Cellscript in writing, or (ii) Company initiates a state or federal lawsuit contesting said termination ("**Contested Termination**"). In the event of a Contested Termination, this covenant shall continue to run during the [***] days, and if a lawsuit is initiated, until said state or federal court enters a final decision from which no appeal has been or can be taken.

9.1.9 Cellscript will not amend the Cellscript Sublicense Agreement in any manner that would negatively affect the rights and/or obligations of the Company under this Agreement.

9.1.10 Cellscript will not exercise any right to terminate the Cellscript Sublicense Agreement.

9.2 Covenants of mRNA RiboTherapeutics. mRNA RiboTherapeutics covenants to Company as follows:

9.2.1 mRNA RiboTherapeutics will not terminate the Cellscript Sublicense Agreement without good and reasonable cause.

9.2.2 In the event of termination of the Cellscript Sublicense Agreement, provided that Company did not cause said termination of the Cellscript Sublicense Agreement and is not in breach or default under this Agreement, this Agreement will be assigned to mRNA RiboTherapeutics without any further action by Cellscript, mRNA RiboTherapeutics will accept

assignment of this Agreement from Cellscript and this Agreement, including all of Company's outstanding Third Party sublicenses thereunder, will remain in full force and effect with respect to the sublicensed Exhibit A-1 Patent Rights and Exhibit A-2 Patent Rights, with mRNA RiboTherapeutics as the sublicensor instead of Cellscript, but the duties and obligations of mRNA RiboTherapeutics under the assigned Agreement will not be greater than the duties of Cellscript under this Agreement and the rights (including all financial consideration and other rights) of mRNA RiboTherapeutics under the assigned Sublicense will not be less than those of Cellscript under this Agreement, and mRNA RiboTherapeutics may, at its sole discretion, amend such assigned agreements to contain terms and conditions found in the Cellscript Sublicense Agreement; and Cellscript shall grant a separate sublicense to Company to use the Exhibit D Patents in the Sublicensed Fields of Use.

9.2.3 Upon mRNA RiboTherapeutics learning of any breach of a sublicense agreement by any sublicensee or any further sublicensees thereof in any manner that could result in mRNA RiboTherapeutics having the right to terminate the Cellscript Sublicense Agreement or Penn having the right to terminate the Penn License Agreement, mRNA RiboTherapeutics will expeditiously take appropriate actions to stop such act or omission, up to and including termination of the applicable sublicense.

9.2.4 mRNA RiboTherapeutics will make all payments due under the Penn License Agreement and will make all required disclosures to Penn in connection therewith, in each case in a timely manner in accordance with the terms thereof.

9.2.5 Promptly following mRNA RiboTherapeutics' or any of its affiliates' receipt of any material written notice or correspondence pertaining to the Company's sublicense agreement from Cellscript that would reasonably be expected to adversely affect Company's rights thereunder, mRNA RiboTherapeutics will, to the extent permissible, furnish a copy of such notice or correspondence to Cellscript and to Company, provided that mRNA RiboTherapeutics, as applicable, may redact portions of any such notice or correspondence that do not relate to or impact Company's rights.

9.2.6 mRNA RiboTherapeutics will promptly notify Cellscript and Company if it receives a notice from Penn of any intent to terminate the Penn License Agreement.

9.2.7 mRNA RiboTherapeutics agrees that mRNA RiboTherapeutics and its affiliates will not sue, bring an action against, or otherwise assert any claim against Company or its Affiliates or Third Party sublicensees or their successors in ownership (to which this Agreement or a sublicense under this Agreement is assigned according to terms and conditions for assignment pursuant to Section 15.5 or Section 1.5.5 herein) for infringement of or misappropriation of any Patent Rights (as defined in Section 1.2) that are used by Company or its Affiliates or Third Party sublicensees or their successors in ownership in the *In Vivo* Field of Use (as defined in Section 1.2) within the Sublicensed Fields of Use. For clarity, the foregoing covenant does not provide Company or its Affiliates or Third Party sublicensees or their successors in ownership immunity from any suit, action or claim for infringement of or misappropriation of Patent Rights if Company or its Affiliates or Third Party sublicensees or their successors in ownership use(s) any Patent Rights in a Field of Use that is not sublicensed to Company. For further clarity, the foregoing covenant also does not provide Company or its Affiliates or Third Party sublicensees or their successors in ownership immunity from any suit, action or claim for infringement of or misappropriation of any patent rights that are not Patent Rights (as defined in Section 1.2) if Company or its Affiliates or Third Party sublicensees or their successors in ownership use(s) any

such other patent rights, whether alone or in combination with use of Patent Rights. This covenant shall terminate with the termination of this Agreement unless the termination is a Contested Termination. In the event of a Contested Termination, this covenant shall continue to run during the [***] days, and if a lawsuit is initiated, until said state or federal court enters a final decision from which no appeal has been or can be taken.

9.2.8 mRNA RiboTherapeutics will not amend the Cellscript Sublicense Agreement in any manner that would negatively affect the rights and/or obligations of the Company under this Agreement.

9.3 Covenants of Company. Company covenants to Cellscript and to mRNA RiboTherapeutics that, during the Term:

9.3.1 Company will not breach this Agreement, and to the extent within its power, will ensure that its Affiliates do not breach or cause breach of any sublicense under this Agreement in a manner that would result in mRNA RiboTherapeutics having the right to terminate the Cellscript Sublicense Agreement, and, in the event of any such breach, Company will use diligent efforts to cure (or cause to be cured) any such breach of this Agreement by Company or any breach of any sublicense under this Agreement by its Affiliates or Third Party sublicensees.

9.3.2 Upon Company learning of any breach of a sublicense agreement by any of its Affiliates or Third Party sublicensees or any of their further sublicensees that results in mRNA RiboTherapeutics having the right to terminate the Cellscript Sublicense Agreement, Company will use diligent efforts to cure (or cause to be cured) any such breach, up to and including termination or causing termination of the applicable sublicense, as stated in Section 1.5.4 of this Agreement.

9.3.3 Company will pay to Cellscript all payments due under this Agreement pursuant to Article 3 and in accordance with the terms in Articles 3 and Section 4.2 and will provide to Cellscript all information, reports and notices required in accordance with Sections 2.1, 2.3, 3.3, 3.4.3(a), 4.1, 4.4, 4.5 and 6.6 and in the form of the sample report attached as Exhibit C, in each case in accordance with the time periods set forth therein.

9.3.4 Promptly following mRNA RiboTherapeutics' or any of its affiliates' receipt of any material written notice or correspondence about an issue pertaining to the Sublicense or to any matter that would reasonably be expected to adversely affect in any respect Company's rights under this Agreement, mRNA RiboTherapeutics will, to the extent permissible, furnish a copy of such notice or correspondence to Company, provided that mRNA RiboTherapeutics may redact portions of any such notice or correspondence that do not relate to or impact Company's rights hereunder.

9.4 Representations and Warranties of Cellscript. As of the Effective Date, Cellscript, on behalf of itself and its affiliates, hereby represents and warrants to Company that:

9.4.1 (a) Cellscript has provided Company a true and correct redacted copy of the Cellscript Sublicense Agreement (including exhibits and amendments thereto), which has been redacted with respect to amounts paid or payable by Cellscript to mRNA RiboTherapeutics for said sublicense and for milestones and other fees and royalties for Fields of Use not sublicensed to Company (e.g., the *Ex Vivo* Field of Use) and certain other terms and conditions that do not pertain to or are immaterial to Company's rights herein, and (b) except for a separate license agreement from Penn to CELLSRIPT, LLC related to certain patents pertaining to

reprogramming to iPS cells (which are the Exhibit D Patents sublicensed to Company solely for the *In Vivo* Field of Use in Section 1.7 of this Agreement), there are no other license or sublicense agreements, written or verbal, between Penn and Cellscript or between Cellscript or any affiliate thereof and mRNA RiboTherapeutics or any affiliate thereof.

9.4.2 Neither mRNA RiboTherapeutics nor Cellscript, nor any affiliate thereof has granted any other license or sublicense in Field of Use B or given any covenant not to sue for infringement of Patent Rights relating to the Penn License Agreement except for: (i) the Cellscript Sublicense Agreement, (ii) this Agreement, (iii) the mRNA RiboTherapeutics Sublicense Agreement, (iv) one Human *In Vivo* Therapeutics Field Sublicense from Cellscript (if any) that will be granted to a Third Party pursuant to Article 10 of this Agreement with respect to the Human *In Vivo* Therapeutics Field, and (v) one sublicense (if any) from mRNA RiboTherapeutics to said Third Party for the Diagnostic and Prognostic Field of Use.

9.4.3 Cellscript has not granted any liens or encumbrances in or to its rights in Patent Rights or the Cellscript Sublicense Agreement.

9.4.4 Cellscript has not breached or defaulted under any provision of the Cellscript Sublicense Agreement in any material respect or received any written notice from mRNA RiboTherapeutics of any claims for indemnification pursuant thereto.

9.4.5 To the knowledge of Cellscript, (a) there are no facts that would preclude Penn from having clear title to the Patent Rights or Exhibit D Patents, (b) there are no pending or threatened litigations, interferences, reexaminations, oppositions or like procedures involving Patent Rights or Exhibit D Patents, and (c) all of the issued patents within the Patent Rights or Exhibit D Patents are valid and enforceable, are in full force and effect and have not lapsed, expired or otherwise terminated.

9.4.6 Cellscript believes the terms and conditions of this Agreement are fully consistent with the terms and conditions of the Cellscript Sublicense Agreement and the Penn License Agreement.

9.4.7 Cellscript has not received any written notice of any claim by any person or entity challenging the sublicense rights of Cellscript or the validity or enforceability of the Patent Rights or Exhibit D Patents.

[Remainder of page left blank]

9.4.8 The Fields of Use sublicensed to Company in this Agreement are different and distinct from and do not overlap with the fields of use sublicensed to Company by mRNA RiboTherapeutics in the mRNA RiboTherapeutics Sublicense Agreement and any products researched, developed, manufactured or commercialized in fields of use granted under this Agreement are subject only to the payment and other obligations under this Agreement, and are not subject to payment and other obligations under the mRNA RiboTherapeutics Sublicense Agreement.

9.4.9 Cellscript believes that the representations and warranties of Cellscript in this Agreement, do not, taken as a whole: (i) contain any untrue statement of a material fact; or (ii) omit to state any material fact necessary to make the statements or facts contained therein, in light of the circumstances under which they were made, not misleading. Cellscript has not knowingly withheld any information with respect to the Cellscript Sublicense Agreement, the Penn License Agreement or the Patent Rights or Exhibit D Patents that would reasonably be expected to be material to Company's decision to enter into this Agreement.

9.5 Representations and Warranties of mRNA RiboTherapeutics. As of the Effective Date, mRNA RiboTherapeutics hereby represents and warrants to Company that:

9.5.1 Either mRNA RiboTherapeutics or Cellscript has provided Company with a true and correct redacted copy of the Penn License Agreement (including exhibits and amendments thereto) which has been redacted with respect to the amounts paid or payable to Penn by licensee for said license and for milestones and other fees and royalties for Fields of Use which are not sublicensed to Company herein (e.g., the *Ex Vivo* Field of Use) and certain other terms and conditions that do not pertain to or are immaterial to Company's rights in the Sublicensed Fields of Use or the fields of use sublicensed to Company under the mRNA RiboTherapeutics Sublicense Agreement, and a paragraph describing Penn's retained right to grant a non-exclusive sublicense to one party for ten products for humans in the Infectious Disease Vaccine Subfield of Field of Use B.

9.5.2 Except for a separate license agreement from Penn to Cellscript related to certain patents and patent applications pertaining to reprogramming to iPS cells that are not part of Patent Rights herein (which are the Exhibit D Patents which are sublicensed to Company as stated in Section 1.7 of this Agreement), and the Cellscript Sublicense Agreement, there is no other outstanding license or sublicense agreement in Field of Use B pertaining to Patent Rights nor any covenant, written or verbal, not to sue for infringement of Patent Rights pertaining to Field of Use B between: (i) Penn and mRNA RiboTherapeutics or any affiliate thereof; or (ii) Penn and Cellscript or any affiliate thereof; or (iii) mRNA RiboTherapeutics or any affiliate thereof and Cellscript or any affiliate thereof.

9.5.3 Neither mRNA RiboTherapeutics nor any affiliate thereof has granted any other license or sublicense or agreed not to sue for infringement of Patent Rights in Field of Use B relating to the Penn License Agreement, except for: (i) the Cellscript Sublicense Agreement; (ii) this Agreement to Company, (iii) the mRNA RiboTherapeutics Sublicense Agreement to Company, (iv) one Human *In Vivo* Therapeutics Field Sublicense from Cellscript (if any) that will be granted to a Third Party pursuant to Article 10 of this Agreement with respect to the Human *In Vivo* Therapeutics Field, and (v) one sublicense (if any) from mRNA RiboTherapeutics to said Third Party for the Diagnostic and Prognostic Field of Use.

9.5.4 Neither mRNA RiboTherapeutics nor any affiliate thereof has granted any liens or encumbrances in or to its rights in Patent Rights or the Cellscript Sublicense Agreement.

9.5.5 Cellscript has not breached or defaulted under any provision of the Cellscript Sublicense Agreement in any material respect or received any written notice from mRNA RiboTherapeutics of any claims for indemnification pursuant thereto and mRNA RiboTherapeutics has not breached or defaulted under any provision of the Penn License Agreement in any material respect or received any written notice from Penn of any claims for indemnification pursuant thereto.

9.5.6 To the knowledge of mRNA RiboTherapeutics, (a) there are no facts that would preclude Penn from having clear title to the Patent Rights, (b) there are no pending or threatened litigations, interferences, reexaminations, oppositions or like procedures involving any such Patent Rights and (c) all of the issued patents within the Patent Rights are valid and enforceable, are in full force and effect and have not lapsed, expired or otherwise terminated.

9.5.7 mRNA RiboTherapeutics believes the terms and conditions of this Agreement are fully consistent with the terms and conditions of the Cellscript Sublicense Agreement and the Penn License Agreement.

9.5.8 mRNA RiboTherapeutics has not received, any written notice of any claim by any person or entity challenging the sublicense rights of Cellscript or the validity or enforceability of the Patent Rights.

9.5.9 The fields of use sublicensed to Company in the mRNA RiboTherapeutics Sublicense Agreement are distinct from and do not overlap with the Fields of Use sublicensed to Company in this Agreement and any products researched, developed, manufactured or commercialized in fields of use granted under the mRNA RiboTherapeutics Sublicense Agreement are subject only to the payment and other obligations of the mRNA RiboTherapeutics Sublicense Agreement, and are not subject to payment and other obligations under this Agreement.

9.5.10 mRNA RiboTherapeutics believes that the representations and warranties of mRNA RiboTherapeutics in this Agreement, do not, taken as a whole, (i) contain any untrue statement of a material fact; or (ii) omit to state any material fact necessary to make the statements or facts contained therein, in light of the circumstances under which they were made, not misleading. mRNA RiboTherapeutics has not knowingly withheld any information with respect to the Cellscript Sublicense Agreement, the Penn License Agreement or the Patent Rights that would reasonably be expected to be material to Company's decision to enter into this Agreement.

9.6 Representations and Warranties of Company. Company hereby represents and warrants to Cellscript and to mRNA RiboTherapeutics that, as of the Effective Date:

9.6.1 Company is duly organized and validly existing under the laws of the jurisdiction of its incorporation and has full corporate power and authority to enter into this Agreement.

9.6.2 Company is in good standing with all relevant governmental authorities.

9.6.3 Company has taken all corporate actions necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement.

9.6.4 The performance of the obligations of Company under this Agreement do not conflict with or constitute a default under its charter documents, any contractual obligation of Company or any court order.

9.6.5 Company and its attorneys have reviewed the patents and patent applications comprising Patent Rights including both Exhibit A-1 Patent Rights and Exhibit A-2 Patent Rights that are listed in Exhibit A attached hereto.

9.6.6 Company has experience with and is familiar with the inventions covered by Patent Rights and understands the use, purpose and benefits thereof.

9.6.7 Company has read the redacted copy of the Penn License Agreement (including exhibits and amendments thereto) that was provided to Company by mRNA RiboTherapeutics or Cellscript.

9.6.8 Company has read the redacted copy of the Cellscript Sublicense Agreement (including exhibits and amendments thereto) that was provided to Company by Cellscript or mRNA RiboTherapeutics.

9.6.9 Company believes that the representations and warranties of Company in this Agreement, do not, taken as a whole, (i) contain any untrue statement of a material fact; or (ii) omit to state any material fact necessary to make the statements or facts contained therein, in light of the circumstances under which they were made, not misleading. Company has not knowingly withheld any information with respect to the any of Company's above statements that would reasonably be expected to be material to Cellscript's decision to enter into this Agreement.

9.7 **Disclaimer of Warranties.** EXCEPT AS SPECIFICALLY SET FORTH IN THIS ARTICLE 9, NO PARTY MAKES ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS OR SUFFICIENCY OF PATENT RIGHTS OR EXHIBIT D PATENTS FOR A PARTICULAR PURPOSE, APPLICATION OR USE, NON-INFRINGEMENT, OR ANY OTHER STATUTORY WARRANTY.

10 ADDITIONAL TERMS REGARDING SUBLICENSING

10.1 **Purpose of this Article.** This Article 10 sets forth terms and conditions for further sublicensing by Primary Sublicensors in the Human *In Vivo* Therapeutics Field, wherein, for the purposes of this Article 10:

- (a) **"sublicensing"** herein means any grant of a sublicense, covenant not to sue, or option for current or future rights under Patent Rights, and the noun **"sublicense"** herein means a document that grants such sublicense, covenant not to sue, or option for current or future rights under Patent Rights;
- (b) **"Primary Sublicensors"** herein means (i) mRNA RiboTherapeutics, (ii) Cellscript, and (iii) any affiliate of (i) or (ii) that is granted a sublicense in the Human *In Vivo* Therapeutics Field; and
- (c) **"Human *In Vivo* Therapeutics Field"** herein means any or all therapeutic and prophylactic use(s) in humans in the *In Vivo* Field of Use in Field of Use B.

For clarity and the absence of doubt, Article 10 shall not be interpreted in any way so as to limit, restrict or impose any terms or conditions on Primary Sublicensors' rights to grant sublicenses under Patent Rights to any party at any time for any Field of Use other than the Human *In Vivo* Therapeutics Field.

10.2 Human *In Vivo* Therapeutics Field Sublicenses. Subject to the rights of the Primary Sublicensors and their respective owners under Section 10.4, Cellscript, mRNA RiboTherapeutics and Company agree that, from the Effective Date [***], mRNA RiboTherapeutics and Cellscript will not grant and will ensure that other Primary Sublicensors will not grant Human *In Vivo* Therapeutics Field Sublicenses, including this Sublicense, to [***]

“**Human *In Vivo* Therapeutics Field Sublicense**” means a sublicense to make, have made, use, import, offer for sale, sell and/or have sold any number of products covered by Patent Rights comprising or incorporating modified RNA for the Human *In Vivo* Therapeutics Field, but excluding Product Sublicenses.

10.3 Product Sublicenses. Subject to the rights of the Primary Sublicensors and their respective owners under Section 10.4, Cellscript, mRNA RiboTherapeutics and Company agree that, from the Effective Date until [***], Cellscript and mRNA RiboTherapeutics will (and will ensure that the other Primary Sublicensors will):

(a) grant Product Sublicenses only to [***],

wherein “**Product Sublicenses**” herein mean sublicenses under Patent Rights to research, develop, manufacture and/or commercialize specific products [***], for a therapeutic or prophylactic use in humans in the *In Vivo* Field of Use, and

wherein [***]

(b) only grant Product Sublicenses for a total of [***] products in the aggregate by all of the Primary Sublicensors across all such Product Sublicenses, [***]

(c) except as set forth in Sections 10.2 and 10.3, not otherwise grant sublicenses under the Patent Rights to research, develop, manufacture and/or commercialize products comprising or incorporating [***].

10.4 Sale of a Primary Sublicensor. Company understands and agrees that the owners of each of mRNA RiboTherapeutics and Cellscript shall have the right to sell all or any part of the outstanding stock or ownership interest or the business or the assets thereof, as applicable, of mRNA RiboTherapeutics and/or Cellscript and/or any of their respective affiliates that [***] at any time and without any conditions pursuant to this Agreement other than the requirements under Section 15.5,

except that, as a condition to any such sale occurring prior to April 1, 2020:

(a) the owners of each of mRNA RiboTherapeutics and Cellscript will sell mRNA RiboTherapeutics or Cellscript to only one (1) Third Party purchaser, [***]; and

(b) without in any way negating or ceding or giving up any of their current rights to sell all or any part of the stock, ownership interest, business or assets of mRNA RiboTherapeutics and/or Cellscript or to discuss any such sale with any potential purchaser at any time, including from the Effective Date of this Agreement until [***], the owners of mRNA RiboTherapeutics and Cellscript agree not to conduct Active Marketing of such sale of a Primary Sublicensor prior to [***],

wherein “[***]” herein means [***]; and

for the avoidance of doubt, Company agrees that this Section 10.4(a) shall not be interpreted so as to prohibit the owners of mRNA RiboTherapeutics and/or Cellscript from proposing or discussing [***];

(c) the purchaser of mRNA RiboTherapeutics or Cellscript, respectively, will pay [***];

(d) on the effective date of any such sale of [***] and the purchaser and their assignees and successors in ownership thereof shall have all the same rights as are held by Company under this Agreement to:

- (i) grant Human *In Vivo* Therapeutics Field Sublicenses to affiliates and Third Parties without being subject to any restrictions, limitations, or terms and conditions that apply to the Primary Sublicensors under Sections 10.2, and
- (ii) grant Product Sublicenses to affiliates and any Third Parties to research, develop, manufacture and/or commercialize any number of products comprising modified RNA covered by Patent Rights for any therapeutic or prophylactic use in humans in the *In Vivo* Field of Use without being subject to any of the restrictions, limitations or requirements that the sublicensee is a Small Biotech Company as is required of the Primary Sublicensors in Section 10.3; and

(e) on the effective date of any such sale of more than fifty percent (50%) of the outstanding stock or ownership interest or all of the business or assets of mRNA RiboTherapeutics or Cellscript, all of the rights of the Primary Sublicensors to grant Product Sublicenses pursuant to Section 10.3 shall remain only with the Primary Sublicensors for which their stock, ownership interest, business and assets were not sold.

[***]

10.5 From [***], Primary Sublicensors and any owners, assignees or successors in ownership thereof shall have the right to grant any number of Human *In Vivo* Therapeutics Field Sublicense(s) to any parties without any conditions (other than those imposed by the Penn License Agreement or the Cellscript Sublicense Agreement) and to grant any number of Product Sublicenses or any other sublicenses of any kind under Patent Rights to any parties without any limitations or restrictions or requirements whatsoever under this Article 10.

11 LIMITATION OF LIABILITY; DISCLAIMER.

11.1 Limitation of Liability. CELLSRIPT, mRNA RIBOTHERAPEUTICS AND PENN WILL NOT BE LIABLE TO COMPANY, ITS AFFILIATES, SUBLICENSEES, SUCCESSORS OR ASSIGNS, OR ANY THIRD PARTY WITH RESPECT TO ANY CLAIM: ARISING FROM COMPANY'S USE OF THE PATENT RIGHTS, EXHIBIT D PATENTS, LICENSED PRODUCTS OR ANY OTHER TECHNOLOGY LICENSED UNDER THIS AGREEMENT; OR ARISING FROM THE COMPANY'S, COMPANY'S AFFILIATES' OR COMPANY'S SUBLICENSEES' DEVELOPMENT, TESTING, MANUFACTURE, USE OR SALE OF LICENSED PRODUCTS. NOTWITHSTANDING ANYTHING IN THIS

AGREEMENT OR OTHERWISE, NONE OF CELLSRIPT, mRNA RIBOTHERAPEUTICS, PENN, OR COMPANY WILL BE LIABLE TO THE OTHER OR ANY THIRD PARTY WITH RESPECT TO ANY SUBJECT MATTER OF THIS AGREEMENT FOR ANY INDIRECT, PUNITIVE, SPECIAL OR CONSEQUENTIAL DAMAGES, EVEN IF SUCH PARTY HAS BEEN INFORMED OR SHOULD HAVE KNOWN OF THE POSSIBILITY OF SUCH DAMAGES; PROVIDED THAT THIS SECTION 11.1 WILL NOT APPLY: (a) TO A PARTY'S INDEMNIFICATION RIGHTS AND OBLIGATIONS UNDER ARTICLE 12 OR ARTICLE 13; (b) IN CIRCUMSTANCES OF GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT BY A PARTY OR ITS AFFILIATES; OR (c) WITH RESPECT TO A PARTY'S LIABILITY FOR BREACH OF ARTICLE 5 or 10.

11.2 Disclaimer. THE PATENT RIGHTS, EXHIBIT D PATENTS, LICENSED PRODUCTS AND ANY OTHER TECHNOLOGY LICENSED UNDER THIS AGREEMENT ARE PROVIDED ON AN "AS IS" BASIS. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NONE OF CELLSRIPT, mRNA RIBOTHERAPEUTICS, PENN, OR COMPANY MAKE ANY REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO ANY WARRANTY OF ACCURACY, COMPLETENESS, PERFORMANCE, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, COMMERCIAL UTILITY, NON-INFRINGEMENT, VALIDITY OR TITLE.

12 PENN INDEMNIFICATION

12.1 Indemnification. Company will defend, indemnify, and hold harmless each Penn Indemnified Party from and against any and all Penn Liabilities with respect to an Indemnification Event. The term "**Penn Indemnified Party**" means each of Penn and its trustees, officers, faculty, students, employees, contractors, and agents. For clarity, Cellscript is not a Penn Indemnified Party. The term "Penn Liabilities" means all damages, awards, deficiencies, settlement amounts, defaults, assessments, fines, dues, penalties, costs, fees, liabilities, obligations, taxes, liens, losses, lost profits and expenses (including, but not limited to, court costs, interest and reasonable fees of attorneys, accountants and other experts) that are incurred by a Penn Indemnified Party or awarded or otherwise required to be paid to Third Parties by a Penn Indemnified Party. The term "Indemnification Event" means any Claim against one or more Penn Indemnified Parties arising out of or resulting from: [***]. The term "**Claim**" in this Article 12 means any charges, complaints, actions, suits, proceedings, hearings, investigations, claims or demands.

12.2 Reimbursement of Costs. Company will pay directly all Penn Liabilities incurred for defense or negotiation of any Claim or will reimburse Penn for all documented Penn Liabilities incident to the defense or negotiation of any Claim within [***] days after Company's receipt of invoices for such fees, expenses and charges.

12.3 Control of Litigation. Company controls any litigation or potential litigation involving the defense of any Claim, including the selection of counsel, with input from Penn. Penn reserves the right to protect its interest in defending against any Claim by selecting its own counsel, with any attorneys' fees and litigation expenses paid for by Company, pursuant to Sections 12.1 and 12.2.

12.4 **Other Provisions.** Company will not settle or compromise any Claim giving rise to Penn Liabilities in any manner that imposes any restrictions or obligations on Penn or grants any rights to the Patent Rights, Exhibit D Patents or the Licensed Products without Penn's prior written consent. If Company fails or declines to assume the defense of any Claim within [***] days after notice of the Claim, or fails to reimburse a Penn Indemnified Party for any Penn Liabilities pursuant to Sections 12.1 and 12.2 within the [***] day time period set forth in Section 12.2, then Penn may assume the defense of such Claim for the account and at the risk of Company, and any Penn Liabilities related to such Claim will be conclusively deemed a liability of Company. The indemnification rights of the Penn Indemnified Parties under this Article 12 are in addition to all other rights that a Penn Indemnified Party may have at law, in equity or otherwise.

13 OTHER INDEMNIFICATION

13.1 **Indemnification by Company.** Company will indemnify, defend and hold harmless Cellscript and its affiliates, and its or their respective directors, officers, employees and agents ("**Cellscript Indemnified Parties**"), from and against any and all liabilities, damages, losses, costs and expenses including the reasonable fees of attorneys (collectively "**Losses**") arising out of or resulting from any and all Third Party suits, claims, actions, proceedings, payment obligations or demands ("**Claims**" in this Article 13) to the extent based upon:

13.1.1 the gross negligence or willful misconduct of Company, its Affiliates or Third Party sublicensees and its or their respective directors, officers, employees and agents, in connection with Company's performance of its obligations or exercise of its rights under this Agreement;

13.1.2 any breach of any representation or warranty or express covenant made by Company under this Agreement; or

13.1.3 the development, testing, use, manufacture, commercialization, sale or other disposition of Licensed Products by or on behalf of Company or its Affiliates or Third Party sublicensees, assignees or vendors or Third Parties, including, but not limited to, for (x) any product liability or other Claim of any kind related to use by a Third Party of a Licensed Product, (y) any Claim by a Third Party that Company's practice of any of the Patent Rights or Exhibit D Patents or the design, composition, manufacture, use, sale or other disposition of any Licensed Product infringes or violates any patent, copyright, trade secret, trademark or other intellectual property right of such Third Party, and (z) any Claim by a Third Party relating to clinical trials or studies for Licensed Products;

except, in each case above, to the extent such Claim arose out of or resulted from or is attributable to any acts or omissions of Cellscript or its directors, officers, employees and agents, or other circumstances for which Cellscript has an indemnity obligation pursuant to Section 13.2 below.

13.2 **Indemnification by Cellscript.** Cellscript will indemnify, defend and hold harmless Company and its Affiliates, and its or their respective directors, officers, employees and agents ("**Company Indemnified Parties**"), from and against any and all Losses arising out of or resulting from any and all Claims to the extent based upon:

13.2.1 the gross negligence or willful misconduct of Cellscript or its directors, officers, employees and agents, in connection with Cellscript's performance of its obligations or exercise of its rights under this Agreement; or

13.2.2 any breach of any representation or warranty or express covenant made by Cellscript under this Agreement; or

except, in each case above, to the extent such Claim arose out of or resulted from or is attributable to any acts or omissions of Company or its Affiliates or Third Party sublicensees or contractors and its or their respective directors, officers, employees and agents or other circumstances for which Company has an indemnity obligation pursuant to Section 13.1 above.

13.3 Procedure. If an Indemnified Party entitled to indemnification under Sections 13.1 or 13.2 seeks such indemnification (wherein “**Indemnified Party**” in this Article 13 means a “Company Indemnified Party” and/or an “Cellscript Indemnified Party”), such Indemnified Party will:

- (i) inform the indemnifying Party in writing of a Claim as soon as reasonably practicable after such Indemnified Party receives notice of such Claim;
- (ii) permit the indemnifying Party to assume direction and control of the defense of the Claim (including the sole right to settle such Claim at the sole discretion of the indemnifying Party, *provided that* (a) such settlement or compromise does not admit any fault or negligence on the part of the Indemnified Party, or impose any obligation on, or otherwise materially adversely affect, the Indemnified Party or other Party and (b) the indemnifying Party first obtains the written consent of the Indemnified Party with respect to such settlement, which consent will not be unreasonably withheld);
- (iii) cooperate as reasonably requested (at the expense of the indemnifying Party) in the defense of the Claim; and
- (iv) undertake reasonable steps to mitigate any Losses with respect to the Claim.

Notwithstanding anything in this Agreement to the contrary, the indemnifying Party will have no liability under Sections 13.1 or 13.2, as the case may be, for Claims settled or compromised by the Indemnified Party without the indemnifying Party’s prior written consent.

14 INSURANCE

14.1 Coverages. Company will procure and maintain insurance or self-insurance that covers the following minimum liability amounts with respect to personal injury, bodily injury and property damage arising out of Company’s performance under this Agreement: (a) during the Term, comprehensive general liability, including broad form and contractual liability, in a minimum amount of [***] combined single limit per occurrence and in the aggregate; (b) prior to the commencement of clinical trials involving Licensed Products, clinical trials a minimum amount of [***] combined single limit per occurrence and in the aggregate; and (c) prior to the Sale of the first Licensed Product, product liability a minimum amount of [***] combined single limit per occurrence and in the aggregate. Penn and Cellscript may review periodically the adequacy of the minimum amounts of insurance or self-insurance for each liability coverage area required by this Section 14.1, and Penn and Cellscript reserve the right to request Company to adjust the limits accordingly to the extent existing limits are not commercially reasonable. The required minimum amounts of insurance or self-insurance do not constitute a limitation on Company’s liability or indemnification obligations to Penn or Cellscript under this Agreement.

15 ADDITIONAL PROVISIONS

15.1 Independent Contractors. The Parties are independent contractors. Nothing contained in this Agreement is intended to create an agency, partnership or joint venture between the Parties. At no time will either Party make commitments or incur any charges or expenses for or on behalf of the other Party.

15.2 No Discrimination. Company will not discriminate against any employee or applicant for employment because of race, color, sex, sexual or affectional preference, age, religion, national or ethnic origin, handicap, or veteran status.

15.3 Compliance with Laws. Company must comply with all prevailing laws, rules and regulations that apply to its activities or obligations under this Agreement. For example, Company will comply with applicable United States export laws and regulations. The transfer of certain technical data and commodities may require a license from the applicable agency of the United States government and/or written assurances by Company that Company will not export data or commodities to certain foreign countries without prior approval of the agency. Penn and Cellscript do not represent that no license is required, or that, if required, the license will issue.

15.4 Modification, Waiver & Remedies. This Agreement may only be modified by a written amendment that is executed by an authorized representative of each Party. Any waiver must be express and in writing. No waiver by either Party of a breach by the other Party will constitute a waiver of any different or succeeding breach. Unless otherwise specified, all remedies are cumulative.

[Remainder of page left blank]

15.5 Assignment. This Agreement may not be assigned (by operation of law or otherwise) by either Party without the prior written consent of the other Party (which consent will not be unreasonably withheld); *except that*, either Party may assign this Agreement without such consent to an affiliate or to a Third Party successor that purchases greater than fifty percent (>50%) of the outstanding stock or ownership interest or all or substantially all of such Party's business or assets to which this Agreement relates, whether by sale of shares or ownership interest, merger, consolidation, sale of assets or otherwise, *provided that*, prior to said transfer, the intended assignee agrees in writing to be legally bound by this Agreement in the place and stead of the assignor and provides the non-assigning Party with a copy of said assignee's written undertaking. Neither Party will grant a security interest in the Sublicense or this Agreement during the Term. Any prohibited assignment or security interest in contravention of the foregoing will be null and void. The rights and obligations of the Parties under this Agreement will be binding upon and inure to the benefit of the successors and permitted assigns of the Parties, and the name of a Party appearing herein will be deemed to include the name of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Section 15.5.

15.6 Notices. Any notice or other required communication (each, a "**Notice**") must be in writing, addressed to the Party's respective Notice Address listed on the signature page, and delivered: (a) personally, with signed receipt; (b) by certified mail, postage prepaid, return receipt requested; (c) by recognized overnight courier service, charges prepaid; or (d) by facsimile. A Notice will be deemed received: if delivered personally, on the date of delivery; if mailed, [***] days after deposit in the United States mail; if sent via courier, [***] business day after deposit with the courier service; or if sent via facsimile, upon receipt of confirmation of transmission provided that a confirming copy of such Notice is sent by certified mail, postage prepaid, return receipt requested.

15.7 Severability & Reformation. If any provision of this Agreement is held to be invalid or unenforceable by a court of competent jurisdiction, then the remaining provisions of this Agreement will remain in full force and effect. Such invalid or unenforceable provision will be automatically revised to be a valid or enforceable provision that comes as close as permitted by law to the Parties' original intent.

15.8 Headings & Counterparts. The headings of the articles and sections included in this Agreement are inserted for convenience only and are not intended to affect the meaning or interpretation of this Agreement. This Agreement may be executed in one or more counterparts, each of which when executed and delivered by facsimile, electronic transmission, or by mail delivery, will be an original and all of which shall constitute one and the same instrument.

15.9 Governing Law. This Agreement will be governed in accordance with the laws of the Commonwealth of Pennsylvania, without giving effect to the conflict of law provisions of any jurisdiction.

15.10 Dispute Resolution. If a dispute arises between the Parties concerning any right or duty under this Agreement, then the Parties will confer, as soon as practicable, in an attempt to resolve the dispute. If the Parties are unable to resolve the dispute amicably, then the Parties will submit to the exclusive jurisdiction of, and venue in, the state and Federal courts located in the Eastern District of Pennsylvania with respect to all disputes arising under this Agreement. Notwithstanding anything herein to the contrary, in the event of an actual or threatened breach of this Agreement, the aggrieved Party may seek provisional equitable relief (including restraining orders, specific performance or other injunctive relief) in any court of competent jurisdiction to protect the interests of such Party.

15.11 Further Assurance. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

15.12 Interpretation. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word “or” is used in the inclusive sense (and/or). The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term “including” as used herein shall mean including, without limiting the generality of any description preceding such term. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party hereto. The Parties acknowledge and agree that new products and uses for products that are covered by Patent rights may be developed based on new advances in scientific knowledge. As such, the Parties’ agree that, if Company is of the opinion that such advances have resulted in changes which warrant interpretation of whether such new products or uses are included within the Sublicensed Fields of Use granted to Company herein, the Parties agree to discuss and negotiate in good faith the need for an amendment or clarification of the meaning of the rights or Fields of Use granted to Company in Section 1.1 of this Agreement in order to try to find a solution that is agreeable to the Parties. Then, if the Parties have not agreed on the necessity or the wording of such amendment within [***] days after beginning good faith discussions, the Parties agree that, either both Parties will jointly agree on and appoint one independent Third Party, or each of the Parties will appoint one independent Third Party and those Third Parties will appoint one additional independent Third Party (all of which Third Parties will be qualified and skilled in the scientific field and have knowledge of law related to patents and licenses) to decide whether such amendment is required to properly reflect this intention. If the appointed independent Third Party or Third Parties decide(s) that said amendment is required, the Parties hereby agree to so amend this Agreement accordingly. If the appointed independent Third Party or Third Parties decide(s) that said amendment is not required, there is no obligation on either Party to amend this Agreement. The costs of the appointed independent Third Party or Third Parties will be borne by the Party whose view has not been confirmed by such Third Party(ies).

15.13 Integration. This Agreement with its Exhibits and the Confidentiality Agreement contain the entire agreement between the Parties with respect to the Patent Rights, Exhibit D Patents and the Sublicense and supersede all other oral or written representations, statements, or agreements with respect to such subject matter.

15.14 Condition Precedent to Execution of this Agreement. The Parties understand and agree that each Party’s willingness to enter into this Agreement is contingent upon the execution of both this Agreement and the mRNA RiboTherapeutics Sublicense Agreement, which grants certain other rights to Company under Patent Rights than the rights granted to Company in this Agreement.

15.15 Entire Agreement. This Agreement and the separate mRNA RiboTherapeutics Sublicense Agreement set forth the complete, final and only agreements with respect to the subject matter hereof and supersede all other agreements and understandings between the Parties with respect to the subject matter hereof. The Parties acknowledge and agree that this Agreement and the mRNA RiboTherapeutics Sublicense Agreement are separate and distinct agreements and there will be no “cross default” with respect to this Agreement and the mRNA RiboTherapeutics Sublicense Agreement.

[SIGNATURE PAGE FOLLOWS]

Each Party has caused this Agreement to be executed by its duly authorized representative.

CELLSCRIPT, LLC

By: [***]
Name: [***]
Title: [***]

Address: CELLSRIPT, LLC
726 Post Road
Madison, WI 53713
USA

BioNTech AG

By: [***]
Name: [***]
Title: [***]

Address: BioNTech AG
An der Goldgrube 12
Mainz
Germany

mRNA RIBOTHERAPEUTICS, INC.,

which is executing this Agreement solely with respect to the following provisions:

- Section 6.5.1, solely with respect to acceptance of sublicense agreements assigned by Cellscript;
- Section 9.2 (9.2.1through 9.2.8);
- Section 9.5 (9.5.1 through 9.5.10); and
- Article 10.

By: [***]
Name: [***]
Title: [***]

Address: mRNA RiboTherapeutics, Inc.
726 Post Road
Madison, WI 53713
USA

EXHIBIT INDEX

Exhibit A	Patents and Patent Applications in Patent Rights
Exhibit B	Sublicense Disclosure Report
Exhibit C	Form of Royalty Report
Exhibit D	Cellscript's Exhibit D Patents

EXHIBIT A – Patents and Patent Applications in Patent Rights

[***]

EXHIBIT A – Patents and Patent Applications in Patent Rights

[***]

Exhibit B
Sublicense Disclosure Report

[***]

Exhibit D

Exhibit D Patents Sublicensed to Company under Section 1.7

THE SYMBOL “[*]” DENOTES PLACES WHERE CERTAIN IDENTIFIED
INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i)
NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE
COMPANY IF PUBLICLY DISCLOSED**

Patent Sublicense Agreement

This Patent Sublicense Agreement (“**Agreement**”) is between mRNA RiboTherapeutics, Inc., a Wisconsin corporation having a place of business at 726 Post Road, Madison, WI 53713, USA (“**mRNA RiboTherapeutics**”) and BioNTech AG, a German corporation having its principal place of business at An der Goldgrube 12, 55131 Mainz, Germany (“**Company**”). This Agreement is effective as of July 14, 2017 (the “**Effective Date**”). Each of Company and mRNA RiboTherapeutics are referred to herein as a “**Party**” and collectively as the “**Parties**”.

BACKGROUND

WHEREAS, The Trustees of the University of Pennsylvania, a Pennsylvania nonprofit corporation (“**Penn**”) owns certain intellectual property comprising patents, patent applications and technology relating to [***], and certain other intellectual property comprising patents, patent applications and technology relating to [***], for all of which intellectual property mRNA RiboTherapeutics has a license from Penn pursuant to the Second Amended and Restated Patent License Agreement which became effective as of December 20, 2016 (the “**Penn License Agreement**”), including the right to sublicense all or any part of said rights to other parties, and under which CELLSCRIPT, LLC (“**Cellscript**”) also has rights pursuant to a patent sublicense agreement from mRNA RiboTherapeutics (the “**Cellscript Sublicense Agreement**”); and

WHEREAS, Company desires a sublicense from mRNA RiboTherapeutics under Patents Rights (as defined below) for diagnostic and prognostic uses in humans and non-human animals and for certain other uses pertaining thereto and mRNA RiboTherapeutics is willing to grant to Company a sublicense under Patents Rights for such uses under the terms and conditions herein;

NOW, THEREFORE, in consideration of the mutual obligations contained in this Agreement, and intending to be legally bound, the Parties agree as follows:

1. SUBLICENSE

1.1 Sublicense Grant. mRNA RiboTherapeutics hereby grants to Company and Company hereby accepts from mRNA RiboTherapeutics a worldwide, non-exclusive sublicense under the Patent Rights during the Term to make, have made, import, use, offer for sale, sell and/or have sold Licensed Products according to the terms and conditions herein: (1) in Field of Use B for all uses in the Diagnostic and Prognostic Field of Use that pertain to or are used in conjunction with products for therapeutic, prophylactic, cosmetic or other uses in or on humans or non-human animals in the *In Vivo* Field of Use in Field of Use B; and (2) in Field of Use A for research and screening uses, including pre-clinical research and screening comprising *ex vivo* uses in human or non-human animal cells or *in vivo* uses in animals, that pertain to and support research, development, manufacture, regulatory approval and commercialization of diagnostic and prognostic products used in conjunction with therapeutic, prophylactic, cosmetic, veterinary or other products for the *In Vivo* Field of Use in Field of Use B, as said terms are defined in Sections 1.2 and 6.1 herein (the “**Sublicense**”). The Sublicense includes the right for Company to grant sublicenses to its affiliates and Third Parties for all or any part of the rights and fields of use granted to Company, under terms that are consistent with this Agreement. No other rights or licenses are granted to Company hereunder by mRNA RiboTherapeutics; [***]

1.2 Related Definitions.

Whenever the words or terms “comprising,” “containing,” “having,” “include,” “includes,” “including,” “such as,” “for example,” “an example,” “examples,” “e.g.,” “for further clarification” or the like are used in this Agreement, they shall be understood to be followed by the words “without limitation” or “but without limitation”. The terms “a,” “an,” and “the” and the use of such terms or nouns in definitions in either the singular or the plural are to be construed to cover both the singular and the plural unless otherwise noted.

“**Licensed Products**” means products that are made, made for, used, imported, offered for sale or sold by Company or its Affiliates or Third Party sublicensees and that, in the absence of a license to Patent Rights, (i) would infringe (or, in the case of pending patent applications, upon issuance, would infringe) at least one claim of the Patent Rights or (ii) use a process or machine covered by a claim of Patent Rights, whether the claim is issued or pending. For clarity, Licensed Products includes any method, procedure or process, the use of which by Company or its Affiliates or Third Party sublicensees, in the absence of a license to Patent Rights by the user, would infringe, induce to infringe or contribute to infringing one or more claims of Patent Rights whether the claim is issued or pending.

“**Exhibit A-1 Patent Rights**” means [***]

“**Exhibit A-2 Patent Rights**” means [***]

“**Patent Rights**” means Exhibit A-1 Patent Rights and/or Exhibit A-2 Patent Rights.

“**Affiliate**” means a legal entity that is controlling, controlled by or under common control with Company and that has executed either this Agreement, a sublicense for at least a portion of the rights granted to Company under this Agreement, or a written joinder agreement agreeing to be bound by all of the terms and conditions of this Agreement. The uncapitalized term “**affiliate**” means, with respect to a first legal entity, any other legal entity that is controlling, controlled by or under common control with said first legal entity. For purposes of the definitions of “Affiliate” and “affiliate” herein, the word “**control**” means (x) the direct or indirect ownership of fifty percent (50%) or more of the outstanding voting securities of a legal entity, (y) the right to receive fifty percent (50%) or more of the profits or earnings of a legal entity, or (z) the right to determine the policy decisions of a legal entity.

“**Field of Use A**” means and is limited to internal laboratory research or screening [***]. For clarity, Field of Use A includes laboratory research use in animals or human or animal cells, living or dead, from any source, including for pre-clinical laboratory research in laboratory animals or cultured human or non-human animal cells for the purpose of generating data and information prior to use in clinical trials for a use that requires approval by the FDA or another regulatory organization. For further clarity, a party that has a sublicense in Field of Use A pertaining to sublicensed therapeutic or prophylactic or diagnostic or prognostic products in Field of Use B shall have the right under Patent Rights to perform pre-clinical research in Field of Use A comprising *in vivo* uses in non-human animals or *ex vivo* uses in human or non-human animal cells in order to obtain data and information to support pre-clinical development of such therapeutic or prophylactic or diagnostic or prognostic products.

[***]

“**Field of Use B**” means the field other than Field of Use A and includes but is not limited to therapeutic, prophylactic, diagnostic, prognostic and cosmetic uses in humans and agricultural, animal improvement and veterinary uses in animals. For clarity, Field of Use B includes any and all fields of use, including the *In Vivo* Field of Use and *Ex Vivo* Field of Use, other than for Field of Use A.

“**Fields of Use**” means Field of Use A and Field of Use B.

“**Ex Vivo Field of Use**” is a subfield of Field of Use A or Field of Use B wherein a product or method that is covered by Patent Rights is used in cells, tissues or organs that are *ex vivo* or outside of a living human or animal body or organism, whether those cells, tissues or organs are subsequently used only *ex vivo*, such as in culture, or are subsequently introduced into, used in or administered or applied to or on a living body or organism. [***]

“**In Vivo Field of Use**” is a subfield of Field of Use A or Field of Use B wherein a product or method that is covered by Patent Rights is used *in vivo*, [***]

“**Diagnostic and Prognostic Field of Use**” is a subfield of use within Field of Use B wherein a product or service covered by Patent Rights is used for diagnosis, prognosis or testing of a human or non-human animal or a sample therefrom in order to detect, identify, determine a cause, evaluate, analyze, understand, predict, rule in, or rule out a medical condition or disease or to predict an effect or response to treatment, and/or to monitor the effect of a treatment of such medical condition or disease. [***]

“**Veterinary Product**” means a product that is covered by Patent Rights which is used for the care, treatment, breeding or use of livestock or companion animals.

“**Third Party**” means any person, corporation, partnership, association, consortium or business, legal or governmental entity other than Penn, mRNA RiboTherapeutics, Company or any of their respective affiliates.

1.3 Reservation of Rights by Penn. Penn reserves the right to use, and to permit other non-commercial entities to use, the Patent Rights for educational and non-commercial research purposes.

1.4 U.S. Government Rights. The Parties acknowledge that the United States government retains rights in intellectual property funded under any grant or similar contract with a Federal agency. The License is expressly subject to all applicable United States government rights, including, but not limited to, any applicable requirement that products, which result from such intellectual property and are sold in the United States, must be substantially manufactured in the United States. To the extent any such U.S. manufacturing requirements apply, mRNA RiboTherapeutics shall, upon request of Company, use commercially reasonable efforts to cause Penn to seek a waiver from the United States government for Company in respect of such U.S. manufacturing requirements.

1.5 Sublicense Conditions. Company’s right to extend any or all of the rights granted to Company by mRNA RiboTherapeutics via a sublicense to affiliates or Third Parties is subject to each of the following conditions:

1.5.1 Company will have the right to grant further sublicenses to its affiliates and to Third Parties (“**sub-sublicensees**”) that permit multiple levels of sublicensing, including in Third Party sub-sublicenses that permit further levels of sublicensing (e.g., to “sub-sub-sublicensees”). In each further sub-sublicense agreement to an affiliate or Third Party, Company will require the sub-sublicensee to comply with terms and conditions that are consistent with this Agreement, and in each agreement for further sublicensing (e.g., by a sub-sublicensee of Company to a sub-sub-sublicensee), the party granting the further sublicense will require the party receiving the further sublicense to comply with terms and conditions that are consistent with its sub-sublicense agreement from Company. Except when used to clarify the meaning of the different terms in this Section 1.5.1, the term sublicense in this Agreement includes any permitted sub-sublicense, sub-sub-sublicense, etc. and the term sublicensee includes any permitted sub-sublicensee, sub-sub-sublicensee, etc.

1.5.2 Within [***] days after Company enters into a sublicense agreement, Company will deliver to mRNA RiboTherapeutics a complete and accurate copy of the entire sublicense agreement written in the English language, provided that Company will have the right to redact the terms and conditions of such sublicense agreement that are not necessary for mRNA RiboTherapeutics to confirm compliance with all terms and conditions required under this Sublicense, including Section 1.5 hereof. mRNA RiboTherapeutics’ receipt of the sublicense agreement will not constitute a waiver of any right or obligation of mRNA RiboTherapeutics or of Company under this Agreement.

1.5.3 In the event that Company causes or experiences a Trigger Event (as defined in Section 6.4), to the extent permissible by law, all payments due to Company from its direct sublicensees pursuant to a sublicense to this Agreement that are payable by Company to Cellscript hereunder, including milestone payments and royalty payments, will, upon notice from mRNA RiboTherapeutics to such sublicensees, become payable directly to mRNA RiboTherapeutics for the account of Company. Upon receipt of any such funds, mRNA RiboTherapeutics will remit to Penn the amounts owed to Penn and will remit to Company the amount (if any) by which such payments from such sublicensees exceed the amounts owed by Company to mRNA RiboTherapeutics. Still further, in the event that mRNA RiboTherapeutics causes or experiences a trigger event according to the terms of the Penn License Agreement, Company agrees that, upon notification from Penn, Company will remit to Penn all amounts payable by Company to mRNA RiboTherapeutics under this Agreement (including but not limited to all milestone payments and royalty payments) for the account of mRNA RiboTherapeutics.

1.5.4 Company’s execution of a sublicense agreement will not relieve Company of any of its obligations under this Agreement. Company is primarily liable to mRNA RiboTherapeutics for any act or omission of a sublicensee that would be a breach of this Agreement if performed or omitted by Company, and Company will be deemed to be in breach of this Agreement as a result of such act or omission. Upon learning of any such breach of this Agreement due to an act or omission of a sublicensee of Company, Company will immediately take appropriate actions to stop such act or omission, including termination of the sublicense by Company. Provided that Company takes such appropriate actions and stops such act or omission, a breach by said sublicensee shall not be considered a breach by Company that will be considered a cause for termination of this Agreement under Section 6.3.

1.5.5 A sublicense granted by the Company or a further sublicensee thereof will not be assignable or transferable by said sublicensee or further sublicensee thereof without the prior written consent of mRNA RiboTherapeutics, except to an affiliate of the sublicensee of Company or an affiliate of said further sublicensee thereof, or to a Third Party company that: (i) can demonstrate based on reliable financial information that it has all technical knowledge, capabilities and/or financial resources needed to perform in all respects in the place and stead of said sublicensee or further sublicensee thereof; (ii) agrees to assume all duties and responsibilities under the sublicense; (iii) warrants that it will invest an amount of money that Company agrees is sufficient to develop and/or commercialize the sublicensed Licensed Product(s); (iv) purchases more than fifty percent (50%) of all of the sublicensee's or the further sublicensee's shares or assets to which the sublicense pertains; and (v) agrees in writing to be bound by all of the terms and conditions of the sublicense and a copy of such written undertaking is promptly provided to Company, which will provide a copy to mRNA RiboTherapeutics, which, in turn, will provide a copy to Penn as required in the Penn License Agreement.

1.6 No License by Implication. Nothing in this Agreement confers by estoppel implication or otherwise, any license or rights under any Penn patent other than rights under a patent included in the Patent Rights, regardless whether such patents are dominant or subordinate to the Patent Rights.

1.7 Relation of this Agreement to the Sublicense Agreement from Cellscript. Concurrent with the execution of this Agreement, Company is entering into a separate sublicense agreement with Cellscript (the "**Sublicense Agreement from Cellscript**"), pursuant to which Cellscript is granting Company a sublicense under Patent Rights with respect to certain fields of use that are different from and are not included within the scope of the Sublicense granted to Company in this Agreement.

2 DILIGENCE

2.1 Development Plan and Sublicense Disclosure Report. By [***] and by [***] of every calendar year thereafter that encompasses the Term, Company will deliver to mRNA RiboTherapeutics: (1) a copy of an annual development plan, including a projected timeline, for the Patent Rights and a summary of material development efforts for Licensed Products since the last development plan ("**Development Plan**"); and [***], certified as correct by the accounting services manager or chief financial officer, that includes all additional information as listed on Exhibit B for the period since the last SDR.

2.2 Company's Efforts. Company will use commercially reasonable efforts to develop, commercialize, market and sell Licensed Products in the sublicensed Fields of Use in a manner consistent with the Development Plan. In addition to Company's own efforts to develop, commercialize, market and sell Licensed Products, the efforts of other parties, including Affiliates, Third Party sublicensees, contractors, Third Parties funded by Company under a research or service agreement, and distributors, will also be deemed as efforts of Company.

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3 FEES AND ROYALTIES

3.1 Sublicense Grant Fees. In partial consideration for the Sublicense, Company will pay to mRNA RiboTherapeutics: (i) [***] and (ii) [***]

3.2 Sublicense Maintenance Fees. In partial consideration of the Sublicense, Company will pay to mRNA RiboTherapeutics [***] on each anniversary of the Effective Date until the date of first Sale of the first Licensed Product in Field of Use B, regardless of whether the Sale is achieved by Company, mRNA RiboTherapeutics, or an affiliate or sublicensee of any of the foregoing. For clarity, the next annual sublicense maintenance fee under this Agreement is payable to mRNA RiboTherapeutics on July 1, 2018 if no Sale of a Licensed Product in Field of Use B occurs prior to July 1, 2018.

3.3 Milestone Payments. In partial consideration of the Sublicense, Company will pay to mRNA RiboTherapeutics the applicable milestone payment listed in Table D in this Section 3.3 the first time after achieving each milestone event for each Licensed Product in Field of Use B, regardless of whether the milestone is achieved by Company or an Affiliate or Third Party sublicensee. Company will provide mRNA RiboTherapeutics with written notice within [***] days after each milestone is achieved by Company or a sublicensee and Company will pay to mRNA RiboTherapeutics all applicable milestone payments owed therefor within [***] days of the end of the calendar quarter in which the milestone event is achieved. For clarity, each time a milestone is achieved with respect to a Licensed Product, then any other milestone payments with respect to earlier milestones that have not yet been paid will be due and payable together with the milestone payment that is actually achieved.

Section 3.3 Table D
MILESTONES for each Licensed Product that is
a Diagnostic, Prognostic or Other Medical Device Product

[***]

3.4 Earned Royalties. In partial consideration of the Sublicense, Company will pay to mRNA RiboTherapeutics royalties on Net Sales of Licensed Products in the sublicensed Fields of Use as stated below.

3.4.1 Earned Royalties on Licensed Products in Field of Use A. In partial consideration of the Sublicense, Company will pay to mRNA RiboTherapeutics a [***] royalty on Net Sales of Licensed Products by Company or its Affiliates or Third Party sublicensees for use in [***]. For clarity, Company and its Affiliates or Third Party sublicensees shall only have the right to sell Licensed Products for use in Field of Use A to Third Parties that have either a sublicense from or a contract with Company or an Affiliate or Third Party sublicensee to research, develop, test, evaluate, screen, manufacture and/or commercialize a Licensed Product for diagnostic or prognostic use pertaining to a therapeutic, prophylactic or other product for humans or non-human animals in the *In Vivo* Field of Use in Field of Use B.

3.4.2 **Earned Royalties on Licensed Products for the Diagnostic and Prognostic Use in Field of Use B.** In partial consideration of the Sublicense, Company will pay to mRNA RiboTherapeutics a [***] royalty on Net Sales of Licensed Products for [***] for the *In Vivo* Field of Use in Field of Use B during the Quarter. For the avoidance of doubt, if Company or its Affiliates or Third Party sublicensees grant sublicenses to sell Licensed Products for such a diagnostic or prognostic use in Field of Use B, Company will pay to mRNA RiboTherapeutics [***]

3.4.3 **Royalty Reduction.** If Company or an Affiliate or Third Party sublicensee of Company is obligated to pay Third Party Royalties (defined below) for a Licensed Product in Field of Use B, then Company may deduct [***] of such Third Party Royalties from any royalties on Net Sales in Field of Use B due to mRNA RiboTherapeutics under Section 3.4.2 of this Agreement, provided that:

(a) On an ongoing basis and prior to reduction of any royalty on Net Sales for a given calendar quarter, Company first provides written evidence to mRNA RiboTherapeutics of Company's or applicable sublicensee's obligation to pay such Third Party Royalties; and

(b) In no event shall royalties on Net Sales due to mRNA RiboTherapeutics in any reporting period be so reduced to less than [***] for Licensed Products in Field of Use B.

“Third Party Royalties” means any royalty obligation [***] that Company or its Affiliates or a Third Party sublicensee owes to one or more other parties pursuant to one or more licenses for patent rights comprising [***] and that are determined to be necessary to avoid infringement-related litigation with respect to the manufacture, use or sale of any Licensed Product.

3.5 **Related Definitions.**

3.5.1 The term **“Sale”** means any bona fide transaction for which consideration is received or expected by Company or its Affiliates or Third Party sublicensees for the sale, use, lease, transfer or other disposition of a Licensed Product to a Third Party. A Sale is deemed completed at the time that Company or an Affiliate or Third Party sublicensee invoices, ships or receives payment for a Licensed Product, whichever occurs first.

3.5.2 The term **“Quarter”** means each three-month period beginning on the first day of January, April, July or October.

3.5.3 The term “**Net Sales**” means the consideration received or expected from, or the fair market value attributable to, each Sale, less Qualifying Costs that are directly attributable to a Sale, specifically identified on an invoice or other documentation and actually borne by Company or its Affiliates or Third Party sublicensees. For purposes of determining Net Sales, the words “fair market value” mean the cash consideration that Company or its Affiliates or Third Party sublicensees would realize from an unrelated buyer in an arm’s length sale of an identical item sold in the same quantity and at the time and place of the transaction.

3.5.4 The term “**Qualifying Costs**” means: (a) credits or refunds for claims or returns that do not exceed the original invoice amount; (b) prepaid outbound transportation expenses and transportation insurance premiums; and (c) sales and use taxes and other fees imposed by and indefeasibly paid to a governmental agency.

3.6 **Minimum Royalties.** In partial consideration of the Sublicense, [***], Company will pay to mRNA RiboTherapeutics the amount, if any, by which the applicable minimum royalties listed in the tables below exceed Company’s actual earned royalties under Section 3.4 for each Quarter after the first Sale of a Licensed Product by Company or its Affiliates or Third Party sublicensees in the applicable Categories. The minimum royalties are divided into two Categories and outlined in the tables below and are tiered, cumulative and individually payable after first Sale of Licensed Product in each of the two respective Categories. For clarity, the highest minimum royalty owed by Company to mRNA RiboTherapeutics under this Agreement would be [***]. For additional clarification, Company is not obligated to pay minimum royalties to mRNA RiboTherapeutics on Category 1 Licensed Products until after the first Sale of a Licensed Product in Field of Use A by Company or its Affiliates or Third Party sublicensees, and Company is not obligated to pay minimum royalties to mRNA RiboTherapeutics on a Category 3 Licensed Product until after the first Sale of Licensed Product in Field of Use B by Company or its Affiliates or Third Party sublicensees in the Diagnostic and Prognostic Field of Use.

Category 1—Licensed Products in Field of Use A

<u>QUARTER:</u>	<u>First Four Quarters</u>	<u>All Subsequent Quarters</u>
MINIMUM:	[***]	[***]

**Category 3—Licensed Products in Field of Use B
That Are Diagnostic or Prognostic Products**

<u>QUARTER:</u>	<u>First Four Quarters</u>	<u>All Subsequent Quarters</u>
MINIMUM:	[***]	[***]

4 REPORTS AND PAYMENTS

4.1 Royalty Reports. Within [***] days after the end of each Quarter following the first Sale, Company will deliver to mRNA RiboTherapeutics a report, certified as accurate by the accounting services manager or chief financial officer of Company, detailing the calculation of all royalties, fees and other payments due to mRNA RiboTherapeutics for such Quarter. The report will include, at a minimum, the following information for the Quarter, each listed by product, by country: [***]

4.2 Payments. Company will pay all royalties, fees and other payments due to mRNA RiboTherapeutics under Sections 3.3, 3.4 and 3.6 within [***] days after the end of the Quarter in which the royalties, fees or other payments accrued. mRNA RiboTherapeutics agrees that it will pay to Penn all royalties, fees and other payments due to Penn according to and within the time periods required by the Penn License Agreement. For clarity, only one royalty will be due with respect to the Sale of the same unit of Licensed Product.

4.3 Records. Company will maintain, and will cause its Affiliates and Third Party sublicensees to maintain, complete and accurate books, records and related background information to verify Sales, Net Sales, and all of the royalties, fees, and other payments due or paid under this Agreement, as well as the various computations reported under Section 4.1. The records for each Quarter will be maintained for at least [***] years after submission of the applicable report required for Section 4.1.

4.4 Audit Rights. Upon reasonable prior written notice to Company, Company and its Affiliates and Third Party sublicensees will provide Penn and its accountants (or mRNA RiboTherapeutics and its accountants in the event that mRNA RiboTherapeutics is Penn's designated auditor) with access to all of the books, records, key personnel and related background information required by Section 4.3 to conduct a review or audit of Sales, Net Sales, and all of the royalties, fees, and other payments payable under this Agreement. Access will be made available: (a) during normal business hours; (b) in a manner reasonably designed to facilitate such accountant's review or audit without unreasonable disruption to Company's business; and (c) no more than once each calendar year during the Term (as defined below) and for a period of [***] years thereafter. Company will promptly pay to mRNA RiboTherapeutics the amount of any underpayment determined by the review or audit, plus accrued interest. If the review or audit determines that Company has underpaid any payment by [***] or more, then Company will also promptly pay the costs and expenses of the auditing party's accountants in connection with the review or audit. In addition, once annual Sales of Licensed Products exceed [***], Company will conduct, at least once every [***] years at its own expense, an independent audit of Sales, Net Sales, and all of the royalties, fees, and other payments due or paid under this Agreement. Promptly after completion of the audit, Company will provide to mRNA RiboTherapeutics a copy of the report of the independent auditors along with any underpayments and interest thereon.

4.5 Currency. All dollar amounts referred to in this Agreement are expressed in United States dollars. All payments will be made in United States dollars. If Company receives payment from a sublicensee in a currency other than United States dollars for which a royalty or fee is owed under this Agreement, then (a) the payment will be converted into United States dollars at the conversion rate for the foreign currency as published in the eastern edition of the Wall Street Journal as of the last business day of the Quarter in which the payment was received by Company, and (b) the conversion computation will be documented by Company in the applicable report delivered to mRNA RiboTherapeutics under Section 4.1.

4.6 Place of Payment. All payments by Company to “mRNA RiboTherapeutics, Inc.” and will be made to the following addresses:

[***]

*(Payment should include the
necessary amount to cover
Sender’s bank wire fees)*

4.7 Interest. All amounts that are not paid by Company when due will accrue interest from the date due until paid at a rate equal to [***] (or the maximum allowed by law, if less).

5 CONFIDENTIALITY AND USE OF NAMES

5.1 Confidentiality. Each Party agrees that it will not, under this Agreement, provide to the other Party or its affiliates any Confidential Information of such Party unless (i) such Party has first identified the general nature of such Confidential Information to such other Party in writing and such other Party has affirmatively agreed in writing to receive such Confidential Information, or (ii) such other Party has specifically requested such Confidential Information in writing. For clarity, any such consent or request issued by email or other written electronic means shall satisfy the foregoing “writing” requirements. Any Confidential Information disclosed by a Party to the other Party other than in accordance with this Section 5.1 will be deemed not to be Confidential Information of such Party. Notwithstanding the foregoing, mRNA RiboTherapeutics is obligated to accept and treat as confidential any Confidential Information disclosed by Company in the reports or notices required by Sections 2.1, 2.3, 3.3, 3.4.3(a), 4.1, 4.4, 4.5, 4.6 and 6.6, which information Company agrees mRNA RiboTherapeutics may disclose to Penn without the prior written consent of Company.

5.2 Confidential Information. Each Party (“**Disclosing Party**”) may disclose to the other Party (“**Receiving Party**”), and Receiving Party may acquire during the course and conduct of activities under the Agreement, certain proprietary or confidential information of Disclosing Party in connection with this Agreement. The term “Confidential Information” shall mean all ideas and information of any kind, whether in written, oral, graphical, machine-readable or other form, whether or not marked as confidential or proprietary, which are transferred, disclosed or made available by Disclosing Party in accordance with Section 5.1.

5.3 Restrictions. During the Term and for [***] years thereafter, Receiving Party shall keep all Disclosing Party’s Confidential Information in confidence with the same degree of care with which Receiving Party holds its own confidential information. Receiving Party shall not use Disclosing Party’s Confidential Information except in connection with the performance of its obligations and exercise of its rights under this Agreement. Receiving Party has the right to disclose Disclosing Party’s Confidential Information without Disclosing Party’s prior written consent, to the extent and only to the extent reasonably necessary, to Receiving Party’s affiliates and their employees, subcontractors, consultants or agents who have a need to know such

Confidential Information in order to perform Receiving Party's obligations or exercise Receiving Party's rights under this Agreement, provided said affiliates and their employees, subcontractors, consultants or agents are required to comply with a written confidentiality agreement having restrictions on use and disclosure of Disclosing Party's Confidential Information which are no less stringent than those in this Section 5.3. Receiving Party assumes responsibility for compliance with such restrictions by its affiliates and their employees, subcontractors, consultants or agents.

5.4 Exceptions. Receiving Party's obligation of nondisclosure and the limitations upon the right to use the Disclosing Party's Confidential Information shall not apply to the extent that Receiving Party can demonstrate, as evidenced by contemporaneous written records, that the Disclosing Party's information: (i) was known to Receiving Party or any of its affiliates prior to the time of disclosure; (ii) is or becomes public knowledge through no fault or omission of Receiving Party or any of its affiliates; (iii) is obtained by Receiving Party or any of its affiliates from a Third Party under no obligation of confidentiality to Disclosing Party; (iv) has been independently developed by employees, subcontractors, consultants or agents of Receiving Party or any of its affiliates without the aid, application or use of Disclosing Party's Confidential Information or (v) is not Confidential Information under Section 5.1.

5.5 Permitted Disclosures. Receiving Party may disclose Disclosing Party's Confidential Information to the extent (and only to the extent) such disclosure is reasonably necessary in the following instances:

5.5.1 in order to comply with applicable law (including any securities law or regulation or the rules of a securities exchange) or with a legal or administrative proceeding;

5.5.2 in connection with prosecuting or defending litigation, regulatory approvals and other regulatory filings and communications, and filing, prosecuting and enforcing Patents in connection with Receiving Party's rights and obligations pursuant to this Agreement; and

5.5.3 in connection with exercising its rights hereunder, to its affiliates; to potential and future collaborators and sublicensees; permitted acquirers or assignees; and investment bankers, investors and lenders, except that, mRNA RiboTherapeutics will obtain the prior written consent of Company before disclosing any information disclosed to mRNA RiboTherapeutics pursuant to Sections 2.1, 2.3, 3.3, 3.4.3(a), 4.1, 4.4, 4.6 and 6.6;

provided that (1) with respect to Sections 5.5.1 or 5.5.2, where reasonably possible, Receiving Party shall notify Disclosing Party of Receiving Party's intent to make any disclosure pursuant thereto sufficiently prior to making such disclosure so as to allow Disclosing Party adequate time to take whatever action it may deem appropriate to protect the confidentiality of the information to be disclosed, and (2) with respect to Section 5.5.3, each of those named people and entities are required to comply with the restrictions on use and disclosure in Section 5.3 (other than investment bankers, investors and lenders, which must be bound prior to disclosure by commercially reasonable obligations of confidentiality).

5.6 Terms of this Agreement. The Parties agree that the terms of this Agreement shall be treated as Confidential Information of both Parties, and thus may be disclosed only as permitted by Section 5.5. Each Party agrees not to issue any press release or public statement disclosing information relating to this Agreement or the terms hereof without the prior written consent of the other Party not to be unreasonably withheld.

5.7 Relationship to the Confidentiality Agreement. This Agreement is in addition to a certain “Confidentiality Agreement” between the Parties dated December 7, 2015, as amended and extended on December 1, 2016, and (a) all “Confidential Information” as defined therein that was disclosed or received by the Parties prior to the Effective Date shall continue to be subject to the terms and conditions of the Confidentiality Agreement and (b) all Confidential Information disclosed or received by the Parties following the Effective Date shall be subject to the terms and conditions of this Agreement. For the avoidance of doubt, all other confidentiality agreements concluded between mRNA RiboTherapeutics and Company prior to the Effective Date of this Agreement shall be superseded by this Agreement.

5.8 Use of Penn’s, mRNA RiboTherapeutics’ or Company’s Name. Company and its Affiliates, Third Party sublicensees, employees, and agents are not granted any rights hereunder to use the name, logo, seal, trademark, or service mark (including any adaptation of them) of Penn or any Penn school, or their respective organizations, employees, students or representatives, without the prior written consent of Penn. Except to the extent permitted pursuant to this Article 5, neither Party shall have any right, express or implied, to use in any manner the name or other designation of the other Party or any other trade name or trademark of the other Party for any Purpose, except as may be required by applicable law or regulation.

6 TERM AND TERMINATION

6.1 Term. This Agreement will commence on the Effective Date and terminate upon the expiration or abandonment of the last patent to expire or become abandoned of the Patent Rights (the “**Term**”).

6.2 Early Termination by Company. Company may terminate this Agreement at any time effective upon completion of each of the following conditions: (a) providing at least [***] days prior written notice to mRNA RiboTherapeutics of such intention to terminate; (b) ceasing to make, have made, use, import, offer for sale and sell all Licensed Products; (c) providing documentation stating that all sublicenses granted by Company which are still in force at the date of termination can be assigned to mRNA RiboTherapeutics and working with mRNA RiboTherapeutics to assign or terminate such sublicenses based on the specific circumstances related thereto; and (d) paying all amounts owed to mRNA RiboTherapeutics under this Agreement through the effective date of termination. For clarity, Company may individually terminate either the Sublicense to Exhibit A-1 Patent Rights or the Sublicense to Exhibit A-2 Patent Rights provided that each of the conditions stipulated in Section 6.2 is met with respect to the Patent Rights terminated from the Sublicense. [***]

6.3 Early Termination by mRNA RiboTherapeutics. mRNA RiboTherapeutics may, to the extent permissible by law, terminate this Agreement if: (a) Company is more than [***] late in paying to mRNA RiboTherapeutics any amounts owed under this Agreement and does not pay mRNA RiboTherapeutics in full, including accrued interest, within [***] days after receiving written notice of the breach from mRNA RiboTherapeutics (a “**Payment Default**”); or (b) other than a Payment Default, Company materially breaches this Agreement and Company does not cure the breach [***] days after receiving written notice of the breach from mRNA RiboTherapeutics; or (c) Company causes or experiences a Trigger Event, or an Affiliate or Third Party sublicensee of Company commences or causes a Patent Challenge (as defined Section in 6.4 below) and Company does not terminate the sublicense or cause the Patent Challenge to be terminated prior to or promptly upon learning of said Patent Challenge. It is understood that, with respect to both of (a) and (b), Company is also responsible for its Affiliates and Third Parties sublicensees.

6.4 **Trigger Event.** The term “**Trigger Event**” means any of the following: (a) Company (i) becomes insolvent, bankrupt or generally fails to pay its debts as such debts become due, (ii) is adjudicated insolvent or bankrupt, (iii) admits in writing its inability to pay its debts, (iv) suffers the appointment of a custodian, receiver or trustee for its assets and, if appointed without its consent, not discharged [***], (v) makes an assignment of its assets for the benefit of creditors, or (vi) suffers proceedings being instituted against it under any law related to bankruptcy, insolvency, dissolution, liquidation or the reorganization, readjustment or release of multiple debtors and, if contested by it, not dismissed or stayed within [***]; (b) the institution or commencement by Company of any proceeding under any law related to bankruptcy, insolvency, liquidation or the reorganization, readjustment or release of multiple debtors; (c) the entering of any order for relief relating to any of the proceedings described in Section 6.4(a) or (b) above; (d) the calling by Company of a meeting of multiple creditors with a view to arranging a composition of adjustment of its debts; (e) the act or failure to act by Company that results in its consent to, approval of, or acquiescence in any of the proceedings described in Section 6.4(a)—(d) above; or (f) the commencement by Company or an Affiliate or Third Party sublicensee of Company of any action against Penn to declare or render invalid or unenforceable the Patent Rights or any claim thereof, including but not limited to an action for declaratory judgment (a “**Patent Challenge**”).

6.5 Effect of Termination.

6.5.1 Effect of Termination Except under Section 6.2 Upon the termination of this Agreement prior to expiration of the Term for any reason except pursuant to Section 6.2: (a) the Sublicense to the Patent Rights will terminate; (b) Company and all its Affiliates will cease all making, having made, using, importing, offering for sale and selling of all Licensed Products with respect to Patent Rights under the Sublicense, except to the extent permitted by Section 6.5.1(f) and Section 6.6; (c) Company will pay to mRNA RiboTherapeutics all amounts, including accrued interest, owed to mRNA RiboTherapeutics under this Agreement through the date of termination, including royalties on Licensed Products invoiced or shipped through the date of termination and any sell off period permitted by Section 6.6, whether or not payment is received prior to termination or expiration of the sell off period permitted by Section 6.6; (d) Company will, at mRNA RiboTherapeutics’ request, return to mRNA RiboTherapeutics all Confidential Information of mRNA RiboTherapeutics (if any) related to exploitation of Patent Rights and provide to mRNA RiboTherapeutics one summary of all work related thereto for Licensed Products generated by Company during the Term in order to facilitate the further development of the technology licensed under this Agreement; (e) in the case of termination under Section 6.3, all duties of mRNA RiboTherapeutics and all rights (but not duties) of Company under this Agreement immediately terminate without further action required by either mRNA RiboTherapeutics or Company; and (f) all outstanding Third Party sublicenses, to the extent each is not in default, will be assigned by Company to mRNA RiboTherapeutics, such assignment, will be accepted by mRNA RiboTherapeutics and each Third Party sublicense agreement will remain in full force and effect with mRNA RiboTherapeutics as the sublicensor instead of Company, but the duties and obligations of mRNA RiboTherapeutics under the assigned sublicense agreements will not be greater than the duties of mRNA RiboTherapeutics under this Agreement and the rights of mRNA RiboTherapeutics under the assigned sublicenses will not be less than those of mRNA RiboTherapeutics under this Agreement, including all financial consideration and other rights of mRNA RiboTherapeutics and mRNA RiboTherapeutics may, at its sole discretion, amend such assigned agreements to contain terms and conditions found in this Agreement. [***]

6.5.2 Effect of Termination under Section 6.2. Upon the termination of this Agreement under Section 6.2: (a) the Sublicense to Company and all further sublicenses to Affiliates and Third Parties terminate (except to the extent that said Third Party sublicenses become direct sublicenses of mRNA RiboTherapeutics pursuant to Section 6.5.2(e)); (b) Company, its Affiliates and Third Party sublicensees will cease all making, having made, using, importing, offering for sale and

selling all Licensed Products under the Sublicense, except to the extent permitted pursuant to Section 6.5.2(e) and Section 6.6; (c) Company will pay to mRNA RiboTherapeutics all amounts, including accrued interest, owed to mRNA RiboTherapeutics under this Agreement through the date of termination, including royalties on Licensed Products invoiced or shipped through the date of termination and any sell off period permitted by Section 6.6, whether or not payment is received prior to termination or expiration of the sell off period permitted by Section 6.6, and (d) Company will, at mRNA RiboTherapeutics' request, return to mRNA RiboTherapeutics all confidential information of mRNA RiboTherapeutics; and (e) all outstanding sublicenses of Company to Third Parties and all outstanding sublicenses of Company's Affiliates to Third Parties, to the extent each is not in default, will be assigned by Company or its Affiliates to mRNA RiboTherapeutics (and Company will contractually obligate its Affiliates to make or cause such assignments), and each such assigned sublicense agreement will remain in full force and effect (including for Exhibit A-1 Patent Rights and Exhibit A-2 Patent Rights) with mRNA RiboTherapeutics as the sublicensor instead of Company, but the duties and obligations of mRNA RiboTherapeutics under the assigned sublicense agreements will not be greater than the duties and obligations of Company under this Agreement, and the rights of mRNA RiboTherapeutics under the assigned sublicense agreements will not be less than the rights of Company under this Agreement, including all financial consideration and other rights of Company. mRNA RiboTherapeutics may, at its sole discretion, amend such assigned sublicense agreements to contain financial or other terms and conditions found in this Agreement (excluding payment obligations which have already been satisfied by Company).

6.6 Inventory & Sell Off. Subject to the remainder of this Section 6.6, upon the termination of this Agreement for any reason, Company will: (1) cause physical inventories to be taken immediately of (a) all completed Licensed Products on hand under the control of Company and its Affiliates and Third Party sublicensees and (b) such Licensed Products as are in the process of manufacture and any component parts on the date of termination of this Agreement; (2) deliver promptly to mRNA RiboTherapeutics a copy of said written inventory, certified by an officer of Company; (3) promptly remove, efface or destroy or require or cause to be removed, effaced or destroyed all references to Penn and mRNA RiboTherapeutics from any advertising, labels, web sites or other materials used in the promotion of the business of Company or its Affiliates or Third Party sublicensees; and (4) not represent in any manner that it has rights in or to the Patent Rights or the Licensed Products under this Sublicense and cause its Affiliates and Third Party sublicensees not to represent that they have any rights in or to the Patent Rights or the Licensed Products. Subject to this Section 6.6, Company and its Affiliates and Third Party sublicensees may sell off its inventory of Licensed Products existing on the date of termination for a period of [***] months and pay mRNA RiboTherapeutics royalties on Sales of such inventory within [***] days following the expiration of such [***] month period. Notwithstanding the foregoing: (i) Company's obligations under this Section 6.6 will not apply to the Sublicense or to Company's sublicense agreements if the Sublicense is assigned to Penn pursuant to Section 6.5.1; and (ii) the obligations of each of Company's sublicensees pursuant to this Section 6.6 will not apply to Company's or its Affiliates' or Third Party sublicensees' sublicense agreements that are assigned to mRNA RiboTherapeutics pursuant to Sections 6.5.1(f) or 6.5.2(e).

6.7 Survival. Company's obligation to pay all amounts, including accrued interest, owed to mRNA RiboTherapeutics under this Agreement will survive the termination of this Agreement for any reason. Articles 5, 6, 11, 12 and 13 and Sections 4.1 (until all Licensed Products which have been manufactured during the Term have been Sold), 4.2, 4.3 (for the time period set forth therein for all Sales of Licensed Products which have been manufactured during the Term), 4.4 (for the time period set forth therein), 9.1.3 (for all amounts paid by Company to

mRNA RiboTherapeutics that are payable to Penn following termination), and 4.5-4.7, 9.1.7 and 9.2.3 will survive the termination of this Agreement in accordance with their respective terms. The Parties acknowledge and agree that the Sublicense is, for the purposes of section 365(n) of the U.S. Bankruptcy Code, a license to “intellectual property” as defined under Section 101 of the U.S. Bankruptcy Code. The Parties intend that all payments under Article 3 of this Agreement constitute “royalties” within the meaning of section 365(n) of the U.S. Bankruptcy Code.

7 PATENT PROSECUTION AND MAINTENANCE

7.1 Patent Control. Penn and mRNA RiboTherapeutics control the preparation, prosecution and maintenance of the Patent Rights and the selection of patent counsel, subject to the remainder of this Section 7.1. For purposes of this Article 7, the word “maintenance” includes any interference negotiations, claims, or proceedings, in any forum, brought by Penn, mRNA RiboTherapeutics, a Third Party, or the United States Patent and Trademark Office or any foreign equivalent pertaining to Patent Rights, and any requests by Penn or mRNA RiboTherapeutics that the United States Patent and Trademark Office or any foreign equivalent re-examine or reissue any patent in the Patent Rights. [***]

8 INFRINGEMENT

8.1 Control. As between Company and mRNA RiboTherapeutics, mRNA RiboTherapeutics shall have the exclusive right to initiate litigation with respect to infringement of the Patent Rights, [***] Subject to the terms of [***], mRNA RiboTherapeutics will provide Company and its counsel with reasonable opportunities to consult with mRNA RiboTherapeutics regarding the enforcement of Patent Rights. Subject to the foregoing, mRNA RiboTherapeutics will: (a) notify Company in writing prior to undertaking an enforcement action or initiating litigation with respect to infringement of any such Patent Rights; (b) provide Company with copies of drafts of substantive communications (including legal briefs or filings) intended to be made by mRNA RiboTherapeutics or its representatives reasonably in advance to permit Company to review and comment on such drafts and incorporate reasonable comments by Company thereon, (c) provide Company with copies of substantive communications made by the relevant infringer in connection with the infringement issue; and (d) take requests and comments made by Company in relation to the infringement issue into account and not unreasonably reject such requests or comments.

8.2 Cooperation. Subject to mRNA RiboTherapeutics’ obligations pursuant to the terms and conditions of the Penn License Agreement, mRNA RiboTherapeutics will cooperate with Company on matters related to infringement in a reasonable and prudent manner, preferably without litigation. In any litigation under this Article 8, each Party, at the reasonable request and sole expense of the other Party, will provide reasonable cooperation to such other Party. This Article 8 will not be construed to require either Party to undertake any activities, including legal discovery, at the request of any Third Party, except as may be required by lawful process of a court of competent jurisdiction.

9 REPRESENTATIONS, WARRANTIES, COVENANTS AND DISCLAIMER OF WARRANTIES

9.1 Covenants of mRNA RiboTherapeutics. mRNA RiboTherapeutics covenants to Company that, during the Term:

9.1.1 mRNA RiboTherapeutics will not breach, and to the extent within its power, will ensure that its sublicensed affiliates do not cause a breach of, the Penn License Agreement in any manner that would result in Penn having the right to terminate the Penn License Agreement, and mRNA RiboTherapeutics will use diligent efforts to cure (or cause to be cured) any such breach of the Penn License Agreement by mRNA RiboTherapeutics or its affiliates or Third Party sublicensees.

9.1.2 Upon mRNA RiboTherapeutics learning of any breach of a sublicense agreement by any of its affiliate or Third Party sublicensees in any manner that would result in Penn having the right to terminate the Penn License Agreement, mRNA RiboTherapeutics will expeditiously take appropriate actions to stop such act or omission, up to and including termination of the applicable sublicense pursuant to the terms of the Penn License Agreement.

9.1.3 mRNA RiboTherapeutics will make all payments due under the Penn License Agreement, and make all required disclosures to Penn in connection therewith, in each case in a timely manner in accordance with the terms thereof.

9.1.4 Promptly following mRNA RiboTherapeutics' or any of its affiliates' receipt of any material written notice or correspondence about an issue pertaining to the Sublicense or to any matter that would reasonably be expected to adversely affect in any respect Company's rights under this Agreement, mRNA RiboTherapeutics will, to the extent permissible, furnish a copy of such notice or correspondence to Company, provided that mRNA RiboTherapeutics may redact portions of any such notice or correspondence that do not relate to or impact Company's rights hereunder.

9.1.5 mRNA RiboTherapeutics will promptly notify Company if mRNA RiboTherapeutics receives a notice from Penn of an intent to terminate the Penn License Agreement.

9.1.6 mRNA will not amend the Penn License Agreement in any way that would negatively affect the rights or obligations of Company under this Agreement.

9.1.7 mRNA RiboTherapeutics agrees that mRNA RiboTherapeutics and its affiliates will not sue, bring an action against, or otherwise assert any claim against Company or its Affiliates or Third Party sublicensees or their successors in ownership (to which this Agreement or a sublicense under this Agreement is assigned according to terms and conditions for assignment pursuant to Section 15.5 or Section 1.5.5 herein) for infringement of or misappropriation of any Patent Rights (as defined in Section 1.2) that are used by Company or its Affiliates or Third Party sublicensees or their successors in ownership in the Sublicensed Fields of Use, as Fields of Use in the Sublicensed Fields of Use are defined in Section 1.2. [***] This covenant shall terminate with the termination of this Agreement unless the termination is: (a) made under Section 6.3, and (b) within [***] days following Company's receipt of notice of termination under Section 6.3, is either: (i) resolved by Company and mRNA RiboTherapeutics in writing, or (ii) Company initiates a state or federal lawsuit contesting said termination ("Contested Termination"). In the event of a Contested Termination, this covenant shall continue to run during the [***] days, and if a lawsuit is initiated, until said state or federal court enters a final decision from which no appeal has been or can be taken.

9.2 Covenants of Company. Company covenants to mRNA RiboTherapeutics that, during the Term:

9.2.1 Upon Company learning of any breach of a sublicense agreement by any of its Affiliates or Third Party sublicensees in any manner that would result in Penn having the right to terminate the Penn License Agreement, Company will use diligent efforts to cure (or cause to be cured) any such breach, up to and including termination of the applicable sublicense, as stated in Section 1.5.4 of this Agreement.

9.2.2 Company will not breach this Agreement, and to the extent within its legal power, will ensure that its Affiliates do not breach or cause breach of any sublicense under this Agreement in any manner that would result in Penn having the right to terminate the Penn License Agreement, and Company will use diligent efforts to cure (or cause to be cured) any such breach of this Agreement by Company or any breach of any sublicense under this Agreement by its Affiliates or Third Party sublicensees.

9.2.3 Company will pay to mRNA RiboTherapeutics all payments due under this Agreement pursuant to Article 3 and in accordance with the terms in Articles 3 and Section 4.2 and will provide to mRNA RiboTherapeutics all information, reports and notices required in accordance with Sections 2.1, 2.3, 3.3, 3.4.3(a), 4.1, 4.4 and 6.6 and in the form of the sample report attached as Exhibit C, in each case in accordance with the time periods set forth therein.

9.2.4 Promptly following Company's or any of its Affiliates' receipt of any material written notice or correspondence pertaining to the Sublicense or to any matter that could reasonably be expected to adversely affect in any respect mRNA RiboTherapeutics' rights or obligations under this Agreement, Company will, to the extent permissible, furnish a copy of such notice or correspondence to mRNA RiboTherapeutics, provided that Company may redact portions of any such letter that do not relate to or impact mRNA RiboTherapeutics' rights hereunder.

9.3 Representations and Warranties of mRNA RiboTherapeutics. As of the Effective Date, mRNA RiboTherapeutics, on behalf of itself and its affiliates, hereby represents and warrants to Company that:

9.3.1 mRNA RiboTherapeutics has provided Company a true and correct redacted copy of the Penn License Agreement (including all exhibits and amendments thereto), and there are no other agreements, written or verbal, between Penn and mRNA RiboTherapeutics.

9.3.2 mRNA RiboTherapeutics has provided Company a true, correct redacted copy of the Cellscript Sublicense Agreement, and: (a) there are no other agreements between mRNA RiboTherapeutics and Cellscript relating to the Penn License Agreement or the Patent Rights; (b) neither mRNA RiboTherapeutics nor Cellscript has granted any other sublicenses under the Patent Rights with respect to Field of Use B; and (c) neither mRNA RiboTherapeutics nor Cellscript has made any agreements with any Third Party not to sue, or granted any liens or other rights or encumbrances in or to its rights in Patent Rights or the Penn License Agreement.

9.3.3 Since the date of the Penn License Agreement, neither mRNA RiboTherapeutics nor any of its affiliates has proposed to Penn, or received from Penn, any correspondence challenging the validity or enforceability of the Penn License Agreement or proposing to amend any provision of the Penn License Agreement.

9.3.4 mRNA RiboTherapeutics has not (a) breached or defaulted under any provision of the Penn License Agreement in any material respect or (b) received any written notice from Penn of any claims for indemnification pursuant to the Penn License Agreement.

9.3.5 To the knowledge of mRNA RiboTherapeutics, (a) there are no facts that would preclude Penn from having clear title to the Patent Rights, (b) there are no pending or threatened litigations, interferences, reexaminations, oppositions or like procedures involving any such Patent Rights and (c) all of the issued patents within the Patent Rights are valid and enforceable, are in full force and effect and have not lapsed, expired or otherwise terminated.

9.3.6 mRNA RiboTherapeutics believes the terms and conditions of this Agreement are fully consistent with the terms and conditions of the Penn License Agreement.

9.3.7 mRNA RiboTherapeutics has not received, and to mRNA RiboTherapeutics' knowledge, Penn has not received, any written notice of any claim by any person or entity challenging the license rights of mRNA RiboTherapeutics, or the ownership of or rights of Penn in and to the Patent Rights, or the validity or enforceability of the Patent Rights.

9.3.8 mRNA RiboTherapeutics does not own or have any licenses for any other patent rights other than Patent Rights.

9.3.9 The Fields of Use sublicensed to Company in this Agreement are distinct from and do not overlap with the fields of use granted to Company in the Sublicense Agreement from Cellscript, and any products researched, developed, manufactured and commercialized in fields of use granted under the Sublicense Agreement from Cellscript are subject only to the payment and other obligations of the Sublicense Agreement from Cellscript, and not under this Agreement.

9.3.10 mRNA RiboTherapeutics believes that the representations and warranties of mRNA RiboTherapeutics in this Agreement, do not, taken as a whole, (i) contain any untrue statement of a material fact; or (ii) omit to state any material fact necessary to make the statements or facts contained therein, in light of the circumstances under which they were made, not misleading. mRNA RiboTherapeutics has not knowingly withheld any information with respect to the Penn License Agreement or the Patent Rights that would reasonably be expected to be material to Company's decision to enter into this Agreement.

9.4 Representations and Warranties of Company. Company, on behalf of itself and its affiliates, hereby represents and warrants to mRNA RiboTherapeutics that, as of the Effective Date:

9.4.1 Company is duly organized and validly existing under the laws of the jurisdiction of its incorporation and has full corporate power and authority to enter into this Agreement.

9.4.2 Company is in good standing with all relevant governmental authorities.

9.4.3 Company has taken all corporate actions necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement.

9.4.4 The performance of the obligations of Company under this Agreement do not conflict with or constitute a default under its charter documents, any contractual obligation of Company or any court order.

9.4.5 Company and its attorneys and technical experts have reviewed the patents and patent applications comprising Patent Rights including both Exhibit A-1 Patent Rights and Exhibit A-2 Patent Rights that are listed in Exhibit A attached hereto.

9.4.6 Company has experience with and is familiar with the inventions covered by Patent Rights and understands the use, purpose and benefits thereof.

9.4.7 Company believes that the representations and warranties of Company in this Agreement, do not, taken as a whole, (i) contain any untrue statement of a material fact; or (ii) omit to state any material fact necessary to make the statements or facts contained therein, in light of the circumstances under which they were made, not misleading. Company has not knowingly withheld any information with respect to the any of Company's above statements that would reasonably be expected to be material to mRNA RiboTherapeutics' decision to enter into this Agreement.

[Remainder of page left blank]

9.5 Disclaimer of Warranties. EXCEPT AS SPECIFICALLY SET FORTH IN THIS ARTICLE 9, NO PARTY MAKES ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS OR SUFFICIENCY OF PATENT RIGHTS FOR A PARTICULAR PURPOSE, APPLICATION OR USE, NON-INFRINGEMENT, OR ANY OTHER STATUTORY WARRANTY.

10 ADDITIONAL TERMS REGARDING SUBLICENSING

10.1 Purpose of this Article. This Article 10 sets forth terms and conditions for further sublicensing by Primary Sublicensors in the Human *In Vivo* Therapeutics Field, wherein, for the purposes of this Article 10:

- (a) “**sublicensing**” herein means any grant of a sublicense, covenant not to sue, or option for current or future rights under Patent Rights, and the noun “**sublicense**” herein means a document that grants such sublicense, covenant not to sue, or option for current or future rights under Patent Rights;
- (b) “**Primary Sublicensors**” herein means (i) mRNA RiboTherapeutics, (ii) Cellscript, and (iii) any affiliate of (i) or (ii) that is granted a sublicense in the Human *In Vivo* Therapeutics Field; and
- (c) “**Human *In Vivo* Therapeutics Field**” herein means any or all therapeutic and prophylactic use(s) in humans in the *In Vivo* Field of Use in Field of Use B.

For clarity and the absence of doubt, Article 10 shall not be interpreted in any way so as to limit, restrict or impose any terms or conditions on Primary Sublicensors’ rights to grant sublicenses under Patent Rights to any party at any time for any Field of Use other than the Human *In Vivo* Therapeutics Field.

10.2 Human *In Vivo* Therapeutics Field Sublicenses. Subject to the rights of the Primary Sublicensors and their respective owners under Section 10.4, mRNA RiboTherapeutics and Company agree that, from the Effective Date [***], mRNA RiboTherapeutics will not grant and will ensure that other Primary Sublicensors will not grant Human *In Vivo* Therapeutics Field Sublicenses, including this Sublicense, to [***]

“**Human *In Vivo* Therapeutics Field Sublicense**” means a sublicense to make, have made, use, import, offer for sale, sell and/or have sold any number of products covered by Patent Rights comprising or incorporating modified RNA for the Human *In Vivo* Therapeutics Field, but excluding Product Sublicenses.

10.3 Product Sublicenses. Subject to the rights of the Primary Sublicensors and their respective owners under Section 10.4, mRNA RiboTherapeutics and Company agree that, from the Effective Date until [***], mRNA RiboTherapeutics will (and will ensure that the other Primary Sublicensors will):

(a) grant Product Sublicenses only to [***]

wherein “**Product Sublicenses**” herein mean sublicenses under Patent Rights to research, develop, manufacture and/or commercialize specific products [***], for a therapeutic or prophylactic use in humans in the *In Vivo* Field of Use, and

wherein [***]

(b) only grant Product Sublicenses for a total of [***] in the aggregate by all of the Primary Sublicensors across all such Product Sublicenses, [***]

(c) except as set forth in Sections 10.2 and 10.3, not otherwise grant sublicenses under the Patent Rights to research, develop, manufacture and/or commercialize products comprising or incorporating [***].

10.4 Sale of a Primary Sublicensor. Company understands and agrees that the owners of each of mRNA RiboTherapeutics and Cellscript shall have the right to sell all or any part of the outstanding stock or ownership interest or the business or the assets thereof, as applicable, of mRNA RiboTherapeutics and/or Cellscript and/or any of their respective affiliates [***] at any time and without any conditions pursuant to this Agreement other than the requirements under Section 15.5, except that, as a condition to any such sale occurring prior to April 1, 2020:

[Remainder of page left blank]

(a) the owners of each of mRNA RiboTherapeutics and Cellscript will sell mRNA RiboTherapeutics or Cellscript to only one (1) Third Party purchaser, [***]; and

(b) without in any way negating or ceding or giving up any of their current rights to sell all or any part of the stock, ownership interest, business or assets of mRNA RiboTherapeutics and/or Cellscript or to discuss any such sale with any potential purchaser at any time, including from the Effective Date of this Agreement [***], the owners of mRNA RiboTherapeutics and Cellscript agree not to conduct Active Marketing of such sale of a Primary Sublicensor prior to [***],

wherein “[***]” herein means [***]; and

for the avoidance of doubt, Company agrees that this Section 10.4(a) shall not be interpreted so as to prohibit the owners of mRNA RiboTherapeutics and/or Cellscript from proposing or discussing [***];

(c) the purchaser of mRNA RiboTherapeutics or Cellscript, respectively, will pay [***];

[Remainder of page left blank]

- (d) on the effective date of any such sale of [***] and the purchaser and their assignees and successors in ownership thereof shall have all the same rights as are held by Company under this Agreement to:
- (i) grant Human *In Vivo* Therapeutics Field Sublicenses to affiliates and Third Parties without being subject to any restrictions, limitations, or terms and conditions that apply to the Primary Sublicensors under Sections 10.2, and
- (ii) grant Product Sublicenses to affiliates and any Third Parties to research, develop, manufacture and/or commercialize any number of products comprising modified RNA covered by Patent Rights for any therapeutic or prophylactic use in humans in the *In Vivo* Field of Use without being subject to any of the restrictions, limitations or requirements that the sublicensee is a Small Biotech Company as is required of the Primary Sublicensors in Section 10.3; and

(e) on the effective date of any such sale of more than fifty percent (50%) of the outstanding stock or ownership interest or all of the business or assets of mRNA RiboTherapeutics or Cellscript, all of the rights of the Primary Sublicensors to grant Product Sublicenses pursuant to Section 10.3 shall remain only with the Primary Sublicensors for which their stock, ownership interest, business and assets were not sold.

[***].

10.5 From [***], Primary Sublicensors and any owners, assignees or successors in ownership thereof shall have the right to grant any number of Human *In Vivo* Therapeutics Field Sublicense(s) to any parties without any conditions (other than those imposed by the Penn License Agreement or the Cellscript Sublicense Agreement) and to grant any number of Product Sublicenses or any other sublicenses of any kind under Patent Rights to any parties without any limitations or restrictions or requirements whatsoever under this Article 10.

[Remainder of page left blank]

11 LIMITATION OF LIABILITY; DISCLAIMER.

11.1 Limitation of Liability. PENN AND mRNA RIBOTHERAPEUTICS WILL NOT BE LIABLE TO COMPANY, ITS AFFILIATES, SUBLICENSEES, SUCCESSORS OR ASSIGNS, OR ANY THIRD PARTY WITH RESPECT TO ANY CLAIM: ARISING FROM COMPANY'S USE OF THE PATENT RIGHTS, LICENSED PRODUCTS OR ANY OTHER TECHNOLOGY LICENSED UNDER THIS AGREEMENT; OR ARISING FROM THE COMPANY'S, COMPANY'S AFFILIATES' OR COMPANY'S SUBLICENSEES' DEVELOPMENT, TESTING, MANUFACTURE, USE OR SALE OF LICENSED PRODUCTS. NOTWITHSTANDING ANYTHING IN THIS AGREEMENT OR OTHERWISE, NONE OF PENN, mRNA RIBOTHERAPEUTICS OR COMPANY WILL BE LIABLE TO THE OTHER OR ANY THIRD PARTY WITH RESPECT TO ANY SUBJECT MATTER OF THIS AGREEMENT FOR ANY INDIRECT, PUNITIVE, SPECIAL OR CONSEQUENTIAL DAMAGES, EVEN IF SUCH PARTY HAS BEEN INFORMED OR SHOULD HAVE KNOWN OF THE POSSIBILITY OF SUCH DAMAGES; PROVIDED THAT THIS SECTION 11.1 WILL NOT APPLY: (a) TO A PARTY'S INDEMNIFICATION RIGHTS AND OBLIGATIONS UNDER ARTICLE 12 OR ARTICLE 13; (b) IN CIRCUMSTANCES OF GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT BY A PARTY OR ITS AFFILIATES; OR (c) WITH RESPECT TO A PARTY'S LIABILITY FOR BREACH OF ARTICLE 5 or 10.

11.2 Disclaimer. THE PATENT RIGHTS, LICENSED PRODUCTS AND ANY OTHER TECHNOLOGY LICENSED UNDER THIS AGREEMENT ARE PROVIDED ON AN "AS IS" BASIS. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NONE OF PENN, mRNA RIBOTHERAPEUTICS OR COMPANY MAKE ANY REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO ANY WARRANTY OF ACCURACY, COMPLETENESS, PERFORMANCE, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, COMMERCIAL UTILITY, NON-INFRINGEMENT, VALIDITY OR TITLE.

12 PENN INDEMNIFICATION

12.1 Indemnification. Company will defend, indemnify, and hold harmless each Penn Indemnified Party from and against any and all Penn Liabilities with respect to an Indemnification Event. The term "**Penn Indemnified Party**" means each of Penn and its trustees, officers, faculty, students, employees, contractors, and agents. For clarity, mRNA RiboTherapeutics is not a Penn Indemnified Party. The term "Penn Liabilities" means all damages, awards, deficiencies, settlement amounts, defaults, assessments, fines, dues, penalties, costs, fees, liabilities, obligations, taxes, liens, losses, lost profits and expenses (including, but not limited to, court costs, interest and reasonable fees of attorneys, accountants and other experts) that are incurred by a Penn Indemnified Party or awarded or otherwise required to be paid to Third Parties by a Penn Indemnified Party. The term "Indemnification Event" means any Claim against one or more Penn Indemnified Parties arising out of or resulting from: [***] The term "**Claim**" in this Article 12 means any charges, complaints, actions, suits, proceedings, hearings, investigations, claims or demands.

12.2 Reimbursement of Costs. Company will pay directly all Penn Liabilities incurred for defense or negotiation of any Claim or will reimburse Penn for all documented Penn Liabilities incident to the defense or negotiation of any Claim within [***] days after Company's receipt of invoices for such fees, expenses and charges.

12.3 Control of Litigation. Company controls any litigation or potential litigation involving the defense of any Claim, including the selection of counsel, with input from Penn. Penn reserves the right to protect its interest in defending against any Claim by selecting its own counsel, with any attorneys' fees and litigation expenses paid for by Company, pursuant to Sections 12.1 and 12.2.

12.4 Other Provisions. Company will not settle or compromise any Claim giving rise to Penn Liabilities in any manner that imposes any restrictions or obligations on Penn or grants any rights to the Patent Rights or the Licensed Products without Penn's prior written consent. If Company fails or declines to assume the defense of any Claim within [***] days after notice of the Claim, or fails to reimburse a Penn Indemnified Party for any Penn Liabilities pursuant to Sections 12.1 and 12.2 within the [***] day time period set forth in Section 12.2, then Penn may assume the defense of such Claim for the account and at the risk of Company, and any Penn Liabilities related to such Claim will be conclusively deemed a liability of Company. The indemnification rights of the Penn Indemnified Parties under this Article 12 are in addition to all other rights that a Penn Indemnified Party may have at law, in equity or otherwise.

13 OTHER INDEMNIFICATION

13.1 Indemnification by Company. Company will indemnify, defend and hold harmless mRNA RiboTherapeutics and its affiliates, and its or their respective directors, officers, employees and agents ("**mRNA RiboTherapeutics Indemnified Parties**"), from and against any and all liabilities, damages, losses, costs and expenses including the reasonable fees of attorneys (collectively "**Losses**") arising out of or resulting from any and all Third Party suits, claims, actions, proceedings, payment obligations or demands ("**Claims**" in this Article 13) to the extent based upon:

13.1.1 the gross negligence or willful misconduct of Company, its Affiliates or Third Party sublicensees and its or their respective directors, officers, employees and agents, in connection with Company's performance of its obligations or exercise of its rights under this Agreement;

13.1.2 any breach of any representation or warranty or express covenant made by Company under this Agreement; or

13.1.3 the development, testing, use, manufacture, commercialization, sale or other disposition of Licensed Products by or on behalf of Company or its Affiliates or Third Party sublicensees, assignees or vendors or Third Parties, including, but not limited to, for (x) any product liability or other Claim of any kind related to use by a Third Party of a Licensed Product, (y) any Claim by a Third Party that Company's practice of any of the Patent Rights or the design, composition, manufacture, use, sale or other disposition of any Licensed Product infringes or violates any patent, copyright, trade secret, trademark or other intellectual property right of such Third Party, and (z) any Claim by a Third Party relating to clinical trials or studies for Licensed Products;

except, in each case above, to the extent such Claim arose out of or resulted from or is attributable to any acts or omissions of mRNA RiboTherapeutics or its directors, officers, employees and agents, or other circumstances for which mRNA RiboTherapeutics has an indemnity obligation pursuant to Section 13.2 below.

13.2 Indemnification by mRNA RiboTherapeutics. mRNA RiboTherapeutics will indemnify, defend and hold harmless Company and its Affiliates, and its or their respective directors, officers, employees and agents ("**Company Indemnified Parties**"), from and against any and all Losses arising out of or resulting from any and all Claims to the extent based upon:

13.2.1 the gross negligence or willful misconduct of mRNA RiboTherapeutics or its directors, officers, employees and agents, in connection with mRNA RiboTherapeutics' performance of its obligations or exercise of its rights under this Agreement; or

13.2.2 any breach of any representation or warranty or express covenant made by mRNA RiboTherapeutics under this Agreement;

except, in each case above, to the extent such Claim arose out of or resulted from or is attributable to any acts or omissions of Company or its Affiliates or Third Party sublicensees and its or their respective directors, officers, employees and agents or other circumstances for which Company has an indemnity obligation pursuant to Section 13.1 above.

13.3 Procedure. If an Indemnified Party entitled to indemnification under Sections 13.1 or 13.2 seeks such indemnification (wherein "**Indemnified Party**" in this Article 13 means a "Company Indemnified Party" and/or an "mRNA RiboTherapeutics Indemnified Party"), such Indemnified Party will:

(i) inform the indemnifying Party in writing of a Claim as soon as reasonably practicable after such Indemnified Party receives notice of such Claim;

(ii) permit the indemnifying Party to assume direction and control of the defense of the Claim (including the sole right to settle such Claim at the sole discretion of the indemnifying Party, *provided that* (a) such settlement or compromise does not admit any fault or negligence on the part of the Indemnified Party, or impose any obligation on, or otherwise materially adversely affect, the Indemnified Party or other Party and (b) the indemnifying Party first obtains the written consent of the Indemnified Party with respect to such settlement, which consent will not be unreasonably withheld);

- (iii) cooperate as reasonably requested (at the expense of the indemnifying Party) in the defense of the Claim; and
- (iv) undertake reasonable steps to mitigate any Losses with respect to the Claim.

Notwithstanding anything in this Agreement to the contrary, the indemnifying Party will have no liability under Sections 13.1 or 13.2, as the case may be, for Claims settled or compromised by the Indemnified Party without the indemnifying Party's prior written consent.

14 INSURANCE

14.1 Coverages. Company will procure and maintain insurance or self-insurance that covers the following minimum liability amounts with respect to personal injury, bodily injury and property damage arising out of Company's performance under this Agreement: (a) during the Term, comprehensive general liability, including broad form and contractual liability, in a minimum amount of [***] combined single limit per occurrence and in the aggregate; (b) prior to the commencement of clinical trials involving Licensed Products, clinical trials a minimum amount of [***] combined single limit per occurrence and in the aggregate; and (c) prior to the Sale of the first Licensed Product, product liability a minimum amount of [***] combined single limit per occurrence and in the aggregate. Penn and mRNA RiboTherapeutics may review periodically the adequacy of the minimum amounts of insurance or self-insurance for each liability coverage area required by this Section 14.1, and Penn and mRNA RiboTherapeutics reserve the right to request Company to adjust the limits accordingly to the extent existing limits are not commercially reasonable. The required minimum amounts of insurance or self-insurance do not constitute a limitation on Company's liability or indemnification obligations to Penn or mRNA RiboTherapeutics under this Agreement.

15 ADDITIONAL PROVISIONS

15.1 Independent Contractors. The Parties are independent contractors. Nothing contained in this Agreement is intended to create an agency, partnership or joint venture between the Parties. At no time will either Party make commitments or incur any charges or expenses for or on behalf of the other Party.

15.2 No Discrimination. Company will not discriminate against any employee or applicant for employment because of race, color, sex, sexual or affectional preference, age, religion, national or ethnic origin, handicap, or veteran status.

15.3 Compliance with Laws. Company must comply with all prevailing laws, rules and regulations that apply to its activities or obligations under this Agreement. For example, Company will comply with applicable United States export laws and regulations. The transfer of certain technical data and commodities may require a license from the applicable agency of the United States government and/or written assurances by Company that Company will not export data or commodities to certain foreign countries without prior approval of the agency. Penn and mRNA RiboTherapeutics do not represent that no license is required, or that, if required, the license will issue.

[Remainder of page left blank]

15.4 Modification, Waiver & Remedies. This Agreement may only be modified by a written amendment that is executed by an authorized representative of each Party. Any waiver must be express and in writing. No waiver by either Party of a breach by the other Party will constitute a waiver of any different or succeeding breach. Unless otherwise specified, all remedies are cumulative.

15.5 Assignment. This Agreement may not be assigned (by operation of law or otherwise) by either Party without the prior written consent of the other Party (which consent will not be unreasonably withheld); *except that*, that either Party may assign this Agreement without such consent to an affiliate or to a successor that purchases greater than fifty percent (>50%) of the outstanding stock or ownership interest or all or substantially all of such Party's business or assets to which this Agreement relates, whether by sale of shares or ownership interest, merger, consolidation, sale of assets or otherwise, *provided* that the assignee agrees in writing to be legally bound by this Agreement in the place and stead of the assignor and provides the non-assigning Party with a copy of said assignee's written undertaking. Neither Party will grant a security interest in the Sublicense or this Agreement during the Term. Any prohibited assignment or security interest in contravention of the foregoing will be null and void. The rights and obligations of the Parties under this Agreement will be binding upon and inure to the benefit of the successors and permitted assigns of the Parties, and the name of a Party appearing herein will be deemed to include the name of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Section 15.5.

15.6 Notices. Any notice or other required communication (each, a "Notice") must be in writing, addressed to the Party's respective Notice Address listed on the signature page, and delivered: (a) personally, with signed receipt; (b) by certified mail, postage prepaid, return receipt requested; (c) by recognized overnight courier service, charges prepaid; or (d) by facsimile. A Notice will be deemed received: if delivered personally, on the date of delivery; if mailed, [***] days after deposit in the United States mail; if sent via courier, [***] business day after deposit with the courier service; or if sent via facsimile, upon receipt of confirmation of transmission provided that a confirming copy of such Notice is sent by certified mail, postage prepaid, return receipt requested.

15.7 Severability & Reformation. If any provision of this Agreement is held to be invalid or unenforceable by a court of competent jurisdiction, then the remaining provisions of this Agreement will remain in full force and effect. Such invalid or unenforceable provision will be automatically revised to be a valid or enforceable provision that comes as close as permitted by law to the Parties' original intent.

15.8 Headings & Counterparts. The headings of the articles and sections included in this Agreement are inserted for convenience only and are not intended to affect the meaning or interpretation of this Agreement. This Agreement may be executed in one or more counterparts, each of which when executed and delivered by facsimile, electronic transmission, or by mail delivery, will be an original and all of which shall constitute one and the same instrument.

15.9 Governing Law. This Agreement will be governed in accordance with the laws of the Commonwealth of Pennsylvania, without giving effect to the conflict of law provisions of any jurisdiction.

15.10 Dispute Resolution. If a dispute arises between the Parties concerning any right or duty under this Agreement, then the Parties will confer, as soon as practicable, in an attempt to resolve the dispute. If the Parties are unable to resolve the dispute amicably, then the Parties will submit to the exclusive jurisdiction of, and venue in, the state and Federal courts located in the Eastern District of Pennsylvania with respect to all disputes arising under this Agreement. Notwithstanding anything herein to the contrary, in the event of an actual or threatened breach of this Agreement, the aggrieved Party may seek provisional equitable relief (including restraining orders, specific performance or other injunctive relief) in any court of competent jurisdiction to protect the interests of such Party.

15.11 Further Assurance. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

15.12 Interpretation. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense (and/or). The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "including" as used herein shall mean including, without limiting the generality of any description preceding such term. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party hereto. The Parties acknowledge and agree that new products and uses for products that are covered by Patent rights may be developed based on new advances in scientific knowledge. As such, the Parties' agree that, if Company is of the opinion that such advances have resulted in changes which warrant interpretation of whether such new products or uses are included within the Sublicensed Fields of Use granted to Company herein, the Parties agree to discuss and negotiate in good faith the need for an amendment or clarification of the meaning of the rights or Fields of Use granted to Company in Section 1.1 of this Agreement in order to try to find a solution that is agreeable to the Parties. Then, if the Parties have not agreed on the necessity or the wording of such amendment within [***] days after beginning good faith discussions, the Parties agree that, either both Parties will jointly agree on and appoint one independent Third Party, or each of the Parties will appoint one independent Third Party and those Third Parties will appoint one additional independent Third Party (all of which Third Parties will be qualified and skilled in the scientific field and have knowledge of law related to patents and licenses) to decide whether such amendment is required to properly reflect this intention. If the appointed independent Third Party or Third Parties decide(s) that said amendment is required, the Parties hereby agree to so amend this Agreement accordingly. If the appointed independent Third Party or Third Parties decide(s) that said amendment is not required, there is no obligation on either Party to amend this Agreement. The costs of the appointed independent Third Party or Third Parties will be borne by the Party whose view has not been confirmed by such Third Party(ies).

15.13 Integration. This Agreement with its Exhibits and the Confidentiality Agreement contain the entire agreement between the Parties with respect to the Patent Rights and the Sublicense and supersede all other oral or written representations, statements, or agreements with respect to such subject matter.

15.14 Condition Precedent to Execution of this Agreement. The Parties understand and agree that each Party's willingness to enter into this Agreement is conditioned upon the execution of both this Agreement and the Sublicense Agreement from Cellscript which grants certain other rights to Company under Patent Rights than the rights granted to Company in this Agreement.

15.15 Entire Agreement. This Agreement and the separate Sublicense Agreement from Cellscript set forth the complete, final and only agreements with respect to the subject matter hereof and supersede all other agreements and understandings between the Parties with respect to the subject matter hereof. The Parties acknowledge and agree that this Agreement and the Sublicense Agreement from Cellscript are separate and distinct agreements and there will be no "cross default" with respect to this Agreement and the Sublicense Agreement from Cellscript.

Each Party has caused this Agreement to be executed by its duly authorized representative.

mRNA RIBOTHERAPEUTICS, INC.

BioNTech AG

By: [***]
Name: [***]
Title: [***]

By: [***]
Name: [***]
Title: [***]

Address: mRNA RIBOTHERAPEUTICS, INC.
726 Post Road
Madison, WI 53713
USA

Address: BioNTech AG
An der Goldgrube 12
55131 Mainz
Germany

EXHIBIT INDEX

Exhibit A	Patents and Patent Applications in Patent Rights
Exhibit B	Sublicense Disclosure Report
Exhibit C	Form of Royalty Report

EXHIBIT A – Patents and Patent Applications in Patent Rights

Exhibit B
Sublicense Disclosure Report

EXHIBIT C – Format of Royalty Report

THE SYMBOL “[*]” DENOTES PLACES WHERE CERTAIN IDENTIFIED
INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i)
NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE
COMPANY IF PUBLICLY DISCLOSED**

LICENSE AND CO-DEVELOPMENT AGREEMENT

THIS LICENSE AGREEMENT (“Agreement”) is made as of July 4, 2018 (“**Effective Date**”), by and between **BioNTech RNA Pharmaceuticals GmbH**, a corporation organized and existing under the laws of Germany (“**BioNTech**”), having its principal place of business at An der Goldgrube 12, 55131 Mainz, Germany, and **Genevant Sciences GmbH**, a corporation organized and existing under the laws of Switzerland (“**Genevant**”), having an address of Viaduktstrasse 8, 4051 Basel, Switzerland. BioNTech and Genevant are referred to individually as a “**Party**” and collectively as the “**Parties**.”

RECITALS

WHEREAS, Genevant has an exclusive license to certain intellectual property rights relating to RNA-based therapeutics enabled by lipid nanoparticle delivery technologies;

WHEREAS, BioNTech is developing certain mRNA payloads for treatment in the field of oncology and infectious diseases and is also developing alone and in collaboration with third parties certain formulations useful for the delivery of mRNA payloads;

WHEREAS, the Parties wish to jointly develop pharmaceutical products that combine the best mRNA payloads with the best lipid nanoparticle technology in the fields of rare diseases and liver diseases, under the terms and conditions set forth herein; and

WHEREAS, BioNTech wishes to obtain from Genevant a license to utilize the lipid nanoparticle delivery technologies in conjunction with its development of mRNA payloads and delivery technologies in the oncology field, and Genevant is willing to grant such license to BioNTech, all under the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, the receipt and sufficiency which are hereby acknowledged, BioNTech and Genevant hereby agree as follows.

**ARTICLE 1
DEFINITIONS**

Unless the context otherwise requires, the terms in this Agreement with initial letters capitalized, shall have the meanings set forth below, or the meaning as designated in the indicated places throughout this Agreement.

1.1 “Accounting Standards” means internationally recognized accounting principles (including IFRS, US GAAP, and the like), in each case, as then in effect and as consistently applied by the applicable Party or its Affiliate or Sublicensee.

1.2 “Affiliate” means, (a) with respect to Genevant, any Person that, directly or indirectly through one or more intermediaries is controlled by Genevant Sciences Ltd., but for only so long as such control exists; and (b) with respect to BioNTech, any Person that, directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with BioNTech, but for only so long as such control exists. For the purpose of this definition, “**control**” (including, with correlative meaning, the terms “controlled by” and “under common control”) means (a) to possess, directly or indirectly, the power to direct the management

or policies of an entity, whether through ownership of voting securities, by contract relating to voting rights or corporate governance, or otherwise; or (b) direct or indirect beneficial ownership of more than fifty percent (50%) of the voting share capital or other equity interest in such entity. Notwithstanding the above, for purposes of this Agreement, [***] and its Affiliates will not be deemed to be Affiliates of Genevant, and AT Impf GmbH, having its place of business at Rosenheimer Platz 6, 81669 Munich, Germany, and any person or entity that, during the Term, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with AT Impf GmbH (other than BioNTech AG or any person or entity that is directly or indirectly controlled by BioNTech AG) shall not be considered an Affiliate of BioNTech.

1.3 “Alliance Manager” has the meaning set forth in Section 3.5 (Alliance Managers).

1.4 “Allowable Expenses” has the meaning set forth in Exhibit F.

1.5 “Applicable Laws” means the applicable provisions of any and all national, supranational, regional, state and local laws, treaties, statutes, rules, regulations, administrative codes, guidances, ordinances, judgments, decrees, directives, injunctions, orders, permits (including MAAs) of or from any court, arbitrator, Regulatory Authority or Governmental Authority having jurisdiction over or related to the subject item.

1.6 [*]** means [***].

1.7 “[*] Agreement”** means the April 11, 2018, Cross License Agreement by and between Genevant Sciences Ltd. and [***].

1.8 “Auditor” has the meaning set forth in Section 8.8 (Audit Dispute).

1.9 “BioNTech Development Milestone Plan” has the meaning set forth in Section 4.2.

1.10 “BioNTech Field” means the treatment, prevention and diagnosis of illnesses in the field of oncology.

1.11 “BioNTech Indemnitees” has the meaning set forth in Section 15.1 (Indemnification by Genevant).

1.12 “BioNTech Joint Inventions” has the meaning set forth in Section 11.1(c) (Joint Patent Committee).

1.13 “BioNTech Joint Patents” has the meaning set forth in Section 11.1(c) (Joint Patent Committee).

1.14 “BioNTech Know-How” means all Know-How that BioNTech Controls as of the Effective Date or during the Term that is necessary or reasonably useful for the Development, Manufacture or Commercialization of: (a) any BioNTech Product in the BioNTech Field; and/or (b) any Co-Development Product in the Co-Development Field. BioNTech Know-How includes BioNTech Joint Inventions, BioNTech Sole Inventions and BioNTech’s interest in Co-Owned Joint Inventions.

1.15 “BioNTech mRNA Payloads” means the five (5) mRNA payloads created by BioNTech and the [***] identified in Exhibit A. The Parties agree that Exhibit A will include [***] mRNA payloads at the time of execution of this Agreement. Within twelve (12) months from execution of this Agreement, BioNTech may propose [***] additional mRNA payloads to be included in the BioNTech mRNA Payloads and [***] the proposal made by BioNTech, [***]. Upon written agreement by the Parties to such final mRNA payload, Exhibit A will be updated to include such mRNA payload.

1.16 “BioNTech Patents” means all Patents that BioNTech Controls as of the Effective Date or during the Term that are necessary or reasonably useful for the Development, Manufacture or Commercialization of: (a) any BioNTech Product in the BioNTech Field; and/or (b) any Co-Development Product in the Co-Development Field. BioNTech Patents includes BioNTech Joint Patents BioNTech’s interest in Co-Owned Joint Patents. A list of BioNTech Patents existing as of the Effective Date is attached as Exhibit H. While the Parties intend Exhibit H to be exhaustive, the failure to list a Patent on Exhibit H will not exclude it from the definition of BioNTech Patents if it otherwise meets the definition provided herein.

1.17 “BioNTech Product” means any pharmaceutical product that contains a BioNTech mRNA Payload encapsulated within a LNP (irrespective of whether such LNP is Controlled by Genevant or BioNTech).

1.18 “BioNTech Product Infringement” has the meaning set forth in Section 11.4(a) (Notice).

1.19 “BioNTech Product Manufacturing Know-How” means Genevant Know-How that is necessary or reasonably useful to Manufacture any BioNTech Product in the BioNTech Field.

1.20 “BioNTech Product Pharmacovigilance Agreement” has the meaning set forth in Section 5.4 (Pharmacovigilance).

1.21 “BioNTech Product Supply Agreement” has the meaning set forth in Section 6.1 (Manufacture of BioNTech Products).

1.22 “BioNTech Products Collaboration Plan” has the meaning set forth in Section 4.4 (Conduct of Development Activities by Genevant).

1.23 “BioNTech Sole Inventions” means any Inventions made solely by BioNTech’s or its Affiliates’ employees, agents or independent contractors.

1.24 “BioNTech Technology” means the BioNTech Know-How and the BioNTech Patents.

1.25 “Blocker Entity” has the meaning set forth in Section 16.5(b) (Taxes of Co-Entrepreneurship).

1.26 “Board of Directors” has the meaning set forth in Section 1.49(a) (Competitor Change of Control).

- 1.27 “Business Day”** means a day other than a Saturday, Sunday or a bank or other public holiday in Mainz, Basel or New York.
- 1.28 “Calendar Quarter”** means each respective period of three (3) consecutive months ending on March 31, June 30, September 30, and December 31.
- 1.29 “Calendar Year”** means each respective period of twelve (12) consecutive months ending on December 31.
- 1.30 “CFR”** means the U.S. Code of Federal Regulations.
- 1.31 “Claims”** means all Third Party demands, claims, actions, proceedings and liability (whether criminal or civil, in contract, tort or otherwise) for losses, damages, legal costs and other expenses of any nature.
- 1.32 “CMC”** means chemistry, Manufacturing, and controls.
- 1.33 “CMO”** means contract Manufacturing organization.
- 1.34 “Code”** has the meaning set forth in Section 3.3 (JSC Decision-Making).
- 1.35 “Co-Development Field”** means the treatment, prevention and diagnosis of liver diseases (as defined by the FDA and/or the EMA), excluding any oncology diseases.
- 1.36 “Co-Development Joint Inventions”** has the meaning set forth in Section 11.1(c) (Joint Patent Committee).
- 1.37 “Co-Development Joint Patents”** has the meaning set forth in Section 11.1(c) (Joint Patent Committee).
- 1.38 “Co-Development mRNA Payloads”** means the six (6) mRNA payloads to be created by BioNTech in the Co-Development Field and the [***] identified in Exhibit B of which five (5) will be selected for Development as part of Co-Development Products.
- 1.39 Co-Development Product** means any pharmaceutical product that contains a Co-Development mRNA Payload encapsulated within a Genevant LNP and/or, if agreed between the Parties in the JSC, within another LNP.
- 1.40 “Co-Development Product Development Plan”** has the meaning set forth in Section 9.2.
- 1.41 “Co-Development Product Commercialization Plan”** has the meaning set forth in Section 10.2 (Commercialization Plan and Report).
- 1.42 “Co-Development Product Infringement”** has the meaning set forth in Section 11.4(a) (Notice).
- 1.43 “Co-Development Product Pharmacovigilance Agreement”** has the meaning set forth in Section 9.10 (Co-Development Product Pharmacovigilance).

1.44 “Co-Development Product Supply Agreement” has the meaning set forth in Section 9.11 (Manufacturing Responsibilities).

1.45 “Combination Product” means any product containing (i) at least one Product and (ii) at least one additional active ingredient that is not a Product.

1.46 “Commercialization” means the conduct of all activities undertaken before and after Regulatory Approval relating to the promotion, marketing, sale and distribution (including importing, exporting, transporting, customs clearance, warehousing, invoicing, handling and delivering products to customers) of products, including: (a) sales force efforts, detailing, advertising, medical education, planning, marketing, sales force training, and sales and distribution; and (b) scientific and medical affairs. For clarity, Commercialization does not include any Development activities, whether conducted before or after Regulatory Approval. “Commercialize” and “Commercializing” have correlative meanings.

1.47 “Commercially Reasonable Efforts” means, with respect to an entity’s obligations under this Agreement relating to BioNTech Products or Co-Development Products, those efforts and resources that are consistent with the exercise of customary scientific and business practices as applied in the pharmaceutical industry for a company of a similar stage and size as the entity and having similar resources (viewed in relation to such Party and all of its Affiliates plus, in the case of Genevant, [***] (applying that term to [***] mutatis mutandis as with respect to Genevant)) for Development, regulatory, Manufacturing and Commercialization activities conducted with respect to products at a similar stage of Development or Commercialization and having similar commercial potential, taking into account relative safety and efficacy, product profile, the regulatory environment, payors’ policies and regulations, competitiveness of the marketplace and the market potential of such products, the nature and extent of market exclusivity, including patent coverage and regulatory data protection, price and reimbursement status, and all other relevant commercial, technical, legal, scientific, regulatory, or medical factors.

1.48 “Competitor” means any of the competitive entities identified and separately agreed to in writing by the Parties or their Affiliates (applying that term mutatis mutandis to such entity).

1.49 “Competitor Change of Control” shall be deemed to have occurred if any of the following occurs after the Effective Date:

(a) any Competitor (i) becomes the beneficial owner, directly or indirectly, of shares of capital stock or other interests (including partnership interests) of such Party then outstanding and normally entitled (without regard to the occurrence of any contingency) to vote in the election of the directors, managers or similar supervisory positions (“**Voting Stock**”) of such Party representing more than fifty percent (50%) of the total voting power of all outstanding classes of Voting Stock of such Party or (ii) has the power, directly or indirectly, to appoint a majority of the Party’s managing directors or to elect a majority of the members of the Party’s board of directors, supervisory board or similar governing body (“**Board of Directors**”); or

(b) such Party enters into a merger, consolidation or similar transaction with a Competitor (whether or not such Party is the surviving entity) and as a result of such merger, consolidation or similar transaction (i) the managing directors or the members of the Board of Directors of such Party immediately prior to such transaction constitute less than a majority of the

managing directors or the members of the Board of Directors of such Party or such surviving Person immediately following such transaction or (ii) the Persons that beneficially owned, directly or indirectly, the shares of Voting Stock of such Party immediately prior to such transaction cease to beneficially own, directly or indirectly, shares of Voting Stock of such Party representing a majority of the total voting power of all outstanding classes of Voting Stock of the surviving Person in substantially the same proportions as their ownership of Voting Stock of such Party immediately prior to such transaction; or

(c) such Party sells or transfers to a Competitor, in one or more related transactions, properties or assets representing all or substantially all of such Party's consolidated total assets to which this Agreement relates.

Notwithstanding the foregoing, the occurrence of neither of the following shall, by itself, be considered a Change in Control, the sale of capital stock of a Party in an initial public offering on an internationally recognized securities exchange, including the NYSE, NASDAQ, London Stock Exchange, Frankfurt Stock Exchange, and Hong Kong Stock Exchange shall not constitute a Competitor Change of Control if entered into in the ordinary course of business and not for the purpose or effect of circumventing any other Party's rights hereunder.

1.50 "Confidential Information" of a Party means all Know-How, unpublished patent applications and other information and data of a financial, commercial, business, operational or technical nature of such Party that is disclosed or made available by or on behalf of such Party or any of its Affiliates to the other Party or any of its Affiliates, whether made available orally, in writing or in electronic or other form. The terms of this Agreement are the Confidential Information of both Parties. All Inventions made under this Agreement will constitute the Confidential Information of the party that owns such Inventions as set forth in Section 11.1 (Ownership). All other data and results generated under this Agreement in relation to BioNTech Products shall constitute Confidential Information of BioNTech, and all other data and results generated under this Agreement in relation to Co-Development Products shall constitute Confidential Information of both Parties.

1.51 "Control" or "Controlled" means, with respect to any Know-How, Patent or other intellectual property rights, that a Party has the legal authority or right (whether by ownership, license or otherwise, other than by virtue of any license granted to such Party by the other Party pursuant to this Agreement) to grant a license, sublicense, access or other right (as applicable) under such Know-How, Patent, or other intellectual property rights to the other Party on the terms and conditions set forth herein, in each case without breaching the terms of any agreement with a Third Party.

1.52 "Develop" or "Development" means to develop (including clinical, non-clinical and CMC development), analyze, test and conduct preclinical, clinical and all other regulatory trials for a product, including all post-approval clinical trials, as well as all related regulatory activities and any and all activities pertaining to new indications, pharmacokinetic studies and all related activities including work on new formulations, new methods of treatment, and CMC activities including new Manufacturing methods. **"Developing"** and **"Development"** have correlative meanings.

1.53 “Development Costs” means FTE Costs and Out-of-Pocket Costs incurred by the Parties and their Affiliates in Developing the Co-Development Products in the Co-Development Field, in each case to the extent incurred in accordance with this Agreement and the budget approved by the JSC as follows:

(a) all Out-of-Pocket Costs and FTE Costs incurred for activities specified in the Co-Development Product Development Plan including the FTE Costs of scientific, medical, technical and other personnel directly engaged in performing Development activities under the Co-Development Product Development Plan, which costs shall be determined based on time actually spent performing the applicable activities, unless another basis is otherwise agreed in advance by the Parties in writing;

(b) all Out-of-Pocket Costs and FTE Costs in connection with any Manufacturing activities for pre-clinical or clinical supplies as set forth in the Co-Development Product Development Plan, including (i) the Manufacturing Expenses for the Co-Development mRNA Payloads, Genevant LNPs, and Co-Development Products; (ii) costs and expenses incurred to purchase or package Third Party comparator or Third Party combination drugs or devices; and (iii) costs and expenses of disposal of clinical samples;

(c) all Out-of-Pocket Costs and FTE Costs incurred in connection with Regulatory Filings with respect to Co-Development Products in the Co-Development Field;

(d) all Out-of-Pocket Costs and FTE Costs associated with [***] commitments mandated by Governmental Authorities, to the extent incurred with respect to Co-Development Products;

(e) all Out-of-Pocket Costs and FTE Costs identifiable to establishing, updating and maintaining a global safety database for Co-Development Products;

(f) all Out-of-Pocket Costs and FTE Costs associated with companion and in vitro diagnostics, if applicable to the Development of a Co-Development Product; and

(g) any other Out-of-Pocket Costs and FTE Costs incurred that are explicitly included in the budget under the Co-Development Product Development Plan approved by the JSC.

Development Costs shall exclude all Allowable Expenses, capital expenditures not previously agreed to by the Parties as part of the Co-Development Product Development Plan, and any other cost not included in Development Costs, including by way of example, costs attributable to general corporate activities, executive management, investor relations, treasury services, business development, corporate government relations, external financial reporting and other overhead unless otherwise agreed to in writing by the Parties. For the avoidance of doubt, Development Costs do not include Out-of-Pocket Costs, FTE Costs, or other amounts that are attributable and allocable to post-approval commercialization studies other than as specified in (d) above.

1.54 “Development Reconciliation Procedures” has the meaning set forth in Section 9.12(b) (Development Costs Reports).

1.55 “Direct Expenses” means, with respect to Co-Development mRNA Payload, Genevant LNP, BioNTech Products or Co-Development Products, those material and services expenses captured in invoices and the like which are specifically attributable to Manufacture of the Co-Development mRNA Payload, Genevant LNP, BioNTech Product or Co-Development Product, including expenses of raw materials, Manufacturing supplies, solvents, containers, container components, packaging, labels and other printed materials used in production.

1.56 “**Disclosing Party**” has the meaning set forth in Section 12.1(a) (Duty of Confidence - subsection (a)).

1.57 “**Dollar**” means U.S. dollars, and “\$” shall be interpreted accordingly.

1.58 “**EMA**” means the European Medicines Agency or any successor entity thereto.

1.59 “**Excluded Claim**” has the meaning set forth in Section 16.10(f) (Dispute Resolution - subsection (f)).

1.60 “**Executive Officers**” has the meaning set forth in Section 3.3 (JSC Decision-Making).

1.61 “**FDA**” means the United States Food and Drug Administration or any successor entity thereto.

1.62 “**First Commercial Sale**” means, (a) with respect to any BioNTech Product in any country or jurisdiction in the Territory, the first arm’s length sale of such BioNTech Product by BioNTech, its Affiliates or Sublicensees to a Third Party for distribution, use or consumption in such country or jurisdiction after Regulatory Approval has been obtained for such BioNTech Product in such country or jurisdiction; and (b) with respect to any Co-Development Product in any country or jurisdiction in the Territory, the first arm’s length sale of such Co-Development Product by a Party, its Affiliates or Sublicensees to a Third Party for distribution, use or consumption in such country or jurisdiction after Regulatory Approval has been obtained for such Co-Development Product in such country or jurisdiction.

1.63 “**FTE**” means a full day of work by one employee recorded in the conduct of the specified activities.

1.64 “**FTE Costs**” means the product of: (a) that number of FTEs (proportionately, on a per-FTE basis) used by a Party or its Affiliates in directly performing activities assigned to such Party under and in accordance with the Co-Development Product Development Plan or the BioNTech Products Collaboration Plan, multiplied by (b) the applicable FTE Rate.

1.65 “**FTE Rate**” means [***].

1.66 “**Genevant Indemnitees**” has the meaning set forth in Section 15.2 (Indemnification by BioNTech).

1.67 “**Genevant Joint Inventions**” has the meaning set forth in Section 11.1(c) (Joint Patent Committee).

1.68 “**Genevant Joint Patents**” has the meaning set forth in Section 11.1(c) (Joint Patent Committee).

1.69 “**Genevant Know-How**” means all Know-How that Genevant Controls as of the Effective Date or during the Term that is necessary or reasonably useful for the Development,

Manufacture or Commercialization of: (a) any BioNTech Product in the BioNTech Field; or (b) any Co-Development Product in the Co-Development Field. Genevant Know-How includes Genevant Sole Inventions, Genevant Joint Inventions, and Genevant's interest in Co-Owned Joint Inventions.

1.70 "Genevant LNP" means the LNP delivery platform Controlled by Genevant. The Parties will identify during Development of the BioNTech Products and/or Co-Development Products which part(s) of the Genevant LNP will be used in the BioNTech Products and/or Co-Development Products in accordance with the terms of this Agreement.

1.71 "Genevant Patents" means all Patents in the Territory that Genevant Controls as of the Effective Date or during the Term that are necessary or reasonably useful for the Development, Manufacture or Commercialization of: (a) any BioNTech Product in the BioNTech Field; or (b) any Co-Development Product in the Co-Development Field. Genevant Patents include Genevant Joint Patents, and Genevant's interest in Co-Owned Joint Patents. A list of Genevant Patents existing as of the Effective Date is attached as Exhibit G. While the Parties intend Exhibit G to be exhaustive, the failure to list a Patent on Exhibit G will not exclude it from the definition of Genevant Patents if it otherwise meets the definition provided herein.

1.72 "Genevant Sole Inventions" means any Inventions made solely by Genevant's or its Affiliates' employees, agents or independent contractors.

1.73 "Genevant Technology" means the Genevant Know-How and Genevant Patents.

1.74 "Government Authority" means any federal, state, national, state, provincial or local government, or political subdivision thereof, or any multinational organization or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof, or any governmental arbitrator or arbitral body).

1.75 "Incremental Withholding Taxes" has the meaning set forth in Section 16.5(b) (Tax Cooperation).

1.76 "IND" means any investigational new drug application, clinical trial application, clinical trial exemption or similar or equivalent application or submission for approval to conduct human clinical investigation filed with or submitted to a Regulatory Authority in conformance with the requirements of such Regulatory Authority.

1.77 "Indemnified Party" has the meaning set forth in Section 15.3 (Indemnification Procedure).

1.78 "Indemnifying Party" has the meaning set forth in Section 15.3 (Indemnification Procedure).

1.79 "Indirect Expenses" means, with respect to either a BioNTech Product or Co-Development Product, labor expenses, including allocated FTE expenses for personnel directly involved in the Manufacturing the Co-Development mRNA Payload, Genevant LNP, BioNTech Products or Co-Development Products in accordance with GMP requirements such as production, quality control, quality assurance, microbiology, and other similar departments as needed and to the extent such personnel participate directly in the production of the Co-Development mRNA

Payload, Genevant LNP, BioNTech Product or Co-Development Product and components thereof, and other indirect production expenses such as a reasonable allocation of expenses associated with either Party's Manufacturing of Co-Development mRNA Payload, Genevant LNP, BioNTech Product or Co-Development Product, including facility costs and personnel costs directly supporting the Manufacturing of the Co-Development mRNA Payload, Genevant LNP, BioNTech Product or Co-Development Product in accordance with GMP requirements, including labor for and indirect expenses of quality control, quality assurance, raw material acquisition and acceptance, microbiology, document control, calibration/validation, and expenses for process development and analytical methods development, but excluding, in each case, any Direct Expenses.

1.80 "Initiation" means, with respect to a clinical trial, the first dosing (whether with investigational drug, comparator drug or placebo) of the third subject in such clinical trial.

1.81 "Initial BioNTech Product Manufacturing Know-How" has the meaning set forth in Section 6.3(a) (BioNTech Product Initial Manufacturing Know-How).

1.82 "Invention" shall mean any process, method, composition of matter, article of Manufacture, discovery or finding, patentable or otherwise, that is made, generated, conceived or otherwise invented as a result of a Party exercising its rights or carrying out its obligations under this Agreement, whether directly or via its Affiliates, agents or independent contractors, including all rights, title and interest in and to the intellectual property rights therein.

1.83 "Joint Inventions" means any Inventions that are made jointly by one or more employees, agents or independent contractors of one Party or its Affiliates and one or more employees, agents or independent contractors of the other Party or its Affiliates.

1.84 "Joint Patent Committee" or "**JPC**" has the meaning set forth in Section 11.1(c) (Joint Patent Committee).

1.85 "Joint Steering Committee" or "**JSC**" has the meaning set forth in Section 3.1 (Joint Steering Committee).

1.86 "Know-How" means any information, including discoveries, improvements, modifications, processes, methods, techniques, protocols, formulas, data, inventions, know-how, trade secrets and results, patentable or otherwise, including physical, chemical, biological, toxicological, pharmacological, safety, and pre-clinical and clinical data, dosage regimens, control assays, and product specifications, but excluding any Patents.

1.87 "Lead Commercialization Party" has the meaning set forth in Section 10.1.

1.88 "LNP" means lipid nanoparticle.

1.89 "Manufacture" or "Manufacturing" means performing all steps of the manufacturing of any BioNTech mRNA Payload, Co-Development mRNA Payload, Genevant LNP, BioNTech Products or Co-Development Products, including: (a) acquisition, testing and release of raw materials, excipients or active pharmaceutical ingredients and stability testing; (b) manufacturing and filling; (c) in-process quality control testing; (d) labeling and packaging; (e) final quality release; and (f) storage prior to shipping and the related controls.

1.90 “Manufacturing Transfer” has the meaning set forth in Section 6.4 (Manufacturing Transfer).

1.91 “MAA” or “Marketing Authorization Application” means an application to the appropriate Regulatory Authority for approval to market a product (but excluding Pricing Approval) in any particular jurisdiction and all amendments and supplements thereto, including an NDA filed with the FDA in the U.S.

1.92 “Manufacturing Expenses” means (a) with respect to a Co-Development mRNA Payload, BioNTech Product or a Co-Development Product that is Manufactured by a Third Party [***] paid by either Party or its Affiliate to such Third Party for such Co-Development mRNA Payload, Genevant LNP, BioNTech Product or Co-Development Product, and (b) with respect to a Co-Development mRNA Payload, Genevant LNP, BioNTech Product or Co-Development Product that is Manufactured directly by either Party or its Affiliate the Direct Expenses and Indirect Expenses incurred in connection with the Manufacture of the BioNTech Product or Co-Development Product [***]. Manufacturing Expenses shall not include any: (x) Manufacturing variances due to idle plant capacity, (y) expenses allocable to other products, or (z) any profit related to intercompany transfer pricing.

1.93 “mRNA Payload” means one or more mRNA constructs, each for the expression of a Protein of Interest, which are contained in a BioNTech Product or in a Co-Development Product.

1.94 “NDA” means a New Drug Application (as more fully defined in 21 C.F.R. § 314.5 *et seq.* or successor regulation) and all amendments and supplements thereto filed with the FDA.

1.95 “Net Sales” means, with respect to any Product, the gross amounts invoiced for sales or other dispositions of such product by or on behalf of a Party, its Affiliates and Sublicensees to Third Parties, less the following deductions to the extent included in the gross invoiced sales price for such Product or otherwise paid or incurred by the Party or its Affiliates or Sublicensees, as applicable, with respect to the sale or other disposition of such Product:

(a) normal and customary trade and quantity discounts, allowances, and credits actually allowed and properly taken with respect to sales of such Product;

(b) credits or allowances given or made for rejection or return of previously sold Products or for retroactive price reductions and billing errors;

(c) discounts, rebates, reimbursements, and chargeback payments granted to managed health care organizations or other health care institutions (including hospitals), health care administrators, patient assistance or similar programs, pharmacy benefit managers (or equivalents thereof), wholesalers and other distributors, pharmacies and other retailers, group purchasing organizations or other buying groups, health maintenance organizations, national, state/provincial, local, and other governments, their agencies and purchasers and reimbursors (including Medicaid, Medicare and similar federal and state programs and other government programs), any other providers of health insurance coverage, or to trade customers related to such Product;

(d) costs of freight, insurance, and other transportation charges related to the distribution of such Product (excluding any Taxes imposed on or with respect to net income, however denominated);

(e) import taxes, export taxes, excise taxes sales taxes, VAT, consumption taxes, duties or other taxes levied on or measured by the billing amount with respect to sales of such Product (for avoidance of doubt, excluding any Taxes imposed on or with respect to net income, however denominated);

(f) the portion of administrative fees paid during the relevant time period to group purchasing organizations or pharmaceutical benefit managers relating to such Product; and

(g) that portion of the annual fee on prescription drug Manufacturers imposed by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (as amended) or any similar Applicable Law in any other jurisdiction that [***] allocates to sales of such Product.

Such amounts shall be determined in accordance with the applicable Accounting Standards. Even if there is overlap between any of the deductions described above, each individual item shall only be deducted once in the overall Net Sales calculation. To the extent that a Party, its Affiliates or Sublicensees receives any consideration other than monies for the sales of any products, Net Sales shall include the fair market value of such consideration.

In the event that the Product is sold as a Combination Product, Net Sales will be determined by multiplying Net Sales of such Combination Product by the fraction $A/(A+B)$, where A is the invoice price of the Product, when sold separately, and B is the invoice price of any other active ingredient(s) in the combination, when sold separately, in each case in the same country and similar class, purity and dosage as in the Combination Product. If, on a country-by-country basis, the Product or the other active ingredient(s) in the Combination Product is/are not sold separately in such country, Net Sales shall be determined by multiplying actual Net Sales of such Combination Product by the fraction $C/(C+D)$, where C is the fair market value of the Product portion of such combination and D is the fair market value of the other active ingredient(s) (such fair market value is to be determined by mutual agreement of the Parties or, in the absence of such mutual agreement, by a neutral Third Party).

1.96 “On-Going Clinical Study” has the meaning set forth in Section 13.6(b)(iv) (Effect of Termination - subsection (iv)).

1.97 “Opt-Out” has the meaning set forth in Section 13.6(a) (Opt-out).

1.98 “Opt-Out Party” has the meaning set forth in Section 13.6(a) (Opt-out).

1.99 “Out-of-Pocket Costs” means amounts paid to Third Party vendors or contractors, for services or materials provided by them directly in the performance of activities under the Co-Development Product Development Plan or BioNTech Products Collaboration Plan to the extent such services or materials apply directly to the Development of any Co-Development Product or BioNTech Product (or such amounts paid to Third Parties for other activities not included in determination of Development Costs or Allowable Expenses, but for which sharing of Out-of-Pocket Costs is otherwise specified in this agreement). For clarity, Out-of-Pocket Costs do not include payments for internal: salaries or benefits; facilities; utilities; general office or facility supplies; insurance; information technology, capital expenditures or the like unless such expenses were pre-approved in writing by the Parties or agreed in the Co-Development Product Development Plan.

1.100 “Patent” means all patents and patent applications, including all provisionals, substitutions, divisionals, reissues, reexaminations, renewals, continuations, continuations-in-part, substitute applications, priority applications and inventors’ certificates, extensions and supplemental certificates and any and all foreign equivalents of the foregoing.

1.101 “Person” means any individual, partnership, limited liability company, firm, corporation, association, trust, unincorporated organization or other entity.

1.102 “Phase 1 Clinical Trial” means a human clinical trial that would satisfy the requirements of 21 C.F.R. § 312.21(a) or any amended or successor regulations) or any equivalent regulations in other countries in the Territory, regardless of where such clinical trial is conducted.

1.103 “Phase 2 Clinical Trial” means a human clinical trial that would satisfy the requirements for a Phase 2 study as defined in 21 CFR § 312.21(b) (or any amended or successor regulations) or any equivalent regulations in other countries in the Territory, regardless of where such clinical trial is conducted.

1.104 “Phase 3 Clinical Trial” means a human clinical trial that would satisfy the requirements for a Phase 3 study as defined in 21 CFR § 312.21(c) (or any amended or successor regulations) or any equivalent regulations in other countries in the Territory, regardless of where such clinical trial is conducted.

1.105 “PMDA” means Japan’s Pharmaceuticals and Medical Devices Agency or any successor entity thereto.

1.106 “Pricing Approval” means such governmental approval, agreement, determination or decision establishing prices for a BioNTech Product that can be charged and/or reimbursed in a regulatory jurisdiction where the applicable Governmental Authorities approve or determine the price and/or reimbursement of pharmaceutical products and where such approval or determination is necessary for the commercial sale of such BioNTech Product in such jurisdiction.

1.107 “Product” shall mean any BioNTech Product and/or any Co-Development Product, as applicable.

1.108 “Protein of Interest” means a protein as identified by a describing name and its amino acid sequence. For the avoidance of doubt, the term “Protein of Interest” comprises [***] protein, including but not limited to [***] (for example: [***] of the Protein of Interest [***]), provided however that [***] possesses [***] the protein as identified by a describing name and its amino acid sequence. If the Protein of Interest is an antibody or another molecule comprised of separated amino acid chains which might be delivered as separate mRNA constructs, such protein will be a single Protein of Interest for the purposes of this definition.

1.109 “Receiving Party” has the meaning set forth in Section 12.1(a) (Duty of Confidence - subsection (a)).

1.110 “Regulatory Approval” means all approvals, including Pricing Approvals and MAAs, that are necessary for the commercial sale of a product in a given country or regulatory jurisdiction.

1.111 “Regulatory Authority” means any applicable Government Authority responsible for granting Regulatory Approvals for products, including the FDA, the EMA, the PMDA, and any corresponding national or regional regulatory authorities.

1.112 “Regulatory Exclusivity” means any exclusive marketing rights or data exclusivity rights conferred by any Regulatory Authority with respect to a pharmaceutical product other than Patents, including orphan drug exclusivity, new chemical entity exclusivity, data exclusivity, or pediatric exclusivity.

1.113 “Regulatory Filings” means, with respect to a BioNTech Product or Co-Development Product, any submission to a Regulatory Authority of any appropriate regulatory application specific to BioNTech Product or Co-Development Product, and shall include any submission to a regulatory advisory board and any supplement or amendment thereto. For the avoidance of doubt, Regulatory Filings shall include any IND, NDA, MAA or the corresponding application in any other country or jurisdiction.

1.114 “Remedial Action” means any recall, corrective action or other regulatory action with respect to BioNTech Product or Co-Development Product taken by virtue of Applicable Laws.

1.115 “Royalty Term” has the meaning set forth in Section 8.3(b) (Royalty Term).

1.116 “SEC” has the meaning set forth in Section 12.6(a) (Publicity/Use of Names - subsection (a)).

1.117 “Sole Inventions” means any Inventions made solely by a Party’s or its Affiliates’ employees, agents or independent contractors.

1.118 “Sublicense” means: (a) a license or sublicense to Develop, make, have made, use, distribute, sell, offer for sale, have sold, import, export or otherwise Commercialize any BioNTech Product and (b) a license or sublicense to Develop, make, use, distribute, sell, offer for sale, have sold, import, export or otherwise Commercialize any Co-Development Product.

1.119 “Sublicensee” means a Third Party to whom BioNTech and/or Genevant has granted a Sublicense in accordance with the terms of this Agreement.

1.120 “Tax” or “Taxes” means any (a) federal, provincial, territorial, state, municipal, local, foreign or other taxes and other charges in the nature of a tax, including all income, excise, franchise, gains, capital, real property, goods and services, transfer, value added, gross receipts, windfall profits, severance, ad valorem, personal property, production, sales, use, license, stamp, documentary stamp, estimated or withholding taxes, and all customs and import duties; (b) any liability for the payment of any amounts of the type described in clause (a) as a result of being or having been a member of an affiliated, consolidated, combined or unitary group; and (c) any liability for the payment of any amounts as a result of being party to any tax sharing agreement or arrangement or as a result of any express or implied obligation to indemnify any other person with respect to the payment of any amounts of the type described in clause (a) or (b).

1.121 “Tax Payment” has the meaning set forth in Section 16.5(b) (Tax Cooperation).

1.122 “Term” has the meaning set forth in Section 13.1 (Term).

1.123 “Territory” means worldwide.

1.124 “Third Party” means any Person other than a Party or an Affiliate of a Party.

1.125 “Third Party Products Liability Action” has the meaning set forth in Section 15.6(a) (Conduct of Product Liability Claims - subsection (a)).

1.126 “Transfer Plan” has the meaning set forth in Section 2.4 (Initial Transfer of Know-How and Materials).

1.127 “Transfer Taxes” has the meaning set forth in Section 16.5(e) (Value Added Tax).

1.128 “United States” or **“U.S.”** means the United States of America including its territories and possessions.

1.129 “Valid Claim” means (a) a claim of an issued and unexpired Patent that has not been revoked or held unenforceable, unpatentable or invalid by a decision of a court or other governmental agency of competent jurisdiction that is not appealable or has not been appealed within the time allowed for appeal, and that has not been abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination or disclaimer or otherwise, or (b) a claim of a Patent application pending for no more than seven (7) years that has not been cancelled, withdrawn or abandoned or finally rejected by an administrative agency action from which no appeal can be taken.

1.130 “VAT” has the meaning set forth in Section 16.5(e) (Value Added Tax).

1.131 “Voting Stock” has the meaning set forth in Section 1.49(a) (Competitor Change of Control - subsection (a)).

1.132 “Withholding Taxes” has the meaning set forth in Section 16.5(b) (Tax Cooperation).

1.133 Interpretation. In this Agreement, unless otherwise specified:

(a) “includes” and “including” shall mean, respectively, includes without limitation and including without limitation;

(b) words denoting the singular shall include the plural and vice versa and words denoting any gender shall include all genders;

(c) words such as “herein”, “hereof”, and “hereunder” refer to this Agreement as a whole and not merely to the particular provision in which such words appear; and

(d) the Exhibits and other attachments form part of the operative provision of this Agreement and references to this Agreement shall include references to the Exhibits and attachments.

ARTICLE 2 LICENSES

2.1 License for BioNTech Products.

(a) **License Grant.** Subject to the terms and conditions of this Agreement, Genevant hereby grants to BioNTech an exclusive (even as to Genevant, except as expressly set forth herein), royalty-bearing license (or, where applicable, sublicense), with the right to grant sublicenses in accordance with Section 2.1(b) (Sublicense Rights), under the Genevant Technology to research, Develop, make, have made, use, distribute, sell, offer for sale, have sold, import, export and otherwise Commercialize BioNTech Products solely in the BioNTech Field in the Territory. For the avoidance of doubt, the above license to make and have made BioNTech Products shall only apply to the extent BioNTech is permitted to conclude a Manufacturing Transfer pursuant to Section 6.4 (Manufacturing Transfer).

(b) **Sublicense Rights.** Subject to the terms of this Section 2.1(b) (Sublicense Rights), BioNTech may grant a sublicense of the licenses granted in Section 2.1(a) (License Grant) to an Affiliate of BioNTech [***] without the prior written authorization of Genevant. BioNTech will provide Genevant with a copy of each fully executed Third Party sublicense agreement promptly upon execution. To the extent reasonably necessary, BioNTech may redact financial and other sensitive terms to the extent not necessary to confirm BioNTech's compliance with the terms of this Agreement. Each authorized sublicense, and each Sublicensee's rights, shall be in compliance with the following terms and conditions of this Agreement: Article 1 (Definitions), Article 2 (Licenses) (except Sections 2.2 (License for Co-Development Products) and 2.4 (Initial Transfer of Know-How and Materials)), Articles 4-8, Article 11 (Intellectual Property Rights) (except Section 11.4(c)), Article 12 (Confidentiality; Publication), Article 13 (Term and Termination); (except Sections 13.4 (Effect of Termination by BioNTech), 13.5(b)(ii) (Effect of Termination by Genevant - subsection (b)(ii)), 13.5(b)(iii) (Effect of Termination by Genevant - subsection (b)(iii)), 13.5(d) (Effect of Termination by Genevant - subsection (d)), and 13.6 (Opt-Out in Relation to Co-Development Product Development)), Article 15 Indemnification; Liability) (except Section 15.6 (Conduct of Product Liability Claims)), and Article 16 (General Provisions). . BioNTech shall cause each Sublicensee to comply with the following terms and conditions of this Agreement as if such Sublicensee were a Party to this Agreement: Article 1 (Definitions), Article 2 (Licenses) (except Sections 2.2 (License for Co-Development Products) and 2.4 (Initial Transfer of Know-How and Materials)), Articles 4-8, Article 11 (Intellectual Property Rights) (except Section 11.4(c)), Article 12 (Confidentiality; Publication), Article 13 (Term and Termination); (except Sections 13.4 (Effect of Termination by BioNTech),), 13.5(b)(ii) (Effect of Termination by Genevant - subsection (b)(ii)), 13.5(b)(iii) (Effect of Termination by Genevant - subsection (b)(iii)), 13.5(d) (Effect of Termination by Genevant - subsection (d)), and 13.6 (Opt-Out in Relation to Co-Development Product Development)), Article 15 Indemnification; Liability) (except Section 15.6 (Conduct of Product Liability Claims)), and Article 16 (General Provisions). No such permitted sublicense shall relieve BioNTech of any of its obligations or liabilities hereunder, for which obligations and liabilities BioNTech shall remain fully responsible and liable.

2.2 License for Co-Development Products.

(a) **License Grant to BioNTech.** Subject to the terms and conditions of this Agreement, Genevant hereby grants to BioNTech: a co-exclusive license (or, where applicable, sublicense) with Genevant, with the right to grant sublicenses including through multiple tiers in accordance with Section 2.2(c) (Sublicense Rights), under the Genevant Technology to research,

Develop, make, have made, use, distribute, sell, offer for sale, have sold, import, export and otherwise Commercialize Co-Development Products solely in the Co-Development Field in the Territory and solely as provided in the Co-Development Product Development Plan and Co-Development Product Commercialization Plan. For the avoidance of doubt, (i) the above license to distribute, sell, offer for sale, have sold, import, export and otherwise Commercialize Co-Development Products shall only apply to BioNTech to the extent BioNTech is the Lead Commercialization Party for such Co-Development Product in accordance with the terms of this Agreement; and (ii) the above license to make and have made Co-Development Products shall only apply to BioNTech to the extent the Parties agree in writing to modify Section 9.11 (Manufacturing Responsibilities) to permit the manufacture of Co-Development Products by BioNTech.

(b) License Grant to Genevant. Subject to the terms and conditions of this Agreement, BioNTech hereby grants to Genevant a co-exclusive license with BioNTech, with the right to grant sublicenses including through multiple tiers in accordance with Section 2.2(c) (Sublicense Rights), under the BioNTech Technology to research, Develop, make, have made, use, distribute, sell, offer for sale, have sold, import, export and otherwise Commercialize Co-Development Products solely in the Co-Development Field in the Territory and solely as provided in Co-Development Product Development Plan and Co-Development Product Commercialization Plan. For the avoidance of doubt, the above license to distribute, sell, offer for sale, have sold, import, export and otherwise Commercialize Co-Development Products shall only apply to Genevant to the extent Genevant is the Lead Commercialization Party for such Co-Development Product in accordance with the terms of this Agreement.

(c) Sublicense Rights.

(i) Subject to the terms of this Section 2.2(c) (Sublicense Rights), each Party may grant a sublicense of the licenses granted in Sections 2.2(a) (License Grant to BioNTech) and 2.2(b) (License Grant to Genevant) to an Affiliate of the Party without the prior written authorization of the other Party.

(ii) [***] prior to the anticipated Regulatory Approval for any Co-Development Product in any country in accordance with the then-current Co-Development Product Development Plan, neither Party may grant a sublicense of the licenses granted in Sections 2.2(a) (License Grant to BioNTech) and 2.2(b) (License Grant to Genevant) in recognition of the fact that the Parties believe the unique nature of their contributions is necessary for the successful development of Co-Development Products. If any Party is approached by a Third Party interested in a Sublicense for a Co-Development Product that has not yet received Regulatory Approval in any country or wishes to consider the possibility of offering a Sublicense for a Co-Development Product that has not yet received Regulatory Approval in any country, that Party will raise such matter with the JSC which will consider it in good faith taking into account the best interests of the Development of all the Co-Development Products and with the understanding that the Parties' intention as expressed in this Agreement is not to grant such Sublicenses.

(iii) [***] prior to the anticipated Regulatory Approval for any Co-Development Product in any country in accordance with the then-current Co-Development Product Development Plan, the Lead Commercialization Party for such Co-Development Product may grant a sublicense of the licenses granted in Sections 2.2(a) (License Grant to BioNTech) or 2.2(b) (License Grant to Genevant), as applicable, with respect to that Co-Development Product without the prior written authorization of the Party only in accordance with the following procedure:

Before granting any such sublicense, the Lead Commercialization Party will notify the other Party and give the other Party the opportunity to negotiate the terms of such a sublicense with the Party before negotiating with any Third Party. If the Parties cannot reach agreement within [***] on the terms of a sublicense, then the Party may grant such a sublicense to a Third Party, provided that (i) the terms of such sublicense granted to the Third Party are not more favorable than those offered to the other Party and (ii) prior to executing the sublicense with the Third Party such Party shall notify the other Party of the terms of the sublicense agreed with the Third Party and [***] with such Third Party [***] If the other Party does not notify the Lead Commercialization Party that [***] upon its receipt of the above notice, the Lead Commercialization Party shall be free to execute the sublicense agreement with the Third Party at the terms notified to the other Party.

(iv) The Party granting any Third Party sublicense hereunder will provide the other Party with a copy of each fully executed Third Party sublicense agreement promptly upon execution. To the extent reasonably necessary, such Party may redact financial and other sensitive terms to the extent not necessary to confirm such Party's compliance with the terms of this Agreement. Each authorized sublicense shall be in compliance with the following terms and conditions of this Agreement Article 1 (Definitions), Article 2 (Licenses) (except Sections 2.1 (Licenses for BioNTech) and 2.4 (Initial Transfer of Know-How and Materials)); Articles 9-10; Article 11 (Intellectual Property Rights) (except Section 11.4 (Infringement by Third Parties)); Article 12 (Confidentiality; Publication); Article 13 (Term and Termination) (except Sections 13.2(a) (Termination by BioNTech), 13.3 (Effect of Termination), 13.4 (Effect of Termination by BioNTech), and 13.5(c) (Effect of Termination by Genevant - subsection (c)); Article 15 (Indemnification; Liability) (except Section 15.2(d) (Indemnification by BioNTech - subsection (d)) and Article 16 (General Provisions). BioNTech shall cause each Sublicensee to comply with the following terms and conditions of this Agreement as if such Sublicensee were a Party to this Agreement: Article 1 (Definitions), Article 2 (Licenses) (except Sections 2.1 (Licenses for BioNTech) and 2.4 (Initial Transfer of Know-How and Materials)); Articles 9-10; Article 11 (Intellectual Property Rights) (except Section 11.4 (Infringement by Third Parties)); Article 12 (Confidentiality; Publication); Article 13 (Term and Termination) (except Sections 13.2(a) (Termination by BioNTech), 13.3 (Effect of Termination), 13.4 (Effect of Termination by BioNTech), and 13.5(c) (Effect of Termination by Genevant - subsection (c)); Article 15 (Indemnification; Liability) (except Section 15.2(d) (Indemnification by BioNTech - subsection (d)) and Article 16 (General Provisions). No such permitted sublicense shall relieve such Party of any of its obligations or liabilities hereunder, for which obligations and liabilities such Party shall remain fully responsible and liable.

2.3 Retained Rights. Genevant retains the right under the Genevant Technology to exercise its rights and perform its obligations under this Agreement. In addition, Genevant retains, and hereby expressly reserves, the exclusive right to practice, and to grant licenses under, the Genevant Technology (a) for any and all purposes outside the BioNTech Field and Co-Development Field; (b) in the BioNTech Field with any product that is not a BioNTech Product; and (c) in the Co-Development Field with any product that is not a Co-Development Product. BioNTech retains the right under the BioNTech Technology to exercise its rights and perform its obligations under this Agreement. In addition, BioNTech retains, and hereby expressly reserves, the exclusive right to practice, and to grant licenses under, the BioNTech Technology (a) for any and all purposes outside the Co-Development Field and (b) in the Co-Development Field with any product that is not a Co-Development Product, subject to the limitations of Section 2.6 (Exclusivity).

2.4 Initial Transfer of Know-How and Materials. As of the Effective Date, the Parties have agreed on a plan for the transfer of Genevant Know-How (including the data therein) and certain tangible materials Controlled by Genevant as of the Effective Date to BioNTech and the transfer of BioNTech Know-How (including the data therein) and certain tangible materials Controlled by BioNTech as of the Effective Date to Genevant which plan is attached hereto as Exhibit D (the “**Transfer Plan**”). The Parties shall commence disclosing and making available to each other their respective Know-How and materials listed in the Transfer Plan according to the timeline set forth in the Transfer Plan. The Parties shall cooperate with each other in good faith to enable a smooth transfer of their respective Know-How to each other. Upon reasonable request by a Party, the other Party shall provide reasonable technical assistance of no more than two (2) FTEs working for three (3) months at the FTE Rate, including making appropriate employees available at reasonable times, places and frequency, and upon reasonable prior notice, for the purpose of assisting the Party to understand and use the other Party’s Know-How in connection with the Party’s Development of BioNTech Products and/or Co-Development Products. If a Party reasonably requests additional FTEs beyond that provided for in the preceding sentence, the Parties will negotiate for the provision of a reasonable amount of additional FTEs. Nothing in this Section 2.4 (Initial Transfer of Know-How and Materials) will apply to the transfer of any Genevant Know-How relating to the Manufacture of BioNTech Products. The transfer of any Genevant Know-How relating to the Manufacture of BioNTech Products is addressed in Article 6 (Manufacturing of BioNTech Products).

2.5 No Implied Licenses; Negative Covenant. Except as set forth herein, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, under any Know-How, Patents, trademarks or other intellectual property rights owned or controlled by the other Party. BioNTech hereby covenants not to practice, and not to permit or cause any of its Affiliate or any Third Party to practice, any Genevant Technology for any purpose other than as expressly authorized in this Agreement, and Genevant hereby covenants not to practice, and not to permit or cause any of its Affiliate or any Third Party to practice, any BioNTech Technology for any purpose other than as expressly authorized in this Agreement. Without limiting the generality of the foregoing, (a) BioNTech shall not, directly or indirectly: (i) practice Genevant Technology to Develop, make, have made, use, distribute, sell, offer for sale, have sold, import, export and otherwise Commercialize any BioNTech Product for use outside the BioNTech Field or any Co-Development Product for use outside the Co-Development Field; or (ii) permit or cause any of its Affiliates or any Third Party to engage in any of the activities described in the preceding clause (i); and (b) Genevant shall not, directly or indirectly: (i) practice BioNTech Technology to Develop, make, have made, use, distribute, sell, offer for sale, have sold, import, export and otherwise Commercialize any Co-Development Product for use outside the Co-Development Field; or (ii) permit or cause any of its Affiliates or any Third Party to engage in any of the activities described in the preceding clause (i).

2.6 Exclusivity. During the Term of this Agreement for the relevant BioNTech Product or any Co-Development Product, BioNTech shall not conduct, itself or through an Affiliate or Third Party, and shall not enable a Third Party to conduct, any clinical Development, promotion or Commercialization of any product involving the use of LNP with any BioNTech mRNA Payload or any Co-Development mRNA Payload contained in such BioNTech Product or Co-Development Product other than in collaboration with Genevant pursuant to the terms of this Agreement.

2.7 [*] Agreement.** BioNTech understands and agrees that any sublicenses granted by Genevant hereunder to any Genevant Technology owned by [***] is subject to the terms of the

[***] Agreement. If the [***] Agreement is terminated, any such sublicenses will convert to a direct license from [***] provided that BioNTech: (a) is not then in breach of this Agreement; (b) agrees in writing to be bound to [***] as a licensee under the terms and conditions of the [***] Agreement; and (c) agrees in writing that in no event shall [***] assume any obligations or liability, or be under any obligation or requirement of performance that extends beyond [***] obligations and liabilities, as applicable, under the [***] Agreement. BioNTech further consents to Genevant providing a copy of this Agreement to [***].

ARTICLE 3 GOVERNANCE

3.1 Joint Steering Committee. Within thirty (30) days after the Effective Date, the Parties shall establish a Joint Steering Committee (the “**Joint Steering Committee**” or the “**JSC**”), composed of two (2) representatives of each Party, to guide the collaboration of the Parties under this Agreement and to oversee the exchange of information between the Parties with respect to (a) the Development and Manufacturing of BioNTech Products (only to the extent it involves or affects Development or Manufacturing activities to be performed by Genevant under the BioNTech Products Collaboration Plan or the Co-Development Product Development Plan) and (b) the Development, Manufacturing and Commercialization of Co-Development Products. For the avoidance of doubt, all Development or Manufacturing activities for BioNTech Products which do not involve or affect Development or Manufacturing activities to be performed by Genevant under this Agreement as well as all Commercialization activities relating to BioNTech Products shall not be subject to guidance or oversight by the JSC pursuant to this Section 3.1. Each JSC representative shall have appropriate knowledge and expertise and sufficient seniority within the applicable Party to make decisions arising within the scope of the JSC’s responsibilities. The JSC shall in particular:

(a) provide a forum for the discussion of and decision making regarding the Development of BioNTech Products (only to the extent it involves or affects Development or Manufacturing activities to be performed by Genevant under the BioNTech Products Collaboration Plan or the Co-Development Product Development Plan);

(b) provide a forum for BioNTech to keep Genevant informed regarding the Development of BioNTech Products in the BioNTech Field by BioNTech, its Affiliates, and Sublicensees, including the status of any Regulatory Filings, Regulatory Approvals, or clinical trials;

(c) oversee the transfer of Genevant Know-How and materials to BioNTech under Section 2.4 (Initial Transfer of Know-How and Materials);

(d) oversee the transfer of BioNTech Know-How and materials to Genevant under Section 2.4 (Initial Transfer of Know-How and Materials);

(e) provide a forum for the discussion of and decision making regarding the Development, Manufacturing and Commercialization of Co-Development Products by the Parties, their Affiliates, and Sublicensees;

(f) review and discuss in good faith any updates to any Co-Development Product Development Plan, and approve any updates to such Co-Development Product Development Plan;

(g) to the extent not set forth in any Co-Development Product Development Plan, allocate responsibility for activities under any Co-Development Product Development Plan;

(h) create and approve budgets for all activities under any Co-Development Product Development Plan;

(i) discuss and agree on the Lead Commercialization Party for each Co-Development Product for the Territory in accordance with Section 10.1 and allocate responsibility for Commercialization of such Co-Development Product in accordance with Section 10.2 (Commercialization Plan and Report);

(j) to the extent not set forth in the Co-Development Commercialization Plan, allocate responsibility for activities under the Co-Development Commercialization Development Plan;

(k) create and approve budgets for all activities under the Co-Development Product Commercialization Plan;

(l) create subcommittees to govern activities under the Agreement;

(m) discuss any proposed Sublicense that a Party wishes to grant for a Co-Development Product; and

(n) discuss and agree which technology developed by BioNTech outside of the collaboration of this Agreement shall be included in the Co-Development Products.

The JSC shall have only such powers as are expressly assigned to it in this Agreement, and such powers shall be subject to the terms and conditions of this Agreement. The JSC, Executive Officers, Subcommittees, and Alliance Managers shall not have any right, power or authority: (i) to determine any issue in a manner that would conflict with the express terms and conditions of this Agreement; or (ii) to modify or amend the terms and conditions of this Agreement. In addition, to the extent a Party grants any Sublicenses in accordance with Section 2.1(b) (Sublicense Rights) or Section 2.2(c) (Sublicense Rights), the Party will be responsible for obtaining from its Sublicensees all information necessary to allow the Party to meet its obligations to the JSC with respect to the subject matter of the Sublicense.

3.2 JSC Membership and Meetings.

(a) **Members.** Genevant's initial JSC representatives will be Peter Lutwyche and James Heyes and BioNTech's initial JSC representatives will be Andreas Kuhn and Katalin Kariko. BioNTech shall designate one of its JSC representatives to act as chairperson of the JSC. Each Party may replace its JSC representatives (and, for BioNTech, the chairperson) on written notice to the other Party, but each Party shall strive to maintain continuity. The JSC members shall jointly prepare an agenda and shall direct the preparation of reasonably detailed minutes for each JSC meeting, which shall be circulated and approved within thirty (30) days of such meeting.

(b) **Meetings.** The JSC shall hold meetings at such times as it elects to do so, but in no event, shall such meetings be held less frequently than once per Calendar Quarter. Meetings may be held in person, or by audio or video teleconference; *provided*, that unless otherwise agreed by both Parties, at least one (1) meeting per year shall be held in person, and all in-person JSC meetings shall be held at locations mutually agreed upon by the Parties. Each Party shall be responsible for all of its own expenses of participating in JSC meetings.

(c) **Non-Member Attendance.** Each Party may from time to time invite a reasonable number of participants, in addition to its representative, to attend JSC meetings in a non-voting capacity; *provided*, that if either Party intends to have any Third Party (including any consultant) attend such a meeting, such Party shall provide at least three (3) days prior written notice to the other Party and obtain the other Party's approval for such Third Party to attend such meeting, which approval shall not be unreasonably withheld or delayed. Such Party shall ensure that such Third Party is bound by confidentiality and non-use obligations consistent with the terms of this Agreement.

3.3 JSC Decision-Making. All decisions of the JSC shall be made by unanimous vote, with each Party's representatives collectively having one (1) vote. If after reasonable discussion and good faith consideration of each Party's view on a particular matter before the JSC, the representatives of the Parties cannot reach an agreement as to such matter within [***] Business Days after such matter was brought to the JSC for resolution, such disagreement shall be referred to the Chief Executive Officer of BioNTech (or his or her designee) and the Chief Executive Officer or Executive Chairman of Genevant (or his or her designee) (collectively, the "**Executive Officers**") for resolution, who shall use good faith efforts to resolve such matter within ten (10) Business Days after it is referred to them. If the Executive Officers are unable to reach consensus on any such matter during such period, then:

(a) for any decision [***] BioNTech Products (except for decisions primarily relating to the Manufacture of BioNTech Products prior to any Manufacturing Transfer); or the Co-Development mRNA Payloads; the Development of any Co-Development Product for which BioNTech is the Lead Commercialization Party after completion of the first Phase 1 Clinical Trial for such Co-Development Product; or Commercialization of any Co-Development Product for which BioNTech is the Lead Commercialization Partner, the Chief Executive Officer of BioNTech shall have the right to decide in good faith, provided that (i) such decision is in compliance with the then-current Co-Development Products Development Plan and does not result in any additional efforts to be provided by Genevant and (ii) the Chief Executive Officer of Genevant has not demonstrated on reasonable grounds before the expiry of the abovementioned period of [***] Business Days (1) that any such decision could reasonably be expected to have a material negative tax impact on Genevant, any of its Affiliates, or any of its direct or indirect shareholders including by causing (A) Genevant or any of its Affiliates to be subject to net income taxation in any jurisdiction in which it does not have a taxable presence or nexus immediately prior to the Effective Date or (B) Genevant, any of its Affiliates, or any of its direct and indirect shareholders to be treated as earning "passive income" for purposes of Section 1297 of the Internal Revenue Code of 1986, as amended (the "**Code**") or "subpart F income" for purposes of Section 952 of the Code, in each case, as a result of or in connection with Commercialization activities and (2) that such material negative tax impact prevails the Parties' business interest, ignoring such tax impact, in the implementation of the relevant decision; and

(b) for any decision [***] Genevant LNPs; the Manufacture of BioNTech Products prior to any Manufacturing Transfer; the Development of any Co-Development Product for which BioNTech is the Lead Commercialization Party prior to completion of the first Phase 1 Clinical Trial for such Co-Development Product; or the Development or Commercialization of any Co-Development Product for which Genevant is the Lead Commercialization Party, the Executive Officer of Genevant shall have the right to decide, provided that (i) such decision is in

compliance with the then-current Co-Development Products Development Plan and does not result in any additional efforts to be provided by BioNTech and (ii) the Chief Executive Officer of BioNTech has not demonstrated on reasonable grounds before the expiry of the abovementioned period of [***] that (1) any such decision could reasonably be expected to have a material negative tax impact on BioNTech, any of its Affiliates, or any of its direct or indirect shareholders including by causing (A) BioNTech or any of its Affiliates to be subject to net income taxation in any jurisdiction in which it does not already have a taxable presence or nexus immediately prior to the Effective Date or (B) Genevant, any of its Affiliates, or any of its direct and indirect shareholders to be treated as earning “passive income” for purposes of the Code or “subpart F income” for purposes of Section 952 of the Code, in each case, as a result of or in connection with Commercialization activities and (2) that such material negative tax impact prevails the Parties’ business interest, ignoring such tax impact, in the implementation of the relevant decision; and

(c) for all other decisions, no Party shall have any final decision-making power. Notwithstanding anything to the contrary in (a) and (b) above, for any decision primarily related to the dosing of a Co-Development mRNA Payload or issues with the safety of a Co-Development mRNA Payload, no Party shall have any final decision-making power.

3.4 Subcommittees. Within two (2) weeks following the Effective Date, the JSC will form the following subcommittees to govern and monitor their collaboration with respect to Co-Development Products: (i) a Joint Development Subcommittee, (ii) a Joint Manufacturing Subcommittee, (iii) a Joint Financial Subcommittee as well as any other subcommittee that the Parties deem appropriate. The related membership, meeting frequencies, responsibilities will be agreed between the Parties prior to forming those subcommittees. Decisions of each subcommittee shall require unanimous consent. Issues that cannot be agreed on subcommittee level shall be escalated to the JSC.

3.5 Alliance Managers. Promptly after the Effective Date, each Party shall appoint an individual to act as the alliance manager for such Party (the “**Alliance Manager**”), which individual may also be a JSC member. Each Alliance Manager shall be responsible for alliance management between the Parties on a day-to-day basis throughout the Term. If not a member of the JSC, each Alliance Manager shall be permitted to attend meetings of the JSC as non-voting participants. The Alliance Managers shall be the primary contact for the Parties regarding the activities contemplated by this Agreement and shall facilitate all such activities hereunder. Each Party may replace its Alliance Manager with an alternative representative at any time upon written notice to the other Party. Any Alliance Manager may designate a substitute to temporarily perform the functions of that Alliance Manager upon written notice to the other Party. Each Alliance Manager shall be charged with creating and maintaining a collaborative work environment within the JSC and between the Parties.

ARTICLE 4 DEVELOPMENT OF BIONTECH PRODUCTS

4.1 General. Subject to the terms and conditions of this Agreement, BioNTech shall be solely responsible for the Development of BioNTech Products in the BioNTech Field in the Territory, including the performance of preclinical and clinical studies of any BioNTech Product in the BioNTech Field.

4.2 BioNTech Products Development. BioNTech shall use Commercially Reasonable Efforts to conduct all Development of BioNTech Products in the BioNTech Field in

the Territory in accordance with a general development plan (as amended in accordance with this Agreement, the “**BioNTech Development Milestone Plan**”), the initial version of which is set forth in Exhibit E. From time to time, but at least every [***], BioNTech will confirm whether the estimated timelines in the BioNTech Development Milestone Plan are still expected to be met or will update the BioNTech Development Milestone Plan to reflect any changes.

4.3 Conduct of Development Activities by BioNTech. BioNTech shall Develop BioNTech Products in the Field in the Territory in compliance with all Applicable Laws, including good scientific and clinical practices under the Applicable Laws of the country in which such activities are conducted.

4.4 Conduct of Development Activities by Genevant. Notwithstanding the above, Genevant will assist BioNTech in the Development and Manufacture of LNP formulations for use in BioNTech Products in accordance with a development plan to be agreed between the Parties (the “**BioNTech Products Collaboration Plan**”), the initial version of which is set forth in Exhibit I. Within the framework of the BioNTech Products Collaboration Plan, Genevant will also assist in the identification of the final LNP to be used with each BioNTech Product to create BioNTech Products. As set forth in Article 6 (Manufacturing of BioNTech Products), Genevant will also be responsible for Manufacture of the BioNTech Products. All activities of Genevant under this Section 4.4 shall be made in compliance with all Applicable Laws, including good scientific and clinical practices under the Applicable Laws of the country in which such activities are conducted.

4.5 Records and Updates. Each Party shall maintain records, in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, which shall fully and properly reflect all work done and results achieved by or on behalf of such Party in the performance of Development or Manufacturing activities in relation to BioNTech Products pursuant to this Agreement. BioNTech shall keep the JSC regularly informed of the status of material Development activities conducted with respect to BioNTech Products in the BioNTech Field in the Territory pursuant to this Agreement. Without limiting the foregoing, at least once every [***] months beginning with the third Calendar Quarter of the Calendar Year 2018, BioNTech shall provide the JSC or Genevant with a summary report about its current and planned development activities for BioNTech Products in the BioNTech Field in the Territory, covering subject matter at a level of detail sufficient to enable Genevant to determine BioNTech’s compliance with its diligence obligations under Section 4.6 (“**Development Diligence**”). BioNTech agrees that Genevant can provide such status reports and summaries to [***] to the extent required under the [***] Agreement.

4.6 Development Diligence. BioNTech, directly and/or with or through Affiliates or Sublicensees, shall use Commercially Reasonable Efforts to Develop, and to obtain Regulatory Approval for, the BioNTech Products in the BioNTech Field in the U.S., Germany, United Kingdom, France, Spain and Italy. It is understood and agreed by the Parties that BioNTech intends to seek Regulatory Approval in the above listed countries first. Following Regulatory Approval in those countries of a BioNTech Product, if it is commercially reasonable to do so, BioNTech will also use Commercially Reasonable Efforts to seek Regulatory Approval for such BioNTech Product in Asia and any other countries in Europe.

4.7 Development Costs. As between the Parties, BioNTech shall be solely responsible for the cost for the Development of BioNTech Products in the BioNTech Field in the Territory. All assistance provided by Genevant pursuant to Section 4.4 (Conduct of Development Activities by Genevant) shall [***] BioNTech, unless otherwise specified in Article 6 (Manufacturing of BioNTech Products).

4.8 Compliance. Each Party agrees that in performing its obligations under this Agreement in relation to BioNTech Products: (a) it shall comply with all Applicable Laws; and (b) it will not employ or engage any Person who has been debarred or disqualified by any Regulatory Authority, or, to its knowledge, is the subject of debarment or disqualification proceedings by a Regulatory Authority.

4.9 Subcontractor. BioNTech shall have the right to engage subcontractors for the performance of its obligations under the Agreement in relation to BioNTech Products, and shall cause the subcontractor(s) engaged by it to be bound by written obligations of confidentiality and non-use of Genevant's Confidential Information and invention assignment consistent with those contained herein, and BioNTech shall remain primarily responsible for the performance of such subcontractor(s).

ARTICLE 5 REGULATORY ACTIVITIES FOR BIONTECH PRODUCTS

5.1 Regulatory Responsibilities. BioNTech shall be responsible for all regulatory activities necessary to obtain and maintain Regulatory Approval of BioNTech Products in the BioNTech Field in the Territory. BioNTech shall keep Genevant informed of regulatory developments related to BioNTech Products in the BioNTech Field in the Territory both via the JSC and BioNTech's reports pursuant to Section 4.5 (Records and Updates).

5.2 Regulatory Filings. BioNTech shall prepare and submit all Regulatory Filings for BioNTech Products in the BioNTech Field in the Territory and shall own all Regulatory Filings and Regulatory Approvals for BioNTech Products in the BioNTech Field in the Territory. Genevant will have the right to review and comment on any portions of Regulatory Filings relating to Genevant LNP or the manufacture of BioNTech Products other than the manufacture of the BioNTech mRNA Payloads prior to the submission of such Regulatory Filings. [***], BioNTech agrees to provide to Genevant copies of any Regulatory Filings or data contained therein requested by Genevant for [***].

5.3 Remedial Actions. BioNTech will notify Genevant without undue delay (and in any event within timelines set by Applicable Law), and promptly confirm such notice in writing, if it obtains information indicating that a BioNTech Product may be subject to any Remedial Action. The Parties will assist each other in gathering and evaluating such information as is necessary to determine the necessity of conducting a Remedial Action. BioNTech shall, and shall ensure that its Affiliates and Sublicensees will, maintain adequate records to permit BioNTech to trace the Manufacture, distribution and use of the BioNTech Products. BioNTech shall have the sole discretion with respect to any matters relating to any Remedial Action with respect to any BioNTech Product in the BioNTech Field in the Territory, including the decision to commence such Remedial Action and the control over the conduct of such Remedial Action, provided that BioNTech shall notify Genevant prior to making any public disclosure of Remedial Action and shall keep Genevant regularly informed regarding any such Remedial Action. BioNTech shall be solely responsible for the cost and expense of any such Remedial Action in the BioNTech Field, except [***] such Remedial Action [***].

5.4 Pharmacovigilance. At least [***] prior to the filing of an IND for any BioNTech Product, the Parties shall define and finalize the actions that the Parties shall employ with respect to such BioNTech Product to protect patients and promote their well-being in a written pharmacovigilance agreement (each a “**BioNTech Product Pharmacovigilance Agreement**”), with BioNTech as the global safety database holder. These responsibilities shall include mutually acceptable guidelines and procedures for the receipt, investigation, recordation, communication, and exchange (as between the Parties) of adverse event reports and any other information concerning the safety of the BioNTech Products. Such guidelines and procedures shall be in accordance with, and enable the Parties to fulfill, local and national regulatory reporting obligations under applicable laws and regulations. Each Party hereby agrees to comply with its respective obligations under such Pharmacovigilance Agreement and to cause its Affiliates and Sublicensees to comply with such obligations. BioNTech will maintain the global safety database pursuant to its own policy and as necessary to comply with Applicable Laws governing adverse experiences in the Territory.

5.5 Development Disparity for BioNTech Products. In recognition of the fact that the Parties do not intend for the Development of BioNTech Products to take precedence over the Co-Development Products and vice versa, the Parties agree to use Commercially Reasonable Efforts to ensure that the Development of both such products are treated equally.

ARTICLE 6 MANUFACTURING OF BIONTECH PRODUCTS

6.1 Manufacture of BioNTech Products. Unless BioNTech requests a Manufacturing Transfer and such Manufacturing Transfer has been fully completed in accordance with Section 6.4 (Manufacturing Transfer), Genevant shall be solely responsible for all preclinical, clinical and commercial Manufacture and supply of all BioNTech Products for all uses under this Agreement. BioNTech will supply to Genevant all BioNTech mRNA Payloads for such Manufacture at BioNTech’s sole expense. Genevant may conduct such Manufacturing activities itself or through a Third Party CMO under Genevant’s control, subject to Section 4.9 (Subcontractor). Within a reasonable time after the Effective Date (and no later than six (6) months following the Effective Date), the Parties will execute a supply agreement to govern the supply of BioNTech Products to BioNTech from Genevant or the Third Party CMO selected and controlled by Genevant (“**BioNTech Product Supply Agreement**”).

6.2 Payment for BioNTech Product Manufacture. BioNTech shall pay Genevant for supply of BioNTech Products at a price equal to Genevant’s Manufacturing Expenses. The mechanism for invoicing, forecasting, and payment for such BioNTech Products will be set forth in the BioNTech Product Supply Agreement.

6.3 Initial Transfer of BioNTech Product Manufacturing Know-How.

(a) **BioNTech Product Initial Manufacturing Know-How.** During a mutually agreed time period prior to any Regulatory Filing for BioNTech Products planned by BioNTech, Genevant shall make available and transfer to BioNTech, copies of the BioNTech Product Manufacturing Know-How that is listed in Exhibit L and is necessary to enable BioNTech to prepare Regulatory Filings and clinical trials for the BioNTech Products. If a Regulatory Authority requests that BioNTech provide additional BioNTech Product Manufacturing Know-How concerning the manufacture of the BioNTech Products beyond the information listed in Exhibit L, BioNTech will inform Genevant of such request and Genevant will provide such

information to BioNTech without any undue delay (and in any event reasonably in advance prior to any timelines set by the Regulatory Authority), provided that Genevant has such information in its possession or control. If BioNTech believes any BioNTech Product Manufacturing Know-How related to the manufacture of the BioNTech Products other than that listed in Exhibit L is necessary to enable BioNTech to prepare Regulatory Filings or clinical trials for the BioNTech Products, BioNTech may request such additional Know-How from Genevant. Provided BioNTech can demonstrate that such additional BioNTech Product Manufacturing Know-How is reasonably necessary to enable BioNTech to prepare Regulatory Filings or clinical trials for the BioNTech Products, Genevant will produce such additional BioNTech Product Manufacturing Know-How to BioNTech without any undue delay. All Genevant Manufacturing Know-How provided to BioNTech pursuant to this Section 6.3(a) (BioNTech Product Initial Manufacturing Know-How) including the BioNTech Product Manufacturing Know-How listed on Exhibit L is herein after referred to as “**BioNTech Product Initial Manufacturing Know-How.**” All services associated with transfer of any BioNTech Product Initial Manufacturing Know-How will be paid by BioNTech in accordance with the FTE Rate.

(b) **Use of BioNTech Product Initial Manufacturing Know-How.** BioNTech hereby covenants and agrees that BioNTech Product Initial Manufacturing Know-How will be used solely for purposes of the preparation of Regulatory Filings and clinical trials and will not be used in the research and development of any products other than BioNTech Products. Only those employees with a need to know such information to prepare Regulatory Filings or clinical trials will be granted access to the BioNTech Product Initial Manufacturing Know-How. Prior to granting access to the BioNTech Product Initial Manufacturing Know-How to any BioNTech employee, BioNTech will identify such employee to Genevant in writing. In addition, prior to granting access to such employee, the employee will sign a nondisclosure agreement with BioNTech relating to the BioNTech Product Initial Manufacturing Know-How, which will include terms requiring the employee to maintain the BioNTech Product Initial Manufacturing Know-How in strict confidence and not to use the BioNTech Product Initial Manufacturing Know-How in the research and development of any products or technology including or relating to LNP (other than BioNTech Products).

(c) **Batch Records.** To the extent any batch records related to the manufacture of BioNTech Products by Genevant are required to be reviewed in order for BioNTech to conduct any clinical trials, such batch records may only be made available to employees of BioNTech or its Affiliates who have signed a separate non-disclosure agreement relating to the use of the batch records under which such employees will agree to only use such batch records for quality purposes relating to the relevant batches Manufactured by Genevant, to maintain the batch records in strict confidence and not to use the batch records in the research and development of any products or technology including or relating to LNP (other than BioNTech Products). Such employees will not be involved in or have any responsibility or decision making authority for the research and development of any products or technology including or relating to LNP (other than BioNTech Products).

6.4 Manufacturing Transfer. With respect to any BioNTech Product, and on a BioNTech Product-by-BioNTech Product basis, at a time following the completion of the first Phase 1 Clinical Trial for such BioNTech Product, BioNTech may request from Genevant that (a) Genevant collaborate with BioNTech to transfer the Manufacturing of such BioNTech Product to BioNTech, a collaboration partner of BioNTech in relation to such BioNTech Product or a CMO selected and controlled by BioNTech or such collaboration partner or (b) Genevant permit BioNTech or such collaboration partner to conclude a direct manufacturing and supply agreement

with the CMO selected by Genevant or such collaboration partner (“**Manufacturing Transfer**”). In the event of any request for Manufacturing Transfer, Genevant shall provide support that is reasonably necessary or useful for BioNTech, the collaboration partner or the CMO to take over the Manufacturing of the relevant BioNTech Product within a reasonable period of time following such request. Further details of the Manufacturing Transfer shall be reasonably agreed between the Parties in a Manufacturing Transfer plan. A Manufacturing Transfer shall be deemed completed, per BioNTech Product, upon both (i) completion of [***] successful batch Manufactured at the facility to which the Manufacturing is transferred and (ii) approval of the change of Manufacturing facility by the Governmental Entity(ies) relevant for the Manufacturing or Commercialization of such BioNTech Product. All Manufacturing Transfer services to be provided by Genevant under this Section 6.4 (Manufacturing Transfer) shall be paid by BioNTech in accordance with the FTE Rate.

6.5 Pre-existing or Publicly Available Manufacturing Know-how. For the avoidance of doubt, nothing in this Article 6 (Manufacturing of BioNTech Products) shall restrict BioNTech or its Affiliates or collaboration partners to use any Manufacturing Know-how that (i) was in the possession of BioNTech or such Affiliate or collaboration partner prior to disclosure of such Manufacturing Know-how by Genevant, as shown by contemporaneous evidence, or (ii) is in the public domain by use and/or publication before its receipt from Genevant, or thereafter enters the public domain through no fault of, or breach of this Agreement by, BioNTech.

ARTICLE 7 COMMERCIALIZATION

7.1 General. Subject to the terms and conditions of this Agreement, BioNTech shall be responsible for all aspects of the Commercialization of the BioNTech Products in the BioNTech Field in the Territory, including: (a) developing and executing a commercial launch and pre-launch plan, (b) negotiating with applicable governmental authorities regarding the price and reimbursement status of the BioNTech Products and obtaining and maintaining Pricing Approvals; (c) marketing, medical affairs, and promotion; (d) booking sales and distribution and performance of related services; (e) handling all aspects of order processing, invoicing and collection, inventory and receivables; (f) providing customer support, including handling medical queries, and performing other related functions; and (g) conforming its practices and procedures to Applicable Law relating to the marketing, detailing and promotion of BioNTech Products in the BioNTech Field in the Territory. As between the Parties, BioNTech shall be solely responsible for the costs and expenses of Commercialization of the BioNTech Products in the BioNTech Field in the Territory.

7.2 Commercial Diligence. BioNTech, directly and/or with or through Affiliates or Sublicensees, shall use Commercially Reasonable Efforts to Commercialize BioNTech Products in the BioNTech Field in countries in the Territory in which a BioNTech Product has received Regulatory Approval.

7.3 Commercialization Reports. BioNTech shall keep Genevant reasonably informed of BioNTech’s, its Affiliates’ and Sublicensees’ Commercialization activities with respect to the BioNTech Products in the BioNTech Field in the Territory. Without limiting the foregoing, on [***] of each Calendar Year, beginning in the Calendar Year of BioNTech’s first submission of an MAA for a BioNTech Product in the BioNTech Field in the Territory, BioNTech shall provide Genevant with a written report summarizing material Commercialization activities with respect to the BioNTech Products in the BioNTech Field in the Territory performed in the [***] and material

Commercialization activities with respect to the BioNTech Products in the BioNTech Field in the Territory planned for the [***]. BioNTech shall promptly respond to Genevant's reasonable questions or requests for additional information relating to the progress and results of its and its Affiliates' and Sublicensees' Commercialization activities under this Agreement.

ARTICLE 8 BIONTECH PRODUCT FINANCIAL PROVISIONS

8.1 [*] Milestone Payments.** Within [***] after the first achievement of each milestone event below for each BioNTech Product by or on behalf of BioNTech or any of its Affiliates or Sublicensees, BioNTech shall notify Genevant of the achievement of such milestone event and shall remit payment to Genevant within [***] of its receipt of Genevant's invoice for such payment.

[***]

For clarity, (a) if a BioNTech Product undergoes [***] only one payment of [***] is due for such BioNTech Product; (b) [***] payments above are payable on each BioNTech Product (for example, if BioNTech [***] for all five (5) BioNTech Products, BioNTech will make [***] and (c) each milestone payment is only due once per BioNTech Product.

8.2 Commercial Milestones.

(a) Within [***] after the end of the Calendar Quarter in which aggregate annual Net Sales of any BioNTech Product by or on behalf of BioNTech or any of its Affiliates or Sublicensees in the BioNTech Field in the Territory first reach any threshold indicated in the milestone events listed below, BioNTech shall notify Genevant of the achievement of such milestone event and shall remit payment to Genevant within [***] of its receipt of Genevant's invoice for such payment.

[***]

For clarity, the commercial milestone payments above are payable only once per BioNTech Product on aggregate annual Net Sales of such BioNTech Product. For example, if aggregate annual Net Sales for each of the five (5) BioNTech Products in a Calendar Year equal [***].

(b) If a commercial milestone event in Section 8.2(a) (Commercial Milestones - subsection(a)) is achieved for a BioNTech Product and payment with respect to any previous milestone event has not been made for the same BioNTech Product, then such previous milestone event shall be deemed achieved for such BioNTech Product and BioNTech shall pay Genevant such unpaid previous milestone payment(s) at the same time it pays the milestone payment for the commercial milestone event it achieved.

8.3 Royalty Payments.

(a) **Royalty Rate.** During the Royalty Term, BioNTech shall pay to Genevant non-refundable, non-creditable royalty of [***] on aggregate annual Net Sales of all BioNTech Products in the BioNTech Field in the Territory in each Calendar Year.

(b) **Royalty Term.** Royalties under this Section 8.3 (Royalty Payments) shall be payable on a country-by-country and BioNTech Product-by-BioNTech Product basis from the First Commercial Sale of each BioNTech Product in a country until the latest of: (i) expiration of the last-to-expire Valid Claim of the Genevant Patents that would, but for the licenses granted hereunder, be infringed by the Manufacture, use or sale of such BioNTech Product in such country in the Territory; (ii) expiration of Regulatory Exclusivity for such BioNTech Product in such country (provided that during such Regulatory Exclusivity no mRNA-based product directed to the same Protein of Interest and the same indication competitive to the relevant BioNTech Product comes on the market in the relevant country); and (iii) the [***] anniversary of the First Commercial Sale of such BioNTech Product in such country (the “**Royalty Term**” for such BioNTech Product and country).

(c) **Royalty Reports and Payment.** Within [***] Calendar Quarter, commencing with the Calendar Quarter during which the First Commercial Sale of any BioNTech Product is made anywhere in the Territory, BioNTech shall provide Genevant with a report that contains the following information for such period, on a BioNTech Product-by-BioNTech Product and country-by-country basis: (i) gross sales and Net Sales in the Territory; (ii) deductions from gross sales permitted pursuant to Section 1.95 (Net Sales) in a reasonable level of detail (by each subsection set forth in the definition of Net Sales); (iii) a calculation of the royalty payment due on Net Sales in the Territory; and (iv) the exchange rates used. BioNTech will pay Genevant all royalties owed with respect to Net Sales for such Calendar Quarter within thirty (30) days of its receipt of Genevant’s invoice for such royalties.

8.4 Royalty Adjustment for Third Party License Payments. If BioNTech, its Affiliates or Sublicensees, in their reasonable judgment, is required or determines it is reasonably necessary to make any payments to a Third Party for a license under any Patent to make, have

made, use, offer for sale, sell and/or import BioNTech Products in the BioNTech Field in any country in the Territory, then the amount of royalties payable under Section 8.3(a) (Royalty Rate) shall be reduced by [***] of the amount of any royalties paid to such Third Party on account of the sale of the BioNTech Products in such country in such Calendar Quarter; *provided, however*, that the royalties payable under Section 8.3(a) (Royalty Rate) shall not be reduced by more than [***] of the amounts set forth in Section 8.3(a) (Royalty Rate) by reason of the adjustment provided for in this Section 8.4 (Royalty Adjustment for Third Party License Payments).

8.5 Currency; Exchange Rate. All payments to be made by BioNTech to Genevant under this Agreement shall be made in Dollars by bank wire transfer in immediately available funds to a bank account designated by written notice from Genevant. If any currency conversion shall be required in connection with any payment hereunder, such conversion shall be made by in accordance with the currency conversion methodology generally applied by BioNTech in accordance with its group accounting practice provided such methodology is consistent with generally accepted accounting principles.

8.6 Late Payments. Late payments shall be subject to an interest charge of [***], or the maximum rate permitted by law, whichever is lower, which additional interest shall be compounded daily.

8.7 Financial Records and Audit. BioNTech shall (and shall ensure that its Affiliates and Sublicensees will) maintain complete and accurate records in sufficient detail to permit Genevant to confirm the accuracy of any royalty payments and other amounts payable under this Agreement and to verify the achievement of milestone events under this Agreement. Upon [***], such records shall be open for examination, during regular business hours, for a period of [***] from the end of the Calendar Year to which such records pertain, and not more often than once each Calendar Year, by an independent certified public accountant selected by Genevant and reasonably acceptable to BioNTech, for the sole purpose of verifying for Genevant the accuracy of the financial reports furnished by BioNTech under this Agreement or of any payments made, or required to be made, by BioNTech to Genevant pursuant to this Agreement. The independent certified public accountant shall disclose to Genevant only whether the audited reports are correct or incorrect and the specific details concerning any discrepancies. No other information shall be provided to Genevant. Genevant shall bear the full cost of such audit unless such audit reveals an underpayment by BioNTech of more than [***] percent ([***]%) of the amount actually due for any Calendar Year being audited, in which case BioNTech shall reimburse Genevant for the reasonable costs for such audit. BioNTech shall pay to Genevant any underpayment discovered by such audit within thirty (30) days after the accountant's report, plus interest (as set forth in Section 8.6 (Late Payments)) from the original due date. If the audit reveals an overpayment by BioNTech, then BioNTech may take a credit for such overpayment against any future payments due to Genevant.

8.8 Audit Dispute. If BioNTech disputes the results of any audit conducted pursuant to Section 8.7 (Financial Records and Audit), the Parties shall work in good faith to resolve the disagreement. If the Parties are unable to reach a mutually acceptable resolution of any such dispute within thirty (30) days, the dispute shall be submitted for resolution to a certified public accounting firm jointly selected by each Party's certified public accountants or to such other Person as the Parties shall mutually agree (the "Auditor"). The decision of the Auditor shall be final and the costs of such procedure as well as the initial audit shall be borne between the Parties in such manner as the Auditor shall determine. If the Auditor determines that there has been an underpayment by BioNTech, BioNTech shall pay to Genevant the underpayment within thirty (30)

days after the Auditor's decision, plus interest (as set forth in Section 8.6 (Late Payments)) from the original due date. If the Auditor determines that there has been an overpayment by BioNTech, then BioNTech may take a credit for such overpayment against any future payments due to Genevant.

ARTICLE 9 DEVELOPMENT AND MANUFACTURING OF CO-DEVELOPMENT PRODUCTS

9.1 General. Subject to the terms and conditions of this Agreement and as further set forth in the Co-Development Product Development Plan, BioNTech and Genevant shall be jointly responsible for the Development of the Co-Development Products in the Co-Development Field in the Territory.

9.2 Co-Development Product Development Plan. BioNTech and Genevant shall conduct all Development of Co-Development Products in the Co-Development Field in the Territory in accordance with a comprehensive development plan ("**Co-Development Product Development Plan**"), the initial version of which is set forth in Exhibit J. From time to time, but at least every [***], the Parties will update the Co-Development Product Development Plan to reflect any new planned Development activities with respect to Co-Development Products. The updated Co-Development Product Development Plan will be submitted to the JSC for review, discussion and approval. If the terms of the Co-Development Product Development Plan contradict, or create inconsistencies or ambiguities with, the terms of this Agreement, then the terms of this Agreement shall govern.

9.3 Conduct of Activities by Both Parties. To the extent such responsibility is allocated to it in the Co-Development Product Development Plan, each Party shall Develop Co-Development Products in the Co-Development Field in the Territory in compliance with all Applicable Laws, including good scientific and clinical practices under the Applicable Laws of the country in which such activities are conducted.

9.4 Records and Updates. The Parties shall maintain records, in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, which shall fully and properly reflect all work done and results achieved by or on behalf of each Party in the performance of Development activities pursuant to this Agreement. Each Party shall keep the JSC regularly informed of the status of all material Development activities including regulatory activities conducted with respect to Co-Development Products in the Co-Development Field in the Territory pursuant to this Agreement. Without limiting the foregoing, at least once every [***] beginning with [***] of the Calendar Year 2018 and at least every [***] thereafter, each Party shall provide the JSC or the other Party with summaries in reasonable detail of all data and results generated or obtained in the course of such Party's and its Affiliates' or Sublicensees' performance of activities with respect to Co-Development Products in the Co-Development Field in the Territory, covering subject matter at a level of detail reasonably requested by the other Party and sufficient to enable the other Party to determine the Party's compliance with its diligence obligations under Section 9.6 (Development Diligence).

9.5 Regulatory Filings. The Lead Commercialization Party will own all Regulatory Filings and Regulatory Approvals for Co-Development Products in the Co-Development Field in the Territory, unless otherwise agreed in writing by the JSC.

9.6 Development Diligence. Each Party, directly and/or with or through Affiliates or Sublicensees, shall use Commercially Reasonable Efforts to perform the activities allocated to it in the Co-Development Product Development Plan in order to Develop, and to obtain Regulatory Approval for the Co-Development Products in the Co-Development Field in the Territory.

9.7 Compliance. Each Party agrees that in performing its obligations under this Agreement: (a) it shall comply with all Applicable Laws; and (b) it will not employ or engage any Person who has been debarred or disqualified by any Regulatory Authority, or, to its knowledge, is the subject of debarment or disqualification proceedings by a Regulatory Authority.

9.8 Rights of Reference. Each Party will have the right to use and reference all Regulatory Filings (including data contained therein) and Regulatory Approvals for the BioNTech Products as part of Development of the Co-Development Products. In addition, BioNTech will have the right to use and reference all Regulatory Filings (including data contained therein) and Regulatory Approvals for Co-Development Products as part of Development of the BioNTech Products

9.9 Remedial Actions. Each Party will notify the other Party without undue delay (and in any event within timelines set by Applicable Law), and promptly confirm such notice in writing, if it obtains information indicating that a Co-Development Product may be subject to any Remedial Action. The Parties will assist each other in gathering and evaluating such information as is necessary to determine the necessity of conducting a Remedial Action. The Parties shall, and shall ensure that their Affiliates and Sublicensees will, maintain adequate records to permit the Parties to trace the Manufacture, distribution and use of the Co-Development Products. The JSC will decide any matters relating to any Remedial Action with respect to any Co-Development Product in the Co-Development Field in the Territory, including the decision to commence such Remedial Action and the control over the conduct of such Remedial Action. To the extent a Remedial Action is caused by a Party's failure to comply with the terms of this Agreement, such Party shall bear the costs of such Remedial Action. In all other event, the costs of the Remedial Action shall be allocated in accordance with profit and loss sharing pursuant to Section 10.4 (Profit or Loss).

9.10 Co-Development Product Pharmacovigilance. At least sixty (60) days prior to the filing of an IND for any Co-Development Product, the Parties shall define and finalize the actions that the Parties shall employ with respect to the Co-Development Products to protect patients and promote their well-being in a written pharmacovigilance agreement (the "**Co-Development Product Pharmacovigilance Agreement**"). The Lead Commercialization Party will be the global safety database holder for each Co-Development Product. These responsibilities shall include mutually acceptable guidelines and procedures for the receipt, investigation, recordation, communication, and exchange (as between the Parties) of adverse event reports and any other information concerning the safety of the Co-Development Products. Such guidelines and procedures shall be in accordance with, and enable the Parties to fulfill, local and national regulatory reporting obligations under applicable laws and regulations. Each Party hereby agrees to comply with its respective obligations under such Co-Development Product Pharmacovigilance Agreement and to cause its Affiliates and Sublicensees to comply with such obligations. The Party responsible for the global safety database will maintain the global safety database pursuant to its own policy and as necessary to comply with Applicable Laws governing adverse experiences in the Territory.

9.11 Manufacturing Responsibilities. Unless otherwise determined by the JSC, Genevant shall be solely responsible for all preclinical, clinical and commercial Manufacture and

supply of all Co-Development Products for all uses under this Agreement. BioNTech will supply to Genevant all Co-Development mRNA Payloads for such Manufacture. The Manufacturing Expenses for Co-Development mRNA Payloads Manufactured for preclinical or clinical use will be included in Development Costs and the Manufacturing Expenses for Co-Development mRNA Payloads Manufactured for commercial use will be included in Allowable Expenses. Genevant may conduct such Manufacturing activities itself or through a Third Party CMO under Genevant's control, subject to Section 4.9 (Subcontractor). Within a reasonable time after the Effective Date, the Parties will execute one or more supply agreements to govern (i) the Manufacturing and supply of Co-Development Products by Genevant or the Third Party CMO selected and controlled by Genevant ("**Co-Development Product Supply Agreement**") and (ii) the Manufacturing and supply of Co-Development mRNA Payloads by BioNTech.

9.12 Costs of Joint Development.

(a) **Cost Sharing.** Development Costs for Co-Development Products incurred during the Term by the Parties shall be borne 50% by Genevant and 50% by BioNTech. For the avoidance of double-counting, the Parties acknowledge and agree that Development Costs shall not include Allowable Expenses for purposes of calculating Profit or Loss in accordance with Section 10.4 (Profit or Loss) and, likewise, that any amounts included in Allowable Expenses shall not be included in Development Costs.

(b) **Development Costs Reports.** Development Costs shall initially be borne by the Party incurring the cost or expense, subject to reimbursement as provided in Section 9.12(c) (Reimbursement of Development Costs). Each Party shall calculate and maintain records of Development Costs incurred by it and its Affiliates, in coordination with the JSC, and the procedures for monthly reporting of actual results, monthly review and discussion of potential discrepancies, quarterly reconciliation, reasonable cost forecasting, and other finance and accounting matters related to Development Costs will be determined by the JSC (the "**Development Reconciliation Procedures**"). Such procedures will provide the ability to comply with financial reporting requirements of each Party. The Development Reconciliation Procedures shall provide that within fifteen (15) days after the end of each Calendar Quarter, each Party shall submit to the Joint Financial Subcommittee of the JSC a report, in such reasonable detail and format as is established by the Joint Financial Subcommittee of all Development Costs incurred by such Party during such Calendar Quarter. Within fourteen (14) days following the receipt of such report, each Party shall have the right to request reasonable additional information related to the other Party's and its Affiliates' Development Costs during such Calendar Quarter in order to confirm that such other Party's spending conforms with the approved budget. The Joint Financial Subcommittee shall establish reasonable procedures for the Parties to share estimated Development Costs for each Calendar Quarter prior to the end of such Calendar Quarter, to enable each Party to appropriately accrue its share of Development Costs for financial reporting purposes, which shall include submission by each Party to the Joint Financial Subcommittee of the JSC, [***], all Development Costs incurred by such Party [***] in such reasonable detail and format as is established by the Joint Financial Subcommittee.

(c) Reimbursement of Development Costs.

(i) The Party (with its Affiliates) that incurs more than its share of the total actual Development Costs for the Co-Development Products shall be paid by the other Party an amount of cash sufficient to reconcile to its agreed percentage of actual Development Costs in each Calendar Quarter. Notwithstanding the foregoing, on a Calendar Year-to-date basis, the

Parties shall not share any Development Costs in excess of the amounts allocated for such Calendar Year-to-date period in the budget approved by the JSC; provided, however, that Development Costs in excess of the such budget shall be included in the calculation of Development Costs to be shared by the Parties if (i) the JSC approves such excess Development Costs (either before or /after they are incurred), which approval shall not be unreasonably withheld to the extent the Development Costs in excess of the budget were not within the reasonable control of the Party (or Affiliate) incurring such expense or (ii) to the extent such excess Development Costs do not exceed by more than 10% the total Development Costs allocated to be incurred by such Party and its Affiliates in the applicable Calendar Year-to-date period in accordance with the applicable budget for such Calendar Year. If any excess Development Costs are excluded from sharing by the Parties for a particular Calendar Year-to-date period pursuant to the foregoing sentence, such excess Development Costs shall be carried forward to the subsequent Calendar Quarters (provided that such Calendar Quarters fall within the same Calendar Year) and, to the extent the total Development Costs incurred by such Party and its Affiliates for the Calendar Year-to-date as of the end of such subsequent Calendar Quarter are less than 110% of the aggregate Development Costs allocated to such Party under the budget for such Calendar Year-to-date period, such carried forward amounts shall be included in Development Costs to be shared by the Parties for such Calendar Year-to-date-period (i.e., so that the total Development Costs incurred by such Party and its Affiliates that are shared pursuant to this Section 9.12 (Costs of Joint Development) during any Calendar Year do not exceed 110% of the Development Costs allocated to such Party under the budget for such Calendar Year, unless otherwise approved by the JSC).

(ii) The Development Reconciliation Procedures shall provide for the JSC to develop a written report setting forth in reasonable detail the calculation of any net amount owed by one Party to the other, as necessary to accomplish the sharing of Development Costs as well as any reimbursement payments that become due from one Party to the other during such Calendar Quarter, and to prepare such reports promptly following delivery of the report described in Section 9.12(b) (Development Costs Reports) and in a reasonable time (to be defined in the Development Reconciliation Procedures) in advance of payment. The net amount payable to accomplish the sharing of Development Costs as provided under this Agreement shall be paid by Genevant or BioNTech, as the case may be, within sixty (60) days after the end of the applicable Calendar Quarter.

(iii) Sections 8.5 to 8.8 shall apply mutatis mutandis to the payment or reimbursement of Development Costs pursuant to this Section 9.12 (Costs of Joint Development).

ARTICLE 10 COMMERCIALIZATION; PROFIT/LOSS SHARING

10.1 General. The Parties have defined in Exhibit B per Co-Development Product which Party shall take the lead responsibility for the Commercialization of such Co-Development Product in the relevant Co-Development Field in the Territory (such Party the “**Lead Commercialization Party**”).

10.2 Commercialization Plan and Report. Within a reasonable time (but no later than [***] prior to the first anticipated Regulatory Approval of a Co-Development Product in each country in the Territory, the Parties shall prepare and provide to the JSC for approval a plan for the Commercialization (including marketing, promotion, or joint co-promotion by the Parties, booking of revenues and pricing) of such Co-Development Products in the relevant Co-Development Field in such country during the [***] after First Commercial Sale in such country,

which plan shall be reasonable in scope and detail and may be amended by the Parties (the “**Co-Development Product Commercialization Plan**” for such country). The Parties shall update each Commercialization Plan [***] (to cover the subsequent [***] period) and shall promptly provide each such update and any material amendments to each Commercialization Plan to the JSC. On an annual basis commencing on the First Commercial Sale of any Co-Development Product anywhere in the Territory, the Parties shall provide the JSC with a report detailing their Commercialization activities with respect to Co-Development Products in the previous [***] period, covering subject matter at a level of detail reasonably requested by the JSC.

10.3 Commercialization Diligence. Each Party, directly and/or with or through Affiliates or Sublicensees, shall use Commercially Reasonable Efforts to perform the activities allocated to it in the Co-Development Product Commercialization Plan and/or by the JSC in order to Commercialize the Co-Development Products in the Co-Development Field in the Territory.

10.4 Profit or Loss. The Parties shall share in the Profit or Loss for Co-Development Products in the Territory as follows: BioNTech shall bear (and be entitled to) 50%, and Genevant shall bear (and be entitled to) 50%. The procedure for calculating Profit or Loss for Co-Development Products is set forth in Exhibit F. The Joint Financial Subcommittee shall establish reasonable procedures to enable each Party to comply with its financial reporting requirements related to its share of Profit or Loss, which shall include submission by each Party to the Joint Financial Subcommittee of the JSC a report, within fifteen (15) days after the end of each Calendar Quarter [***], commencing with the Calendar Quarter during which the First Commercial Sale of any Co-Development Product is made anywhere in the Territory, its Net Sales of Co-Development Products, any Other Income and the Allowable Expenses incurred during such period, in each case in such reasonable detail and format as is established by the Joint Financial Subcommittee. To the extent any other matter relating to calculating Profit or Loss for Co-Development Products is not explicitly addressed in Exhibit F it will be determined by the JSC. Sections 8.5 to 8.8 shall apply mutatis mutandis to the payment of profits or losses pursuant to this Section 10.4.

ARTICLE 11 INTELLECTUAL PROPERTY RIGHTS

11.1 Ownership.

(a) **Ownership of Sole Inventions.** Ownership of all Sole Inventions shall be based on inventorship, as determined in accordance with the rules of inventorship under United States patent laws. Genevant shall solely own any Genevant Sole Inventions and BioNTech shall solely own any BioNTech Sole Inventions.

(b) **Disclosure of Inventions.** Genevant shall promptly disclose to BioNTech all Sole Inventions that are related to BioNTech Products. In addition, each Party shall promptly disclose to the other Party (i) all Sole Inventions that are related to Co-Development Products and (ii) all Joint Inventions. For the avoidance of doubt, all such Invention disclosure shall include any invention disclosures or other similar documents submitted by its respective employees, agents or independent contractors describing such Inventions, and shall promptly respond to reasonable requests from the other Party for additional information relating to such Inventions.

(c) **Joint Patent Committee.** Within thirty (30) days after the Effective Date, the Parties shall establish a Joint Patent Committee (the “**Joint Patent Committee**” or the “**JPC**”), composed of two (2) representatives of each Party. Any Invention that a Party believes is a Joint

Invention will be brought to the attention of the JPC. The JPC will first determine if the Invention is a Joint Invention and, if so, whether patent protection should be filed for such Joint Invention. If the JPC determines that the Invention is a Sole Invention, then ownership of the Invention will be as set forth in Section 11.1(a) (Ownership of Sole Inventions). If the JPC determines that the Invention is a Joint Invention, then the JPC will determine whether the Joint Invention shall be solely owned by BioNTech (“**BioNTech Joint Inventions**”), solely owned by Genevant (“**Genevant Joint Inventions**”), or jointly owned by both Parties (“**Co-Owned Joint Inventions**”). Such determination will be made based on the Parties relative contributions to the Joint Invention and the degree to which the Joint Invention is an improvement on any pre-existing BioNTech Technology or Genevant Technology. All Patents claiming BioNTech Joint Inventions shall be referred to herein as “**BioNTech Joint Patents**.” All Patents claiming Genevant Joint Inventions shall be referred to herein as “**Genevant Joint Patents**.” All Patents claiming Co-Owned Joint Inventions shall be referred to herein as “**Co-Owned Joint Patents**.” Genevant agrees to assign, and hereby assigns, to BioNTech its entire right, title, and interest in and to all BioNTech Joint Inventions and BioNTech Joint Patents. BioNTech agrees to assign, and hereby assigns, to Genevant its entire right, title, and interest in and to all Genevant Joint Inventions and Genevant Joint Patents. The JPC may also be used by the Parties to coordinate any other activities of the Parties under this Article 11 (Intellectual Property Rights). If the JPC is unable to agree on any matter in this Section 11.1(c) (Joint Patent Committee), then any such disagreement shall be referred to the Executive Officers for resolution, who shall use good faith efforts to resolve such matter within [***] after it is referred to them.

(d) **Use of Joint Inventions.** Subject to the exclusive licenses granted in Article 2 (Licenses) above, each Party shall be entitled to use and commercialize (including granting licenses to Third Parties) itself any BioNTech Joint Inventions, Genevant Joint Inventions, Co-Owned Joint Inventions, BioNTech Joint Patents, Genevant Joint Patents, and Co-Owned Joint Patents in any field in any country without any payment obligation to the other Party. Notwithstanding the above, either Party may only grant a license to a Third Party under any BioNTech Joint Inventions, Genevant Joint Inventions, Co-Owned Joint Inventions, BioNTech Joint Patents, Genevant Joint Patents, or Co-Owned Joint Patents with the prior written consent of the other Party, such consent not to be unreasonably withheld. In the event one Party desires to grant a license under any BioNTech Joint Inventions, Genevant Joint Inventions, Co-Owned Joint Inventions, BioNTech Joint Patents, Genevant Joint Patents, or Co-Owned Joint Patents to any Third Party, such Party shall inform the other Party thereof by disclosing to other Party the relevant licensee as well as the licensed field. BioNTech hereby expressly consents to the grant by Genevant to [***] of a license under Genevant’s shares in the BioNTech Joint Inventions, Genevant Joint Inventions, Co-Owned Joint Inventions, BioNTech Joint Patents, Genevant Joint Patents, or Co-Owned Joint Patents consistent with Genevant’s obligations under the [***] Agreement.

11.2 Patent Prosecution and Maintenance.

(a) **BioNTech Patents and Genevant Patents.** BioNTech shall have the sole right, but not the obligation, to control the preparation, filing, prosecution (including any interferences, reissue proceedings and reexaminations) and maintenance of all BioNTech Patents (excluding Co-Owned Joint Patents) worldwide, at its sole cost and expense and by counsel of its own choice. Genevant shall have the sole right, but not the obligation, to control the preparation, filing, prosecution (including any interferences, reissue proceedings and reexaminations) and maintenance of all Genevant Patents (excluding Co-Owned Joint Patents) worldwide, at its sole cost and expense and by counsel of its own choice.

(b) Co-Owned Joint Patents.

(i) Genevant shall have the first right, but not the obligation, to control the preparation, filing, prosecution (including any interferences, reissue proceedings and reexaminations) and maintenance of all Co-Owned Joint Patents (except Co-Owned Joint Patents that relate primarily to BioNTech Products), at its sole cost and expense and by counsel selected by Genevant and reasonably acceptable to BioNTech. Genevant shall consult with BioNTech and keep BioNTech reasonably informed of the status of such Patents and shall promptly provide BioNTech with all material correspondence received from any patent authority in connection therewith. In addition, Genevant shall promptly provide BioNTech with drafts of all proposed material filings and correspondence to any patent authority with respect to such Patents for BioNTech's review and comment prior to the submission of such proposed filings and correspondence. Genevant shall confer with BioNTech and consider in good faith BioNTech's comments prior to submitting such filings and correspondence, provided that BioNTech provides such comments within fourteen (14) days (or a shorter period reasonably designated by Genevant if fourteen (14) days is not practicable given the filing deadline) of receiving the draft filings and correspondence from Genevant. In the event that Genevant desires to abandon or cease prosecution or maintenance of any such Patent in any country or jurisdiction, Genevant shall provide reasonable prior written notice to BioNTech of such intention to abandon (which notice shall, to the extent possible, be given no later than [***] prior to the next deadline for any action that must be taken with respect to any such Patent in the relevant patent office). In such case, upon BioNTech's written election provided no later than [***] after such notice from Genevant, BioNTech shall have the right to assume prosecution and maintenance of such Patent at BioNTech's expense. If BioNTech does not provide such election within [***] after such notice from Genevant, Genevant may, in its sole discretion, continue prosecution and maintenance of such Patent or discontinue prosecution and maintenance of such Patent.

(ii) BioNTech shall have the first right, but not the obligation, to control the preparation, filing, prosecution (including any interferences, reissue proceedings and reexaminations) and maintenance of Co-Owned Joint Patents that relate primarily to BioNTech Products, at its sole cost and expense and by counsel selected by BioNTech and reasonably acceptable to Genevant. BioNTech shall consult with Genevant and keep Genevant reasonably informed of the status of such Patents and shall promptly provide Genevant with all material correspondence received from any patent authority in connection therewith. In addition, BioNTech shall promptly provide Genevant with drafts of all proposed material filings and correspondence to any patent authority with respect to such Patents for Genevant's review and comment prior to the submission of such proposed filings and correspondence. BioNTech shall confer with Genevant and consider in good faith Genevant's comments prior to submitting such filings and correspondence, provided that Genevant provides such comments within fourteen (14) days (or a shorter period reasonably designated by BioNTech if fourteen (14) days is not practicable given the filing deadline) of receiving the draft filings and correspondence from BioNTech. In the event that BioNTech desires to abandon or cease prosecution or maintenance of any such Patent in any country or jurisdiction, BioNTech shall provide reasonable prior written notice to Genevant of such intention to abandon (which notice shall, to the extent possible, be given no later than [***] prior to the next deadline for any action that must be taken with respect to any such Patent in the relevant patent office). In such case, upon Genevant's written election provided no later than [***] after such notice from BioNTech, Genevant shall have the right to assume prosecution and maintenance of such Patent at Genevant's expense. If Genevant does not provide such election within [***] after such notice from BioNTech, BioNTech may, in its sole discretion, continue prosecution and maintenance of such Patent or discontinue prosecution and maintenance of such Patent.

11.3 Cooperation of the Parties. Each Party agrees to cooperate fully in the preparation, filing, prosecution and maintenance of Patents under Section 11.2 (Patent Prosecution and Maintenance), at its own cost. Such cooperation includes: (a) executing all papers and instruments, or requiring its employees or contractors, to execute such papers and instruments, so as enable the other Party to apply for and to prosecute patent applications in any country as permitted by Section 11.2 (Patent Prosecution and Maintenance); and (b) promptly informing the other Party of any matters coming to such Party's attention that may affect the preparation, filing, prosecution or maintenance of any such patent applications.

11.4 Infringement by Third Parties.

(a) **Notice.** In the event that either Genevant or BioNTech becomes aware of (i) any infringement or threatened infringement by a Third Party of any Genevant Patent, BioNTech Patent, Genevant Joint Patent, BioNTech Joint Patent, or Co-Owned Joint Patent in the Territory, which infringing activity involves the using, making, importing, offering for sale or selling of a product competing with a BioNTech Product or Co-Development Product (regardless of whether or not a Party is currently Developing using, making, importing, offering for sale, selling, or otherwise Commercializing the same BioNTech Product or Co-Development Product), or the submission to a Party or a Regulatory Authority in the Territory of an application for a product referencing a BioNTech Product or Co-Development Product, or any declaratory judgment or equivalent action (including an action before the U.S. Patent and Trademark Office such as an inter partes review) challenging any Genevant Patent, BioNTech Patent, Genevant Joint Patent, BioNTech Joint Patent, or Co-Owned Joint Patent in connection with any such infringement (each, a "**BioNTech Product Infringement**" or a "**Co-Development Product Infringement**," as applicable), or (ii) any infringement or threatened infringement by a Third Party of any Co-Owned Joint Patent, which infringing activity is unrelated to a BioNTech Product or a Co-Development Product, it will promptly notify the other Party in writing to that effect. Any such notice shall include evidence to support an allegation of infringement or threatened infringement, or declaratory judgment or equivalent action, by such Third Party.

(b) Enforcement of Patents against BioNTech Product Infringements.

(i) BioNTech Patents and Co-Owned Joint Patents. BioNTech shall have the sole right, as between Genevant and BioNTech, but not the obligation, to bring an appropriate suit or take other action against any Person or entity engaged in, or to defend against, a BioNTech Product Infringement of any BioNTech Patent or Co-Owned Joint Patent at its own expense and by counsel of its own choice. Notwithstanding the above, if in the event of the filing of any declaratory judgment or equivalent action (including an action before the U.S. Patent and Trademark Office such as an inter partes review) challenging any Co-Owned Joint Patent, BioNTech does not inform Genevant of an intent to defend such action with respect to such Co-Owned Joint Patent within (A) [***] days following the notice of such action or (B) [***] days before the time limit, if any, set forth in the appropriate laws and regulations for responding to such action, whichever comes first, Genevant shall have the right, but not the obligation, to bring and control the defense of any such action at its own expense and by counsel of its own choice, and BioNTech shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. If such declaratory judgment or action challenging an Co-Owned Joint Patent was brought in response to BioNTech initiating a suit or other action or otherwise making

a claim for a BioNTech Product Infringement or if BioNTech initiates a suit or other action for a BioNTech Product Infringement in response to such challenge to an Co-Owned Joint Patent, then BioNTech will reimburse Genevant for all costs, expenses, and fees (including attorney's fees) spent defending such action.

(ii) Genevant Patents. Genevant shall have the first right, as between Genevant and BioNTech, but not the obligation, to bring an appropriate suit or take other action against any Person or entity engaged in, or to defend against, a BioNTech Product Infringement of any Genevant Patent at its own expense and by counsel of its own choice. BioNTech shall have the right, at its own expense, to be represented in any such action by counsel of its own choice, and Genevant and its counsel will reasonably cooperate with BioNTech and its counsel in strategizing, preparing and prosecuting any such action or proceeding. If Genevant fails to bring an action or proceeding with respect to such BioNTech Product Infringement of any Genevant Patent within (A) [***] days following the notice of alleged infringement or declaratory judgment or (B) [***] days before the time limit, if any, set forth in the appropriate laws and regulations for the filing of such actions, whichever comes first, BioNTech shall have the right, but not the obligation, to bring and control any such action at its own expense and by counsel of its own choice, and Genevant shall have the right, at its own expense, to be represented in any such action by counsel of its own choice.

(iii) Recovery. Except as otherwise agreed by the Parties as part of a cost-sharing arrangement, any recovery or damages realized as a result of any action or proceeding with respect to any BioNTech Product Infringement shall be used first to reimburse the Parties' documented out-of-pocket legal expenses relating to the action or proceeding, and any remaining damages relating to BioNTech Product Infringement (including lost sales or lost profits) shall be retained by the Party responsible for the action or proceeding except that any remaining damages retained by BioNTech shall be deemed to be Net Sales subject to royalty payments to Genevant in accordance with the royalty provisions of Section 8.3 (Royalty Payments).

(c) Enforcement of Patents against Co-Development Product Infringements.

(i) Genevant shall have the first right, as between Genevant and BioNTech, but not the obligation, to bring an appropriate suit or take other action against any Person or entity engaged in, or to defend against, a Co-Development Product Infringement of any Genevant Patent or Co-Owned Joint Patent at its own expense and by counsel of its own choice. BioNTech shall have the right, at its own expense, to be represented in any such action by counsel of its own choice, and Genevant and its counsel will reasonably cooperate with BioNTech and its counsel in strategizing, preparing and prosecuting any such action or proceeding. If Genevant fails to bring an action or proceeding with respect to such Co-Development Product Infringement of any Genevant Patent or Co-Owned Joint Patent within (A) [***] days following the notice of alleged infringement or declaratory judgment or (B) [***] days before the time limit, if any, set forth in the appropriate laws and regulations for the filing of such actions, whichever comes first, BioNTech shall have the right, but not the obligation, to bring and control any such action at its own expense and by counsel of its own choice, and Genevant shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. Except as otherwise agreed by the Parties as part of a cost-sharing arrangement, any recovery or damages realized as a result of such action or proceeding with respect to such Co-Development Product Infringement of any Genevant Patent or Co-Owned Joint Patent shall be used first to reimburse the Parties' documented out-of-pocket legal expenses relating to the action or proceeding, and any remaining

compensatory and punitive damages relating to such Co-Development Product Infringement of a Genevant Patent or Co-Owned Joint Patent (including lost sales or lost profits) shall be deemed to be Net Sales subject to the sharing of profits in accordance with the provisions of Section 10.4 (Profit or Loss).

(ii) BioNTech shall have the first right, as between Genevant and BioNTech, but not the obligation, to bring an appropriate suit or take other action against any Person or entity engaged in, or to defend against, a Co-Development Product Infringement of any BioNTech Patent at its own expense and by counsel of its own choice. Genevant shall have the right, at its own expense, to be represented in any such action by counsel of its own choice, and BioNTech and its counsel will reasonably cooperate with Genevant and its counsel in strategizing, preparing and prosecuting any such action or proceeding. If BioNTech fails to bring an action or proceeding with respect to such Co-Development Product Infringement of any BioNTech Patent within (A) [***] days following the notice of alleged infringement or declaratory judgment or (B) [***] days before the time limit, if any, set forth in the appropriate laws and regulations for the filing of such actions, whichever comes first, Genevant shall have the right, but not the obligation, to bring and control any such action at its own expense and by counsel of its own choice, and BioNTech shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. Except as otherwise agreed by the Parties as part of a cost-sharing arrangement, any recovery or damages realized as a result of such action or proceeding with respect to such Co-Development Product Infringement of any BioNTech Patent shall be used first to reimburse the Parties' documented out-of-pocket legal expenses relating to the action or proceeding, and any remaining damages relating to such Co-Development Product Infringement of a BioNTech Patent (including lost sales or lost profits) shall be deemed to be Net Sales subject to the sharing of profits in accordance with the provisions of Section 10.4 (Profit or Loss).

(d) Enforcement of Co-Owned Joint Patents against Infringements unrelated to BioNTech Products or Co-Development Products

(i) Genevant shall have the first right, as between Genevant and BioNTech, but not the obligation, to bring an appropriate suit or take other action against any Person or entity engaged in, or to defend against, an infringement of any Co-Owned Joint Patent, if such infringing activity is unrelated to a BioNTech Product or a Co-Development Product and occurs in any field other than the BioNTech Field, at its own expense and by counsel of its own choice. BioNTech shall have the right, at its own expense, to be represented in any such action by counsel of its own choice, and Genevant and its counsel will reasonably cooperate with BioNTech and its counsel in strategizing, preparing and prosecuting any such action or proceeding. If Genevant fails to bring an action or proceeding with respect to such infringement within (A) [***] days following the notice of alleged infringement or declaratory judgment or (B) [***] days before the time limit, if any, set forth in the appropriate laws and regulations for the filing of such actions, whichever comes first, BioNTech shall have the right, but not the obligation, to bring and control any such action at its own expense and by counsel of its own choice, and Genevant shall have the right, at its own expense, to be represented in any such action by counsel of its own choice.

(ii) BioNTech shall have the first right, as between Genevant and BioNTech, but not the obligation, to bring an appropriate suit or take other action against any Person or entity engaged in, or to defend against, an infringement of any Co-Owned Joint Patent, if such infringing activity is unrelated to a BioNTech Product or a Co-Development Product and occurs in the BioNTech Field, at its own expense and by counsel of its own choice. Genevant shall have the right, at its own expense, to be represented in any such action by counsel of its own

choice, and BioNTech and its counsel will reasonably cooperate with Genevant and its counsel in strategizing, preparing and prosecuting any such action or proceeding. If BioNTech fails to bring an action or proceeding with respect to such infringement within (A) [***] days following the notice of alleged infringement or declaratory judgment or (B) [***] days before the time limit, if any, set forth in the appropriate laws and regulations for the filing of such actions, whichever comes first, Genevant shall have the right, but not the obligation, to bring and control any such action at its own expense and by counsel of its own choice, and Genevant shall have the right, at its own expense, to be represented in any such action by counsel of its own choice.

(e) **Cooperation.** In the event a Party brings an action in accordance with this Section 11.4, the other Party shall cooperate fully, including, if required to bring such action, the furnishing of a power of attorney or being named as a party to such action.

11.5 Infringement of Third Party Rights.

(a) Each Party shall promptly notify the other in writing of any allegation by a Third Party that the Manufacture, Development, importation, use, marketing, offer for sale, or sale of any BioNTech Product or Co-Development Product in the Territory infringes or may infringe the intellectual property rights of a Third Party.

(b) If a Third Party asserts that any of its Patents or other rights are infringed by the Manufacture, Commercialization or Development by BioNTech or its Affiliates of any BioNTech Product in the Territory, BioNTech shall have the sole right but not the obligation to defend against any such assertions at its sole cost and expense. Genevant shall cooperate fully and shall provide full access to documents, information and witnesses as reasonably requested by BioNTech in connection with such defense. BioNTech will reimburse to Genevant all Third Party costs incurred in connection with such requested cooperation.

(c) If a Third Party asserts that any of its Patents or other rights are infringed by the Manufacture, Commercialization or Development by either Party or its Affiliates of any Co-Development Product in the Territory, the Parties shall jointly defend against any such assertions and share equally the costs and expenses of such defense.

11.6 Consent for Settlement. Neither Party shall unilaterally enter into any settlement or compromise of any action or proceeding under this Article 11 (Intellectual Property Rights) that would in any manner alter, diminish, or be in derogation of the other Party's rights under this Agreement without the prior written consent of such other Party, which shall not be unreasonably withheld.

11.7 Patent Extensions. The JSC will make all decisions concerning patent term restoration, supplemental protection certificates or their equivalents, and patent term extensions with respect to the BioNTech Patents, Genevant Patents, and Co-Owned Joint Patents in any country in the Territory where applicable with respect to Co-Development Products.

11.8 Trademarks. The JSC will determine who shall own and be responsible for all trademarks, trade names, branding or logos related to Co-Development Products in the Co-Development Field in the Territory.

11.9 Delegation to [*]** BioNTech understand and agrees that, to the extent required by the [***] Agreement, Genevant may permit [***] to exercise any of Genevant's rights under this Article 11 (Intellectual Property Rights) with respect to the Genevant Patents.

ARTICLE 12 CONFIDENTIALITY; PUBLICATION

12.1 Duty of Confidence. Subject to the other provisions of this Article 12 (Confidentiality; Publication):

(a) all Confidential Information disclosed by a Party (the "**Disclosing Party**") or its Affiliates under this Agreement will be maintained in confidence and otherwise safeguarded by the recipient Party (the "**Receiving Party**") and its Affiliates using at least the same standard of care as the Receiving Party uses to protect its own proprietary or Confidential Information (but in no event less than reasonable care);

(b) the Receiving Party may only use any such Confidential Information for the purposes of performing its obligations or exercising its rights under this Agreement; and

(c) the Receiving Party may disclose Confidential Information of the Disclosing Party only to: (i) the Receiving Party's Affiliates; and (ii) employees, directors, agents, contractors, consultants and advisers of the Receiving Party and its Affiliates, in each case to the extent reasonably necessary for the purposes of, and for those matters undertaken pursuant to, this Agreement; *provided*, that such Persons are bound to maintain the confidentiality, and not to make any unauthorized use, of the Confidential Information in a manner consistent with this Article 12 (Confidentiality; Publication).

12.2 Exceptions. The foregoing obligations as to particular Confidential Information of a Disclosing Party shall not apply to the extent that the Receiving Party can demonstrate by competent evidence that such Confidential Information:

(a) is known by the Receiving Party at the time of its receipt, and not through a prior disclosure by the Disclosing Party, as shown by contemporaneous written documents of the Receiving Party;

(b) is in the public domain by use and/or publication before its receipt from the Disclosing Party, or thereafter enters the public domain through no fault of, or breach of this Agreement by, the Receiving Party;

(c) is subsequently disclosed to the Receiving Party on a non-confidential basis by a Third Party who may lawfully do so and is not under an obligation of confidentiality to the Disclosing Party; or

(d) is developed by the Receiving Party independently and without use of or reference to any Confidential Information disclosed to it by or on behalf of the Disclosing Party, as shown by contemporaneous written documents of the Receiving Party.

12.3 Authorized Disclosures. Notwithstanding the obligations set forth in Section 12.1 (Duty of Confidence), the Receiving Party may disclose Confidential Information of the Disclosing Party and the terms of this Agreement to the extent such disclosure is reasonably necessary in the following instances:

- (a) filing or prosecuting of Patents as permitted by this Agreement;
- (b) enforcing the Receiving Party's rights under this Agreement or performing the Receiving Party's obligations under this Agreement;
- (c) in Regulatory Filings that such Party has the right to file under this Agreement;
- (d) prosecuting or defending litigation as permitted by this Agreement;

(e) to the Receiving Party's directors, Affiliates, actual or potential Sublicensees, commercial partners, independent contractors, consultants, attorneys, independent accountants or financial advisors who, in each case, have a need to know such Confidential Information in order for the Receiving Party to exercise its rights or fulfill its obligations under this Agreement, *provided*, in each case, that any such Person agrees to be bound by terms of confidentiality and non-use (or, in the case of the Receiving Party's attorneys and independent accountants, such Person is obligated by applicable professional or ethical obligations) at least as restrictive as those set forth in this Article 12 (Confidentiality; Publication);

(f) to actual or potential investors, investment bankers, lenders, other financing sources or acquirors (and attorneys and independent accountants thereof) in connection with potential investment, acquisition, collaboration, merger, public offering, due diligence or similar investigations by such Third Parties or in confidential financing documents, *provided*, in each case, that any such Third Party agrees to be bound by terms of confidentiality and non-use (or, in the case of the Receiving Party's attorneys and independent accountants, such Third Party is obligated by applicable professional or ethical obligations) that are no less stringent than those contained in this Agreement (except to the extent that a shorter confidentiality period is customary in the industry); and

(g) such disclosure is required by court order, judicial or administrative process or Applicable Law, *provided* that in such event the Receiving Party shall promptly inform the Disclosing Party of such required disclosure and provide the Disclosing Party an opportunity to challenge or limit the disclosure obligations. Confidential Information that is disclosed as required by court order, judicial or administrative process or Applicable Law shall remain otherwise subject to the confidentiality and non-use provisions of this Article 12 (Confidentiality; Publication), and the Receiving Party shall take all steps reasonably necessary, including seeking of confidential treatment or a protective order, to ensure the continued confidential treatment of such Confidential Information.

12.4 Publication in relation to BioNTech Products. Genevant shall not publish nor otherwise publicly disclose any data or results regarding any BioNTech Product without the prior written consent of BioNTech. Prior to publishing the results of any studies carried out by Genevant in relation to BioNTech Products under this Agreement, BioNTech shall provide Genevant with the opportunity to review and comment on the proposed publication at least thirty (30) days prior to its intended submission for publication. BioNTech shall: (i) consider in good faith any comments thereto provided by Genevant within such thirty (30) day period; and (ii) remove any Confidential Information of Genevant identified by Genevant as part of its review.

12.5 Publication in relation to Co-Development Products. Neither Party shall publish or otherwise publicly disclose any data or results regarding any Co-Development Products without the prior written consent of the other Party.

12.6 Publicity/Use of Names. No disclosure of the existence, or the terms, of this Agreement may be made by either Party or its Affiliates, and neither Party shall use the name, trademark, trade name or logo of the other Party, its Affiliates or their respective employee(s) in any publicity, promotion, news release or disclosure relating to this Agreement or its subject matter, without the prior express written permission of the other Party, except as may be required by law. Notwithstanding the above, each Party and its Affiliates may disclose on its website and in its promotional materials that the other Party is a development partner of such Party for the BioNTech Products and may use the other Party's name and logo in conjunction with such disclosure.

(a) A Party may disclose this Agreement and its terms, and material developments or material information generated under this Agreement, in securities filings with the U.S. Securities and Exchange Commission ("SEC") (or equivalent foreign agency) to the extent required by law after complying with the procedure set forth in this Section 12.6 (Publicity/Use of Names). In such event, the Party seeking to make such disclosure will, to the extent and permitted under Applicable Law, prepare a draft confidential treatment request and proposed redacted version of this Agreement to request confidential treatment for this Agreement, and the other Party agrees to promptly (and in any event, [***] days after receipt of such confidential treatment request and proposed redactions) give its input in a reasonable manner in order to allow the Party seeking disclosure to file its request within the time lines prescribed by applicable SEC regulations. The Party seeking such disclosure shall exercise Commercially Reasonable Efforts to obtain confidential treatment of this Agreement from the SEC (or equivalent foreign agency) as represented by the redacted version reviewed by the other Party.

(b) Further, each Party acknowledges that the other Party may be legally required, or may be required by the listing rules of any exchange on which the other Party's or its Affiliate's securities are traded, to make public disclosures (including in filings with the SEC or other agency) of certain material developments or material information generated under this Agreement and agrees that each Party may make such disclosures as required by law or such listing rules, *provided* that the Party seeking such disclosure shall provide the other Party with a copy of the proposed text of such disclosure sufficiently in advance of the scheduled release to afford such other Party a reasonable opportunity to review and comment thereon.

(c) If either Party desires to issue a press release or make a public announcement concerning the material terms of this Agreement or the Development or Commercialization of the BioNTech Product under this Agreement, such as the achievement of Regulatory Approvals of the BioNTech Product, such Party shall provide the other Party with the proposed text of such announcement for prior review and, except to the extent such press release or public announcement is permitted by subsection (a) or (b) above, approval by such other Party.

(d) The Parties agree that after a public disclosure has been made or a press release or other public announcement has been issued in compliance with subsection (a), (b) or (c) hereof, each Party may make subsequent public disclosures or issue press releases or other public announcements disclosing the same content without having to obtain the other Party's prior consent and approval.

12.7 Prior Confidentiality Agreement. As of the Effective Date, the terms of this Article 12 (Confidentiality; Publication) shall supersede any prior non-disclosure, secrecy or confidentiality agreement between the Parties (or their Affiliates) relating to the subject of this Agreement, including the Operationally Enabling Agreement dated 23 April 2018. Any information disclosed pursuant to any such prior agreement shall be deemed Confidential Information for purposes of this Agreement.

ARTICLE 13 TERM AND TERMINATION

13.1 Term. Unless earlier terminated as permitted by this Agreement, the term of this Agreement will commence upon the Effective Date and continue in full force and effect, until the later of (a) the expiration of the last Royalty Term for any BioNTech Product in the Territory; or (b) the date on which all Co-Development Products have ceased being Developed or Commercialized by the Parties (the “**Term**”). Upon the expiration (but not early termination) of the Term, the licenses granted herein for BioNTech Products and Co-Development Products shall continue in effect, as non-exclusive, fully paid-up, royalty-free, transferable, perpetual and irrevocable.

13.2 Termination.

(a) **Termination by BioNTech for Convenience with respect to BioNTech Products.** At any time, BioNTech may terminate this Agreement with respect to one or more BioNTech Products, at its sole discretion and for any reason or no reason, by providing written notice of termination to Genevant, which notice includes an effective date of termination at least (i) ninety (90) days after the date of the notice if the notice is given before the Regulatory Approval of the relevant BioNTech Product; or (ii) one hundred eighty (180) days after the date of the notice if the notice is given after the Regulatory Approval of the relevant BioNTech Product.

(b) **Termination for Cause.** If either Party believes that the other is in material breach of its obligations hereunder, then the non-breaching Party may deliver notice of such breach to the other Party. The allegedly breaching Party shall have ninety (90) days (or forty-five (45) days in the case of any payment breach) to cure such breach from the receipt of the notice. If the allegedly breaching Party fails to cure that breach within the applicable period set forth above, then the Party originally delivering the notice of breach may terminate this Agreement, entirely or in relation to the Products affected by such breach only at such Party’s discretion, on written notice of termination. Any right to terminate this Agreement under this Section 13.2(b) (Termination for Cause) shall be stayed and the applicable cure period tolled in the event that, during such cure period, the Party alleged to have been in material breach shall have initiated dispute resolution in accordance with Section 16.10 (Dispute Resolution) with respect to the alleged breach, which stay and tolling shall continue until such dispute has been resolved in accordance with Section 16.10 (Dispute Resolution). If a Party is determined to be in material breach of this Agreement, the other Party may terminate this Agreement if the breaching Party fails to cure the breach within thirty (30) days after the conclusion of the dispute resolution procedure (and such termination shall then be effective upon written notification from the notifying Party to the breaching Party).

(c) **Termination for Patent Challenge.** Except to the extent the following is unenforceable under the laws of a particular jurisdiction, (i) Genevant may terminate this

Agreement immediately upon written notice to BioNTech if BioNTech or its Affiliates or Sublicensees, individually or in association with any other person or entity, commences a legal action challenging the validity, enforceability or scope of any Genevant Patents and does not dismiss or withdraw such legal action within thirty (30) days of receiving notice from Genevant; and (ii) BioNTech may terminate this Agreement immediately upon written notice to Genevant if Genevant or its Affiliates or Sublicensees, individually or in association with any other person or entity, commences a legal action challenging the validity, enforceability or scope of any BioNTech Patents and does not dismiss or withdraw such legal action within thirty (30) days of receiving notice from BioNTech. For purposes of this Section, "challenging" includes (i) filing a declaratory judgment action in which the applicable Patent is alleged to be invalid or unenforceable, (ii) becoming party to an interference with the applicable Patent pursuant to 35 U.S.C. §135 or similar provisions under non-US law or (iii) filing or commencing any reexamination, opposition, cancellation, nullity or similar proceedings against the applicable Patent, or petitioning for any form of administrative or judicial (or arbitration) review of the applicable Patent, including post-grant review, inter partes review, or opposition proceedings. Notwithstanding the above, nothing in this clause will prevent a Party from challenging the validity, enforceability or scope of any Patent in response to a claim of infringement made against it concerning that Patent.

(d) **Termination for Bankruptcy.** This Agreement may be terminated at any time during the Term by either Party upon the other Party's filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; *provided, however*, that in the case of any involuntary bankruptcy proceeding such right to terminate shall only become effective if the Party consents to the involuntary bankruptcy or such proceeding is not dismissed within ninety (90) days after the filing thereof.

(e) **Termination for Competitor Change of Control.** This Agreement may be terminated by either Party immediately upon written notice to the other Party if the other Party undergoes a Competitor Change of Control before the earlier of (i) three (3) years from the Effective Date or (ii) the other Party undergoing an Initial Public Offering.

13.3 Effect of Termination for Convenience pursuant to Section 13.2(a). Upon termination of this Agreement by BioNTech pursuant to Section 13.2(a) (Termination by BioNTech for Convenience), the following consequences shall apply and shall be effective as of the effective date of such termination:

(a) BioNTech's licenses under Section 2.1 (License for BioNTech Products) as well as either Party's rights and obligations under Article 4 (Development of BioNTech Products), Article 5 (Regulatory Activities for BioNTech Products), Article 6 (Manufacturing of BioNTech Products), Article 7 (Commercialization), and Article 8 (BioNTech Product Financial Provisions) shall terminate for the BioNTech Product(s) which are the subject matter of the relevant termination.

(b) [***] following the termination of this Agreement with respect to any BioNTech Product pursuant to Section 13.2(a) (Termination by BioNTech for Convenience), before granting any Third Party a license with respect to the BioNTech mRNA Payload included in the terminated BioNTech Product, BioNTech will notify Genevant and give Genevant the opportunity to negotiate the terms of such a license with BioNTech before negotiating with any Third Party. If the Parties cannot reach agreement within [***] on the terms of a license, then BioNTech may grant such a license to a Third Party, provided that the terms of such license granted to the Third Party are not more favorable than those offered to Genevant.

(c) For the avoidance of doubt, all other licenses granted to BioNTech under this Agreement and either Party's rights and obligations in relation to any other BioNTech Product or any Co-Development Product shall remain unaffected by such termination.

13.4 Effect of Termination by BioNTech for Cause, Patent Challenge, Bankruptcy or Competitor Change of Control. Upon termination of this Agreement by BioNTech pursuant to Section 13.2(b) (Termination for Cause), 13.2(c) (Termination for Patent Challenge), 13.2(d) (Termination for Bankruptcy) or 13.2(e) (Termination for Competitor Change of Control), the following consequences shall apply and shall be effective as of the effective date of such termination:

(a) All rights and obligations of either Party under this Agreement shall terminate unless otherwise specified in this Section 13.4 (Effect of Termination by BioNTech) or Section 13.7 (Survival). To the extent termination is limited to certain Products only, only the rights and obligations of the Parties related to such Products shall terminate and all rights and obligations relating to all other Products shall survive such termination.

(b) BioNTech shall (i) keep all licenses granted to BioNTech under this Agreement, (ii) have the sole right, but not the obligation, to Develop, Manufacture and Commercialize any BioNTech Products in the BioNTech Field and Co-Development Products in the Co-Development Field, at its sole cost and expense, and (iii) become the Lead Commercialization Party for all Co-Development Products in the Co-Development Field in the Territory. To the extent that any royalties will be owed to [***] pursuant to the terms of the [***] Agreement for BioNTech's continued exercise of any of the licenses granted to BioNTech under this Agreement, BioNTech will contact [***] and arrange to pay such royalties directly to [***].

(c) Genevant shall transfer to BioNTech or destroy, at BioNTech's election, all Confidential Information relating to its activities under this Agreement, including any copies thereof, and all materials, substances and compositions generated under this Agreement and shall provide reasonable technical assistance to BioNTech in connection with the understanding and use of such Confidential Information, materials, substances and compositions at its own cost and expense, except that Genevant shall be permitted to retain electronic copies of Confidential Information that are created pursuant to automatic IT backup or disaster recovery procedures (and any Confidential Information so retained will continue to be subject to Article 12(Confidentiality; Publication).

(d) Upon request of BioNTech, Genevant shall comply with its obligations pursuant to Section 6.4 (Manufacturing Transfer) [***] BioNTech under such Section.

(e) Genevant shall assign to BioNTech all Regulatory Filings and Regulatory Approvals for any BioNTech Product and Co-Development Product, and any Genevant Know-How contained in such Regulatory Filings and Regulatory Approvals shall be subject to the licenses granted Section 2.1 (License for BioNTech Products) and 2.2(a) (License Grant to BioNTech).

(f) Genevant shall disclose to BioNTech all Genevant Know-How and all Joint Inventions to the extent not already known to BioNTech, which may be necessary or reasonably

useful for BioNTech to continue to Develop, Manufacture and Commercialize BioNTech Products in the BioNTech Field and/or Co-Development Products in the Co-Development Field. In addition, Genevant shall, at BioNTech's request, provide reasonable technical assistance and transfer all Genevant Know-How and Joint Inventions necessary to Manufacture BioNTech Products and Co-Development Products to BioNTech or its designee.

(g) Genevant shall, at BioNTech's request and election, use Commercially Reasonable Efforts to facilitate negotiations between BioNTech and Genevant's Third Party providers of clinical research, Manufacturing and/or Commercialization services.

(h) Genevant shall, and hereby does, effective on such termination, assign to BioNTech all of Genevant's and its Affiliates' right, title and interest in and to any and all trademarks used by Genevant and its Affiliates in the Territory in connection with its Development, Manufacture or Commercialization of Co-Development Products (excluding any such trademarks that include, in whole or part, any corporate name or logo of Genevant or its Affiliates), including all goodwill therein, and Genevant shall promptly take such actions and execute such instruments, assignments and documents as may be necessary to effect, evidence, register and record such assignment.

(i) All rights of Genevant to prosecute, maintain or enforce any Co-Owned Joint Patent pursuant to Section 11.2 (Patent Prosecution and Maintenance) and 11.4 (Infringement by Third Parties) shall terminate, and all such rights shall solely vest in BioNTech.

13.5 Effect of Termination by Genevant for Cause, Patent Challenge, Bankruptcy or Competitor Change of Control. Upon termination of this Agreement by Genevant pursuant to Section 13.2(b) (Termination for Cause), 13.2(c) (Termination for Patent Challenge), 13.2(d) (Termination for Bankruptcy) or) or 13.2(e) (Termination for Competitor Change of Control), the following consequences shall apply and shall be effective as of the effective date of such termination:

(a) All rights and obligations of either Party under this Agreement shall terminate unless otherwise specified in this Section 13.5 (Effect of Termination by Genevant) or Section 13.7 (Survival). To the extent termination is limited to certain Products only, only the rights and obligations of the Parties related to such Products shall terminate and all rights and obligations relating to all other Products shall survive such termination.

(b) Genevant shall (i) keep all licenses granted to Genevant under this Agreement, (ii) have the sole right, but not the obligation, to Develop, Manufacture and Commercialize any Co-Development Products in the Co-Development Field, at its sole cost and expense, and (iii) become the Lead Commercialization Party for all Co-Development Products in the Co-Development Field in the Territory. To the extent that any royalties will be owed by BioNTech to any Third Party pursuant to the terms of any agreement concluded by BioNTech or its Affiliates with such Third Party for Genevant's continued exercise of any of the licenses granted to Genevant under this Agreement, the Parties will work together with the Third Party to arrange for the payment of such royalties directly from Genevant to such Third Party.

(c) Upon request of Genevant, the Parties shall enter into good faith negotiations relating to the grant by BioNTech to Genevant of an exclusive, worldwide license, with the right to grant sublicenses through multiple tiers, under the BioNTech Technology and the Co-Owned Joint Patents, to research, Develop, make, have made, use, distribute, sell, offer for

sale, have sold, import, export and otherwise Commercialize the BioNTech Product(s) which are the subject matter of the relevant termination in the BioNTech Field at commercial terms then to be agreed.¹

(d) BioNTech shall transfer to Genevant or destroy, at Genevant's election, all Confidential Information relating to its activities under this Agreement, including any copies thereof, and all materials, substances and compositions generated under this Agreement and shall provide reasonable technical assistance to Genevant in connection with the understanding and use of such Confidential Information, materials, substances and compositions at its own cost and expense, except that BioNTech shall be permitted to retain electronic copies of Confidential Information that are created pursuant to automatic IT backup or disaster recovery procedures (and any Confidential Information so retained will continue to be subject to Article 12 (Confidentiality; Publication)).

(e) BioNTech shall assign to Genevant all Regulatory Filings and Regulatory Approvals for any Co-Development Product, and any BioNTech Know-How contained in such Regulatory Filings and Regulatory Approvals shall be subject to the licenses granted Section 2.2(b) (License Grant to Genevant).

(f) BioNTech shall disclose to Genevant all BioNTech Know-How and all Joint Inventions to the extent not already known to Genevant, which may be necessary or reasonably useful for Genevant to continue to Develop, Manufacture and Commercialize Co-Development Products in the Co-Development Field. In addition, BioNTech shall, at Genevant's request, provide reasonable technical assistance and transfer all BioNTech Know-How and Joint Inventions necessary to Manufacture Co-Development Products to Genevant or its designee.

(g) BioNTech shall, at Genevant's request and election, use Commercially Reasonable Efforts to facilitate negotiations between Genevant and BioNTech's Third Party providers of clinical research, Manufacturing and/or Commercialization services.

(h) BioNTech shall, and hereby does, effective on such termination, assign to Genevant all of BioNTech's and its Affiliates' right, title and interest in and to any and all trademarks used by BioNTech and its Affiliates in the Territory in connection with its Development, Manufacture or Commercialization of Co-Development Products (excluding any such trademarks that include, in whole or part, any corporate name or logo of BioNTech or its Affiliates), including all goodwill therein, and BioNTech shall promptly take such actions and execute such instruments, assignments and documents as may be necessary to effect, evidence, register and record such assignment.

(i) All rights of BioNTech to prosecute, maintain or enforce any Co-Owned Joint Patent pursuant to Section 11.2 (Patent Prosecution and Maintenance) and 11.4 (Infringement by Third Parties) shall terminate, and all such rights shall solely vest in Genevant.

13.6 Opt-out in relation to Co-Development Product Development.

(a) **Opt-out.** At any time after the filing of an IND (or equivalent foreign filing) of any Co-Development Product, either Party (“**Opt-Out Party**”) may elect to terminate its participation in the Development of such Co-Development Products (“**Opt-Out**”) at its sole discretion and for any reason or no reason, by providing written notice of termination to the other Party, which notice includes an effective date of the Opt-Out at least [***] after the date of the notice.

(b) **Effect of Termination.** Upon any Opt-Out pursuant to Section 13.6(a) (Opt-out), the following consequences shall apply and shall be effective as of the effective date of such Opt-Out:

(i) the Opt-Out Party’s license under Section 2.2 (License for Co-Development Products) shall terminate and the license granted to the other Party under Section 2.2 (License for Co-Development Products) shall become an exclusive license (even as to the Opt-Out Party);

(ii) if BioNTech is the Opt-Out Party, BioNTech will continue to support GMP Manufacturing of Co-Development Products in accordance with Section 9.11 (Manufacturing Responsibilities);

(iii) if Genevant is the Opt-Out Party, Genevant will continue to support GMP Manufacturing of Co-Development Products in accordance with Section 9.11 (Manufacturing Responsibilities) until [***] to Co-Development Products;

(iv) except as provided above, the other Party shall be solely responsible for all future Development, Manufacture and Commercialization of such Co-Development Product in the Co-Development Field, at its sole cost and expense;

(v) the Opt-Out Party shall assign to the other Party all Regulatory Filings and Regulatory Approvals for such Co-Development Product, shall transfer control and responsibility for the global safety database to the other Party, and any Know-How contained in such Regulatory Filings and Regulatory Approvals shall be subject to the license grants in 2.2 (License for Co-Development Products), as amended by Section 13.6(b)(i) (Effect of Termination - subsection (i)) above;

(vi) if any clinical studies with respect to the Co-Development Product have been initiated and are on-going as of the effective date of any Opt-Out (each, an “**On-Going Clinical Study**”), the Opt-Out Party shall continue to fund its share of Development Costs with respect to such On-Going Clinical Study for [***]. In addition, if there are any On-Going Clinical Studies being conducted by or under authority of the Opt-Out Party or its Affiliates at the time of notice of the Opt-Out, the Opt-Out Party agrees, as the other Party may request, to (A) promptly transition to the other Party or its designee some or all of such On-Going Clinical Studies and the activities related to or supporting such trials, (B) continue to conduct such On-Going Clinical Studies after the effective date of such Opt-Out until they have been completed, or (C) terminate such On-Going Clinical Studies in a manner consistent with Applicable Laws;

(vii) the Opt-Out Party shall disclose to the other Party all Know-How and all Joint Inventions to the extent not already known to the other Party, which may be necessary

or reasonably useful for the other Party to continue to Develop, Manufacture and Commercialize Co-Development Products in the Co-Development Field. In addition, shall, at the other Party's request, provide reasonable technical assistance and transfer all Know-How and Joint Inventions necessary to Manufacture Co-Development Products to the other Party or its designee;

(viii) the other Party shall pay the Opt-Out Party the milestone and royalties set forth in Exhibit K (and the terms of Article 8 (BioNTech Product Financial Provisions) shall apply mutatis mutandis);

(ix) the Opt-Out Party shall, at the other Party's request and election, use Commercially Reasonable Efforts to facilitate negotiations between the other Party and the Opt-Out Party's Third Party providers of clinical research, Manufacturing and/or Commercialization services;

(x) the Opt-Out Party shall, and hereby does, effective on such termination, assign to the other Party all of its and its Affiliates' right, title and interest in and to any and all trademarks used by it in the Territory in connection with its Development, Manufacture or Commercialization of Co-Development Products (excluding any such trademarks that include, in whole or part, any corporate name or logo of the Opt-Out Party or its Affiliates), including all goodwill therein, and the Opt-Out Party shall promptly take such actions and execute such instruments, assignments and documents as may be necessary to effect, evidence, register and record such assignment; and

(xi) the other Party may choose to terminate its efforts with respect to the Co-Development Products in its sole-discretion for any reason or no reason at any time after the Opt-Out Party elects to terminate.

13.7 Survival. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination, nor shall expiration or any termination of this Agreement preclude either Party from pursuing all rights and remedies it may have under this Agreement, at law or in equity, with respect to breach of this Agreement. In addition, the provisions of Article 1 (Definitions), Sections 6.3(b) (Use of BioNTech Product Initial Manufacturing Know-How); 6.3(c) (Batch Records) 6.5 (Pre-existing or Publicly Available Manufacturing Know-How); 8.6 (Late Payments); 8.7 (Financial Records and Audit); 8.8 (Audit Dispute) 11.1(a) (Ownership of Sole Inventions); 11.1(b) (Disclosure of Inventions), 11.1(d) (Use of Joint Inventions); 11.2 (Patent Prosecution and Maintenance); 11.3 (Cooperation of the Parties); Article 12 (Confidentiality; Publication); Article 13 (Term and Termination); Article 15 (Indemnification; Liability) and Article 16 (General Provisions) hereof shall survive the expiration or termination of this Agreement.

13.8 Termination Not Sole Remedy. Termination is not the sole remedy under this Agreement and, whether or not the Agreement is terminated and notwithstanding anything contained in this Agreement to the contrary, all other remedies will remain available except as agreed to otherwise herein.

ARTICLE 14
REPRESENTATIONS AND WARRANTIES

14.1 Representations and Warranties of Each Party. Each Party represents and warrants to each other Party as of the Effective Date that:

(a) it has the full right, power and authority to enter into this Agreement, to perform its obligations hereunder; and

(b) this Agreement has been duly executed by it and is legally binding upon it, enforceable in accordance with its terms, and does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.

14.2 Representations and Warranties by Genevant. Genevant represents and warrants to BioNTech as of the Effective Date that:

(a) it has not previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in Genevant Technology in a manner that is inconsistent with the licenses granted to BioNTech under Section 2.1 (Licenses for BioNTech) and Section 2.2(a) (License Grant to BioNTech) or its obligations under this Agreement;

(b) Genevant has not received any notice from a Third Party that the Genevant LNP infringes any Patents of any Third Party or misappropriates any other intellectual property of any Third Party and is not aware of any imminent or likely threat from a Third Party of such infringement or misappropriation;

(c) Genevant has not as of the Effective Date, and will not during the Term, grant any right to any Third Party under the Genevant Technology that would conflict with the rights granted to BioNTech hereunder;

(d) Genevant has no knowledge as of the Effective Date of any Third Party that is infringing or misappropriating any of the Genevant Technology;

(e) no Claim or action has been brought or, to Genevant's knowledge, threatened in writing by any Third Party alleging that the Genevant Patents are invalid or unenforceable, and no Genevant Patent is the subject of any interference, opposition, cancellation or other similar proceeding except as identified in Exhibit G; and

(f) the patents and patent applications listed on **Exhibit G** constitute all existing Genevant Patents as of the Effective Date.

14.3 Representations and Warranties by BioNTech. BioNTech represents and warrants to Genevant as of the Effective Date that:

(a) it has not previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in the BioNTech mRNA Payloads, Co-Development mRNA Payloads, or BioNTech Technology in a manner that is inconsistent with the licenses granted to Genevant under Section 2.2(b) (License Grant to Genevant) its obligations under this Agreement;

(b) BioNTech has not received any notice from a Third Party that any BioNTech mRNA Payload or Co-Development mRNA Payloads infringes any Patents of any Third Party or misappropriates any other intellectual property of any Third Party and is not aware of any imminent or likely threat from a Third Party of such infringement or misappropriation;

(c) BioNTech has not as of the Effective Date, and will not during the Term, grant any right to any Third Party under the BioNTech Technology that would conflict with the rights granted to Genevant hereunder;

(d) BioNTech has no knowledge as of the Effective Date of any Third Party that is infringing or misappropriating any of the BioNTech Technology;

(e) no Claim or action has been brought or, to BioNTech's knowledge, threatened in writing by any Third Party alleging that the BioNTech Patents are invalid or unenforceable, and no BioNTech Patent is the subject of any interference, opposition, cancellation or other similar proceeding; and

(f) the patents and patent applications listed on **Exhibit H** constitute all existing BioNTech Patents as of the Effective Date.

14.4 No Other Warranties. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES, AND EACH PARTY EXPRESSLY DISCLAIMS, ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY OF PATENTS, NON-INFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES.

ARTICLE 15 INDEMNIFICATION; LIABILITY

15.1 Indemnification by Genevant. Genevant shall indemnify and hold BioNTech, its Affiliates and Sublicensees, and their respective officers, directors, agents and employees ("**BioNTech Indemnitees**") harmless from and against any Claims arising under or related to this Agreement against them to the extent arising or resulting from:

- (a) the gross negligence or willful misconduct of or violation of Applicable Laws by any of the Genevant Indemnitees;
- (b) the material breach of any of the covenants, warranties or representations made by Genevant to BioNTech under this Agreement; or
- (c) any material breach by Genevant of its obligations pursuant to this Agreement;

except in each case, to the extent such Claims result from the material breach by BioNTech of any covenant, representation, warranty or other agreement made by BioNTech in this Agreement or the negligence or willful misconduct of any BioNTech Indemnitee. Notwithstanding the above, Genevant will have no obligation to defend or indemnify BioNTech or its Affiliates for any claim brought by a shareholder or a class of shareholders of BioNTech or its Affiliates including, but not limited to, securities fraud claims, shareholder direct claims, and shareholder derivative claims, except to the extent resulting from the gross negligence or willful misconduct on the part of Genevant or any Affiliate.

15.2 Indemnification by BioNTech. BioNTech shall indemnify and hold Genevant, its Affiliates and Sublicensees, and their respective officers, directors, agents and employees (“**Genevant Indemnitees**”) harmless from and against any Claims arising under or related to this Agreement against them to the extent arising or resulting from:

- (a) the gross negligence or willful misconduct of or violation of Applicable Laws by any of the BioNTech Indemnitees;
- (b) the material breach of any of the covenants, warranties or representations made by BioNTech to Genevant under this Agreement; or
- (c) any material breach by BioNTech of its obligations pursuant to this Agreement; or
- (d) product recall, products’ liability, infringement claims, or similar claims based on the research, Development, Manufacture or Commercialization of a BioNTech Product including any such claims made against [***]

except in each case, to the extent such Claims result from the material breach by Genevant of any covenant, representation, warranty or other agreement made by Genevant in this Agreement or the negligence or willful misconduct of any Genevant Indemnitee. Notwithstanding the above, BioNTech will have no obligation to defend or indemnify Genevant or its Affiliates for any claim brought by a shareholder or a class of shareholders of Genevant or its Affiliates including, but not limited to, securities fraud claims, shareholder direct claims, and shareholder derivative claims, except to the extent resulting from the gross negligence or willful misconduct on the part of BioNTech or any Affiliate.

15.3 Indemnification Procedure. If either Party is seeking indemnification under Sections 15.1 (Indemnification by Genevant) or 15.2 (Indemnification by BioNTech) (the “**Indemnified Party**”), it shall inform the other Party (the “**Indemnifying Party**”) of the Claim giving rise to the obligation to indemnify pursuant to such section as soon as reasonably practicable after receiving notice of the Claim. The Indemnifying Party shall have the right to assume the defense of any such Claim for which it is obligated to indemnify the Indemnified Party. The Indemnified Party shall cooperate with the Indemnifying Party and the Indemnifying Party’s insurer as the Indemnifying Party may reasonably request, and at the Indemnifying Party’s cost and expense. The Indemnified Party shall have the right to participate, at its own expense and with counsel of its choice, in the defense of any Claim or suit that has been assumed by the Indemnifying Party. Neither Party shall have the obligation to indemnify the other Party in connection with any settlement made without such Party’s written consent, which consent shall not be unreasonably withheld or delayed. If the Parties cannot agree as to the application of Section 15.1 (Indemnification by Genevant) or 15.2 (Indemnification by BioNTech) as to any Claim, pending resolution of the dispute pursuant to Section 16.10 (Dispute Resolution), the Parties may conduct separate defenses of such Claims, with each Party retaining the right to claim indemnification from the other Party in accordance with Section 15.1 (Indemnification by Genevant) or 15.2 (Indemnification by BioNTech) upon resolution of the underlying Claim.

15.4 Mitigation of Loss. Each Indemnified Party will take and will procure that its Affiliates take all such reasonable steps and action as are reasonably necessary or as the Indemnifying Party may reasonably require in order to mitigate any Claims (or potential losses or damages) under this Article 15 (Indemnification; Liability). Nothing in this Agreement shall or shall be deemed to relieve any Party of any common law or other duty to mitigate any losses incurred by it.

15.5 Special, Indirect and Other Losses. EXCEPT IN THE EVENT OF A PARTY'S BREACH OF SECTION 2.6 (EXCLUSIVITY) OR Article 10 (CONFIDENTIALITY; PUBLICATION), NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT OR ANY LICENSE GRANTED HEREUNDER; *provided, however*, that this Section 15.5 shall not be construed to limit either Party's indemnification obligations under Section 15.1 (Indemnification by Genevant) or Section 15.2 (Indemnification by BioNTech), as applicable.

15.6 Conduct of Product Liability Claims.

(a) Each of the Parties shall promptly notify the other in the event that any Third Party asserts or files any products liability claim or other Claim relating to alleged defects in the Co-Development Product (whether design defects, Manufacturing defects or defects in sales or marketing) ("**Third Party Products Liability Action**") against such Party. In the event of a Third Party Products Liability Action against such a single Party, the unnamed Party shall have the right, in the unnamed Party's sole discretion, to join or otherwise participate in such legal action with legal counsel selected by the unnamed Party and reasonably acceptable to the named Party. The Party named in such Third Party Products Liability Action shall have the right to control the defense of the action, but shall notify and keep the unnamed Party apprised in writing of such action and shall consider and take into account the unnamed Party's reasonable interests and requests and suggestions regarding the defense of such action. In the event of a Third Party Products Liability Action against both Parties, the Parties shall mutually agree upon which Party shall control the response to such Third Party Products Liability Action.

(b) The non-controlling Party of a Third Party Products Liability Action shall reasonably cooperate with the controlling Party in the preparation and formulation of a defense to such Third Party Products Liability Action, and in taking other steps reasonably necessary to respond to such Third Party Products Liability Action. The controlling Party shall have the sole and exclusive right to select its counsel for the defense to such Third Party Products Liability Action. If required under Applicable Law in order for the controlling Party to maintain a suit in response to such Third Party Products Liability Action, the non-controlling Party shall join as a party to the suit. The controlling Party shall assume and pay all of its own costs incurred in connection with any litigation or proceedings related to such Third Party Products Liability Action, including the fees and expenses of the counsel selected by it, as well as the costs of the non-controlling Party associated with providing assistance requested by the controlling Party or joining the suit if requested by the controlling Party or required to maintain the suit. The non-controlling Party shall also have the right to participate and be represented in any such suit by its own counsel at its own expense. All Out-of-Pocket Costs and FTE Costs incurred in connection with any litigation or proceeding related to such Third Party Products Liability Action shall be taken into account in determining Profit or Loss as, and to the extent, provided in Exhibit F. The controlling Party shall not settle or compromise any Third Party Products Liability Action without the consent of the other Party, which consent shall not be unreasonably withheld.

15.7 Insurance. Each Party, at its own expense, shall maintain product liability and other appropriate insurance (or self-insure) in an amount consistent with sound business practice and reasonable in light of its obligations under this Agreement during the Term. Each Party shall provide a certificate of insurance (or evidence of self-insurance) evidencing such coverage to the other Party upon request.

ARTICLE 16
GENERAL PROVISIONS

16.1 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the United Kingdom without reference to any United Kingdom rules of conflict of laws.

16.2 Assignment. Except as expressly provided hereunder, neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred by either Party without the prior written consent of the other Party (which consent shall not be unreasonably withheld); *provided, however,* that either Party may assign or otherwise transfer this Agreement and its rights and obligations hereunder without the other Party's consent (a) in connection with the transfer or sale of all or substantially all of the business or assets of such Party to which this Agreement relates to a Third Party (except where such transfer or sale results in termination of the Agreement pursuant to Section 13.2(e) (Termination for Competitor Change of Control)), whether by merger, consolidation, divestiture, restructure, sale of stock, sale of assets or otherwise; *provided* that in the event of any such transaction (whether this Agreement is actually assigned or is assumed by the acquiring party by operation of law (e.g., in the context of a reverse triangular merger)), intellectual property rights of the acquiring party to such transaction (if other than one of the Parties to this Agreement) and its affiliates existing prior to the transaction shall not be included in the technology licensed hereunder; or (b) to an Affiliate, *provided* that the assigning Party shall remain liable and responsible to the non-assigning Party hereto for the performance and observance of all such duties and obligations by such Affiliate. The rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties, and the name of a Party appearing herein will be deemed to include the name of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this section. Any assignment not in accordance with this Section 16.2 (Assignment) shall be null and void.

16.3 Entire Agreement; Modification. This Agreement is both a final expression of the Parties' agreement and a complete and exclusive statement with respect to all of its terms. This Agreement supersedes all prior and contemporaneous agreements and communications, whether oral, written or otherwise, concerning any and all matters contained herein. This Agreement may only be modified or supplemented in a writing expressly stated for such purpose and signed by the Parties to this Agreement.

16.4 Relationship Between the Parties. The Parties' relationship with one another, as established by this Agreement, is solely that of independent contractors. This Agreement does not create any partnership, joint venture or similar business relationship between the Parties. Neither Party is a legal representative of the other Party. Neither Party can assume or create any obligation, representation, warranty or guarantee, express or implied, on behalf of the other Party for any purpose whatsoever.

16.5 Taxes

(a) **Taxes on Income.** Except as otherwise set forth in this Section 16.5 (Taxes), each Party shall be solely responsible for the payment of all Taxes imposed on such Party's income arising directly or indirectly from the activities of the Parties under this Agreement.

(b) **Taxes of Co-Entrepreneurship.** If and to the extent the Parties are considered to be partners of a co-entrepreneurship for Tax purposes because of their collaboration governed by this Agreement and Taxes allocated to the co-entrepreneurship (e.g. German trade tax, but excluding any Taxes imposed on or with respect to net income other than German trade tax) are owed by either of the Parties such Tax (as well as any related cost of reporting and preparation of relevant Tax returns) shall be considered a cost item to be borne by the Parties in accordance with the Profit and Loss split set out in Section 10.4 and the principles set out in Exhibit C. The Parties shall cooperate in good faith to agree on a mutual tax filing position for their collaboration governed by this Agreement in due course after the Effective Date. Each Party shall have the right to assign its contractual position under this Agreement to a wholly owned corporate subsidiary ("**Blocker Entity**") provided that the relevant Party (i) remains secondarily liable for any liabilities of the Blocker Entity under this Agreement and (ii) shall indemnify the other Party from any Taxes triggered by the transfer of the contractual position to the Blocker Entity.

(c) **Taxes as Development Costs.** For the avoidance of doubt, any non-recoverable import taxes, export taxes, excise taxes, sales taxes, VAT, consumption taxes and comparable taxes and duties accruing in connection with any activity to be performed under the Co-Development Product Development Plan, including any Taxes described in Section 16.5(e) that accrue in connection with any activity to be performed under the Co-Development Product Development Plan, shall qualify as Development Costs and considered a cost item to be borne by the Parties in accordance with the Profit and Loss split set out in Section 10.4.

(d) **Tax Cooperation.** The Parties agree to use commercially reasonable efforts to cooperate with one another and use commercially reasonable efforts to avoid or reduce, to the extent permitted by Applicable Laws, Tax withholding or similar obligations in respect of royalties, milestone payments, and other payments made by the paying Party to the receiving Party under this Agreement ("**Withholding Taxes**"). If Withholding Taxes are imposed on any payment under this Agreement, the liability for such Withholding Taxes shall be the sole responsibility of the receiving Party, and the paying Party shall (i) deduct or withhold such Withholding Taxes from the payment made to the receiving Party, (ii) timely pay such Withholding Taxes to the proper taxing authority, and (iii) send proof of payment to the receiving Party within thirty (30) days following such payment. If and to the extent the paying Party failed to retain Withholding Taxes (e.g. because the Parties assumed that Withholding Taxes will not be imposed) or if Withholding Taxes are imposed on "deemed payments" the receiving Party shall reimburse the paying Party for any Withholding Tax obligation vis-à-vis the tax authorities. Each Party shall comply with (or provide the other Party with) any certification, identification or other reporting requirements that may be reasonably necessary in order for the paying Party to not withhold Withholding Taxes or to withhold Withholding Taxes at a reduced rate under an applicable bilateral income tax treaty. Each Party shall provide the other with commercially reasonable assistance to enable the recovery, as permitted by Applicable Laws, of Withholding Taxes or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing the cost of such Withholding Taxes under this Section 16.5(d) (Tax Cooperation). Notwithstanding the foregoing, if as a result of any assignment or sublicense by the paying Party, any change in the paying Party's tax residency, any change in the entity that originates the payment, or any failure on the part of the paying Party to comply with Applicable Laws with respect to Withholding Taxes (including filing or record retention requirements), Withholding Taxes are imposed that would not

otherwise have been imposed (“**Incremental Withholding Taxes**”), then the paying Party shall be solely responsible for the amount of such Incremental Withholding Taxes and shall increase the amounts payable to the receiving Party so that the receiving Party receives a sum equal to the sum which it would have received had there been no such imposition of Incremental Withholding Taxes. If a Party makes a payment in accordance with the sentence above (gross-up) (“**Tax Payment**”) and

- (i) a credit against, relief or remission for, or repayment of any Tax (“**Tax Credit**”) is attributable to that Tax Payment and
- (ii) the receiving Party determines in good faith that it has obtained and utilised that Tax Credit on an affiliated group basis,

the receiving Party shall pay to the paying Party an amount equal to such Tax Credit, net of all out-of-pocket expenses (including Taxes) of such receiving Party and without interest (other than interest paid by the relevant taxing authority with respect to such Tax Credit). Notwithstanding anything else in this Section 16.5(d), in no event will the receiving Party be required to pay any amount to paying Party pursuant to this Section 16.5(d) the payment of which would place the receiving Party in a less favorable net after-Tax position than the receiving Party would have been in if the Tax giving rise to such Tax Credit had not been deducted, withheld or otherwise imposed and the applicable Tax Payment had never been paid. This paragraph shall not be construed to require the receiving Party to make available its Tax returns (or any other information relating to its Taxes that it deems confidential) to the paying Party or any other Person. The receiving Party shall use its commercially reasonable efforts to obtain and utilise that Tax Credit on an affiliated group basis.

(e) **Value Added Tax.** All payments between the Parties under this Agreement are exclusive of applicable statutory value added tax (“**VAT**”), if any, which shall be listed separately on each invoice. If and to the extent any VAT will become payable due to any supplies or services rendered under this Agreement and if and to the extent such VAT is to be paid by the Party providing the supply or service to the competent tax authorities, the receiving Party shall pay an amount equal to such VAT to the providing Party upon receipt of a valid invoice allowing for the recovery of such VAT. The same shall apply mutatis mutandis for potential other transfer taxes such as stamp, sales, use or similar taxes (“**Transfer Tax**”) imposed on any payments under this Agreement. In case there will be new Transfer Taxes introduced after the Effective Date, the Parties will agree on the burden of such Transfer Taxes in good faith. The Parties shall cooperate in good faith to minimize and/or recover (such recovery to be for the benefit of the Party bearing the cost of such Transfer Tax) any Transfer Tax, as permitted by Applicable Laws.

16.6 Non-Waiver. The failure of a Party to insist upon strict performance of any provision of this Agreement or to exercise any right arising out of this Agreement shall neither impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or in any other instance. Any waiver by a Party of a particular provision or right shall be in writing, shall be as to a particular matter and, if applicable, for a particular period of time and shall be signed by such Party.

16.7 Force Majeure. Neither Party shall be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement to the extent such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, potentially including embargoes, war,

acts of war (whether war be declared or not), acts of terrorism, insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, fire, floods, or other acts of God, or acts, omissions or delays in acting by any governmental authority or unavailability of materials related to the Manufacture of Products. The affected Party shall notify the other Party of such force majeure circumstances as soon as reasonably practical, and shall promptly undertake and continue diligently all reasonable efforts necessary to cure such force majeure circumstances or to perform its obligations in spite of the ongoing circumstances.

16.8 Severability. If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties shall in such an instance use their best efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the purposes of this Agreement.

16.9 Notices. Any notice to be given under this Agreement must be in writing and delivered either (a) in person, (b) by air mail (postage prepaid) requiring return receipt, (c) by overnight courier, or (d) by e-mail with delivery and return receipts requested and confirmation of delivery thereafter, to the Party to be notified at its address(es) given below, or at any address such Party may designate by prior written notice to the other. Notice shall be deemed sufficiently given for all purposes only upon receipt.

If to Genevant: Genevant Science Inc.
90 Broadway, Suite 204
Cambridge MA 02142
Attention: [***]

With a copy to: Roivant Sciences GmbH
Viaduktstrasse 8
4051 Basel, Switzerland
Attention: [***]

If to BioNTech: BioNTech RNA Pharmaceuticals GmbH
Goldgrube 13
55131 Mainz
Germany
Attn.: [***]

16.10 Dispute Resolution

(a) The Parties shall negotiate in good faith and use reasonable efforts to settle any dispute, controversy or claim arising from or related to this Agreement or the breach thereof. Subject to Section 16.10(g) (Dispute Resolution - subsection (g)), in the event the Parties cannot resolve such dispute, controversy or claim within a period of thirty (30) days, then the matter shall be referred to designated senior executives of the Parties for resolution. The initial designated senior executives shall be BioNTech's Head Alliance Management . Each Party shall be entitled to name substitute senior executives upon written notice to the other Party.

(b) Except as expressly set forth in Section 16.10(g) (Dispute Resolution - subsection (g)), if, after going through this procedure, the Parties do not fully settle, and a Party wishes to pursue the matter, each such dispute, controversy or claim that is not an Excluded Claim (defined in Section 16.10(f) (Dispute Resolution - subsection (f)) below) shall be finally resolved by binding arbitration according to the International Chamber of Commerce (ICC) Rules of Arbitration, as applicable on the date of commencement of the arbitration proceedings. Place of arbitration shall be London, England. Exclusive language of the proceedings shall be English. In addition to the ICC Rules of Arbitration, the procedural law in force at the seat of arbitration shall apply. The arbitration shall be conducted by a panel of three (3) neutral arbitrators who shall be attorneys and have (i) at least [***] of dispute resolution experience (which may include judicial experience) or (ii) at least [***] of legal or business experience in the biotechnology or pharmaceutical industry, none of whom shall be a current or former employee or director, or a current stockholder, of either Party or any of their respective Affiliates or any Sublicensee: within thirty (30) days after initiation of arbitration, each Party shall select one (1) person to act as arbitrator and the two (2) Party-selected arbitrators shall select a third (3rd) arbitrator within thirty (30) days of their appointment. If the arbitrators selected by the Parties are unable or fail to agree upon the third (3rd) arbitrator, the third (3rd) arbitrator shall be appointed in accordance with the ICC Rules. In addressing any of the subjects within the scope of the Preliminary Conference, the arbitrators shall take into account both the desirability of making discovery efficient and cost-effective and the needs of the Parties for an understanding of any legitimate issue raised in the arbitration. The award rendered by the arbitrators shall be final, binding and non-appealable, and judgment may be entered upon it in any court of competent jurisdiction.

(c) Either Party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. The arbitrators' authority to award punitive or any other type of damages not measured by a Party's compensatory

damages shall be subject to the limitation set forth in Section 15.5 (Special, Indirect and Other Losses). Each Party shall bear its own costs and expenses and attorneys' fees and an equal share of the arbitrators' fees and any administrative fees of arbitration.

(d) Except to the extent necessary to confirm or enforce an award or as may be required by law, neither Party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of the other Party. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable statute of limitations of the United Kingdom.

(e) The Parties agree that, in the event of a dispute over the nature or quality of performance under this Agreement, neither Party may terminate this Agreement until final resolution of the dispute through arbitration or other judicial determination. The Parties further agree that any payments made pursuant to this Agreement pending resolution of the dispute shall be refunded if an arbitrator or court determines that such payments are not due.

(f) As used in this Section, the term "**Excluded Claim**" means a dispute, controversy or claim that concerns (i) the construction, scope, validity, enforceability, inventorship or infringement of a patent, patent application, trademark or copyright; or (ii) any antitrust, anti-monopoly or competition law or regulation, whether or not statutory.

(g) Nothing contained in this Agreement shall deny either Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a *bona fide* emergency or prospective irreparable harm, and such an action may be filed and maintained notwithstanding any ongoing discussions between the Parties or any ongoing arbitration proceeding. In addition, either Party may bring an action in any court of competent jurisdiction to resolve disputes pertaining to the validity, construction, scope, enforceability, infringement or other violations of Patents or other intellectual property rights, and no such claim shall be subject to arbitration pursuant to subsections (b) and (c) of this Section 16.10 (Dispute Resolution).

16.11 Performance by Affiliates. Each Party may discharge any obligations and exercise any rights hereunder through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

16.12 Headings. The captions to the several Articles, Sections and subsections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the several Articles and Sections hereof.

16.13 Waiver of Rule of Construction. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

16.14 Business Day Requirements. In the event that any notice or other action or omission is required to be taken by a Party under this Agreement on a day that is not a Business Day then such notice or other action or omission shall be deemed to require to be taken on the next occurring Business Day.

16.15 English Language. This Agreement has been prepared in the English language, and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral or other communications between the Parties regarding this Agreement shall be in the English language.

16.16 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

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IN WITNESS WHEREOF, the Parties intending to be bound have caused this License and Co-Development Agreement to be executed by their duly authorized representatives.

BIONTECH RNA PHARMACEUTICALS GMBH

By: [***] _____

Name: [***]

Title: [***]

Date: July 4, 2018

GENEVANT SCIENCES GMBH

By: [***] _____

Name: [***]

Title: [***]

Date: July 4, 2018

LIST OF EXHIBITS

- Exhibit A: **BioNTech mRNA Payloads**
- Exhibit B: **Co-Development mRNA Payloads and Lead Commercialization Party**
- Exhibit C: **Taxes of Co-Entrepreneurship**
- Exhibit D: **Transfer Plan**
- Exhibit E: **BioNTech Development Milestone Plan**
- Exhibit F: **Procedure for Calculating Profit and Loss**
- Exhibit G: **Genevant Patents**
- Exhibit H: **BioNTech Patents**
- Exhibit I: **BioNTech Products Collaboration Plan**
- Exhibit J: **Co-Development Products Development Plan**
- Exhibit K: **Opt-Out Financial Terms**
- Exhibit L: **BioNTech Product Initial Manufacturing Know-How**

EXHIBIT A

BIONTECH MRNA PAYLOADS

[***]

A-1

EXHIBIT B

CO-DEVELOPMENT MRNA PAYLOADS AND LEAD COMMERCIALIZATION PARTY

[***]

B-1

EXHIBIT C

TAXES OF CO-ENTREPRENEURSHIP

Burden-sharing trade tax in case of a co-entrepreneurship

1. If and to the extent the Parties are considered to be partners of a co-entrepreneurship for Tax purposes because of their collaboration governed by this Agreement and trade tax (including possible ancillary charges related thereto) with regard to this co-entrepreneurship (**Common Tax**) accrues, this Common Tax shall be borne and, where required, compensated between the Parties (**Tax Equalization**) according to the following provisions:
2. In principle, both Parties bear Common Taxes at a ratio of 50% | 50%.
3. If and to the extent
 - i. attributions from special business balance sheets (assets, equity and liabilities, special business income, special business expenses) or from (positive or negative) supplementary tax balance sheets of a Party or
 - ii. the transfer of the interest in the co-entrepreneurship of a Party or the withdrawal of a Party from the co-entrepreneurship

Lastenverteilung Gewerbesteuer im Fall einer Mitunternehmerschaft

1. Wenn und soweit die Parteien wegen ihrer Zusammenarbeit unter dieser Vereinbarung als Mitunternehmer einer Mitunternehmerschaft anzusehen sind und Gewerbesteuer (einschließlich etwaiger damit zusammenhängender steuerlicher Nebenleistungen) betreffend dieser Mitunternehmerschaft (**Gemeinsame Steuer**) geschuldet wird, soll diese Gemeinsame Steuer von den Parteien nach Maßgabe der folgenden Bestimmungen getragen und ggf. ausgeglichen (**Steuerausgleich**) werden:
2. Die Parteien tragen eine Gemeinsame Steuer grundsätzlich im Verhältnis 50% | 50%.
3. Wenn und soweit eine Gemeinsame Steuer
 - i. durch Zurechnungen aus Sonderbilanzen (Aktiva, Passiva, Sonderbetriebseinnahmen, Sonderbetriebsaufwendungen) oder (positiven oder negativen) Ergänzungsbilanzen einer Partei oder
 - ii. durch Übertragung des Mitunternehmeranteils einer Partei oder durch das Ausscheiden einer Partei aus der Mitunternehmerschaft

cause either in this or (e.g. due to a bigger or smaller loss carry-forward) one of the following years an additional Common Tax (**Additional Tax Burden**) or a reduced Common Tax (**Reduced Tax Burden**), the following shall apply: Additional Tax Burdens are, in derogation from No. 2 of this Exhibit, borne solely by the causative Party and, where required, refunded to the other Party in accordance with this burden-sharing; Reduced Tax Burdens are, in derogation from No. 2 of this Exhibit, exclusively for the benefit of the causative Party and, where required, partly refunded by the other Party to the causative Party in accordance with this burden-sharing; for the avoidance of doubt, the Parties clarify that a Tax Equalization shall also take place if a Common Tax is saved.

If an Additional Tax Burden or a Reduced Tax Burden is caused by a direct or indirect shareholder of a Party, this Additional Tax Burden or Reduced Tax Burden shall be deemed to have been caused by this Party for the purposes of this Exhibit.

4. Trade tax disadvantages which result from the fact that, due to the termination of the co-entrepreneurship or a relevant transfer of a participation (section 10a sentence 10 German Trade Tax Act, section 8c German Corporate Income Tax Act), trade tax losses carried-forward may be forfeited, shall not be compensated by the causative Party.

in diesem oder (z.B. wegen eines erhöhten oder geminderten Verlustvortrags) einem der folgenden Jahre höher ausfällt (**Steuerliche Mehrbelastungen**) oder niedriger ausfällt (**Steuerliche Minderbelastungen**), wird im Fall einer Steuerlichen Mehrbelastung diese Steuerliche Mehrbelastung abweichend von Ziffer 2 dieses Exhibit ausschließlich von der verursachenden Partei getragen und ggf. entsprechend dieser Lastenverteilung der anderen Partei erstattet, und kommt im Fall einer Steuerlichen Minderbelastung diese Steuerliche Minderbelastung abweichend von Ziffer 2 dieses Exhibit ausschließlich der verursachenden Partei zugute und hat die andere Partei der verursachenden Partei die Steuerliche Minderbelastung ggf. entsprechend dieser Lastenverteilung anteilig zu erstatten; die Parteien stellen klar, dass auch im Fall einer ersparten Gemeinsamen Steuer ein Steuerausgleich stattfinden soll.

Werden Steuerliche Mehrbelastungen oder Steuerliche Minderbelastungen durch einen direkten oder indirekten Anteilseigner einer Partei verursacht, gilt dies für Zwecke dieses Exhibit als durch die jeweilige Partei verursacht.

4. Gewerbesteuerliche Nachteile, die dadurch entstehen, dass gewerbesteuerliche Fehlbeträge wegen der Beendigung der Mitunternehmerschaft oder eines schädlichen Beteiligungserwerbs (§§ 10a S. 10 GewStG, 8c KStG) nicht mehr genutzt werden können, sind von der verursachenden Partei nicht auszugleichen.

5. The amounts of the Tax Equalization according to this Exhibit are to be calculated by way of an iterative calculation process which takes into account the respective additional or reduced income tax or corporate income tax of the Parties which results from the fact that, on the one hand, the Common Tax is not tax deductible, while, on the other hand, the equalization payment is taxable by the receiving Party and possibly tax deductible by the paying Party.
 6. To the extent the Tax Equalization has neither yet taken place nor can take place in the course of the application of section 10.4 of the Agreement, the Party entitled to the compensation shall have a compensation claim against the other Party pursuant to this Exhibit. This claim shall become time-barred upon expiration of six months after the relevant tax trade tax assessment has become formally and substantially binding. Additional Tax Burdens or Reduced Tax Burdens, which arise after the termination of the co-entrepreneurship, are to be compensated (notwithstanding a possible termination of the Agreement) between the Parties as well.
 7. If and to the extent the Parties are considered to be partners of a co-entrepreneurship for Tax purposes because of their collaboration governed by this Agreement and there are, due to a
5. Bei der Berechnung des Steuerausgleichs nach diesem Exhibit ist im Rahmen eines iterativen Rechenprozesses jeweils eine einkommen- bzw. körperschaftsteuerliche Mehr- bzw. Minderbelastung der Parteien zu berücksichtigen, die aus dem Umstand resultiert, dass einerseits die Gemeinsame Steuer einem steuerlichen Abzugsverbot unterliegt, hingegen andererseits die Ausgleichszahlung bei der erstattungsberechtigten Partei steuerpflichtig und ggf. bei der erstattungspflichtigen Partei steuerlich abzugsfähig ist.
 6. Soweit der Steuerausgleich einer Gemeinsamen Steuer nicht bereits im Rahmen von Section 10.4 der Vereinbarung erfolgt ist oder erfolgen kann, hat die zum Ausgleich berechnete Partei einen Ausgleichsanspruch gegen die andere Partei nach Maßgabe dieses Exhibit. Dieser Anspruch verjährt 6 Monate nach formeller und materieller Bestandskraft des jeweiligen Gewerbesteuerbescheides. Steuerliche Mehr- oder Minderbelastungen, die erst nach Beendigung der Mitunternehmerschaft eintreten, sind zwischen den Parteien (auch nach Vertragsbeendigung) ebenfalls auszugleichen.
 7. Wenn und soweit die Parteien wegen ihrer Zusammenarbeit unter dieser Vereinbarung als Mitunternehmer einer Mitunternehmerschaft anzusehen sind und es aufgrund von Abzugsverboten

deduction prohibition (e.g. the German interest barrier or royalty barrier), other special income tax effects (especially regarding corporate income tax and trade tax), which are caused by the respective other Party, an equalization shall take place between the Parties according to the principles set out in this Exhibit.

(z.B. der deutschen Zins- und/oder Lizenzschranke) zu anderen ertragsteuerlichen Sondereffekten (insbesondere betreffend Körperschaftsteuer und Gewerbesteuer) kommt, die durch die jeweils andere Partei verursacht sind, soll ein Ausgleich zwischen den Parteien entsprechend den in diesem Exhibit festgelegten Grundsätzen erfolgen.

8. In the event of discrepancies between the German and the English version of this Exhibit, the German version of this Exhibit shall prevail.

8. Im Falle von Abweichungen zwischen der deutschen und der englischen Fassung dieses Exhibit geht die deutsche Fassung vor.

EXHIBIT D

TRANSFER PLAN

The following activities will be subject to a detailed 2-way transfer plan for know-how and materials between BioNTech and Genevant on an as-needed basis to support the collaboration:

- Analytical Development
- Pharmaceutical Development
- Nonclinical

Development of the detailed transfer plans will be initiated within [***] weeks of the Effective Date.

EXHIBIT E

BIONTECH DEVELOPMENT MILESTONE PLAN

[***]

E-1

EXHIBIT F**PROCEDURE FOR CALCULATING PROFIT OR LOSS
OF CO-DEVELOPMENT PRODUCTS**

Profit or Loss from Co-Development Products in the Territory shall be calculated in accordance with this Exhibit F.

Calculation of Profit or Loss

Profit or Loss shall be calculated for each Calendar Quarter by determining the Net Sales of Co-Development Products, adding any Other Income and subtracting the sum of the Allowable Expenses incurred during such Calendar Quarter. Notwithstanding the foregoing, on a Calendar Year-to-date basis, Allowable Expenses shall not be included in such calculation if such expenses are in excess of the amounts allocated for such Calendar Year-to-date period, in the budget for Commercialization approved by the JSC; provided, however, that Allowable Expenses in excess of the Commercialization budget shall be included in the calculation of Profit or Loss in (i) if the JSC approves such excess Allowable Expenses (either before or after they are incurred), which approval shall not be unreasonably withheld to the extent the Allowable Expenses in excess of the applicable budget were not within the reasonable control of the Party (or Party's Affiliate) incurring such expense or (ii) to the extent such excess does not [***] in the applicable Calendar Year-to-date period in accordance with the Commercialization budget for such Calendar Year. If any excess Allowable Expenses are excluded from sharing by the Parties for a particular Calendar Year-to-date period pursuant to the foregoing sentence, such excess Allowable Expenses shall be carried forward to subsequent Calendar Quarters (provided that such Calendar Quarters fall within the same Calendar Year) and, to the extent the total Allowable Expenses incurred by such Party and its Affiliates for the Calendar Year-to-date as of the end of such subsequent Calendar Quarter are less than [***] of the aggregate Allowable Expenses allocated to such Party under the commercialization budget for such Calendar Year-to-date period, such carried forward amounts shall be included in Allowable Expenses to be shared by the Parties for such Calendar Year-to-date period (*i.e.*, so that the total Allowable Expenses incurred by such Party and its Affiliates that are shared pursuant to this paragraph do not exceed [***] of the Allowable Expenses allocated to such Party under the commercialization budget, unless otherwise approved by the JSC).

Definitions

The following definitions shall apply for purposes of calculating Profit or Loss in accordance this Exhibit F.

- (1) "Allowable Expenses" means [***]

- (2) **“Blocking Third Party Patent Costs”** means [***]
- (3) **“Distribution Costs”** means [***]
- (4) [***]
- (5) [***]
- (6) **“Health Care Reform Fees”** [***]
- (7) **“Marketing Expenses”** means [***]
- (8) **“Medical Affairs Expenses”** [***]
- (9) **“Other Commercialization Costs”** [***]
- (10) [***]
- (11) [***]
- (12) [***]
- (13) [***]
- (14) **“Selling Costs”** means [***]

(15) “**Total Sales Representative Costs**” means [***]

(16) “**Trademark Costs**” [***]

Reconciliations

The JSC will coordinate to resolve any differences in or disputes regarding the calculation of Profit or Loss, or any component thereof.

EXHIBIT G

GENEVANT PATENT

Patents

I. [***]

[***]

G-1

CSN5

G-2

G-7

II [***]

[***]

G-9

1:57 SNALP

[***]

G-10

7:54 SNALP

[***]

G-11

SNALP structure

[***]

ApoB C2K SNALP

G-13

II. NOVEL LIPID CASES DLinDMA/DLenDA

IV. MODIFIED siRNA CASES Chem mod

V. MISCELLANEOUS CASES

Combination therapy w/NA & conventional drugs

Combination therapy w/NA & radiotherapy

[***]

G-17

Lipid-mediated GDEPT

G-18

Use of temperature to control lipoplex size

08155 Matters

[***]

G-20

EXHIBIT H
BIONTECH PATENTS

H-1

EXHIBIT I
BIONTECH PRODUCTS COLLABORATION PLAN

Consists of the following PDF files attached:

- [***].

EXHIBIT J
CO-DEVELOPMENT PRODUCTS DEVELOPMENT PLAN

Consists of the following PDF files attached:

- [***].

**EXHIBIT K
OPT-OUT FINANCIAL TERMS**

[*] Milestones**

Within [***] days after the first achievement of each milestone event below for the Co-Development Product that is the subject of the Opt-Out, the other Party shall notify the Opt-Out Party of the achievement of such milestone event and shall remit payment to the Opt-Out Party within [***] days of its receipt of the Opt-Out Party's invoice for such payment

[***]

Commercial Milestones

Within [***] days after the end of the Calendar Quarter in which aggregate annual Net Sales of the Co-Development Product that is the subject of the Opt-Out by or on behalf of the other Party or any of its Affiliates or Sublicensees in the Co-Development Field in the Territory first reach any threshold indicated in the milestone events listed below, the other Party shall notify the Opt-Out Party of the achievement of such milestone event and shall remit payment to the Opt-Out Party within [***] days of its receipt of the Opt-Out Party's invoice for such payment.

[***]

K-1

Royalty Payments

During the Royalty Term (as applied *mutatis mutandis* for the Co-Development Product and provided that only Valid Claims of Patents Controlled by the Opt-Out Party shall be taken into account for evaluating the time period under Section (b) (Royalty Term)) for the Co-Development Product, the other Party shall pay to the Opt-Out Party non-refundable, non-creditable royalty at the rates below on aggregate annual Net Sales of the Co-Development Product in the Co-Development Field in the Territory in each Calendar Year.

EXHIBIT L
BIONTECH PRODUCT INITIAL MANUFACTURING KNOW-HOW

As required for Regulatory Approvals for clinical trials:

[***]

L-1

THE SYMBOL “[*]” DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED**

RESEARCH COLLABORATION AND LICENSE AGREEMENT

by and between

PFIZER INC.

and

BIONTECH RNA PHARMACEUTICALS GmbH

and

BIONTECH AG

July 20, 2018

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RESEARCH COLLABORATION AND LICENSE AGREEMENT

This Research Collaboration and License Agreement (the "Agreement") is entered into as of July 20, 2018 (the "Execution Date"), by and between Pfizer Inc., a corporation organized and existing under the laws of Delaware and having a principal place of business at 235 East 42nd Street, New York, New York, 10017 United States ("Pfizer") and BioNTech RNA Pharmaceuticals GmbH, a corporation organized and existing under the laws of Germany and having a place of business at An der Goldgrube 12, D-55131 Mainz, Germany ("BioNTech RNA") and BioNTech AG, a corporation organized and existing under the laws of Germany and having a place of business at An der Goldgrube 12, D-55131 Mainz, Germany ("BioNTech AG"). BioNTech RNA and BioNTech AG are collectively referred to herein as "BioNTech". Pfizer and BioNTech may each be referred to herein individually as a "Party" and collectively as the "Parties."

WHEREAS, BioNTech owns or otherwise Controls (as defined below) certain patents, patent applications, technology, know-how, scientific and technical information and other proprietary rights and information relating to the identification, research and development of Candidates (as defined below);

WHEREAS, Pfizer has extensive experience and expertise in the development and commercialization of pharmaceutical and biopharmaceutical products;

WHEREAS, subject to the terms of this Agreement, BioNTech wishes to grant to Pfizer, and Pfizer wishes to receive from BioNTech, an exclusive license in the Field (as defined below) in the Territory (as defined below) under BioNTech's and its licensors' patents, patent applications, technology, know-how, scientific and technical information and other proprietary rights and information relating to Candidates and Products (as defined below) to use, research, develop, manufacture and commercialize Candidates and Products; and

WHEREAS, Pfizer and BioNTech wish to engage in collaborative research pursuant to the Research Plan (as defined below) to identify and develop Candidates for inclusion in Products for further development and commercialization by Pfizer.

NOW THEREFORE, in consideration of the mutual promises and covenants set forth below and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

1. DEFINITIONS

As used in this Agreement, the following terms will have the meanings set forth below:

1.1. "Affiliate" means any entity directly or indirectly controlled by, controlling, or under common control with, a Person, but only for so long as such control will continue. For purposes of this definition, "control" (including, with correlative meanings, "controlled by", "controlling" and "under common control with") means (a) possession, direct or indirect, of the power to direct or cause direction of the management or policies of an entity (whether through ownership of securities or other ownership interests, by contract or otherwise), or (b) beneficial ownership of more than 50% of the voting securities or other ownership or general partnership interest (whether directly or pursuant to any option, warrant or other similar arrangement) or other comparable equity interests of an entity; *provided, however*, that where an entity owns a majority of the voting power necessary to elect a majority of the board of directors or other

governing board of another entity, but is restricted from electing such majority by contract or otherwise, such entity will not be considered to be in control of such other entity until such time as such restrictions are no longer in effect. Notwithstanding the foregoing, for the purposes of this Agreement, AT Impf GmbH, having its place of business at Rosenheimer Platz 6, 81669 Munich, Germany, and any entity that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with AT Impf GmbH (other than BioNTech AG or any entity that is directly or indirectly controlled by BioNTech AG) (collectively, the "Impf Group") shall not be considered Affiliates of BioNTech.

1.2. "Antigen" means a non-human polypeptide that is capable of eliciting an immune response.

1.3. "Antitrust Clearance Date" means the earliest date on which the Parties have actual knowledge that all applicable waiting periods under the HSR Act and any Foreign Antitrust Laws with respect to consummation of the transactions contemplated hereunder have expired or have been terminated.

1.4. "Bankruptcy Code" means Section 101(35A) of Title 11 of the United States Code, as amended, or such other legislation, Law or code with effect in another jurisdiction to which BioNTech or its Affiliates is subject having equivalent or reasonably similar purpose or provisions to the foregoing.

1.5. "Binding Obligation" means, with respect to a Party (a) any oral or written agreement or arrangement that binds or affects such Party's operations or property, including any assignment, license agreement, loan agreement, guaranty, or financing agreement, (b) the provisions of such Party's charter, bylaws or other organizational documents or (c) any order, writ, injunction, decree or judgment of any court or Governmental Authority entered against such Party or by which any of such Party's operations or property are bound.

1.6. "BioNTech Improvement" means any Research Program Technology, regardless of inventorship, that is a modification or improvement made to the RNA Technology or RNA Process Technology and (a) would also be applicable to one or more candidates or products other than the Candidates or Products (b) is not predominantly directed to the Candidates, or Products or the Pfizer Technology and (c) could have reasonable been developed without the aid, use or application of Pfizer Materials, Pfizer Improvements or Pfizer's Confidential Information or any improvements or enhancements thereto. For avoidance of doubt, BioNTech Improvements excludes RNA Improvements.

1.7. "BioNTech Know-How" means any Know-How, other than any Research Program Know-How or Pfizer Technology that (a) is Controlled by BioNTech or any of its Affiliates as of the Effective Date or that comes into the Control of BioNTech or any of its Affiliates during the Research Term (other than through the grant of a license by Pfizer) and (b) relates to (i) any Replicons or Modified RNA; or (ii) the Development, Manufacture or Commercialization of any immunogenic composition comprising RNA in the Field, provided that BioNTech Know-How shall exclude any Know-How Controlled by BioNTech or any of its Affiliates that predominantly relates to Payloads (including, for example, cytokines or antibodies) other than Antigens.

1.8. "BioNTech Materials" means any tangible materials (but not information about or contained in such materials) owned or Controlled by BioNTech that relate to or embody the BioNTech Know-How or BioNTech Patent Rights.

1.9. "BioNTech Patent Right" means any Patent Right (other than Research Program Patent Rights and Pfizer Patent Rights) in any form and whether pending or issued that (a) is Controlled by BioNTech or any of

its Affiliates as of the Effective Date or comes into the Control of BioNTech or any of its Affiliates during the Research Term (other than through the grant of a license by Pfizer) and (b) claims any (i) Candidate, or Product (including the composition of matter thereof), (ii) method of making any Candidate or Product, (iii) methods of using any Candidate or Product or (iv) BioNTech Know-How, provided that BioNTech Patent Rights shall exclude any Patent Right Controlled by BioNTech or any of its Affiliates that predominantly relates to Payloads (including, for example, cytokines or antibodies) other than Antigens. BioNTech Patent Rights include the existing Patent Rights listed in Schedule 9.3.4.

1.10. "BioNTech Technology" means the BioNTech Patent Rights, BioNTech Materials and BioNTech Know-How.

1.11. "BioNTech Third Party Agreement" means any agreement between BioNTech (or any of its Affiliates) and any Third Party (such Third Party, a "Third Party Licensor") that (a) relates to any of the BioNTech Technology or Research Program Technology (b) otherwise grants a license or otherwise transfers any right to practice under any Patent Rights or Know-How, in each case that relate to the Candidates or Products or activities under this Agreement. For clarity, all Current Licenses shall be deemed BioNTech Third Party Agreements hereunder and all Current Licensors shall be deemed Third Party Licensors hereunder.

1.12. "Biologics License Application" or "BLA" means an application requesting permission from the FDA to introduce, or deliver for introduction, a biological product into interstate commerce, or any similar application or submission for marketing authorization of a product filed with a Regulatory Authority to obtain Regulatory Approval for such product in a country or group of countries.

1.13. "Biosimilar Notice" means a copy of any application submitted by a Third Party to the FDA under 42 U.S.C. § 262(k) of the Public Health Service Act (or, in the case of a country of the Territory outside the United States, any similar law) for Regulatory Approval of a biopharmaceutical product, which application identifies a Product as the Reference Product with respect to such product, and other information that describes the process or processes used to manufacture the biopharmaceutical product.

1.14. "Biosimilar Version" means, with respect to a Product that is being sold in a country or regulatory jurisdiction in the Territory (the "Reference Product"), a biopharmaceutical product sold by a Third Party (other than a Third Party acting on behalf of or in concert with Pfizer or any Pfizer Affiliate or Sublicensee) in such country or regulatory jurisdiction in the Territory that through reference to the Regulatory Approval of the Reference Product, is eligible for and has achieved Regulatory Approval in such country or regulatory jurisdiction pursuant to an abbreviated follow-on biological approval pathway established by the Regulatory Authority in such country or regulatory jurisdiction pursuant to the applicable Law, or otherwise is approved for marketing and sale in such country or regulatory jurisdiction by an abridged procedure in reliance, in whole or in part, on the prior Regulatory Approval of the Reference Product or on the safety and efficacy data generated for the prior Regulatory Approval (in such country or regulatory jurisdiction) of the Reference Product, including any such biopharmaceutical product that (i) with respect to such biopharmaceutical product in the United States, has been approved as a biosimilar or interchangeable product by the FDA pursuant to 42 U.S.C. § 262 of the Public Health Service Act, (ii) with respect to such biopharmaceutical product subject to the regulatory jurisdiction of the EMA, has been approved as a similar biological medicine product by EMA as described in CHMP/437/04, issued 30 October 2005, as may be amended, or any subsequent or superseding law, statute or regulation or (iii) with respect to such biopharmaceutical product outside the United States and in a country which is not subject to the regulatory jurisdiction of the EMA, has otherwise obtained Regulatory Approval from a Regulatory Authority pursuant to similar statutory or regulatory requirement as that described in the foregoing subsections (i) and (ii) in such other country or regulatory jurisdiction in the Territory.

1.15. "Business Day" means a day other than a Saturday, Sunday or bank or other public holiday in New York, New York, United States of America or Mainz, Germany.

1.16. "CAN Selection Criteria" means the criteria used by Pfizer's Vaccines Research and Development organization to determine whether to select a candidate as a CAN. Pfizer's current CAN Selection Criteria is set forth in Schedule 1.16, which may be updated from time-to-time by Pfizer during the term.

1.17. "Candidate" means an immunogenic composition in the Field that comprises Modified RNA Technology or Replicon Technology that (a) arises from the Research Plan, (b) is Controlled by BioNTech and exists as of the Effective Date or (c) is Exploited by Pfizer, its Affiliates or Sublicensees pursuant to the exercise or use of the rights licensed under Section 2.1 of this Agreement. Those Candidates Controlled by BioNTech and existing as of the Execution Date are set forth on Schedule 9.3.3.

1.18. "Calendar Quarter" means the respective periods of three consecutive calendar months ending on March 31, June 30, September 30 and December 31.

1.19. "Calendar Year" means any twelve (12) month period beginning on January 1 and ending on the next subsequent December 31.

1.20. "Change of Control" means, with respect to a Party (a) the acquisition of beneficial ownership, directly or indirectly, by any Person (other than such Party or an Affiliate of such Party, and other than by virtue of obtaining irrevocable proxies) of securities or other voting interest of such Party representing of the combined voting power of such Party's then outstanding securities or other voting interests, (b) any merger, reorganization, consolidation or business combination involving such Party with a Third Party that results in the holders of beneficial ownership (other than by virtue of obtaining irrevocable proxies) of the voting securities or other voting interests of such Party (or, if applicable, the ultimate parent of such Party) immediately prior to such merger, reorganization, consolidation or business combination ceasing to hold beneficial ownership of at least 50% of the combined voting power of the surviving entity immediately after such merger, reorganization, consolidation or business combination, (c) any sale, lease, exchange, contribution or other transfer (in one transaction or a series of related transactions) of all or substantially all of the assets of such Party to which this Agreement relates, other than a sale or disposition of such assets to an Affiliate of such Party or (d) the approval of any plan or proposal for the liquidation or dissolution of such Party (other than in circumstances where such Party is deemed a Debtor pursuant to Section 10.8).

1.21. "Clinical Trial" means a human clinical study conducted on sufficient numbers of human subjects that is designed to (a) establish that a pharmaceutical product is reasonably safe for continued testing, (b) investigate the safety and efficacy of the pharmaceutical product for its intended use, and to define warnings, precautions and adverse reactions that may be associated with the pharmaceutical product in the dosage range to be prescribed or (c) support Regulatory Approval of such pharmaceutical product or label expansion of such pharmaceutical product. Without limiting the foregoing, Clinical Trial includes any Phase I Clinical Trial, Phase II Clinical Trial or Phase III Clinical Trial conducted by or on behalf of one or both Parties in connection with this Agreement.

1.22. "Clinical Trial Material" or "CTM" means a batch of one or more Candidates or Products, as applicable, Manufactured to cGMP by or on behalf of either Party for Clinical Trials.

1.23. "Combination Product" means a product comprising a Candidate or Product in combination with one or more other therapeutically active ingredients (which includes any prophylactic activity) that are co-formulated as part of the same dosage form or packaged and administered to patient together. For the avoidance of doubt, adjuvants, including molecular adjuvants, are not considered therapeutically active ingredients for the purposes of this definition regardless of whether or not such adjuvant is packaged together with a Candidate or Product but in a separate container.

1.24. "Commercialize" or "Commercializing" means to (a) market, promote, distribute, offer for sale, sell, have sold, import, have imported, export, have exported or otherwise commercialize a compound or product and (b) conduct discovery, pre-clinical, research or other Development activities with respect to a compound or product after such compound or product has received Regulatory Approval. When used as a noun, "Commercialization" means any and all activities involved in Commercializing.

1.25. "Commercially Reasonable Efforts" means, with respect to the efforts to be expended by a Party with respect to any objective, those reasonable, good faith efforts to accomplish such objective as such Party would normally use to accomplish a similar objective under similar circumstances. With respect to any efforts relating to the Development, Regulatory Approval or Commercialization of a Candidate or Product by a Party, generally or with respect to any particular country in the Territory, a Party will be deemed to have exercised Commercially Reasonable Efforts if such Party has exercised those efforts normally used by such Party, in the relevant country, with respect to a compound or protein, product or product candidate, as applicable (a) of similar modality Controlled by such Party, (b) to which such Party has similar rights, (c) which is of similar market potential in such country, and (d) which is at a similar stage in its development or product life cycle, as any Candidate or Product, in each case, taking into account all Relevant Factors in effect at the time such efforts are to be expended. Further, to the extent that the performance of a Party's obligations hereunder is adversely affected by the other Party's failure to perform its obligations hereunder, the impact of such performance failure will be taken into account in determining whether such Party has used its Commercially Reasonable Efforts to perform any such affected obligations.

1.26. "Compassionate Use Purposes" means, with respect to the Product, providing Product under compassionate use or expanded access programs, or in jurisdictions or to vulnerable populations experiencing emergency pandemic, or crisis epidemic, flu conditions.

1.27. "Competitive Product" means a pharmaceutical product [***] that has been or is being Exploited by a Third Party. For avoidance of doubt, Competitive Product does not include Candidates or Products.

1.28. "Compliance" means the adherence by the Parties in all material respects to all applicable Laws and Party Specific Regulations, in each case with respect to the activities to be conducted under this Agreement.

1.29. "Confidential Information" means, with respect to each Party, all Know-How or other information, including proprietary information and materials (whether or not patentable) regarding or embodying such Party's or its Representatives' technology, products, business information or objectives, that is communicated by or on behalf of the Disclosing Party to the Receiving Party or its permitted recipients, on or after the Execution Date, but only to the extent that: (a) such Know-How or other

information in written form is marked in writing as “confidential” at the time of disclosure, (b) such Know-How or other information disclosed orally or in non-tangible form is identified by the Disclosing Party as “confidential” at the time of disclosure or within 30 days thereafter, or (c) such Know-How or other information (regardless of the form of disclosure) is disclosed in circumstances of confidence or would be understood by the Parties, exercising reasonable business judgment, to be confidential. Confidential Information does not include any Know-How or other information to the extent the Receiving Party can demonstrate by competent proof that such Know-How or other information (a) was already known by the Receiving Party (other than under an obligation of confidentiality to the Disclosing Party) at the time of disclosure by or on behalf of the Disclosing Party, (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party, (c) became generally available to the public or otherwise part of the public domain after its disclosure to the Receiving Party, other than through any act or omission of the Receiving Party in breach of its obligations under this Agreement, (d) was disclosed to the Receiving Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the Disclosing Party not to disclose such information to the Receiving Party or (e) was independently discovered or developed by or on behalf of the Receiving Party without the use of any Confidential Information belonging to the Disclosing Party. The terms and conditions of this Agreement will be considered Confidential Information of both Parties. Joint Know-How shall be deemed Confidential Information of either Party and either Party shall be deemed the Receiving Party in respect of Joint Know-How.

1.30. “Control” or “Controlled” means with respect to any Intellectual Property Right or material (including any Patent Right, Know-How or other data, information or material), the ability (whether by sole, joint or other ownership interest, license or otherwise, other than pursuant to this Agreement) to, without violating the terms of any agreement with a Third Party, grant a license or sublicense or provide access or other right in as provided in this Agreement, to or under such Intellectual Property Right or material.

1.31. “Copyright” means any copyright which pertains to the promotional materials and literature utilized by Pfizer in connection with the Commercialization of Products in the Territory.

1.32. “Core BioNTech Patent Rights” means those of the BioNTech Patent Rights (excluding any Patent Rights solely owned by a Third Party and licensed hereunder pursuant to a Current Licence to the extent BioNTech has no enforcement rights in the Field in respect of the same) and Patent Rights Covering BioNTech Improvements that are material to and used by BioNTech, its Affiliates or its or their licensees in connection with the Development or Commercialization of products outside the Field (excluding those Patent Rights and countries for which Pfizer is paying for maintenance or Prosecution Proceedings pursuant to Section 7.3.1). Once any such product is Commercialized, a Patent Right shall be regarded as “material” for such product if the Manufacturing or sale of such product would, but for the ownership of or licence to the applicable Patent Right, infringe such Patent Right. The Core BioNTech Patent Rights identified at the time of the Execution Date are designated as such in Schedule 9.3.4.

1.33. “Core RNA Technology” means the mRNA technology platform [***].

1.34. “Cover” means, with respect to a given Candidate or Product and Patent Right, that a Valid Claim of such Patent Right would, absent a license thereunder or ownership thereof, be infringed by the making, sale, offer for sale or importation of such Candidate or Product.

1.35. “Current Good Manufacturing Practices” or “cGMP” means all applicable standards and applicable Laws relating to manufacturing practices for products (including ingredients, testing, storage, handling, intermediates) promulgated by the U.S. Food and Drug Administration and any other governmental authority (including, European Union or member state level and Japan), including, but not limited to, standards in the form of applicable laws, guidelines, advisory opinions and compliance policy guides, and current interpretations of the applicable authority or agency thereof (as applicable to pharmaceutical and biological products and ingredients), as the same may be updated, supplemented or amended from time to time, in each case of those jurisdictions in which the products are Manufactured.

1.36. “Current Licenses” means any agreement (a) that BioNTech or its Affiliates has entered into or enters into prior to the Effective Date with a Third Party and (b) pursuant to which BioNTech or its Affiliates are (i) granted rights to any BioNTech Technology as of the Effective Date or (ii) granted a license or otherwise transferred any right to practice under any Patent Rights or Know-How, in each case that relate to the Candidates or Products or activities under this Agreement. BioNTech’s Current Licenses are disclosed on Schedule 9.3.12.

1.37. “Current Licensor” means any Third Party that is a party to a Current License.

1.38. “Delivery Technology” means the BioNTech Know-How applicable to formulating nucleic acids to enable the delivery of such nucleic acids to target cells *in vivo*. For clarity, Delivery Technology does not include Replicon Technology or Modified RNA Technology.

1.39. “Develop” or “Developing” means to discover, research or otherwise develop or improve a process, compound or product, including planning and conducting non-clinical and clinical research and development activities prior to Regulatory Approval. When used as a noun, “Development” means any and all activities involved in Developing.

1.40. “Development Event” means each Development event listed in the table that appears in Section 3.3.

1.41. “Effective Date” means the later of (a) the Execution Date, (b) if a determination is made pursuant to Section 10.2 that a notification of this Agreement is not required to be made under the HSR Act or under any antitrust, competition or other similar laws, rules, regulations and judicial doctrines of jurisdictions other than the United States (“Foreign Antitrust Laws”), the date of such determination, or (c) if notification of this Agreement is required to be made under the HSR Act or any Foreign Antitrust Laws, the Antitrust Clearance Date.

1.42. “EMA” means the European Medicines Agency or any successor agency thereto.

1.43. “Exploit” means to Develop, Manufacture, Commercialize, use or otherwise exploit. Cognates of the word “Exploit” will have correlative meanings.

1.44. “FD&C Act” means the United States Federal Food, Drug, and Cosmetic Act, as amended, and the rules and regulations promulgated thereunder.

1.45. “FDA” means the United States Food and Drug Administration or any successor agency thereto.

1.46. “FIH Study” means one or more limited Phase I Clinical Trials sponsored by BioNTech and conducted in Germany for the purpose of initial clinical translation and evaluation of one or more Candidates or Products selected by the JSC for such clinical evaluation, as further described in the Research Plan.

1.47. “Field” means [***].

1.48. “First Commercial Sale” means, with respect to any Product and with respect to any country of the Territory, the first sale of such Product by Pfizer or an Affiliate or Sublicensee of Pfizer to a Third Party in the Field in such country after such Product has been granted Regulatory Approval by the appropriate Regulatory Authority in such country.

1.49. “GAAP” means United States generally accepted accounting principles, consistently applied.

1.50. “GEIA” means the German Employee Invention Act.

1.51. “GEIA Technology” means all BioNTech Technology and Research Program Technology invented by employees of BioNTech or its Affiliates (solely or jointly with employees of Third Parties) under the jurisdiction of GEIA.

1.52. “Governmental Authority” means any court, agency, department, authority or other instrumentality of any national, state, county, city or other political subdivision.

1.53. “Government Official”, to be broadly interpreted, means (a) any elected or appointed government official (e.g., a member of a ministry of health), (b) any employee or person acting for or on behalf of a government official, Governmental Authority, or other enterprise performing a governmental function, (c) any political party, candidate for public office, officer, employee, or person acting for or on behalf of a political party or candidate for public office, and (d) any employee or person acting for or on behalf of a public international organization (e.g., the United Nations). For clarity, healthcare providers employed by government-owned hospitals will be considered Government Officials.

1.54. “HSR Act” means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the rules and regulations promulgated thereunder.

1.55. “HSR Filing” means filings by Pfizer and BioNTech with the United States Federal Trade Commission and the Antitrust Division of the United States Department of Justice of a Notification and Report Form for Certain Mergers and Acquisitions (as that term is defined in the HSR Act) with respect to the matters set forth in this Agreement, together with all required documentary attachments thereto.

1.56. “Human Material” means any biological samples of one or more Subjects collected, provided or utilized by BioNTech during the Research Plan pursuant to this Agreement.

1.57. “ICF” means an informed consent form that was approved by a qualified Institutional Review Board or Independent Ethics Committee (“IRB / IEC”) in accordance with all applicable Laws and recognized international standards for the protection of human research subjects.

- 1.58. “IND” means an Investigational New Drug Application submitted under the FD&C Act, or an analogous application or submission with any analogous agency or Regulatory Authority outside of the United States for the purposes of obtaining permission to conduct Clinical Trials.
- 1.59. “Intellectual Property Rights” means any and all (a) Patent Rights, (b) proprietary rights in Know-How, including trade secret rights, (c) proprietary rights associated with works of authorship and software, including copyrights, moral rights, and copyrightable works, and all applications, registrations, and renewals relating thereto, and derivative works thereof, (d) other forms of proprietary or intellectual property rights however denominated throughout the world, other than trademarks, service marks, trade names, domain names and other indicators of origin.
- 1.60. “Joint Steering Committee” or “JSC” means the steering committee described in Section 4.3.2(a).
- 1.61. “Joint Know-How” means any Research Program Know-How, whether or not patentable, made or created jointly by (a) BioNTech or any of its Representatives and (b) Pfizer or any of its Representatives.
- 1.62. “Joint Patent Rights” means Research Program Patent Rights that claim or disclose any invention included in Joint Know-How.
- 1.63. “Joint Technology” means the Joint Know-How and the Joint Patent Rights.
- 1.64. “Know-How” means any proprietary invention, discovery, development, data, information, process, method, technique, technology, result, cell line, cell, antibody or other protein, compound, probe, nucleic acid, (including RNAi) or other sequences or other know-how, whether or not patentable, and any physical embodiments of any of the foregoing or any information contained in any of the foregoing.
- 1.65. “Law” means any law, statute, rule, regulation, order, judgment or ordinance of any Governmental Authority.
- 1.66. “Major EU Market Country” means any of France, Germany, Italy, Spain or the United Kingdom.
- 1.67. “Major Market Country” means the Major EU Market Countries, the United States and Japan.
- 1.68. “Manufacture” or “Manufacturing” means to make, produce, manufacture, process, fill, finish, package, label, perform quality assurance testing, release, ship or store, and for the purposes of further Manufacturing, distribute, import or export, a compound or product or any component thereof. When used as a noun, “Manufacture” or “Manufacturing” means any and all activities involved in Manufacturing a compound or protein, device or product or any component thereof.
- 1.69. “Modified RNA Product” means any Product comprising Modified RNA Technology.
- 1.70. “Modified RNA” means an mRNA that has been modified by the incorporation of one or more modified nucleotides, excluding the 5’ CAP.

1.71. “Modified RNA Technology” means the BioNTech Know-How applicable to Modified RNA. For clarity, Modified RNA Technology does not include Replicon Technology or Delivery Technology.

1.72. “Net Sales” means with respect to a Product, gross receipts from sales by Pfizer and its Affiliates and Sublicensees of such Product to Third Parties in the Territory, less in each case (a) bad debts and (b) sales returns and allowances actually paid, granted or accrued, including trade, quantity and cash discounts and any other adjustments, including those granted on account of price adjustments, billing errors, rejected goods, damaged or defective goods, recalls, returns, rebates, chargeback rebates, reimbursements or similar payments granted or given to wholesalers or other distributors, buying groups, health care insurance carriers, chain pharmacies, mass merchandisers, staff model HMO’s, pharmacy benefit managers or other institutions, adjustments arising from consumer discount programs or other similar programs, customs or excise duties, sales tax, consumption tax, value added tax, and other taxes (except income taxes) or duties relating to sales, any payment in respect of sales to the United States government, any state government or any foreign government, or to any other Governmental Authority, or with respect to any government-subsidized program or managed care organization, and freight and insurance (to the extent that Pfizer, its Affiliates or its Sublicensees bear the cost of freight and insurance for the Product).

Net Sales will be determined from books and records maintained in accordance with GAAP, as consistently applied by Pfizer with respect to sales of the Product. If, in respect of Product, Pfizer, its Affiliates or Sublicensees receive non-cash consideration or in the case of transactions not at arm’s length (except in each case where the case of disposal of Product is in furtherance of Compassionate Use Purposes), Net Sales will be calculated based on the fair market value of such consideration or transaction, at the time of the transaction, assuming an arm’s length transaction made in the ordinary course of business.

Net Sales for Products sold as part of a Combination Product in a country shall be calculated as follows: Net Sales will be calculated by multiplying the Net Sales (as described above) of the Combination Product during the applicable royalty reporting period by the fraction $A/(A+B)$, where A is the average sale price of the Product when sold separately in finished form (or where such average sale price cannot be determined, the fair market value of such Product), and B is the average sale price of the other therapeutically active ingredient(s) included in the Combination Product when sold separately in finished form (or where such average sale price cannot be determined, the fair market value of such other therapeutically active ingredient(s)), in each case in the applicable country of sale during the applicable royalty reporting period. To the extent Net Sales are calculated on the basis of fair market values, the Parties shall seek to determine such fair market values by mutual agreement and, in the absence of such mutual agreement, the Parties shall engage an independent valuation firm (and equally bear the costs of engaging such firm) to determine such fair market values.

1.73. “Party Specific Regulations” means all non-monetary judgments, decrees, orders or similar decisions issued by any Governmental Authority specific to a Party, and all consent decrees, corporate integrity agreements, or other agreements or undertakings of any kind by a Party with any Governmental Authority, in each case as the same may be in effect from time to time and applicable to a Party’s activities contemplated by this Agreement.

1.74. “Patent Rights” means any and all (a) issued patents, (b) pending patent applications, including all provisional applications, non-provisional applications, substitutions, continuations, continuations-in-part, divisions and renewals, applications sharing a priority claim and all patents granted thereon, (c) patents-of-addition, reissues, reexaminations and extensions or restorations by existing or future

extension or restoration mechanisms, including patent term adjustments, patent term extensions, supplementary protection certificates or the equivalent thereof, (d) inventor's certificates, (e) other forms of government-issued rights substantially similar to any of the foregoing and (f) United States and foreign counterparts of any of the foregoing.

1.75. "Payload" means a [***]. The term "Payload" excludes polypeptides that are used to enable expression of a payload from the RNA, such as an RNA-dependent RNA polymerase.

1.76. "Person" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization, including a government or political subdivision or department or agency of a government.

1.77. "Pfizer Diligence Obligations" means Pfizer's Development and Regulatory Approval diligence obligations under Section 6.2.1 and Pfizer's Commercialization diligence obligations under Section 6.2.2.

1.78. "Pfizer Improvements" means any Research Program Technology, regardless of inventorship, that is a modification or improvement to the Pfizer Technology and (a) would also be applicable to one or more candidates or products other than the Candidates or Products, (b) is not predominantly directed to the Candidates or Products or the RNA Technology or RNA Process Technology and (c) could have reasonably been developed without the aid, use or application of BioNTech Materials, BioNTech Improvements or BioNTech's Confidential Information or any improvements or enhancements thereto.

1.79. "Pfizer Know-How" means any Know-How that (a) is Controlled by Pfizer or any of its Affiliates on the Effective Date or that comes into the Control of Pfizer or any of its Affiliates during the Term (other than through the grant of a license by BioNTech), including Pfizer's rights in any Research Program Know-How, and (b) relates to one or more Candidates or Products or the Development, Manufacture or Commercialization of any of the foregoing.

1.80. "Pfizer Patent Right" means any Patent Right that (a) is Controlled by Pfizer or any of its Affiliates on the Effective Date or that comes into the Control of Pfizer or any of its Affiliates during the Term (other than through the grant of a license by BioNTech), including Pfizer's rights in any Research Program Patent Rights, and (b) claims any (i) Candidate or Product (including the composition of matter thereof), (ii) method of making any Candidate or Product, (iii) methods of using any Candidate or Product or (iv) Pfizer Know-How.

1.81. "Pfizer Quarter" means each of the four (4) thirteen (13) week periods (a) with respect to the United States, commencing on January 1 of any Pfizer Year and (b) with respect to any country in the Territory other than the United States, commencing on December 1 of any Pfizer Year.

1.82. "Pfizer Technology" means the Pfizer Patent Rights, Pfizer Materials and Pfizer Know-How.

1.83. "Pfizer Year" means the twelve month fiscal periods observed by Pfizer (a) commencing on January 1 with respect to the United States and (b) commencing on December 1 with respect to any country in the Territory other than the United States.

1.84. “Phase I Clinical Trial” means a Clinical Trial that generally provides for the first introduction into humans of a pharmaceutical product with the primary purpose of determining safety, metabolism and pharmacokinetic properties and clinical pharmacology of such product, in a manner that is generally consistent with 21 CFR § 312.21(a), as amended (or its successor regulation), provided, however, a Phase I Clinical Trial does not include any study generally characterized by the FDA as an “exploratory IND study” in CDER’s Guidance for Industry, Investigators, and Reviewers Exploratory IND Studies, January 2006, irrespective of whether or not such study is actually performed in the United States or under an IND. A so-called Phase I/II Clinical Trial shall be deemed to be a Phase I Clinical Trial unless such trial, when completed, allows Pfizer to proceed directly to a Phase III Clinical Trial.

1.85. “Phase II Clinical Trial” means a Clinical Trial, the principal purpose of which is to make a preliminary determination as to whether a pharmaceutical product is safe for its intended use and to obtain sufficient information about such product’s efficacy, in a manner that is generally consistent with 21 CFR § 312.21(b), as amended (or its successor regulation), to permit the design of further Clinical Trials.

1.86. “Phase III Clinical Trial” means a pivotal Clinical Trial with a defined dose or a set of defined doses of a pharmaceutical product designed to ascertain efficacy and safety of such product, in a manner that is generally consistent with 21 CFR § 312.21(c), as amended (or its successor regulation), for the purpose of enabling the preparation and submission of an NDA.

1.87. “Price Approval” means, in any country where a Governmental Authority authorizes reimbursement for, or approves or determines pricing for, pharmaceutical products, receipt (or, if required to make such authorization, approval or determination effective, publication) of such reimbursement authorization or pricing approval or determination (as the case may be).

1.88. “Product” means any pharmaceutical product in a formulation suitable for administration to human subjects that incorporates (a) a Candidate selected by Pfizer for further Development in a Phase I Clinical Trial (other than the FIH Study) or Phase II Clinical Trial, including by selection as CAN based on Pfizer’s CAN Selection Criteria, or (b) any derivative of such Candidate Developed by or on behalf of Pfizer or its Affiliates or Sublicensees in the Field comprising Modified RNA Technology or Replicon Technology.

1.89. “Product Know-How” means (a) any Research Program Know-How or (b) any BioNTech Know-How Controlled by BioNTech as of the Effective Date, in each case of (a) and (b) that is predominantly directed to the composition of matter, treatment with, or the delivery of, Manufacture, form, formulation, or use of a Candidate or Product in the Field. For avoidance of doubt, Product Know-How shall exclude Know-How Controlled by BioNTech as of the Effective Date that is predominantly directed to the use or application of Modified RNA Technology or Replicon Technology that are generally applicable to products in the field of infectious disease or oncology.

1.90. “Product Patent Rights” means any Patent Right that claims any invention included in Product Know-How.

1.91. “Product Technology” means all Product Know-How and Product Patent Rights.

1.92. “Public Health Service Act” or “PHS Act” means the United States Public Health Service Act (42 U.S.C. 201 *et seq*), as amended from time to time (including any rules and regulations promulgated thereunder) or any subsequent or superseding law, statute or regulation

1.93. “RNA Improvement” means any Intellectual Property Right arising after the expiration of the Research Term and [***] solely or jointly made by Pfizer’s Representatives, and solely to the extent such Intellectual Property Right is an improvement or modification made to the Replicon Technology, Modified RNA Technology, Delivery Technology or RNA Process Technology and provided that such Replicon Technology, Modified RNA Technology, Delivery Technology or RNA Process Technology used (a) had been disclosed to Pfizer or Pfizer’s Representatives by BioNTech prior to the time of improvement or modification and (b) was BioNTech’s Confidential Information at the time of such disclosure.

1.94. “RNA Process Technology” means the BioNTech Know-How used to Manufacture Candidates or Products.

1.95. “RNA Technology” means Replicon Technology, Modified RNA Technology and Delivery Technology that is, in each case, used by BioNTech in the Research Program

1.96. “Regulatory Approval” means all technical, medical and scientific licenses, registrations, authorizations and approvals (including approvals of NDAs, supplements and amendments, pre- and post-approvals and labeling approvals) of any Regulatory Authority, necessary or useful for the use, Development, Manufacture, and Commercialization of a pharmaceutical or biopharmaceutical product in a regulatory jurisdiction, including commercially reasonable Price Approvals and commercially reasonable Third Party reimbursement approvals.

1.97. “Regulatory Authority” means, with respect to a country in the Territory, any national (e.g., the FDA), supra-national (e.g., the European Commission, the Council of the European Union, or the European Medicines Agency), regional, state or local regulatory agency, department, bureau, commission, council or other Governmental Authority involved in the granting of a Regulatory Approval or, to the extent required in such country, Price Approval, for pharmaceutical products in such country.

1.98. “Relevant Factors” means all relevant factors that may affect the Development, Regulatory Approval or Commercialization of a Candidate or Product, including (as applicable): [***].

1.99. “Replicon” means an RNA molecule(s) that comprises a gene encoding a polymerase that can, when the RNA molecule(s) is introduced into a cell, replicate the same or a different RNA molecule(s), that also comprises a gene encoding at least one Antigen and does not comprise the full set of genes required to make an infectious virus and is capable, when introduced into a cell, of expressing detectable levels of the encoded Antigen.

1.100. “Replicon Product” means any Product comprising Replicon Technology.

1.101. “Replicon Technology” means the BioNTech Know-How applicable to Replicons. For clarity, Replicon Technology does not include Modified RNA Technology or Delivery Technology.

1.102. “Representatives” means (a) with respect to Pfizer, Pfizer, its Affiliates, its Sublicensees and each of their respective officers, directors, employees, consultants, contractors and agents and (b) with respect to BioNTech, BioNTech, its Affiliates and each of their respective officers, directors, employees, consultants, contractors and agents.

1.103. “Research Plan” means the research plan attached hereto as Exhibit A, as it may be amended from time to time pursuant to Section 4.1.

1.104. “Research Program” means the program of collaboration between the Parties to Develop and Manufacture Candidates and Products in the Field including the activities described in the Research Plan.

1.105. “Research Program Know-How” means any and all Know-How, Candidates and Products, whether or not patentable, made or created solely by or on behalf of either Party or its Representatives in the conduct of activities under the Research Plan or made jointly by or on behalf of (i) BioNTech or its Representatives and (ii) Pfizer or its Representatives in the conduct of activities under the Research Plan.

1.106. “Research Program Patent Rights” means any and all Patent Rights claiming or disclosing any invention included in Research Program Know-How.

1.107. “Research Program Technology” means the Research Program Patent Rights and Research Program Know-How.

1.108. “Research Term” means the period of time beginning on the Effective Date and expiring on the date that is the third anniversary thereof or such later date as may be established pursuant to Section 4.4, unless earlier terminated pursuant to the terms of this Agreement.

1.109. “Residual Knowledge” means knowledge, techniques, experience and Know-How that (a) are, or are based on, any Confidential Information of the Disclosing Party and (b) are retained in the unaided memory of any authorized Representative of the Receiving Party after having access to such Confidential Information. An individual’s memory will be considered to be unaided if the individual has not intentionally memorized the Confidential Information for the purpose of retaining and subsequently using or disclosing it.

1.110. “Reversion Technology” means, as of the effective date of termination of this Agreement and with respect to a Continuation Product, (a) Pfizer’s rights in any Research Program Know-How and (b) any Pfizer Patent Right if and solely to the extent such Pfizer Patent Right claims any Research Program Know-How described in clause (a) above, in each case of clause (a) and (b) to the extent necessary or useful to Develop, Commercialize or Manufacture such Continuation Product.

1.111. “Royalty Term” means (a) for all Modified RNA Products, on a country-by-country basis, the period of time from the First Commercial Sale of the first Modified RNA Product in such country in the Field until the later of (i) the period during which the manufacture, sale, offer for sale or importation of such first Modified RNA Product in such country would infringe, but for the license granted herein, a Valid Claim Covering such first Modified RNA Product in such country, (ii) the tenth (10th) anniversary of the date of the First Commercial Sale of such first Modified RNA Product in such country in the Field, or (iii) lapse of regulatory data exclusivity for such first Modified RNA Product in such country (or region to which the country is a member state); and (b) for all Replicon Products, on a country-by-country basis, the period of time from the First Commercial Sale of the first Replicon Product in such country in the Field until the later of (i) the period during which the manufacture, sale, offer for sale or importation of such first Replicon Product in such country would infringe, but for the license granted herein, a Valid Claim Covering such first Replicon Product in such country, (ii) the tenth (10th) anniversary of the date of the First Commercial Sale of such first Replicon Product in such country in the Field, or (iii) lapse of regulatory data exclusivity for such first Replicon Product in such country (or region to which the country is a member state). If a Product comprises both Modified RNA Technology and Replicon Technology (“Combined Product”), where it is the first Product to achieve a First Commercial Sale in any country in the Territory, it shall be

classified by Pfizer as either a Modified RNA Product or a Replicon Product (but not both) for the purposes of this definition in such country until such time as a different Product that comprises either Modified RNA Technology or Replicon Technology (but not both) achieves a First Commercial Sale in such country, whereupon the second Product shall be classified under this definition as either a Modified RNA Product or Replicon Product according to the technology it comprises and the Combined Product shall thereafter be deemed to fall within the other definition. If a Combined Product is the second Product to achieve a First Commercial Sale in a country in the Territory, it will be deemed to fall within the definition of Modified RNA Product if the first Product was a Replicon Product and vice versa. For the avoidance of doubt, per country there will be no more than two (2) different Royalty Terms for all Products in such country.

1.112. “Specified Persons” means the list of companies set forth in Schedule 1.112, their subsidiaries and any of their successors and assigns in respect of their vaccines business.

1.113. “Subject” means the individual donor of the Human Material or of the original tissues from which the Human Material was derived.

1.114. “Sublicensee” means any Person to whom Pfizer grants or has granted, directly or indirectly, a sublicense of rights licensed by BioNTech to Pfizer under this Agreement.

1.115. “Territory” means worldwide.

1.116. “Third Party” means any Person other than Pfizer, BioNTech or their respective Affiliates.

1.117. “Trademark” means any trademark, trade name, service mark, service name, brand, domain name, trade dress, logo, slogan or other indicia of origin or ownership, including the goodwill and activities associated with each of the foregoing.

1.118. “UPC Agreement” means the treaty Agreement on the Unified Patent Court signed 19 February 2013, as may be amended or superseded from time.

1.119. “Valid Claim” means, with respect to a particular country, (a) a claim of an issued and unexpired Patent Right included within the BioNTech Patent Rights, or Research Program Patent Rights claiming the Product or the Manufacture or use thereof that (i) has not been held permanently revoked, unenforceable or invalid by a decision of a court or other governmental authority of competent jurisdiction, which decision is unappealed or unappealable within the time allowed for appeal, and (ii) has not been cancelled, withdrawn, abandoned, disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise; or (b) a bona fide claim of a pending patent application included within the BioNTech Patent Rights or Research Program Patent Rights claiming the Product or the Manufacture or use thereof that has not been (i) cancelled, withdrawn or abandoned without being refiled in another application in the applicable jurisdiction or (ii) finally rejected by an administrative agency action from which no appeal can be taken or that has not been appealed within the time allowed for appeal, provided that any claim in any patent application pending for more than seven (7) years from the earliest date on which such patent application claims priority shall not be considered a Valid Claim for purposes of the Agreement from and after such seven (7) year date; provided, further, that in no event will any claim of Patent Right that would otherwise be expired except for a Patent Term Extension with respect to a product that is not a Product or Candidate be considered a Valid Claim.

1.120. The following terms are defined in the section of this Agreement listed opposite each term:

Defined Term	Section in Agreement
Acquirer	10.10.2
Acquisition Program	2.10.3
Additional Patent Jurisdictions	7.3.1(a)
Additional Third Party License	3.5.3(a)
Agreement	Preamble
Antitrust Filings	10.1
Approved Subcontractors	4.2.2
BioNTech	Preamble
BioNTech AG	Preamble
BioNTech Indemnified Party	11.2
BioNTech JSC Members	4.3.2(a)
BioNTech Owned Research Program Patent Rights	7.3.1(b)
BioNTech Prosecution Patent Rights	7.3.1(a)
BioNTech Review Period	8.5.3
BioNTech RNA	Preamble
BioNTech ROFN Notice	2.12.1
BioNTech ROFR Notice	2.11.1
Change of Control Party	8.6
Change of Control Term	10.9
CMO	5.4
Combined Product	1.111
Competitive Product Infringement	7.3.2(b)
Continuation Product	10.7.1(a)(ii)(A)
Continuation Product Net Sales	Schedule 10.7.1(a)
Continuation Product Royalty Term	Schedule 10.7.1(a)
Continuing Party	7.3.1(c)
Cure Plan	2.8.3
Debtor	10.8.1
Declining Party	7.3.1(c)
Development Payment	3.3
Diligence Issue	6.2.5
Disputed Matter	4.3.2(e)
Disclosing Party	8.1
Enforcement Action	7.3.2(a)
Execution Date	Preamble
Foreign Antitrust Laws	1.41
Future BioNTech Third Party Agreement	2.9
Global Trade Control Laws	12.11
hCMV	2.11
HCPs	9.3.23
Impf Group	1.1
Incremental Withholding Tax	3.6.4(a)
Indemnified Party	11.4.1
Indemnifying Party	11.4.1
Infringement Claim	7.3.6

Defined Term	Section in Agreement
IRB / IEC	1.57
JSC Chair	4.3.2(b)
Key Patent Jurisdictions	7.3.1(a)
Liabilities	11.2
Licensed Activities	7.3.5(a)
Litigation Conditions	11.4.2
Marginal Royalty Rate	3.5.1
Manufacturing Technology Transfer Plan	5.4
Necessary	3.5.3(a)
Notice of Dispute	12.12.1
Other BioNTech Technology	2.13
Partnered Field and Partnered Fields	2.11
Party or Parties	Preamble
Patent Committee	7.1
Patent Term Extension	7.3.1(e)
Pfizer	Preamble
Pfizer Indemnified Party	11.3
Pfizer JSC Members	4.3.2(a)
Pfizer Materials	4.6.1
Pfizer Review Period	8.5.2
Product Technology Transfer Plan	4.3.2(d)(x)
Prosecution Proceedings	7.3.1(f)
Policies	9.3.24
Program Director and Program Directors	4.3.1(a)
Receiving Party	8.1
Reference Product	1.14
Regulatory Materials	Schedule 10.7.1(a)
Restricted Market	12.11.1
Restricted Parties	12.11.2
Right of First Negotiation	2.12
Right of First Refusal	2.11
RNA	1.33
ROFN Negotiation Period	2.12.2
ROFN Partnering Terms	2.12.2
ROFN Term	2.12
ROFR Negotiation Period	2.11.3
ROFR Partnering Terms	2.11.3
ROFR Term	2.11
RSV	2.11
Sales Milestone Payment	3.4
Term	10.4
Third Party Claim	11.4.1
Third Party IP Rights	7.3.5(b)
Third Party Licensor	1.11
Total Annual Net Sales	3.4
Transition Plan	Schedule 10.7.1(a)

Defined Term	Section in Agreement
Useful	3.5.3(a)
VAT	3.6.4(b)
Withholding Tax	3.6.4(a)

2. **LICENSE GRANTS, TECHNOLOGY TRANSFER, EXCLUSIVITY AND OTHER RIGHTS**

2.1. **Exclusive License from BioNTech to Pfizer.** Subject to the terms and conditions of this Agreement, effective as of the Effective Date, BioNTech on behalf of itself and its Affiliates hereby grants (and will procure that its Affiliates grant) to Pfizer an exclusive (exclusive even as to BioNTech and its Affiliates except to the extent necessary (a) to perform BioNTech’s activities under the Research Plan during the Research Term and (b) to Manufacture Clinical Trial Material as provided in this Agreement or the Supply Agreement) sublicensable (through multiple tiers) license and, to the extent any BioNTech Technology is Controlled by BioNTech or its Affiliates pursuant to a BioNTech Third Party Agreement existing as of the Effective Date and, subject to Section 2.9, Future BioNTech Third Party Agreements, a sublicense, as applicable, under the BioNTech Technology and BioNTech’s and its Affiliates’ interest in the Research Program Technology (including any BioNTech Improvements), to use, have used, Develop, have Developed, Manufacture, have Manufactured, Commercialize, have Commercialized and otherwise Exploit Candidates, Products and [***] in the Territory. Without prejudice to Section 2.10.2, the foregoing license shall not prevent BioNTech and its Affiliates from conducting internal research directed outside the Field where flu antigens or BioNTech Technology are used solely as comparators in such research. For avoidance of doubt, [***]: (i) which is not a Candidate or Product, (ii) which is Exploited by Pfizer under the foregoing license, and (iii) the Exploitation of which would, absent such foregoing license, infringe a valid claim under the BioNTech Patent Rights or BioNTech’s rights in the Research Program Patent Rights (with “valid claim” being construed by applying Section 1.119 *mutatis mutandis*) shall be considered a Candidate or Product for the purposes of this Agreement.

2.2. **Non-Exclusive License from BioNTech to Pfizer.** Without limiting any other license or sublicense granted under this Agreement and subject to the terms and conditions of this Agreement, BioNTech on behalf of itself and its Affiliates, effective as of the Effective Date, hereby grants (and will procure that its Affiliates grant) to Pfizer a non-exclusive, royalty-free, fully paid-up, sublicensable license and, to the extent any BioNTech Technology is Controlled by BioNTech or its Affiliates pursuant to a BioNTech Third Party Agreement existing as of the Effective Date and, subject to Section 2.9, Future BioNTech Third Party Agreements, a sublicense, as applicable, under all Patent Rights, Know-How and other Intellectual Property Rights Controlled by BioNTech or its Affiliates and existing as of or after the Effective Date (to the extent such Patent Rights, Know-How and other Intellectual Property Rights are not exclusively licensed or sublicensed to Pfizer pursuant to Section 2.1), to use, have used, Develop, have Developed, Manufacture, have Manufactured, Commercialize, have Commercialized and otherwise Exploit Candidates and Products in the Field in the Territory during the Term.

2.3. Additional Licenses.

2.3.1. **To Pfizer.**

Without limiting any other license or sublicense granted under this Agreement and subject to the terms and conditions of this Agreement, BioNTech on behalf of itself and its Affiliates, effective as of the Effective Date, hereby grants (and will procure that its Affiliates grant) to Pfizer a non-exclusive, royalty-free, fully paid-up, sublicensable license under all BioNTech Improvements that were solely or jointly invented by Pfizer Representatives to use, have used, Develop, have Developed, Manufacture, have Manufactured, Commercialize, have Commercialized and otherwise Exploit any products or processes in any field. In addition to the obligations set forth in Section 2.10 for the avoidance of doubt, the license granted in this Section 2.3.1 shall not include or imply a right of Pfizer to use any BioNTech's Confidential Information (that is not a BioNTech Improvement) outside the Field.

2.3.2. **To BioNTech.**

(a) Without limiting any other license or sublicense granted under this Agreement and subject to the terms and conditions of this Agreement, Pfizer, effective as of the Effective Date, hereby grants to BioNTech a non-exclusive, royalty-free, fully paid-up, sublicensable license under all Pfizer Improvements that were solely or jointly invented by BioNTech Representatives to use, have used, Develop, have Developed, Manufacture, have Manufactured, Commercialize, have Commercialized and otherwise Exploit any products or processes outside the Field.

(b) Without limiting any other license or sublicense granted under this Agreement and subject to the terms and conditions of this Agreement, Pfizer, effective as of the Effective Date, hereby grants to BioNTech a non-exclusive, royalty-free, fully paid-up, sublicensable license under (i) all RNA Improvements and (ii) Pfizer's interest in the Research Program Technology, in each case of (i) and (ii) to use, have used, Develop, have Developed, Manufacture, have Manufactured, Commercialize, have Commercialized and otherwise Exploit any products or processes outside the Field.

(c) For the avoidance of doubt, the licenses granted in this Section 2.3.2 shall not include or imply a right of BioNTech to use any Pfizer Confidential Information (that is not a Pfizer Improvement, RNA Improvements or Research Program Technology).

2.4. Pfizer Sublicensees. Pfizer will have the right through multiple tiers to grant sublicenses and, as applicable, sub-sublicenses to its Affiliates and Third Parties of any and all rights granted to Pfizer under this Agreement by BioNTech, including any and all rights licensed to Pfizer pursuant to Section 2.1 or Section 2.2. In respect of such sublicenses (or sub-sublicenses):

(a) Pfizer will remain responsible for the payment to BioNTech of all Sales Milestone Payments and royalties payable under this Agreement with respect to Net Sales of Products made by such Pfizer Affiliates or Sublicensees;

(b) Pfizer shall be responsible for failure by its Sublicensees to comply with the terms and conditions of this Agreement;

(c) Pfizer shall notify BioNTech in writing of any sublicenses granted to Third Parties and, upon BioNTech's written request, provide BioNTech with a written summary of key terms of the respective sublicense agreement (excluding any terms reasonably deemed commercially sensitive or confidential by Pfizer); and

(d) Unless otherwise agreed between the Parties on a case-by-case basis (e.g. with a view of converting certain sublicenses into direct licenses with BioNTech), all sublicenses shall automatically terminate (and Pfizer shall ensure that all sublicenses automatically terminate) upon termination (for whatever reason) of a license granted hereunder, but only to the extent necessary to terminate the sublicense in so far as it corresponds to any terminated licenses granted in this Agreement.

2.5. Direct Licenses to Affiliates. Pfizer may, from time to time, request that BioNTech grants on behalf of itself and its Affiliates (and will procure that its Affiliates grant) licenses or sublicenses directly to Affiliates of Pfizer by giving written notice, upon receipt of which BioNTech and its Affiliates will enter into and sign a separate direct license or sublicense agreement with such designated Affiliate of Pfizer. All such direct license or sublicense agreements will be consistent with the terms and conditions of this Agreement, except for such modifications as may be required by applicable Laws in the country in which the direct license or sublicense will be exercised. The Parties further agree to make any amendments to this Agreement that are necessary to conform the combined terms of such direct licenses or sublicenses and this Agreement to the terms of this Agreement as set forth on the Execution Date. All reasonable costs of making such direct license or sublicense agreement(s), including BioNTech's reasonable attorneys' fees, under this Section 2.5 will be borne by Pfizer.

2.6. Non-Exclusive License from Pfizer to BioNTech. Subject to the terms and conditions of this Agreement, Pfizer hereby grants to BioNTech a non-exclusive, royalty-free, fully paid-up license in the Territory in the Field, with no right to grant sublicenses other than to its Affiliates, and to permitted subcontractors under Section 4.2.2, under the Pfizer Technology solely: (i) during the Research Term to the extent necessary to perform BioNTech's activities under the Research Plan; and (ii) to the extent necessary to Manufacture Clinical Trial Material as provided in this Agreement or the Supply Agreement.

2.7. Right of Reference. BioNTech on behalf of itself and its Affiliates hereby grants (and will procure that its Affiliates grant) to Pfizer, its Affiliates and its Sublicensees a "Right of Reference," as that term is defined in 21 C.F.R. § 314.3(b) (or any analogous Law recognized outside of the United States), to all data (including any regulatory filings or Regulatory Approvals) Controlled by BioNTech or its Affiliates that relates to any Candidate or Product, and BioNTech will provide a signed statement to this effect, if requested by Pfizer, in accordance with 21 C.F.R. § 314.50(g)(3) (or any analogous Law outside of the United States).

2.8. Current Licenses.

2.8.1. **Maintenance of Current Licenses.** BioNTech will maintain in full effect and will perform all of its obligations in a timely manner under each of the Current Licenses. Absent Pfizer's prior written consent (which may be provided, conditioned or withheld in Pfizer's sole discretion), BioNTech will not terminate, modify or amend any Current License in any manner that would adversely affect any of the rights granted or that may be granted to Pfizer under this Agreement or that would impose any obligations upon Pfizer hereunder that are in addition to those obligations that would exist under this Agreement based on the Current Licenses as they exist on the Effective Date or adversely affect BioNTech's ability to perform its obligations under this Agreement. Further, BioNTech will not take any action or omit to take any action that would cause it to be in breach of any Current License or that would give rise to a right of any Current Licensor to terminate the applicable Current License.

2.8.2. Communications and Performance. Notwithstanding anything to the contrary in this Agreement, BioNTech will use Commercially Reasonable Efforts to facilitate any communications between Pfizer and any Current Licensor required for Pfizer to exercise the rights granted to it pursuant to Section 2 and will use Commercially Reasonable Efforts to cause each applicable Current Licensor to perform all of its obligations under the applicable Current License.

2.8.3. Breach of Current License by BioNTech. If BioNTech receives notification of any actual or potential breach or otherwise becomes aware of its breach of any Current License (and if uncured, such breach could give rise to the termination of the applicable Current License), then BioNTech will immediately notify Pfizer of such breach. To the extent that any act or omission on the part of Pfizer is the cause of such breach of a Current License, Pfizer will take all actions and provide BioNTech with all cooperation necessary to cure such breach, in each case as reasonably requested by BioNTech and at Pfizer's sole cost and expense. To the extent that Pfizer is not the cause of such breach of a Current License, BioNTech will have the first opportunity to cure such breach in accordance with a plan to be mutually agreed upon by the Parties in writing, acting reasonably (each, a "Cure Plan"). If (a) BioNTech, at any time, is not using diligent efforts to cure such breach pursuant to the applicable Cure Plan or (b) BioNTech is unable to cure such breach in accordance with the applicable Cure Plan or it becomes reasonably apparent that BioNTech will not be able to cure such breach pursuant to the applicable Cure Plan, then Pfizer may, at its election and in its sole discretion and without prejudice to its other remedies against BioNTech, act reasonably to cure such breach and BioNTech will take all actions and provide Pfizer with all cooperation to cure such breach, in each case as directed by Pfizer. Further, if Pfizer is not the cause of such breach of a Current License, then BioNTech will, at Pfizer's sole election, (i) reimburse Pfizer for all out-of-pocket costs and expenses incurred by or on behalf of Pfizer or any of its Representatives in connection with curing such breach; or (ii) permit Pfizer to offset any such costs and expenses incurred by or on behalf of Pfizer or any of Pfizer's Representatives in connection with curing such breach against Pfizer's future payment obligations to BioNTech (or any of its successor or assigns) under this Agreement.

2.8.4. Termination of any Current License. In the event that any Current License is terminated by the applicable Current Licensor and this Agreement, as of the effective date of such termination, has not otherwise been terminated, Pfizer, to the extent permitted by such Current License (or if not permitted or addressed in such Current License, to the extent permitted by the applicable Current Licensor), will have the right without prejudice to its other remedies against BioNTech, at Pfizer's election, to convert the sublicenses granted under this Agreement by BioNTech to Pfizer under such Current License to a direct license from the applicable Current Licensor to Pfizer on the terms and conditions contained in such Current License (with Pfizer assuming the applicable obligations of BioNTech thereunder) or such other terms and conditions as may be negotiated by Pfizer and the applicable Current Licensor. In the event Pfizer enters into any such direct license with a Current Licensor, BioNTech will, at Pfizer's sole election and without prejudice to its other remedies hereunder:

(a) in respect of royalties payable by Pfizer under such direct license to the Current Licensor, to the extent such royalties are due in connection with the sale of Candidates or Products hereunder, reimburse to Pfizer the difference between (i) the amount that would have been payable by BioNTech to the Current Licensor under the Current License if the Current License had not been terminated and (ii) the amount that would have to be reimbursed by Pfizer to BioNTech in accordance with Section 3.5.3(b) in relation to the Current License if the Current License had not been terminated; or

(b) permit Pfizer to offset any such reimbursement amounts (to the extent not reimbursed pursuant to clause (a) above), against Pfizer's future payment obligations to BioNTech (or any of its successor or assigns) under this Agreement.

2.8.5. Consents and Waivers. BioNTech represents, warrants and covenants to Pfizer that, to the extent any terms and conditions of this Agreement do not (or will not at any time during the Term) conform to any requirements relating to the grant of sublicenses under any Current License, it has obtained the irrevocable consent (or, if applicable, the waiver of any resultant conflict) from the applicable Current Licensor that is necessary to permit the activities contemplated under this Agreement, including, such that BioNTech may grant the applicable sublicenses granted or to be granted hereunder and perform all of its obligations hereunder and Pfizer may exercise all of its rights and perform all of its obligations hereunder, in each case, without breaching the applicable Current License. In the event that any provision in any Current License which conflicts with this Agreement or adversely impacts the activities contemplated under this Agreement comes to the attention of either BioNTech or Pfizer or which otherwise, at any time during the Term, would cause the representation, warranty and covenant set forth in the preceding sentence to be untrue, BioNTech, in consultation with Pfizer, will obtain any and all additional required consents or waivers from the applicable Current Licensor(s) which may be necessary to align the conflicting provision(s) of the applicable Current License with this Agreement and to permit the activities contemplated by this Agreement.

2.9. Future BioNTech Third Party Agreements. If BioNTech enters into bona fide discussions with a Third Party after the Effective Date which would, if an agreement is finally executed with such Third Party, give BioNTech rights to any Intellectual Property Rights that could reasonably be applicable to the Candidates or Products in the Field, then BioNTech shall notify the JSC for discussion pursuant to Section 4.3.2(d)(vii). Any Intellectual Property Rights Controlled by BioNTech pursuant to a BioNTech Third Party Agreement executed between BioNTech and such Third Party (each, a "Future BioNTech Third Party Agreement") shall only be included in the licenses granted to Pfizer under this Agreement if and when Pfizer: (a) notifies BioNTech in writing that such Intellectual Property Rights be included in the licenses granted to Pfizer under this Agreement; (b) agrees to reimburse BioNTech [***] of the royalties payable by BioNTech to the Third Party Licensor under such Future BioNTech Third Party Agreements (i) solely to the extent such royalties are due in connection with the sale of Candidates or Products hereunder and (ii) provided that the [***] cap on royalties payable by Pfizer to BioNTech set forth in Section 3.5.3(b)(y) shall not apply in respect of such reimbursement; and (c) agrees to comply with the terms of such Future BioNTech Third Party Agreement applicable to Pfizer as a sublicensee. BioNTech shall not in any circumstance conclude any agreement with a Third Party so as to prevent Pfizer gaining access to such Third Party's Intellectual Property Rights within the Field for any Candidate or Product.

2.10. No Implied Rights. Except as expressly provided in this Agreement, neither Party will be deemed to have granted the other Party (by implication, estoppel or otherwise) any right, title, license or other interest in or with respect to any Patent Rights, Know-How or other Intellectual Property Rights or information Controlled by such Party.

2.10.1. Exclusivity.

2.10.2. Except for the Research Program, during the Term, BioNTech shall not, and shall procure that its Affiliates shall not Develop, have Developed, Manufacture, have Manufactured, Commercialize, have Commercialized or otherwise Exploit or have Exploited any [***] itself or with or on behalf of a Third Party in the Field, except that BioNTech may continue any BioNTech Third Party Agreement for non-clinical research in the Field with academic institutions and consortia. As of the Effective Date, BioNTech shall not (and shall procure that its Affiliates shall not) enter into any new agreements with any Third Party in the Field without a discussion at and pre-approval by the JSC pursuant to Section 4.3.

2.10.3. During the Research Term, Pfizer and its existing Affiliates shall not enter into any research collaboration or other license agreement with [***] unless and until the JSC mutually agrees pursuant to Section 4.3. For avoidance of doubt, the foregoing exclusivity obligation shall not apply to any agreement with a Third Party possessing supplementary technology to RNA that may enhance the efficiency of a Candidate or Product in the Field, including bioinformatics, automation, DNA synthesis, formulations, selection of epitopes, syringe or other delivery device companies, or the like.

Notwithstanding the foregoing, if a Change of Control occurs with respect to Pfizer and a Third Party during the Research Term, or if Pfizer or any of its existing Affiliates acquires or merges with a Third Party during the Research Term, and such Third Party is, at the time of such Change of Control or acquisition or merger, conducting activities that would cause Pfizer or one of its Affiliates to violate this Section 2.10.3 (such activities, a "Acquisition Program"), then Pfizer or such Third Party shall be permitted to continue such Acquisition Program and such continuation will not constitute a violation of this Section 2.10.3; provided that (a) no Confidential Information of BioNTech or its Affiliates is used in such Acquisition Program and (b) Pfizer shall implement and maintain, in accordance with Pfizer's internal commercially reasonable practices, an information barrier between the working teams involved in the day to day conduct of Pfizer's internal program of Development and Manufacture of Candidates and Products under this Agreement and the equivalent teams under such Acquisition Program.

2.11. Right of First Refusal. Commencing on the Effective Date and expiring on the [***] anniversary thereof ("ROFR Term"), BioNTech on behalf of itself and its Affiliates hereby grants (and procures the grant to) Pfizer the exclusive right of first refusal ("Right of First Refusal") to acquire a worldwide, exclusive license, with the right to sublicense (through multiple tiers), under Intellectual Property Rights Controlled by BioNTech and its Affiliates to use, have used, Develop, have Developed, Manufacture, have Manufactured, Commercialize, have Commercialized and otherwise Exploit immunogenic compositions comprising RNA that encodes at least one Antigen for prophylaxis against respiratory syncytial virus ("RSV") or human cytomegalovirus ("hCMV") in the Territory (each a "Partnered Field" and collectively, the "Partnered Fields") as follows:

2.11.1. During the ROFR Term, BioNTech shall notify Pfizer in writing before it or any Affiliate enters into an agreement with a Third Party in the Territory in one or both of the Partnered Fields. BioNTech's writing shall identify the Partnered Field(s) and provide reasonable details of the terms of the proposed agreement with the Third Party, including the financial terms, and a written report in reasonable detail of any of BioNTech's and its Affiliates' existing data that may be relevant to candidates/products in the Partnered Field(s) that Pfizer is otherwise unaware of

(“BioNTech ROFR Notice”), and, if Pfizer so requests, BioNTech shall provide access to the same set of data and information that such Third Party has had access via a data room or other means. For avoidance of doubt, if BioNTech’s written notice applies to only one Partnering Field, then Pfizer’s Right of First Refusal for the other Partnering Field shall not be affected and continue to apply.

2.11.2. Within [***] days after receiving a BioNTech ROFR Notice, Pfizer shall respond in writing as to whether Pfizer has a good faith desire to obtain such rights on the same terms as set out in the BioNTech ROFR Notice. If Pfizer responds in the negative, or fails to respond within the [***] days, then Pfizer shall have no further rights under this Section 2.11 as to the applicable Partnering Field(s), provided however, that under no circumstances may BioNTech nor its Affiliate during the ROFR Term enter into an agreement with a Third Party with respect to such Partnering Field(s) containing terms, taken as a whole, that are more favorable to such Third Party than the terms and conditions set forth in the BioNTech ROFR Notice.

2.11.3. If Pfizer responds in the affirmative within the [***] days, then this shall commence a [***] day period (“ROFR Negotiation Period”) of good faith exclusive negotiations between the Parties acting reasonably as to the terms upon which BioNTech would partner with or license to Pfizer in the applicable Partnering Field(s) (“ROFR Partnering Terms”). During the ROFR Negotiation Period, BioNTech shall not and shall procure its Affiliates shall not negotiate with any Third Party the terms upon which BioNTech or its Affiliates would partner with or license to such Third Party in the Partnering Field(s). If the Parties are unable to agree on the ROFR Partnering Terms and conclude a respective definitive written agreement during the ROFR Negotiation Period, then Pfizer shall have no further rights under this Section 2.11 as to the Partnering Field(s), provided, however, that under no circumstances may BioNTech nor its Affiliates during the ROFR Term enter into an agreement with a Third Party with respect to such Partnering Field(s) containing terms, taken as a whole, that are more favorable to such Third Party than the terms and conditions set forth in the BioNTech ROFR Notice.

2.11.4. The ROFR excludes agreements for research in the Field with academic institutions and consortia, which are subject to JSC approval under Section 4.3.2(d).

2.12. Right of First Negotiation. Effective as of the expiration of the ROFR Term and terminating as of the expiration of the Research Term (“ROFN Term”), if BioNTech or its Affiliate elects to license or otherwise grant rights to a Third Party under Intellectual Property Rights Controlled by BioNTech or its Affiliates in Partnering Field(s), then Pfizer shall have a right of first negotiation with respect to the first license or other partnership agreement for each of the Partnering Field(s) (“Right of First Negotiation”) as follows:

2.12.1. During the ROFN Term, upon the request of the JSC, such request not to be made more than twice per Calendar Year, BioNTech shall provide the JSC with an oral summary regarding any Development activities it may have conducted or is planning to conduct in respect of the Partnering Fields. During the ROFN Term, (a) if Pfizer provides BioNTech with a written notice electing the Right of First Negotiation with respect to one or both Partnering Fields or (b) prior to BioNTech entering into bona fide negotiations with a Third Party with respect to the negotiation of a definitive legal agreement for a grant of rights to Intellectual Property Rights Controlled by BioNTech and its Affiliates for the Partnering Field(s), BioNTech shall first notify Pfizer in writing. BioNTech’s written notice shall identify the Partnered Field(s) and provide a

written report in reasonable detail of any of BioNTech's and its Affiliates' existing data that may be relevant to candidates/products in the Partnered Field(s) that Pfizer is otherwise unaware of ("BioNTech ROFN Notice"), and, if Pfizer so requests, provide access to any relevant data and information via a data room or by other mutually agreed upon means. For avoidance of doubt, if BioNTech's written notice applies to only one Partnering Field, then Pfizer's Right of First Negotiation for the other Partnering Field shall not be affected and shall continue.

2.12.2. Within [***] days after receiving a BioNTech ROFN Notice, Pfizer shall respond in writing as to whether Pfizer elects to negotiate terms with BioNTech. If Pfizer responds in the negative, or fails to respond within the [***] days, then Pfizer shall have no further rights under this Section 2.13, as to the applicable Partnering Field(s). If Pfizer elects to commence a ROFN or responds to a ROFN Notice in the affirmative within the [***] days, then this shall commence an exclusive [***] day negotiation period ("ROFN Negotiation Period") during which the Parties shall negotiate, in good faith and acting reasonably, a definitive written agreement between the Parties as to the terms upon which BioNTech and its Affiliates would partner with or license to Pfizer Intellectual Property Rights Controlled by BioNTech and its Affiliates for the Partnering Field(s) ("ROFN Partnering Terms"). During the ROFN Negotiation Period, BioNTech shall not and shall procure its Affiliates shall not negotiate with any Third Party the terms upon which BioNTech or its Affiliates would partner with or license to such Third Party Intellectual Property Rights Controlled by BioNTech and its Affiliates for the Partnering Field(s). If the Parties are unable to agree on the ROFN Partnering Terms and do not conclude a respective definitive written agreement during the ROFN Negotiation Period, then the ROFN Negotiation Period shall expire and BioNTech shall be free to continue discussions with Pfizer or institute discussions on the same opportunity for the applicable Partnering Field(s) with Third Parties. For clarity, the Right of First Negotiation set forth in this Section 2.12 shall apply a maximum of [***] times only; once for each of the RSV and hCMV fields.

2.13. Access to Other BioNTech Technology. From time to time, Pfizer may, in addition to the licences granted hereunder, request a license from BioNTech to Other BioNTech Technology for use in a Candidate or Product in the Field as Pfizer may identify, such license to be of comparable scope and comparable terms to the licenses granted under Sections 2.1 in respect of Candidates and Products in the Field. For the purposes of this Agreement, "Other BioNTech Technology," means those Intellectual Property Rights Controlled by BioNTech or its Affiliates from time to time that do not constitute BioNTech Know-how or BioNTech Patent Rights. Upon Pfizer's election for such as license, the Parties shall negotiate such license terms in good faith and acting reasonably (which shall be based on the terms of this Agreement) for a period of not more than [***] days and BioNTech shall neither seek nor require any royalty rate or other financial provisions greater than (i) the mean royalty rate due to BioNTech by other licensees of the same Other BioNTech Technology (reasonably adjusted in so far as it is licensed with other Intellectual Property Rights) in existence as of the date of any notice electing for such a licence pursuant to this Section or (ii) if no such other licenses are in existence as of the date of such notice, the average royalty rate applied in comparable license agreements for similar technologies in the market. Any such license fees agreed pursuant to this Section shall be deemed license payments due under Additional Third Party Licenses for the purposes of Section 3.5.3(a) and accordingly Pfizer shall be entitled to deduct [***] of such license fees. If, however, the Parties cannot reach an agreement within such [***] day period, then the terms of such license for such Other BioNTech Technology shall be determined, taking into account all then-relevant factors including the provisions of this Section 2.13, by an independent Third Party expert knowledgeable in pharma licensing to be agreed between the Parties (and if the Parties cannot agree on such Third Party expert within [***] days of the expiration of the above negotiation period, the Third Party expert shall be

independently appointed upon either Party's request by the International Chamber of Commerce). Each Party shall be obliged to submit its final proposal for the terms of such transition of or license to the Other BioNTech Technology to the Third Party expert, and such proposal shall remain confidential and shall not be disclosed to the other Party. The decision of the Third Party expert shall be final and binding on both Parties. The costs of the Third Party Expert shall be borne by both Parties at equal shares.

3. PAYMENTS BY PFIZER TO BIONTECH

3.1. Up-Front Payment. Pfizer will make a one-time payment of Fifty Million Dollars (\$50,000,000) to BioNTech RNA within 30 days of receipt of BioNTech RNA's invoice (such invoice to be delivered on or following the Effective Date of this Agreement).

3.2. Equity Investment. Pfizer and BioNTech AG shall enter into an "Investment Agreement" contemporaneously with this Agreement pursuant to which Pfizer shall agree to subscribe for shares in BioNTech AG subject to achievement of certain conditions as prescribed in such Investment Agreement.

3.3. Development Payments. Pfizer will pay BioNTech RNA the one-off amounts set forth below within 60 days following the first occurrence of each event described below for the first Candidate or Product (as applicable) Covered by a Valid Claim in the applicable country of Development or Commercialization in the Territory to achieve such event (each, a "Development Payment").

	<u>Development Event</u>	<u>Development Payment</u>
(i)	Initiation of Manufacture of the CTM for such Candidate for the FIH Study (whereas "Initiation of Manufacture" shall mean the start of the Manufacturing of the first batch of CTM by BioNTech that is suitable for use in the FIH Study)	[***]
(ii)	Dosing of the first subject in the first FIH Study of such Candidate	[***]
(iii)	Pfizer's selection of such Candidate for further Development in a Phase I Clinical Trial (other than the FIH Study) or Phase II Clinical Trial including by selection as CAN based on Pfizer's CAN Selection Criteria	[***]
(iv)	Dosing of the first subject in the first Phase I or Phase I/II Clinical Trial (neither being the FIH Study) of a Product	[***]
(v)	Initiation of Manufacture of the CTM that is suitable for a Product for a Phase III Clinical Trial by or on behalf of Pfizer following technology transfer (whereas "Initiation of Manufacture" shall mean the first successful completion of the Manufacturing of an engineering run by or on behalf of Pfizer)	[***]
(vi)	Dosing of the first subject in the first Phase III Clinical Trial of such Product in a Major Market Country	[***]

	<u>Development Event</u>	<u>Development Payment</u>
(vii)	First Commercial Sale of such Product by Pfizer, its Affiliates or Sublicensees in the United States	[***]
(viii)	First Commercial Sale of such Product by Pfizer, its Affiliates or Sublicensees in at least three of the Major EU Market Countries	[***]
(ix)	First Commercial Sale of such Product by Pfizer, its Affiliates or Sublicensees in Japan	[***]

Each of the Development Payments set forth above will be payable one time only (regardless of the number of Candidates or Products with respect to which, or the number of times with respect to any Candidate or Product, the specified Development Event occurs). No Development Payments will be payable by Pfizer for any subsequent Candidate or Product regardless of the number of Candidates or Products Developed. For clarification, if one Candidate or Product replaces another Candidate or Product in Development, then such replacement Candidate or Product will only be subject to Development Payments that have not previously been triggered by one or more prior Candidates or Products. The maximum amount payable by Pfizer under this Agreement with respect to all Development Payments if all Development Events occur will be [***].

If Pfizer achieves one of the Development Events set forth in rows (iii), (iv) or (vi) of the table set forth in Section 3.3, but had not achieved the preceding Development Event set forth (as applicable) in rows (iii) or (iv) of the table set forth in Section 3.3, then those preceding Development Event(s) set forth (as applicable) in rows (iii) or (iv) of the table set forth in Section 3.3 shall be deemed to have occurred and all Development Payments for such preceding Development Event(s) shall become payable. If Pfizer achieves one of the Development Events set forth in rows (vii), (viii) or (ix) of the table set forth in Section 3.3, but had not achieved any of Development Events set forth in rows (iii), (iv) or (vi) of the table set forth in Section 3.3, then those Development Event(s) set forth (as applicable) in rows (iii), (iv) or (vi) of the table set forth in Section 3.3 shall be deemed to have occurred and all Development Payments for such Development Event(s) shall become payable. Notwithstanding the foregoing, Pfizer's achievement of one of the Development Events set forth in rows (iii), (iv), (vi), (vii), (viii) or (ix) of the table set forth in Section 3.3 in response to a request by a Governmental Authority or Regulatory Authority to perform such Development Event due to pandemic flu emergency conditions shall not trigger the payment of any preceding Development Event.

3.4. Sales Milestone Payments. Pfizer will pay BioNTech RNA the following one-time payments (each, a "Sales Milestone Payment") when aggregate Net Sales of all Products on which royalties have been paid to BioNTech under Section 3.5.1 in a Pfizer Year in the Territory (the "Total Annual Net Sales") first reach the respective thresholds indicated below:

[***]

Pfizer will make any Sales Milestone Payment payable with respect to a Pfizer Year within [***] days after the end of the applicable Pfizer Year, and such payment will be accompanied by a report identifying the Products, Net Sales of each Product (including breakdown of gross receipts and permitted deductions), and the amount payable to BioNTech under this Section 3. 4. For the avoidance of doubt: (a) each of the Sales Milestone Payments set forth above will be payable one time only, regardless of the number of times the corresponding Total Annual Net Sales levels are achieved in any number of Pfizer Years; and (b) if Total Annual Net Sales first reach multiple thresholds indicated above in the same Pfizer Year, all respective Sales Milestone Payments shall be payable with respect to that Pfizer Year and shall not be payable again.

3.5. Royalty Payments.

3.5.1. **Royalties.** Subject to the provisions of Section 3.5.3, Pfizer will pay BioNTech RNA royalties on a tiered marginal royalty rate basis during the course of a Pfizer Year as set forth below (the “Marginal Royalty Rates”) based on the applicable royalty percentage calculated against the applicable proportion of the annual aggregate Territory-wide Net Sales resulting from the sale of all Products in all countries in the Territory for which the applicable Royalty Term is in effect, during each Pfizer Year:

[***]

Each Marginal Royalty Rate set forth in the table above will apply only to that portion of the Net Sales of the Products in all countries in the Territory for which the applicable Royalty Term is in effect during a given Pfizer Year and that falls within the indicated range. An example calculation of royalties under this Section 3.5.1 is set forth in Schedule 3.5.1.

3.5.2. **Fully Paid-Up, Royalty Free License.** Following expiration of the Royalty Term for any Product in a given country, no further royalties will be payable in respect of sales of such Product in such country and, thereafter the licenses granted to Pfizer under Sections 2.1, 2.2, 2.3.1 and 2.7 with respect to such Product in such country will automatically become exclusive, fully paid-up, perpetual, irrevocable and royalty-free.

3.5.3. **Royalty Adjustments.** The following adjustments will be made, on a Product-by-Product and country-by-country basis, to the royalties payable pursuant to Section 3.5.1:

(a) **Third Party Patents.** If it is Necessary or Useful for Pfizer to license one or more Patent Rights from one or more Third Parties in respect of the Development, Manufacture, Commercialization, Exploitation or use of any Product in any country, whether directly or through any Pfizer Affiliate or Sublicensee, then Pfizer may, in its reasonable discretion, negotiate and obtain a license under such Patent Right(s) (each such Third Party license referred to herein as an “Additional Third Party License”). Any royalty otherwise payable to BioNTech under this Agreement with respect to Net Sales of such Product in such country by Pfizer, its Affiliates or Sublicensees will be [***] For the avoidance of doubt, this Section 3.5.3(a) shall not apply to any direct licenses entered into

by Pfizer with a Current Licensor in accordance with Section 2.8.4. For the purposes of this Section 3.5.3(a): (i) “Necessary” means that, without a license to use the Patent Right in question, the Development, Manufacture, Commercialization or use of any Candidate or Product, in Pfizer’s opinion, infringes such Patent Right and (ii) “Useful” means that Pfizer has determined that such Third Party’s Patent Right would reasonably enhance the potential, including by reducing cost or complexity of Manufacture, of such Licensed Product.

(b) **No Adjustment for BioNTech Third Party Agreements.** Subject to Section 2.9, BioNTech will be solely responsible for (i) all obligations (including any royalty or other obligations that relate to the BioNTech Technology or BioNTech’s interest in the Research Program Technology) under its agreements with Third Parties that are in effect as of the Effective Date or that BioNTech enters into during the Term and (ii) all payments to inventors (other than inventors that are Representatives of Pfizer) of BioNTech Technology or Research Program Technology, including payments under inventorship compensation Laws, except that Pfizer will [***] (x) solely to the extent such royalties are due in connection with the sale of Candidates or Products hereunder and (y) provided that, notwithstanding anything in the Agreement to the contrary, [***].

(c) **Expiry of Valid Claim Coverage.** In the event that, with respect to any particular Product in any particular country in the Territory, the Royalty Term for such Product in such country extends beyond the date on which such Product is not Covered by any Valid Claim in such country, Net Sales in any such country shall be reduced by [***] for the remainder of the applicable Royalty Term, provided, however, that if this Section 3.5.3(c) applies to a Product, Pfizer may not also apply Section 3.5.3(e).

(d) **Existing Pfizer Third Party Agreements.** Pfizer will be solely responsible for all obligations (including royalty obligations) that relate to Products under its agreements with Third Parties that are in effect on or prior to the Effective Date.

(e) **Biosimilar Entry.** Notwithstanding the foregoing, for any royalty otherwise payable to BioNTech under this Agreement with respect to Net Sales based on sales of a Product in a given country in the Territory, any payments owed with respect to such Product in such country pursuant to this Section 3.5 [***].

(f) **Royalty Floor.** Notwithstanding the provisions of this Section 3.5.3, the maximum reduction of royalties [***].

3.6. Reports and Payments.

3.6.1. **Cumulative Royalties.** The obligation to pay royalties under this Agreement will be imposed only once with respect to any sale of any Product.

3.6.2. **Single Payee.** All payments due and payable by Pfizer or its Affiliates or sublicenses under this Section 3 shall be solely made to BioNTech RNA in full satisfaction of all consideration due hereunder in exchange for the rights granted by BioNTech.

3.6.3. Royalty Statements and Payments. Within [***] days of the end of each Calendar Quarter, Pfizer will deliver to BioNTech a report setting forth, for the most recent Pfizer Quarter ending during such Calendar Quarter, the following information, on a country-by-country and Territory-wide basis: [***]. No such reports will be due for any such Product (i) before the First Commercial Sale of such Product or (ii) after the Royalty Term for such Product has expired in all countries in the Territory. The total royalty due for the sale of all such Products during such Pfizer Quarter will be remitted at the time such report is made; *provided* that to the extent any royalties are payable by Pfizer hereunder on Net Sales of a Product in a country solely due to a Valid Claim Covering such Product in such country that is subject to a revocation, invalidity or unenforceability ruling that is appealable or being appealed, during the time of such appeal or appealability, such royalties payable by Pfizer shall be placed into an escrow account and either (x) returned to Pfizer upon a final, unappealable determination that such revocation, invalidity or unenforceability ruling is upheld or (y) released to BioNTech in the event such revocation, invalidity or unenforceability ruling is not upheld in a final, unappealable determination. In the event that BioNTech disagrees with the basis of Pfizer's calculations of royalties due because BioNTech believes that a Valid Claim Covering a Product was incorrectly omitted from Pfizer's royalty calculations, BioNTech shall notify Pfizer within [***] days of receipt of the relevant royalty statement.

3.6.4. Taxes and Withholding.

(a) **Withholding Taxes.** The Parties agree to use commercially reasonable efforts to cooperate with one another and use commercially reasonable efforts to avoid or reduce, to the extent permitted by applicable Law, tax withholding or similar obligations in respect of royalties, milestone payments, and other payments made by the paying Party to the receiving Party under this Agreement ("Withholding Taxes"). If Withholding Taxes are imposed on any payment under this Agreement, the liability for such Withholding Taxes shall be the sole responsibility of the receiving Party, and the paying Party shall (i) deduct or withhold such Withholding Taxes from the payment made to the receiving Party, (ii) timely pay such Withholding Taxes to the proper taxing authority, and (iii) send proof of payment to the receiving Party within [***] days following such payment. Each Party shall comply with (or provide the other Party with) any certification, identification or other reporting requirements that may be reasonably necessary in order for the paying Party to not withhold Withholding Taxes or to withhold Withholding Taxes at a reduced rate under an applicable bilateral income tax treaty. Each Party shall provide the other with commercially reasonable assistance to enable the recovery, as permitted by applicable Law, of Withholding Taxes or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing the cost of such Withholding Taxes under this Section 3.6.4 (Taxes and Withholding). Notwithstanding the foregoing, if as a result of any assignment or sublicense by the paying Party, any change in the paying Party's tax residency, any change in the entity that originates the payment, or any failure on the part of the paying Party to comply with applicable Law with respect to Withholding Taxes (including filing or record retention requirements), Withholding Taxes are imposed that would not otherwise have been imposed ("Incremental Withholding Taxes"), then the paying Party shall be solely responsible for the amount of such Incremental Withholding Taxes and shall increase the amounts payable to the receiving Party so that the receiving Party receives a sum equal to the sum which it would have received had there been no such imposition of Incremental Withholding Taxes.

(b) **Value Added Tax.** All payments between the Parties under this Agreement are exclusive of applicable statutory value added tax or similar taxes (“VAT”), if any, which shall be listed separately on each invoice. If and to the extent any VAT will become payable due to any supplies or services rendered under this Agreement and if and to the extent such VAT is to be paid by the Party providing the supply or service to the competent tax authorities, the receiving Party shall pay an amount equal to such VAT to the providing Party upon receipt of a valid invoice allowing for the recovery of such VAT.

3.6.5. Currency, Source of Payments. All amounts payable and calculations under this Agreement will be in United States dollars, and Pfizer agrees to make all payments from a source in the United States of America. As applicable, Net Sales and any royalty deductions will be translated into United States dollars at the exchange rate used by Pfizer for public financial accounting purposes. If, due to restrictions or prohibitions imposed by national or international authority, a given payment cannot be made as provided in this Section 3.6.5, the Parties will consult with a view to finding a prompt and acceptable solution. If the Parties are unable to identify a mutually acceptable solution regarding such payment, then Pfizer may elect, in its sole discretion, to deliver such payment in the relevant jurisdiction and in the local currency of the relevant jurisdiction.

3.6.6. Method of Payment. Except as permitted pursuant to Section 3.6.5, each payment hereunder will be made by electronic transfer in immediately available funds via either a bank wire transfer, an ACH (automated clearing house) mechanism, or any other means of electronic funds transfer, at Pfizer’s election, to such bank account set forth below or as BioNTech RNA will designate in writing to Pfizer at least [***] days before the payment is due. All invoice or billing related questions should be referred to Pfizer’s Accounting Department at 800.601.1357 or go to the Accounts Payable Invoice Portal at ap.pfizer.com.

[***]

3.6.7. Record Keeping. Pfizer will keep and will cause its Affiliates and use Commercially Reasonable Efforts to cause its Sublicensees to keep books and accounts of record in connection with the sale of Products in sufficient detail to permit accurate determination of all figures necessary for verification of royalties and Sales Milestone Payments to be paid hereunder. Pfizer and its Affiliates will maintain, and Pfizer shall use Commercially Reasonable Efforts to cause its Sublicensees to maintain, such records for a period of at least [***] years, or such longer period of time required under a Current License, insofar as applicable to the rights sub-licensed pursuant to such Current License and used by Pfizer, its Affiliates and Sublicensees, after the end of the Pfizer Quarter in which they were generated.

3.6.8. Audits. Upon [***] days prior notice from BioNTech, Pfizer will permit (and shall use Commercially Reasonable Efforts to cause its Sublicensees to permit) an independent certified public accounting firm of nationally recognized standing selected by BioNTech and reasonably acceptable to Pfizer, to examine, at BioNTech’s sole expense, the relevant books and records of Pfizer and its Affiliates (and where possible, its Sublicensees) as may be reasonably necessary to verify the amounts reported by Pfizer in accordance with Section 3.6.3 and the payment of royalties and Sales Milestone Payments hereunder. An examination by BioNTech under this Section 3.6.8 will occur not more than once in any Calendar Year and will be limited to the pertinent books and records for any Calendar Year ending not more than [***] years before the date of the request. The

accounting firm will be provided access to such books and records at Pfizer's or its Affiliates' (or where possible its Sublicensees') facility(ies) where such books and records are normally kept and such examination will be conducted during Pfizer's or its Affiliates' (or, where possible, its Sublicensees') normal business hours. Pfizer may require the accounting firm to sign a reasonably acceptable non-disclosure agreement before providing the accounting firm with access to Pfizer's or its Affiliates' (or where possible its Sublicensees') facilities or records. Upon completion of the audit, the accounting firm will provide both Pfizer and BioNTech the same written report disclosing any discrepancies in the reports submitted by Pfizer or the royalties or Sales Milestone Payments paid by Pfizer, and, in each case, the specific details concerning any discrepancies. No other information will be provided to BioNTech. Where Pfizer is not able to cause its Sublicensees to permit an audit according to this Section 3.6.8 (despite using Commercially Reasonable Efforts), Pfizer shall on BioNTech's request exercise its own audit rights under the relevant sublicense agreement; provided, however, that (a) BioNTech shall not request such audit exercise more than once in a Calendar Year, (b) the audit shall be limited to the pertinent books and records for any Calendar Year ending not more than [***] years before the date of the request and (c) if the amount of any underpayment of royalties by any such Sublicensee is less than [***] of the royalties properly payable to BioNTech, then BioNTech shall reimburse Pfizer for Pfizer's out-of-pocket costs in connection with the audit.

3.6.9. Underpayments/Overpayments. If such accounting firm concludes that additional royalties or Sales Milestone Payments were due to BioNTech, then Pfizer will pay to BioNTech the additional royalties or Sales Milestone Payments within [***] days of the date Pfizer receives such accountant's written report. Further, if the amount of such underpayments exceeds more than [***] of the amount that was properly payable to BioNTech, then Pfizer will reimburse BioNTech for BioNTech's out-of-pocket costs in connection with the audit. If such accounting firm concludes that Pfizer overpaid royalties or Sales Milestone Payments to BioNTech, then BioNTech will refund such overpayments to Pfizer, within [***] days of the date BioNTech receives such accountant's report.

3.6.10. Confidentiality. Notwithstanding any provision of this Agreement to the contrary, all reports and financial information of Pfizer, its Affiliates or its Sublicensees which are provided to or subject to review by BioNTech will be deemed to be Pfizer's Confidential Information and subject to the provisions of Section 8.

3.7. No Guarantee of Success.

3.7.1. Pfizer and BioNTech acknowledge and agree that payments to BioNTech pursuant to Section 3.3, Section 3.4 and Section 3.5: (a) have been included in this Agreement on the basis that they are only payable or otherwise relevant if a certain Product is successfully Developed or Commercialized in such country, as applicable; (b) are solely intended to allocate amounts that may be achieved upon successful Development or Commercialization of such Product as applicable, between Pfizer (who will receive all Product sales revenues) and BioNTech; (c) are not intended to be used as a measure of damages if this Agreement is terminated for any reason, including pursuant to Pfizer's right to terminate for convenience, before any such success is achieved and such amounts become due; and (d) will only be triggered, and will only be relevant as provided, in accordance with the terms and conditions of such provisions.

3.7.2. Pfizer and BioNTech further acknowledge and agree that nothing in this Agreement, or in any document or presentation provided by Pfizer to BioNTech prior to the Effective Date will be construed as representing any estimate or projection of (i) the successful Development or Commercialization of any Product under this Agreement, (ii) the number of Products that will or may be successfully Developed or Commercialized under this Agreement, (iii) anticipated sales or the actual value of any Products that may be successfully Developed or Commercialized under this Agreement or (iv) the damages, if any, that may be payable if this Agreement is terminated for any reason.

3.7.3. Pfizer makes no representation, warranty or covenant, either express or implied, that (A) it will successfully Develop, Manufacture, Commercialize or continue to Develop, Manufacture or Commercialize any Product in any country, (B) if Commercialized, that any Product will achieve any particular sales level, whether in any individual country or cumulatively throughout the Territory or (C) Pfizer will devote, or cause to be devoted, any level of diligence or resources to Developing or Commercializing any Product in any country, or in the Territory in general, other than is expressly required under Section 6.2.

4. **RESEARCH PLAN**

4.1. **Scope of Research and Research Plan.** Pfizer and BioNTech will collaborate during the Research Term to conduct research to identify, Develop and evaluate Candidates and Products in accordance with the Research Plan and the terms and conditions set forth in this Section 4. Pfizer reserves the right to modify the Research Plan, in its sole discretion, at any time during the Research Term; provided that any such changes shall be approved by JSC pursuant to Section 4.3.

4.2. **Allocation of Responsibilities.**

4.2.1. **General.** Each Party will use Commercially Reasonable Efforts to perform its obligations and activities identified under the Research Plan in a professional manner in accordance with target dates set forth in Research Plan. Further, each Party will perform its obligations under the Research Plan in compliance with all Laws applicable to its activities under the Research Plan.

4.2.2. **Subcontractors.** BioNTech will not subcontract any of its responsibilities under the Research Plan or otherwise under this Agreement without Pfizer's prior written consent; *provided* that (a) any Affiliates of BioNTech, (b) any subcontractors expressly identified in the Research Plan to conduct specific activities thereunder and (c) those subcontractors set forth on Schedule 4.2.2 ("Approved Subcontractors") shall be deemed to have received such consent from Pfizer. BioNTech shall be responsible for the management of all permitted subcontractors (which will include any BioNTech Affiliate). The engagement by BioNTech or its Affiliate of any subcontractor in compliance with this Section 4.2.2, including the Approved Subcontractors, shall be in writing and shall not relieve BioNTech of its obligations under this Agreement or the Research Plan. Any agreement between BioNTech or its Affiliate and a permitted subcontractor or Approved Subcontractor pertaining to the Research Plan activities shall be consistent with the provisions of this Agreement including (i) an obligation to assign all Intellectual Property rights generated during its performance of such Research Plan to BioNTech free of any encumbrance such that BioNTech may fulfil its licensing and assignment obligations hereunder and (ii) terms and conditions under which such Third Party is obligated to preserve the confidentiality of the Research Program, Research Program Technology and any Confidential Information of Pfizer received by such Third Party from the BioNTech that are at least as restrictive as those described in Section 8.2.1.

4.2.3. Personnel Matters. Each Party acknowledges and agrees that it is solely responsible for the compensation of its personnel assigned to the Research Plan, and shall be responsible for withholding all national, state, local or other applicable taxes and similar items for such personnel. Each Party also shall be responsible for all other of its employer related obligations, including providing appropriate insurance coverage and employee benefits, and making all other deductions required by law affecting the gross wages of each of its employees. BioNTech personnel assigned to the Research Plan activities are not nor shall they be deemed to be employees of Pfizer, and Pfizer personnel assigned to the Research Plan activities are not nor shall they be deemed to be employees of BioNTech.

4.2.4. BioNTech Disclosure and Knowledge Transfer Obligations. Without limiting BioNTech's obligations pursuant to Section 4.2.1, during the Research Term, BioNTech will:

(a) disclose to Pfizer all newly developed RNA Technology and RNA Process Technology and all other newly generated data developed in connection with the Research Plan, in each case in such format as Pfizer may reasonably request (including by download of digital files to a secure website or e-room designated and controlled by Pfizer);

(b) upon Pfizer's request, disclose and provide to Pfizer research grade samples of each Candidate identified by BioNTech as a potential development candidate within a commercially reasonable period not to exceed [***] days;

(c) provide to Pfizer a written summary of all activities, discoveries, developments and results attained by BioNTech under the Research Plan in the regular course of research and no less frequently than every [***] days;

(d) promptly notify Pfizer of any suspected or actual research misconduct, issues pertaining to data integrity or any other information that could reasonably signify or result in a lack of confidence in the accuracy or collection methods of data, each as such may relate to the activities being conducted under the Research Plan;

(e) in accordance with the Product Technology Transfer Plan agreed upon by the JSC pursuant to Section 4.3.2(d)(x), or earlier upon request by Pfizer in the event that BioNTech commits a material breach of any of its obligations under this Agreement and such material breach remains uncured for [***] Business Days, measured from the date written notice of such material breach is given to BioNTech, transfer the Candidates or Products requested by Pfizer and all BioNTech Know-How relating to such Candidates or Products

4.3. Research Governance.

4.3.1. **Collaboration Management.**

(a) *Program Directors.* Each Party will appoint a program director to oversee all activities conducted under the Research Plan (each, a “Program Director” and together the “Program Directors”). Each Party may change its designated Program Director at any time upon written notice to the other Party. The Program Directors will coordinate the efforts of their respective Party in conducting activities under the Research Plan. The Program Directors for Pfizer and BioNTech are Philip Dormitzer and Birgit Pless, respectively.

4.3.2. **Joint Steering Committee.**

(a) *Composition.* As of the Effective Date, the Parties will establish a Joint Steering Committee, comprised of at least two (2) representatives of BioNTech (including the Program Director for BioNTech) and at least two (2) representatives of Pfizer (including the Program Director for Pfizer). The JSC representatives for each of Pfizer and BioNTech will be referred to herein as the “Pfizer JSC Members” and the “BioNTech JSC Members,” respectively. As of the Effective Date, the Pfizer JSC Members shall be (1) [***] and (2) [***] and the BioNTech JSC Members shall be (1) [***] and (2) [***].

Each Party may replace its representatives to the JSC at any time upon notice to the other Party, *provided that* at all times an equal number of representatives from each Party are appointed to the JSC and each Party shall be responsible for ensuring any replaced representative is fully briefed and apprised of the Research Project. Each Party shall procure that its JSC representatives shall make themselves available to attend JSC meetings upon reasonable notice and in accordance with this Agreement. Each Party may invite non-voting employees and consultants to attend meetings of the JSC. All members of the JSC and any invitees of either Party described above will agree in writing to be bound to obligations of confidentiality and assignment of Intellectual Property Rights no less restrictive than those that bind the Parties under this Agreement.

(b) *Committee Chair.* The JSC will be chaired by a Pfizer JSC Member (the “JSC Chair”). Pfizer may replace the JSC Chair at any time upon notice to BioNTech. The responsibilities of the JSC Chair will be:

(i) to notify each Party at least 30 days in advance of each JSC meeting;

(ii) to collect and organize agenda items for each JSC meeting; and

(iii) to prepare the written minutes of each JSC meeting and circulate such minutes for review and approval by the Parties, and identify action items to be carried out by the Parties.

(c) *Meetings.* During the Research Term, the JSC will meet on a Calendar Quarter basis (or less or more frequently as the JSC so determines), either in-person or by audio or video teleconference. Meetings of the JSC will occur at such times and places as mutually agreed by the Parties; provided, however, that no more than two (2) in-person meetings will be required in any Calendar Year. Any sub-committees or working groups established in accordance with Section 4.3.2(d) may meet via audio or video teleconference on a regular basis and in-person at such times and places as the Parties may agree. Meetings of the JSC will only occur if at least one representative of each Party is present at the

meeting or participating by teleconference or videoconference. Each Party will be responsible for, and will not be entitled to any reimbursement from the other Party with respect to, any and all personnel costs or expenses (including travel expenses) which are incurred by or on behalf of its personnel in connection with participation in any JSC meetings or sub-committee or working group meetings, or any other travel required to be undertaken by either Party's personnel in connection with the performance of the Agreement. The Parties will endeavor to schedule meetings of the JSC at least [***] months in advance. The JSC Chair will use good faith efforts to (i) prepare and circulate to BioNTech each JSC meeting agenda no later than five Business Days prior to the scheduled date for each JSC meeting and (ii) circulate for review and approval by BioNTech written minutes of each JSC meeting within [***] days after such meeting. The Parties will agree on the minutes of each meeting promptly, but in no event later than the next meeting of the JSC.

(d) *Responsibilities.* The JSC will coordinate and provide operational and strategic oversight of the activities to be performed under the Research Plan by each Party and, within such scope will:

(i) monitor and assess the progress of activities under the Research Plan;

(ii) determine whether to initiate GLP toxicology studies for any Candidate prior to the FIH Study;

(iii) select the Candidates or Products that will be studied in the FIH Study on a schedule that takes into account BioNTech's manufacturing schedule capacity;

(iv) determine the design of the FIH Study, including the protocol governing the FIH Study;

(v) revise and approve any revisions of the Research Plan, except that (i) any modification to the Research Plan that would result in an increase in more than [***] by BioNTech ([***) (ii) any decision who will bear the costs which exceed [***] and (iii) subject to Section 2.13, any revision to the Research Plan that would require BioNTech to use, disclose or license any Other BioNTech Technology, would require the JSC's unanimous vote, *provided that* if BioNTech's Representatives withhold their consent, the fact that BioNTech has refused (in whole or part) to participate in additional or revised Development or Manufacturing activities, or to share in the respective costs, or to use, disclose or license such Other BioNTech Technology, as applicable, shall be a factor considered in determining whether Pfizer has exercised its Commercially Reasonable Efforts under this Agreement;

(vi) assess and discuss any future agreement between BioNTech and a Third Party involving the use or application of the RNA Technology in the Field or any future agreement between Pfizer and a Third Party for the research or development of Core RNA Technology in the Field during the Research Term, in each case which would require a unanimous vote of the JSC;

(vii) discuss any Intellectual Property Rights of a Third Party which may be relevant to Candidates and Products that are brought to the JSC pursuant to Section 2.9;

(viii) oversee the Development of Manufacturing processes relating to the Candidates or Products; any decisions relating to such Development shall require a unanimous vote;

(ix) form such other committees and sub-committees as the JSC may deem appropriate, *provided that* such committees and sub-committees may make recommendations to the JSC but may not be delegated JSC decision-making authority;

(x) develop a plan, upon Pfizer's written request and not later than [***] days prior to completion of the FIH Study to transfer and oversee the transfer of BioNTech Know-How to Pfizer to enable the rights licensed to Pfizer in Sections 2.1 and 2.3.1 which shall set out at minimum the responsibilities of each Party in connection with the transfer, deliverables and estimated timelines and budgets ("Product Technology Transfer Plan");

(xi) address such other matters relating to the activities of the Parties under the Research Plan as either Party may bring before the JSC, including any matters that are expressly for the JSC to decide as provided in this Agreement; and

(xii) attempt to resolve any disputes between the Parties with respect to (i) the performance of activities under the Research Plan on an informal basis or (ii) matters before the Patent Committee, in each case subject to Section 4.3.2(e).

(e) *Decision-making.* Notwithstanding the number of Pfizer JSC Members or BioNTech JSC Members, each Party will have one (1) vote, and the JSC will make decisions on a unanimous basis. The JSC will use good faith efforts to reach agreement on any and all matters properly brought before it. If, despite such good faith efforts, the JSC is unable to reach unanimous agreement on a particular matter, within [***] days after the JSC first meets to consider such matter, or such later date as may be mutually acceptable to the Parties (each such matter, a "Disputed Matter"), then either Party may refer that Disputed Matter for resolution by the appropriate senior officer of each Party, and such senior officers will promptly initiate discussions in good faith to resolve such Disputed Matter. If the senior officers of each Party are unable to resolve the Disputed Matter within [***] days of it being referred to them, then Pfizer will have final decision-making authority with respect to all Disputed Matters, subject only to specific issues identified in this Agreement as expressly requiring mutual consent or unanimous vote of the Parties.

(f) *Limits on JSC Authority.* Notwithstanding any provision of this Section 4.3 to the contrary, (i) each Party will retain the rights, powers and discretion granted to it under this Agreement and no such rights, powers, or discretion will be delegated to or vested in the JSC unless such delegation or vesting of rights is expressly provided for in

this Agreement or the Parties expressly so agree in writing, (ii) the JSC will not have the power to amend this Agreement or otherwise modify or waive compliance with this Agreement in any manner and (iii) neither Party will require the other Party to (A) breach any obligation or agreement that such other Party may have with or to a Third Party to the extent such obligation or agreement existed prior to the Execution Date or (B) perform any activities that are materially different or greater in scope or more costly than those provided for in the Research Plan then in effect.

(g) *JSC Term*. The JSC will be dissolved immediately upon the later of the expiration of the Research Term or the completion of the Manufacturing technology transfer described in Section 5.4.

4.4. Research Term Extension. During the Research Term, to the extent the completion of the activities or deliverables set forth in the Research Plan in accordance with the specifications set forth for such activities or deliverables in the Research Plan is delayed as a consequence of BioNTech's material breach of its obligations under the Research Plan notified by Pfizer to BioNTech in writing, then the Research Term shall be automatically extended by a reasonable amount of time corresponding to the amount of time between the time predicted for completion of such activity in the Research Plan and actual time the activity is completed. In addition, Pfizer may in its sole discretion extend the Research Term at its option by (a) up to [***] days or (b) until the [***] of the initial Research Term. The extension option pursuant to (a) above must be exercised by providing notice to BioNTech no later than on the last JSC meeting before the end of the initial Research term. The extension option pursuant to (b) above must be exercised by providing notice to BioNTech no later than on the last JSC meeting before the end of the initial Research term or, if the option according to (a) has already been exercised, no later than [***] days after the end of the initial Research Term. [***]

4.5. Research Plan Expenses. Except as expressly set forth otherwise in this Agreement (including in Section 4.3.2(d)(v)), each Party will bear all costs and expenses it incurs in connection with its activities under the Research Plan.

4.6. Materials and Permitted Activities.

4.6.1. **Transfer**. From time to time during the Research Term, Pfizer shall provide BioNTech with tangible chemical or biological materials (the "Pfizer Materials") as set forth in the Research Plan or as otherwise mutually agreed between the Parties (if any). Pfizer represents and warrants to BioNTech as of the date of delivery of the Pfizer Material (i) to Pfizer's knowledge, Pfizer has the right to provide the Pfizer Materials to BioNTech for the uses in accordance with the Research Plan, (ii) the Pfizer Materials comply with any requirements set forth in the Research Plan or otherwise mutually agreed between the Parties (if any) in writing and (iii) to Pfizer's knowledge, the use of the Pfizer Materials authorized herein does not infringe any Third Party rights. Except as expressly set forth in the preceding sentence, the Pfizer Materials are provided by Pfizer on an "as-is" basis without any representation or warranty of any type, express or implied, including any representation or warranty of merchantability or fitness for a particular purpose, each of which is hereby expressly disclaimed by Pfizer.

4.6.2. **Title to Pfizer Materials and BioNTech Materials**. All right, title and interest in and to the Pfizer Materials (including any modifications or progeny thereof) will remain the sole and exclusive property of Pfizer notwithstanding the transfer to and use by BioNTech of the same. All right, title and interest in and to the BioNTech Materials will remain the sole and exclusive property of BioNTech notwithstanding the transfer to and use by Pfizer of the same.

4.6.3. **Permitted Activities.** Notwithstanding anything to the contrary in this Agreement save for BioNTech's exclusivity obligations and restrictions (including those at Section 2.1 and 2.10.2) and Pfizer's exclusivity obligations and restrictions (including those at Section 2.10.3, nothing in this Agreement shall be deemed to prevent or restrict in any way the ability of either Party or its Affiliates to conduct any activities in the Territory, which activities would be allowed under any safe harbor, research exemption, government or executive declaration of urgent public health need, or similar right available in law or equity if conducted by a Third Party.

4.6.4. **Return of Proprietary Materials.** Upon termination or expiration of the Research Term, BioNTech shall, at Pfizer's option, either destroy or return to Pfizer all unused Pfizer Materials.

5. **MANUFACTURING AND SUPPLY**

5.1. **Development of Manufacture Process.** Beginning on the Effective Date of the Agreement and throughout the Research Term (including any extension pursuant to Section 4.4), BioNTech and Pfizer shall jointly Develop a scalable process for Manufacture of Candidates and Products in the Field. Should Pfizer request any assistance from BioNTech to Develop (or continue to Develop) a scalable process for Manufacture of the Candidates and Products in the Field after the Research Term (including any extension pursuant to Section 4.4), BioNTech shall provide such assistance after such Research Term at an hourly rate of [***] for its support and efforts in connection with such Development. Such payments shall be governed by the terms of Section 3.6 and BioNTech shall be required to keep, and provide to Pfizer, detailed reports and timesheets for those personnel involved.

5.2. **Manufacture of CTM for FIH Study.** BioNTech shall Manufacture, at its cost, all CTM for the Candidates or Products that are the subject of the FIH Study described in the Research Plan.

5.3. **Supply of CTM to Pfizer.** BioNTech shall supply Pfizer with CTM for the Products it studies in any Phase I Clinical Trial and Phase II Clinical Trial. Without prejudice to that obligation, the Parties shall negotiate in good faith and acting reasonably a mutually agreed upon Quality Agreement and Supply Agreement which shall be executed on or before [***]; such Supply Agreement shall be consistent with the heads of terms set forth in Schedule 5.3. Pfizer's schedule for Clinical Trials would take into account the Manufacturing capacity available at BioNTech and the Parties would agree on a [***] month Manufacturing capacity plan for Clinical Trial batches no later than [***] months in advance of any delivery date for such batch. If Pfizer so requests during the term of such Supply Agreement, Pfizer and BioNTech shall discuss an extension of such Supply Agreement at an appropriate time and negotiate in good faith if Pfizer requires a bridge to Pfizer for CTM for Pfizer's Phase III Clinical Trials or for Pfizer's commercial supply.

5.4. **Technology Transfer of Manufacturing Process.** BioNTech will provide Pfizer with all reasonable assistance necessary or useful to effect the timely and orderly transfer of the process for Manufacturing Products in the Field to enable Pfizer or Pfizer's named contract manufacturing organization ("**CMO**") to successfully Manufacture such Products on Pfizer's behalf. Without limiting BioNTech's obligations set forth elsewhere under this Agreement, the Parties will use their Commercially Reasonable Efforts to perform all technology transfer activities as set forth under the initial Manufacturing technology

transfer plan set forth in Exhibit D (the “Manufacturing Technology Transfer Plan”). BioNTech will cause all technology transfer activities to be performed under the Manufacturing Technology Transfer Plan to be carried out by the specific individuals identified to perform such activities in the Manufacturing Technology Transfer Plan (if any) and otherwise by appropriately skilled and experienced individuals familiar with the Manufacture of such Products. Such Manufacturing Technology Transfer Plan will be updated by the JSC no later than [***] months after the Effective Date. In case of a technology transfer to a CMO, technology transfer shall only be initiated if and when: (a) such CMO has entered into confidentiality undertakings in respect of BioNTech Technology, Research Program Technology and Confidential Information of BioNTech or its Representatives on customary terms comparable to and no less restrictive than those that bind the Parties under this Agreement either (i) directly with BioNTech or (ii) with Pfizer but including BioNTech as third party beneficiary, and (b) BioNTech has been provided with a copy of such confidentiality undertakings. For clarity, such CMO would not have the right to use any BioNTech Technology, Research Program Technology or Confidential Information of BioNTech or its Representatives licensed to and transferred to Pfizer or the CMO for any purpose other than the Manufacture of Products in the Field on Pfizer’s behalf.

5.5. Transfer Activities and Consulting Support. In addition to the support provided under the Manufacturing Technology Transfer Plan and the Product Technology Transfer Plan, BioNTech will provide Pfizer with up to [***] hours of FTE support reasonably requested by Pfizer and associated with Pfizer’s Development, Manufacture or Commercialization of the Candidates and Products. Pfizer will pay BioNTech [***] for each FTE. Such payments shall be governed by the terms of Section 3.6 and BioNTech shall be required to keep, and provide to Pfizer, detailed reports and timesheets for those personnel involved. Any Intellectual Property Rights generated pursuant to services under this Section shall be deemed work product from a work for hire arrangement and shall be owned by Pfizer.

6. PRODUCT DEVELOPMENT AND COMMERCIALIZATION

6.1. General. Subject to the provisions of Sections 4.2, 4.3, 5.2, 5.3 and 6.2, Pfizer will have sole authority over and control of the Development, Manufacture, Regulatory Approval and Commercialization of Candidates and Products and will retain final decision-making authority with respect thereto.

6.2. Diligence.

6.2.1. **Development Diligence**. Pfizer will use its Commercially Reasonable Efforts to Develop and seek Regulatory Approval for one Product in the Field in [***]. Pfizer will have no other diligence obligations with respect to the Development or Regulatory Approval of Products under this Agreement.

6.2.2. **Commercial Diligence**. Pfizer will use its Commercially Reasonable Efforts to Commercialize a given Product in the Field in each Major Market Country in the Territory where Pfizer or its designated Affiliates or Sublicensees has received Regulatory Approval for such Product. Pfizer will have no other diligence obligations with respect to the Commercialization of Products under this Agreement.

6.2.3. Exceptions to Diligence Obligations. Notwithstanding any provision of this Agreement to the contrary, Pfizer will be relieved from and will have no obligation to undertake any efforts with respect to any diligence obligation under Section 6.2.1 or Section 6.2.2 with respect to a given Candidate or Product in the event that:

(a) Pfizer or BioNTech receives or generates any safety, tolerability or other data reasonably indicating or signaling, as measured by Pfizer's safety and efficacy evaluation criteria and methodology, that such Candidate or Product has or would have an unacceptable risk-benefit profile or is otherwise not reasonably suitable for initiation or continuation of Clinical Trials;

(b) Pfizer or BioNTech receive any notice, information or correspondence from any applicable Regulatory Authority, or any applicable Regulatory Authority takes any action, that reasonably indicates that such Candidate or Product is unlikely to receive Regulatory Approval; or

(c) that BioNTech fails to fulfill its Development or other obligations under the Research Plan or this Agreement and such failure prevents Pfizer from fulfilling the Pfizer Diligence Obligations.

For the avoidance of doubt, the Pfizer Diligence Obligations in respect of Candidates and Products not affected by the circumstances described in this Section 6.2.3 shall continue to apply.

6.2.4. Deemed Satisfaction of Pfizer Diligence Obligations. Without in any way expanding Pfizer's obligations under this Agreement:

(a) Pfizer's achievement of any Development Event entitling BioNTech to receive a specific Development Payment described in Section 3.3 will be conclusive evidence that Pfizer has satisfied all Pfizer Diligence Obligations under this Agreement up to the date that such Development Event is achieved;

(b) on a Major Market Country-by-Major Market Country basis, Pfizer's payment, and BioNTech's acceptance, of any royalties to BioNTech pursuant to Section 3.5 with respect to Net Sales in such Major Market Country will be conclusive evidence that Pfizer has satisfied all Pfizer Diligence Obligations under this Agreement in respect of such Major Market Country to the date of such payment; provided that if BioNTech does not return in full a payment of royalties by Pfizer with a written rejection of such payment within ten days of receipt, BioNTech shall be deemed to have accepted such royalty payment; and

(c) Pfizer's payment of any Sales Milestone Payment as set forth in Section 3.4 will be conclusive evidence that Pfizer has satisfied all Pfizer Diligence Obligations under this Agreement to the date of such payment.

For the avoidance of doubt, the provisions of Sections 6.2.4(a) through 6.2.4(c) are intended only as examples of diligence constituting satisfaction of the Pfizer Diligence Obligations. Pfizer may fully satisfy the Pfizer Diligence Obligations without achieving any of the specific diligence examples set forth in Sections 6.2.4(a) through 6.2.4(c) above, *provided that* Pfizer otherwise complies with the provisions of Section 6.2.1 or Section 6.2.2, as applicable.

6.2.5. Assertion of Pfizer Diligence Obligation Claims. If BioNTech is or becomes aware of facts that might form a reasonable basis to allege that Pfizer has failed to meet any Pfizer Diligence Obligation, then BioNTech will promptly notify Pfizer in writing of such potential alleged performance failure (each such potential alleged performance failure, a “Diligence Issue”). Promptly upon Pfizer’s receipt of any notice of a Diligence Issue pursuant to this Section 6.2.5, the Pfizer Program Director will contact the BioNTech Program Director to discuss the specific nature of such Diligence Issue and seek to identify an appropriate corrective course of action. If, no later than [***] days after Pfizer’s receipt of such a notice, (a) the Parties have not reached consensus regarding whether Pfizer has failed to satisfy its obligations pursuant to Section 6.2.1 or Section 6.2.2 and (b) the Parties’ respective Program Directors have not agreed upon an appropriate corrective course of action for such Diligence Issue, then such Diligence Issue will be escalated and resolved pursuant to the dispute resolution provisions set forth in Section 12.12. If BioNTech fails to notify Pfizer of a Diligence Issue pursuant to this Section 6.2.5 within [***] days after the date on which BioNTech first discovers such Diligence Issue, then Pfizer will be deemed to have satisfied its Diligence Obligations with respect to such Diligence Issue.

6.2.6. Remedies for Breach of Pfizer Diligence Obligations. If Pfizer materially breaches any Pfizer Diligence Obligation and fails to remedy such breach within [***] days of Pfizer’s receipt of notice of such breach from BioNTech, then BioNTech may, in its sole discretion, elect to either: (a) terminate this Agreement pursuant to the provisions of Section 10.5, but only to the extent that a Product in a given Major Market Country in the Territory is directly and adversely impacted by such uncured material breach (and for the avoidance of doubt, the [***] day period set forth in this Section 6.2.6, shall be deemed the same [***] day cure period set out pursuant to Section 10.5); or (b) convert any exclusive license or sublicense granted to Pfizer under this Agreement with respect to a Product in a given Major Market Country in the Territory where such breach occurred and remains unremedied into a non-exclusive license or sublicense, as applicable, but only to the extent that such Product in such Major Market Country is directly and adversely impacted by such uncured material breach. BioNTech acknowledges and agrees that the elections set forth in this Section 6.2.6: (i) have been negotiated by the Parties to fully address any harm that BioNTech may incur as a result of Pfizer’s material breach of the Pfizer Diligence Obligations and (ii) constitute BioNTech’s sole and exclusive remedies with respect to any breach by Pfizer of any Pfizer Diligence Obligation.

6.2.7. Performance by Pfizer’s Affiliates or Sublicensees. For avoidance of doubt, any actions taken by Pfizer’s Affiliates or Sublicensees (or their respective subcontractors) under this Agreement shall be treated as actions taken by Pfizer in regard to satisfaction of the requirements of this Section 6.2.

6.3. Regulatory Matters.

6.3.1. Regulatory Reporting. Pfizer or its designated Affiliate(s) will have the sole authority to make or file all filings, reports and communications with all Regulatory Authorities with respect to any Candidate or Product in the Field in the Territory, including all reports required to be filed in order to obtain or maintain any Regulatory Approvals granted for Products in the Field in the Territory and adverse drug experience reports with the exception of the FIH Study, which will be managed and sponsored by BioNTech. Upon Pfizer’s request, BioNTech will provide to Pfizer the data arising from the FIH Study, as well as any data or other information in BioNTech’s possession or Control reasonably necessary or useful to support its filings, reports or communications with Regulatory Authorities and otherwise provide reasonable assistance to Pfizer in connection with any such filings, reports and communications with Regulatory Authorities.

6.3.2. Regulatory Approvals. Pfizer or its designated Affiliate(s) will have the sole authority to prepare and file applications, in its own name, for Regulatory Approval for Candidates or Products in the Field in the Territory, including communicating with any Regulatory Authority both prior to and following Regulatory Approval. BioNTech hereby assigns any and all INDs, Regulatory Approvals or any other rights or permissions granted by any Regulatory Authority to Pfizer, together with all other regulatory filings and development data, to the extent such assignment is permissible under applicable Law and requested by Pfizer. Further, BioNTech will take all actions and provide all assistance reasonably requested by Pfizer to effect the assignments in this Section 6.3.2.

6.3.3. Cooperation. If reasonably requested by Pfizer, BioNTech shall assist and cooperate with Pfizer in connection with the preparation of filings, reports and communications to Regulatory Authorities with respect to any Candidate or Product in the Field in the Territory, at Pfizer's sole expense. BioNTech will and will cause its Affiliates to cooperate with Pfizer and all Pfizer Representatives in the event of any inspection by a Regulatory Authority related to any Candidate or Product or any activities to be performed under this Agreement.

6.4. Commercialization Activities.

6.4.1. General. Subject to Section 6.2, Pfizer will have sole and exclusive control over all matters relating to the Commercialization of Products in the Field in the Territory, including sole and exclusive control over (a) pricing of Products and (b) the negotiation of Product pricing with Regulatory Authorities and other Third Parties, in each case in the Field in the Territory.

6.4.2. Branding and Product Packaging. Pfizer or its designated Affiliates or Sublicensees will select and own all Trademarks and Copyrights used in connection with the Commercialization of any and all Products in the Field in the Territory. Neither BioNTech nor its Affiliates will use or seek to register, anywhere in the world, any Trademark which is confusingly similar to any Trademark used by or on behalf of Pfizer, its Affiliates or Sublicensees in connection with any Product. [***].

6.5. Manufacturing. With respect to Candidates or Products to be Commercialized in the Field in the Territory and except to the extent BioNTech has Manufacturing obligations under the Research Plan or as described in Section 5, Pfizer will have the exclusive right to Manufacture such Candidates or Products itself or through one or more Affiliates or Third Parties selected by Pfizer in its sole discretion. For clarity, Pfizer will have no diligence obligations with respect to the Manufacture of Products except to the extent necessary to fulfill its obligations under Section 6.2.1 or Section 6.2.2.

6.6. Progress Reporting. After the first to occur of expiration of the Research Term or dissolution of the JSC and expiring on the First Commercial Sale of a Product, Pfizer will provide BioNTech with annual written reports summarizing Pfizer's activities to Develop and Commercialize Products in the preceding year. Any information or written report provided by Pfizer to BioNTech pursuant to this Section 6.6 will be deemed to be Pfizer's Confidential Information and subject to the provisions of Section 7.1.

6.7. **Other Pfizer Programs.** Subject to Pfizer's exclusivity obligations set forth in Section 2.10.3, BioNTech understands and acknowledges that Pfizer may have present or future initiatives or opportunities, including initiatives or opportunities with its Affiliates or Third Parties, involving products, programs, technologies or processes that are similar to, and in some instances may compete with, a Candidate or Product, program, technology or process covered by this Agreement. BioNTech acknowledges and agrees that nothing in this Agreement will be construed as a representation, warranty, covenant or inference that Pfizer will not itself Develop, Manufacture or Commercialize or enter into business relationships with one or more of its Affiliates or Third Parties to Develop, Manufacture or Commercialize products, programs, technologies or processes that are similar to or that may compete with any Candidate or Product, program, technology or process covered by this Agreement, *provided that*, for clarity, Pfizer will not use BioNTech's Confidential Information in breach of this Agreement.

7. **INTELLECTUAL PROPERTY**

7.1. Patent Committee. Within the first [***] months following the Effective Date, the Parties will establish a patent committee (the "**Patent Committee**"), comprised of at least one (1) representative of BioNTech and at least one (1) representative of Pfizer (which representative may be replaced by either Party at any time through written notice to the other Party). The Patent Committee shall coordinate all activities in relation to Patent Rights applicable to the terms of this Agreement. In particular, the Patent Committee shall:

7.1.1. coordinate all activities in relation to the filing and prosecution of Patent Rights relating to this Agreement pursuant to Sections 7.2.1 and 7.3.1 of this Agreement,

7.1.2. discuss any actual, potential or suspected infringement of such Patent Rights pursuant to Section 7.3.2(a),

7.1.3. regularly review which BioNTech Patent Rights may be relevant to Candidates and Products, and

7.1.4. regularly review and update the Core BioNTech Patent Rights listed in Schedule 9.3.4 on the basis of the then-existing Development or Commercialization activities and programs of BioNTech, its Affiliates and licensees outside the Field, and acting in good faith to add and remove BioNTech Patent Rights from time to time, provided that no Core BioNTech Patent Rights shall be removed from the list in Schedule 9.3.4 which BioNTech continues to regard in good faith as material for Development or Commercialization activities and programs of BioNTech, its Affiliates and licensees outside the Field.

The Patent Committee shall meet (either in-person or by audio or video conference) as often as determined by the Patent Committee as well as upon the reasonable request of either Party. It is acknowledged that particularly in the case of any Enforcement Action the Patent Committee may need to meet at very short notice and be required to expedite and make decisions very quickly and the Parties shall procure that the Patent Committee shall meet urgently as quickly as reasonably required in connection with any Enforcement Action. The Patent Committee will be chaired by a Pfizer Patent Committee member. The Patent Committee shall operate in good faith and acting reasonably. Sections 4.3.2(b) and 4.3.2(c), unless otherwise mutually agreed between the Parties, shall apply *mutatis mutandis*. The Patent Committee will use good faith efforts to reach agreement on all matters properly brought before it. If, despite such good faith efforts, the Patent Committee is unable to reach unanimous agreement on a particular matter, such matter shall be escalated in accordance with Section 4.3.2(e), and following the JSC's dissolution, such Section being interpreted omitting the reference to the JSC in such provision.

7.2. Ownership of Intellectual Property.

7.2.1. **Ownership of Research Program Technology.** Except for BioNTech Improvements and Pfizer Improvements, the ownership of Research Program Technology will be allocated based on inventorship as defined under the Laws of the United States. Notwithstanding the foregoing:

(a) During the Term, and without prejudice to Section 7.3 the Parties (through the Patent Committee) shall cooperate and discuss in good faith with respect to the timing, scope and filing of any Patent Rights claiming or disclosing any Research Program Technology; and

(b) Except as otherwise agreed in writing by the Parties, neither Party shall file any patent applications under the Product Patent Rights without Pfizer's prior consent.

7.2.2. **Ownership of Joint Technology.** Subject to Section 7.2.1 (and excluding Pfizer Improvements and BioNTech Improvements), the Parties will jointly own any Joint Technology. Subject to (a) the grant of licenses or sublicenses to Pfizer under Section 2.1, (b) BioNTech's representations, warranties and covenants under Section 9 and (c) the Parties' other rights and obligations under this Agreement (including Section 2.10.1), each Party will be free to exploit, either itself or through the grant of licenses to Third Parties (which Third Party licenses may be further sublicensed), Joint Technology throughout the world without restriction, without the need to obtain further consent from or provide notice to the other Party, and without any duty to account or otherwise make any payment of any compensation to the other Party.

7.2.3. **Ownership of BioNTech Improvements and Pfizer Improvements.** As between the Parties, BioNTech will own all BioNTech Improvements and Pfizer will own all Pfizer Improvements and RNA Improvements.

7.2.4. **Ownership of Other Intellectual Property.** Except as set forth in Sections 7.2.1, 7.2.2 and 7.2.3, each Party will own all right, title and interest in and to any and all Know-How, Patent Rights or other Intellectual Property Rights that such Party owns as of the Effective Date or otherwise acquires during the Term. For the purposes of determining ownership under this Agreement, as applicable, inventorship will be determined in accordance with United States patent laws.

7.3. Patent Rights.

7.3.1. **Filing, Prosecution and Maintenance of Patent Rights.**

(a) *Prosecution by BioNTech.* BioNTech will have the first right, and a Commercially Reasonable Efforts obligation, to file, prosecute and maintain the BioNTech Patent Rights owned by BioNTech or its Affiliates and Patent Rights claiming BioNTech Improvements (together the "BioNTech Prosecution Patent Rights") at BioNTech's sole

expense using counsel of its own choice reasonably acceptable to Pfizer in Australia, Canada, the member states of the European Patent Convention, Japan, the United States, Brazil, Russia, India, China, Mexico and South Korea (“Key Patent Jurisdictions”). Upon request of Pfizer, BioNTech shall file one or more BioNTech Prosecution Patent Rights in one or more jurisdictions other than the Key Patent Jurisdictions (“Additional Patent Jurisdictions”), and BioNTech will have the first right, and a Commercially Reasonable Efforts obligation, to file, prosecute and maintain such BioNTech Prosecution Patent Rights in such Additional Patent Jurisdictions at Pfizer’s sole expense (until such time as Pfizer elects not to maintain such Patent Rights in such Additional Patent Jurisdictions whereupon BioNTech can elect to abandon or surrender the same or to continue the prosecution and maintenance of such Patent Rights at its own expense) using counsel of its own choice reasonably acceptable to Pfizer. BioNTech will keep Pfizer advised on the status of the preparation, filing, prosecution, and maintenance of the Patent Rights included within BioNTech Prosecution Patent Rights in all the jurisdictions where filed. Further, in respect of any jurisdiction, BioNTech will (i) allow Pfizer a reasonable opportunity and reasonable time to review and provide comments to BioNTech’s patent counsel regarding relevant substantive communications to BioNTech and drafts of any responses or other proposed substantive filings by BioNTech before any applicable filings are submitted to any relevant patent office (or Governmental Authority) with respect to any BioNTech Prosecution Patent Rights and (ii) reflect any reasonable and timely comments offered by Pfizer in any final filings submitted by BioNTech to any relevant patent office (or Governmental Authority) with respect to any BioNTech Prosecution Patent Rights. If BioNTech elects not to file a Patent Right included in the BioNTech Prosecution Patent Rights in any Key Patent Jurisdiction or Additional Patent Jurisdiction or elects to cease the prosecution or maintenance of one or more Patent Rights included in the BioNTech Prosecution Patent Rights in any Key Patent Jurisdiction or Additional Patent Jurisdiction and no Third Party has agreed to continue the prosecution or maintenance of such Patent Rights under agreements concluded before the Effective Date, BioNTech will provide Pfizer with written notice of its decision not to file, prosecute or maintain not less than 60 days before any action is required to avoid abandonment or lapse. In the event of any such notice, if Pfizer elects to file or continue such prosecution or maintenance in the name of BioNTech at Pfizer’s sole expense, (x) Pfizer shall be entitled to do so and take all steps in such prosecution and maintenance at its sole discretion; (y) BioNTech will reasonably cooperate to promptly transfer the necessary files and execute the necessary forms regarding such transfer and (z) Pfizer will keep BioNTech advised on the status of such filing, prosecution and maintenance and will reasonably consider any comments made by BioNTech in connection therewith. If Pfizer elects not to file or continue such prosecution or maintenance, then BioNTech may immediately abandon, allow to lapse, or omit to prosecute such Patent Right, as the case may be. BioNTech will promptly, and no later than 60 days after written request by Pfizer, by written notice to Pfizer update Schedule 9.3.4 to identify all BioNTech Patent Rights to be added thereto.

(b) *Prosecution by Pfizer.*

(i) *BioNTech Owned Research Program Patent Rights.* Pfizer will have the first right, but not the obligation, to file, prosecute and maintain any Research Program Patent Rights (excluding Patent Rights claiming BioNTech Improvements) that are solely owned by BioNTech or its Affiliates (the

“BioNTech Owned Research Program Patent Rights”) at Pfizer’s sole expense using counsel of its own choice reasonably acceptable to BioNTech in the Key Patent Jurisdictions. Upon request of BioNTech, Pfizer shall file one or more BioNTech Owned Research Patent Rights in Additional Patent Jurisdictions, and Pfizer will have the first right, but not the obligation, to file, prosecute and maintain such BioNTech Owned Research Program Patent Rights in such Additional Patent Jurisdictions at BioNTech’s sole expense (until such time as BioNTech elects not to maintain such Patent Rights in such Additional Patent Jurisdictions whereupon Pfizer can elect to abandon or surrender the same or to continue the prosecution and maintenance of such Patent Rights at its own expense) using counsel of its own choice reasonably acceptable to BioNTech. Pfizer will keep BioNTech advised on the status of the preparation, filing, prosecution, and maintenance of the Patent Rights included within BioNTech Owned Research Program Patent Rights in all the jurisdictions where filed. Further, in respect of any jurisdiction, Pfizer will (i) allow BioNTech a reasonable opportunity and reasonable time to review and provide comments to Pfizer’s patent counsel regarding relevant substantive communications to Pfizer and drafts of any responses or other proposed substantive filings by Pfizer before any applicable filings are submitted to any relevant patent office (or Governmental Authority) with respect to any BioNTech Owned Research Program Patent Rights and (ii) reflect any reasonable and timely comments offered by BioNTech in any final filings submitted by Pfizer to any relevant patent office (or Governmental Authority) with respect to any BioNTech Owned Research Program Patent Rights. If Pfizer elects not to file a Patent Right included in the BioNTech Owned Research Program Patent Rights in any Key Patent Jurisdiction or Additional Patent Jurisdiction or elects to cease the prosecution or maintenance of one or more Patent Rights included in the BioNTech Owned Research Program Patent Rights in any Key Patent Jurisdiction or Additional Patent Jurisdiction, Pfizer will provide BioNTech with written notice of its decision not to file, prosecute or maintain not less than 60 days before any action is required to avoid abandonment or lapse. In the event of any such notice, if BioNTech elects to file or continue such prosecution or maintenance at BioNTech’s sole expense, (x) BioNTech shall be entitled to do so and take all steps in such prosecution and maintenance at its sole discretion; (y) Pfizer will reasonably cooperate to promptly transfer the necessary files and execute the necessary forms regarding such transfer and (z) BioNTech will keep Pfizer advised on the status of such filing, prosecution and maintenance and will reasonably consider any comments made by Pfizer in connection therewith. If BioNTech elects not to file or continue such prosecution or maintenance, then Pfizer may immediately abandon, allow to lapse, or omit to prosecute such Patent Right, as the case may be.

(ii) *Other Patent Rights*. Except as provided in Sections 7.3.1(a), 7.3.1(b)(i) and 7.3.1(c), Pfizer will have the sole right, but not the obligation, to file, prosecute and maintain the Product Patent Rights, the Research Program Patent Rights, the Pfizer Patent Rights (including RNA Improvements) and Patent Rights that it owns or to which it otherwise has control of prosecution rights in its sole discretion. At BioNTech’s reasonable request, Pfizer will provide to BioNTech status information for any Research Program Patent Right in any Key Patent Jurisdiction and will consider in good faith any recommendations made by BioNTech in regard to the filing, prosecution or maintenance of any such Patent Right.

(iii) *Reference of Research Program Know-how.* If Pfizer chooses to file, and thereafter prosecute and maintain, Patent Rights after the expiration of the Research Term, including any extension to the Research Term under Section 4.4, Pfizer may use or incorporate Research Program Know-How in the filing or prosecution of such Patent Rights filed after the Research Term, if Pfizer determines in its sole discretion that it is necessary or useful to use or incorporate such Research Program Know-How.

(c) *Joint Patent Rights.* In the event the Parties make any Joint Know-How, the Parties will promptly meet to discuss and determine, based on mutual consent, whether to seek patent protection thereon. Neither Party will file any Joint Patent Right without mutual consent. Unless otherwise agreed between the Parties, if the Parties decide to seek patent protection for any Joint Know-How: (i) BioNTech will have the first right, but not the obligation, to prepare, file, prosecute and maintain any Joint Patent Right predominantly relating to the RNA Technology or RNA Process Technology throughout the world, and (ii) Pfizer will have the first right, but not the obligation, to prepare, file, prosecute and maintain any other Joint Patent Right throughout the world, in each case of (i) and (ii) with the respective provisions of Section 7.3.1(a) or 7.3.1(b)(i) to apply *mutatis mutandis* except as provided in this Section 7.3.1(c). The non-filing Party will reimburse the filing Party for 50% of the costs reasonably incurred by the filing Party in preparing, filing, prosecuting and maintaining such Joint Patent Rights, which reimbursement will be made pursuant to, and within 75 days of, invoices (including supporting documentation) submitted by the filing Party to the non-filing Party no more often than once per Calendar Quarter. The non-prosecuting Party will cooperate with the prosecuting Party in taking reasonable measures to control costs and non-prosecuting Party shall be responsible for 100% of (x) any fees or costs related to any correspondence of outside counsel with or instructions to outside counsel by such Party (or any of such Party's Representatives) which is independent of joint prosecution efforts, or (y) any patent office fees, and associated counsel/agent fees and costs, for extensions which are not incurred at the request of, and not due to the actions of, the prosecuting Party. If, once the Parties have agreed to prepare and file an application of Joint Patent Rights, either Party (the "Declining Party") at any time thereafter declines to participate in the preparation, filing, prosecution or maintenance of any Joint Patent Right or share in the costs of filing, prosecuting and maintaining any Joint Patent Right, on a country-by-country basis, the Declining Party will provide the other Party (the "Continuing Party") with 30 days prior written notice to such effect, in which event, the Declining Party will (A) have no responsibility with respect to the filing, prosecution or maintenance of the applicable Joint Patent Right after the end of such 30 day period, (B) have no responsibility for any expenses incurred in connection with such Joint Patent Right after the end of such 30 day period and (C) if the Continuing Party elects to continue filing, prosecution or maintenance, the Declining Party, upon the Continuing Party's request, will execute such documents and perform such acts, at the Continuing Party's expense, as may be reasonably necessary (1) to assign to the Continuing Party all of the Declining Party's right, title and interest in and to such Joint Patent Right and (2) to permit the Continuing Party to file, prosecute and maintain such Joint Patent Right at its

sole expense. Where such Joint Patent Right is assigned to Pfizer as the Continuing Party, BioNTech will retain a non-exclusive, sublicensable, perpetual, irrevocable, royalty-free, fully paid-up worldwide right and license to practice and exploit such Patent Right for any and all purposes excluding, during the Term, in the Field in the Territory; and where such Joint Patent Right is assigned to BioNTech as the Continuing Party, it will be excluded from the definition of BioNTech Patent Rights, and Pfizer will retain a non-exclusive, sublicensable, perpetual, irrevocable, royalty-free, fully paid-up worldwide right and license to practice and exploit such Joint Patent Right for any and all purposes.

(d) *Prosecution by Third Party Licensors.* Except in the ordinary course of filing continuation applications, BioNTech shall not decline to pay for or participate in the filing, prosecution or maintenance of any Patent Right under any BioNTech Third Party Agreement in any Key Patent Jurisdiction (or other country to the extent doing so may result in BioNTech's loss of license to such Patent Right in such country), to the extent BioNTech is obligated to pay for, or has the right to participate in, such filing, prosecution or maintenance, that is included in the BioNTech Patent Rights and that, in Pfizer's reasonable opinion, covers any Candidate, Product [***] in the Field, and the loss of which would result in loss of right to or would materially diminish the overall protection of such Candidate or Product, without Pfizer's prior written consent, not to be unreasonably withheld or delayed.

(e) *Patent Term Restoration and Extension.* Upon the request of either Party, the Parties will (through the Patent Committee) reasonably discuss patent term extension and supplemental protection certificate strategies in relation to Patent Rights Covering Candidates or Products at any time. Notwithstanding the above, within the time period specified by applicable Law upon receiving Regulatory Approval for a Product in any country in the Territory, Pfizer will have the right, but not the obligation, exercisable through written notice to BioNTech, to seek, in BioNTech's name, if so required, patent term extensions, and supplemental protection certificates and the like available under Law, including 35 U.S.C. § 156 and applicable foreign counterparts (the "Patent Term Extension"), in such country in the Territory in relation to (i) any Research Program Patent Right other than Patent Rights claiming BioNTech Improvements and (ii) any BioNTech Prosecution Patent Right which is still eligible for Patent Term Extension at that time under the applicable Law in such country, in each case of (i) and (ii) that Cover such Product. If Pfizer exercises such right, BioNTech and Pfizer will cooperate in connection with all such activities at Pfizer's expense. Pfizer, its agents and attorneys will give due consideration to all suggestions and comments of BioNTech regarding any such activities, but, in the event of a disagreement between the Parties in relation to a Patent Term Extension for a BioNTech Prosecution Patent Right or Research Program Patent Right, Pfizer will have the final decision-making authority. For the avoidance of doubt, nothing in this Section 7.3.1(e) shall prevent BioNTech from seeking, or allowing any other collaboration partner of BioNTech to seek, any Patent Term Extension in relation to any BioNTech Prosecution Patent Right prior to Pfizer exercising its rights under this Section 7.3.1(e). Notwithstanding the foregoing, BioNTech shall not seek any Patent Term Extension in relation to any Patent Right with respect to any Product or Candidate without Pfizer's prior written consent.

(f) *Clarifications.* For clarity, prosecution under this Section 7.3.1 includes opposition, revocation and post-grant review proceedings before the granting patent office or other patent office proceedings (“Prosecution Proceeding”). If such Prosecution Proceedings are concurrent with Third Party litigation under Section 7.3.2 and are applicable to or part of a coordinated enforcement of such rights, the prosecuting Party and the enforcing Party shall work together and closely align their prosecution and enforcement strategy in accordance with Section 7.3.3 (including the right for one Party to have final control as stipulated in Section 7.3.3).

(g) *Liability.* To the extent that a Party is obtaining, prosecuting or maintaining a Patent Right or otherwise exercising its rights under this Section 7.3.1, such Party, and its Affiliates, employees, agents or representatives, will not be liable to the other Party in respect of any act, omission, default or neglect on the part of any such Party, or its Affiliates, employees, agents or representatives, in connection with such activities undertaken in good faith.

(h) *Recording.* If either Party deems it necessary or useful to register or record this Agreement or evidence of this Agreement with any patent office or other appropriate Governmental Authority(ies) in one or more jurisdictions in the Territory, the other Party will reasonably cooperate to execute and deliver to such Party any documents accurately reflecting or evidencing this Agreement that are necessary or useful, in such Party’s reasonable judgment, to complete such registration or recordation.

(i) *Joint Research Agreement.* This Agreement shall be understood to be a joint research agreement under 35 U.S.C. § 103(c)(3) for pre-AIA Patent Rights and 35 U.S.C. § 100(h) for post-AIA Patent Rights entered into for the purpose of researching, identifying and Developing Candidates and Products.

7.3.2. Enforcement of Patent Rights.

(a) *Notification of Infringement and Decision about Enforcement Actions.* Each Party will promptly notify the other (through the Patent Committee) in the event of any actual, potential or suspected infringement of a patent under the BioNTech Patent Rights or Research Program Patent Rights by any Third Party. In the event of any such notification, the Parties will (through the Patent Committee) discuss in good faith the relevant actual, potential and suspected infringement and the risks and chances of success as well as chances of settlement connected with the institution of any litigation or other step to remedy infringement (any such steps, or threat of or assertion or enforcement of a Patent Right being an “Enforcement Action”) taking into account the possible uses of the relevant Patent Rights by each Party, its respective Affiliates or its or their licensees and the revenues relating to or impacted by such Patent Rights, with the goal to agree on whether or not any Enforcement Action should be taken and, if yes, to closely coordinate so far as reasonably possible their respective efforts and strategies. The Parties acknowledge that time shall be of the essence in connection with any Enforcement Action and each shall move urgently and expeditiously to discuss and seek agreement on any actual or proposed Enforcement Action.

(b) *Enforcement of Core BioNTech Patent Rights.* Subject to Section 7.3.2(a), and unless otherwise agreed between the Parties on a case-by-case basis, as between Pfizer and BioNTech, BioNTech shall have the first right, but not the obligation, to institute any Enforcement Action in connection with the Core BioNTech Patent Rights in the Field, and any such Enforcement Action will be at BioNTech's expense including BioNTech indemnifying and holding harmless Pfizer and its Affiliates from and against any adverse cost award, where Pfizer or its Affiliates join any such Enforcement Action upon BioNTech's request or where required by Law. BioNTech will not, without the prior written consent of Pfizer, enter into any compromise or settlement relating to such litigation that (i) admits the invalidity or unenforceability of any Core BioNTech Patent Right or (ii) requires BioNTech to abandon any Core BioNTech Patent Right. Pfizer, upon request of BioNTech, agrees to timely commence or to join in any such Enforcement Action, at BioNTech's expense, and in any event to cooperate with BioNTech in such Enforcement Action at BioNTech's expense. Pfizer will have the right to consult with, and provide comments to, BioNTech about such Enforcement Action and to participate in and be represented by independent counsel in such Enforcement Action at Pfizer's own expense, and BioNTech shall take into account any reasonable comments provided by Pfizer in such Enforcement Action. Neither Party will incur any liability to the other Party (other than that related to a Party's indemnification obligation pursuant to Section 11) as a consequence of any Enforcement Action initiated or pursued pursuant to this Section 7.3.2(b) or any unfavorable decision resulting therefrom, including any decision holding any Core BioNTech Patent Right invalid or unenforceable. Any infringement recoveries resulting from such litigation or steps relating to a claim of Third Party infringement, after deducting BioNTech's out of pocket expenses (including counsel fees and expenses including any adverse cost award) in pursuing such claim, will be for Pfizer's sole account and be deemed Net Sales on which Pfizer will pay royalties.

In respect of an infringement of a BioNTech Core Patent Right in the Field in connection with a Competitive Product in a Major Market Country ("Competitive Product Infringement"), if, following (i) discussion of any potential Enforcement Action pursuant to Section 7.3.2(a) and (ii) a subsequent written request by Pfizer to initiate any Enforcement Action in connection with such Competitive Product Infringement, BioNTech does not initiate any Enforcement Action in connection with such Competitive Product Infringement within thirty (30) days following receipt of such notices, or as soon as possible and in any event no later than ten (10) Business Days if preliminary injunction proceedings are a potential or likely recourse to remedy the infringement), or ten (10) days before the time limit, if any, set forth in the applicable Laws for the filing of such actions, Pfizer shall have the right, but not the obligation, in place of BioNTech to institute any Enforcement Action in connection with such Competitive Product Infringement (including Enforcement Actions in countries in which the Manufacturing of the Competitive Product (or part thereof) reasonably believed to be designated for Major Market Countries takes place as well as Enforcement Actions in Belgium, Ireland or the Netherlands that are in parallel with Enforcement Actions in any of the Major EU Market Countries), and any such Enforcement Action will be at Pfizer's expense and the provisions set forth in the first paragraph of this Section 7.3.2(b) shall apply mutatis mutandis, *provided that* any infringement recoveries resulting from such litigation or steps relating to a claim of Third Party infringement, after deducting Pfizer's out of pocket expenses (including counsel fees and expenses including any adverse cost award) in pursuing such claim, shall be for Pfizer's sole account and be deemed Net Sales on which Pfizer will pay royalties.

(c) *Pfizer Enforcement in the Field.* Subject to Section 7.3.2(a) and unless otherwise agreed between the Parties on a case-by-case basis, as between Pfizer and BioNTech, Pfizer shall have the sole right, but not the obligation, to institute any Enforcement Action in the Territory in connection with any BioNTech Patent Right (other than Core BioNTech Patent Rights or those solely owned by Third Parties and licensed pursuant to a Current Licence to the extent BioNTech has no enforcement rights in the Field in respect of the same) or Research Program Patent Rights in the Field, and any such Enforcement Action will be at Pfizer's expense including Pfizer indemnifying and holding harmless BioNTech and its Affiliates from and against any adverse cost award, where BioNTech or its Affiliates join any such Enforcement Action upon Pfizer's request or where required by Law, subject to BioNTech's obligation to indemnify Pfizer for such expenses pursuant to Section 11; *provided that* any infringement recoveries resulting from such litigation or steps relating to a claim of Third Party infringement, after deducting Pfizer's out of pocket expenses (including counsel fees and expenses including any adverse cost award) in pursuing such claim, will be deemed Net Sales. Pfizer will not, without the prior written consent of BioNTech, enter into any compromise or settlement relating to such Enforcement Action that (i) admits the invalidity or unenforceability of any BioNTech Patent Right or Research Program Patent Right or (ii) requires Pfizer or BioNTech to abandon any BioNTech Patent Right or Research Program Patent Right. BioNTech, upon request of Pfizer, agrees to timely commence or to join in any such Enforcement Action, at Pfizer's expense, and in any event to cooperate with Pfizer in such Enforcement Action at Pfizer's expense. BioNTech will have the right to consult with, and provide comments to, Pfizer about such Enforcement Action and to participate in and be represented by independent counsel in such Enforcement Action at BioNTech's own expense, and Pfizer shall take into account any reasonable comments provided by BioNTech in such Enforcement Action. Neither Party will incur any liability to the other Party (other than that related to a Party's indemnification obligation pursuant to Section 11 or otherwise in this sub-section) as a consequence of any Enforcement Action initiated or pursued pursuant to this Section 7.3.2(c) or any unfavorable decision resulting therefrom, including any decision holding any Patent Right invalid or unenforceable.

(d) *BioNTech Enforcement outside the Field.* Subject to Section 7.3.2(b) and 7.3.2(c) and unless otherwise agreed between the Parties on a case-by-case basis, as between Pfizer and BioNTech, BioNTech shall have the sole right, but not the obligation, to institute any Enforcement Action in the Territory in connection with any BioNTech Patent Right or Research Program Patent Right (excluding the Product Patent Rights) solely or jointly owned by BioNTech outside the Field, and any such Enforcement Action will be at BioNTech's expense including BioNTech indemnifying and holding harmless Pfizer and its Affiliates from and against any adverse cost award, where Pfizer or its Affiliates join any such Enforcement Action upon BioNTech's request or where required by Law. BioNTech will not, without the prior written consent of Pfizer, enter into any compromise or settlement relating to such Enforcement Action that (i) admits the invalidity or unenforceability of any BioNTech Patent Right or Research Program Patent Right solely or jointly owned by BioNTech or (ii) requires BioNTech to abandon any BioNTech Patent Right or Research Program Patent Right solely or jointly owned by BioNTech. Pfizer, upon

request of BioNTech, agrees to timely commence or to join in any such Enforcement Action, at BioNTech's expense, and in any event to cooperate with BioNTech in such Enforcement Action at BioNTech's expense. Pfizer will have the right to consult with, and provide comments to, BioNTech about such Enforcement Action and to participate in and be represented by independent counsel in such Enforcement Action at Pfizer's own expense, and BioNTech shall take into account any reasonable comments provided by Pfizer in such Enforcement Action. Neither Party will incur any liability to the other Party (other than that related to a Party's indemnification obligation pursuant to Section 11 or otherwise in this sub-section) as a consequence of any Enforcement Action initiated or pursued pursuant to this Section 7.3.2(d) or any unfavorable decision resulting therefrom, including any decision holding any BioNTech Patent Right or Research Program Patent Right invalid or unenforceable.

(e) *Pfizer Patent Rights.* Subject to Sections 7.3.2(b) and 7.3.2(c), Pfizer shall have the sole right, but no obligation, to institute litigation or take other steps to remedy infringement in connection with in any field in respect of any Patent Rights that it solely owns including any Pfizer Patent Right. In the event that any such Patent Rights are based on inventions made or created solely or jointly by BioNTech, its Affiliates or its Representatives acting on BioNTech's behalf, BioNTech shall provide reasonable assistance to Pfizer at Pfizer's expense in connection with such litigation.

(f) *Biosimilar Notices.*

(i) *BioNTech Cooperation.* Upon Pfizer's request, BioNTech will use Commercially Reasonable Efforts to assist and cooperate with Pfizer in (A) establishing a strategy for responding to requests for information from Regulatory Authorities and Third Party requestors and (B) preparing submissions responsive to any Biosimilar Notices received by Pfizer; *provided* that Pfizer will make the final decisions with respect to such strategy and any such responses.

(ii) *Compliance with Biosimilar Notices.* Pfizer will have the sole right in its discretion to comply with the applicable provisions of 42 U.S.C. § 262(l) (or any amendment or successor statute thereto), any similar statutory or regulatory requirement enacted in the future regarding biologic products in the United States, or any similar statutory or regulatory requirement in any non-U.S. country or other regulatory jurisdiction, in each case, with respect to any Biosimilar Notice received by Pfizer from any Third Party regarding any Product that is being Commercialized in the Field in the applicable jurisdiction, and the exchange of information between any Third Party and Pfizer pursuant to such requirements; *provided that*, prior to any submission of information by Pfizer to a Third Party, BioNTech will have the right to review the patent information included in such proposed submission, solely with respect to BioNTech Patent Rights, and to make suggestions as to any changes to such patent information that BioNTech reasonably believes to be necessary; *provided further* that Pfizer will determine the final content of any such submission. In the case of a Product approved in the United States under the PHS Act (or, in the case of a country in the Territory other than the United States, any similar Law), to the extent permitted by applicable Law, Pfizer, as the sponsor of the application for the Product, will be the "reference

product sponsor” under the PHS Act. Pfizer will give written notice to BioNTech of receipt of a Biosimilar Notice received by Pfizer with respect to a Product, and Pfizer will consult with BioNTech with respect to the selection of any BioNTech Patent Rights to be submitted pursuant to 42 U.S.C. § 262(l) (or any similar law in any country of the Territory outside the United States); *provided* that Pfizer will have final say on such selection of BioNTech Patent Rights. BioNTech agrees to be bound and will cause its Affiliates and use Commercially Reasonable Efforts to cause all Third Party Licensors to be bound by the confidentiality provisions of 42 U.S.C. § 262(l)(1)(B)(iii). In connection with any action brought by Pfizer under this Section 7.3.2(f), BioNTech, upon Pfizer’s request, will reasonably cooperate and will cause its Affiliates and use Commercially Reasonable Efforts to cause all Third Party Licensors to reasonably cooperate with Pfizer in any such action, including timely commencing or joining in any action brought by Pfizer under this Section 7.3.2(f). Solely to the extent any BioNTech Patent Rights are involved in any such action, the Parties’ rights and responsibilities regarding any action will be determined in accordance with this Section 7.3.2(f).

(g) *Unified Patent Court*. In respect of BioNTech Patent Rights, Research Program Patent Rights, Product Patent Rights and Pfizer Patent Rights, for each and every such Patent Right having effect anywhere within any member state that was or is, from time to time, a signatory to the UPC Agreement, the Party in control of the filing, prosecution and maintenance of such Patent Right (as determined in accordance with Section 7.3.1) shall have the sole discretion to decide whether to (i) opt in or opt out (and to opt in again), pursuant to Article 83 of the UPC Agreement, of the Unified Patent Court system; and (ii) elect if such Patent Rights should, during their prosecution, be designated as a Unitary Patent or a European Patent. The other Party shall promptly do all things necessary and execute all documents and make all necessary elections required to give effect to such decision(s) or election(s).

(h) *Settlement Cross-Licensing*. If pursuant to a bona fide settlement of any Enforcement Action or Infringement Claim controlled by Pfizer, Pfizer grants to a Third Party (that was a party to the Enforcement Action or Infringement Claim) any sublicense to any of the Patent Rights licensed to Pfizer under this Agreement in respect of that Third Party’s Competitive Product, then Pfizer shall pay to BioNTech (i) at a minimum, if such sublicense includes any of the rights granted to Pfizer under a Current License or Future BioNTech Third Party Agreement (subject to Sections 2.1, 2.2, 2.9), all royalties due by BioNTech to the relevant Third Party for such sublicense under any Current License and Future BioNTech Third Party Agreement in respect of licensed sales of such Competitive Product and (ii) all other royalties received by Pfizer shall be deemed Net Sales pursuant to Section 7.3.2(c) provided that in no event shall such payment obligations exceed the maximum royalty that would be due had such Third Party become a Sublicensee. For the avoidance of doubt, should the Third Party as part of the same agreement grant any cross-license to Pfizer for any Candidates or Products, such cross-license shall not be deemed “non-cash” consideration for the purpose of the Net Sales definition.

7.3.3. Other Actions by Third Parties. Separate from Prosecution Proceedings, each Party will promptly notify the other Party in the event of any legal action by any Third Party involving any BioNTech Patent Right or Research Program Patent Right of which it becomes aware, including any nullity, revocation, declaratory judgment, interference, *inter partes* reexamination, reexamination or compulsory license proceeding. The right to defend against any such action shall be with the Party controlling the filing, prosecution and maintenance of the affected Patent Right (as determined in accordance with Section 7.3.1), and the provisions of Section 7.3.1 shall apply *mutatis mutandis* in respect of such defense. If any such action has been instituted by any Third Party in response to, or in connection with, any Enforcement Action pursuant to Section 7.3.2, or any Enforcement Action is to be pursued as a consequence of such action being instituted by any Third Party, the Party controlling the Enforcement Action and the Party controlling the defense shall work together and closely align their enforcement and defense strategy, which may include the (joint) appointment of the same patent counsel for all concurrent Third Party litigation and patent office proceedings taking into account the impact on enforcement and potential for revenues relating to such Patent Rights, and in the absence of agreement, the enforcing Party shall have the final say over the Prosecution Proceedings in so far as the Prosecution Proceeding will adversely impact the ongoing enforcement of such right, subject to having given good faith consideration to the comments and suggestions of the prosecuting Party. Further details of such joint proceeding may be agreed between the Parties from time to time.

7.3.4. Purple Book Listings. To the extent of any BioNTech Patent Rights Covering a Product, the Parties shall cooperate with each other to enable Pfizer to make filings with Regulatory Authorities, as required or allowed in connection with (i) in the United States, the FDA's Purple Book and the Biologics Price Competition and Innovation Act and (ii) outside the United States, under the national implementations of Article 10.1(a)(iii) of Directive 2001/EC/83 or other international equivalents thereof. Pfizer shall consider BioNTech's reasonable requests in connection therewith, including meeting any submission deadlines, in each case, to the extent required or permitted by applicable Law.

7.3.5. Allegations of Infringement and Right to Seek Third Party Licenses.

(a) *Notice.* If either Party becomes aware that the Development, Manufacture, Commercialization or use of any Candidate or Product, the practice of any BioNTech Technology or Research Program Technology in the Field, or the exercise of any other right granted by BioNTech to Pfizer or any of its Affiliates or Sublicensees hereunder (collectively, the "Licensed Activities") is alleged by a Third Party to infringe, misappropriate or otherwise violate such Third Party's Patent Rights or other Intellectual Property Rights or either Party otherwise identifies any Third Party Patent Rights or other Intellectual Property Rights that may be relevant to such Licensed Activities, such Party will, as soon as reasonably practicable, notify the other Party in writing.

(b) *Pfizer Option to Negotiate.* If Pfizer determines, in its sole discretion, that, in order for Pfizer, its Affiliates or Sublicensees to engage in the Licensed Activities, it is necessary or useful to obtain a license under one or more Patent Rights or other Intellectual Property Rights Controlled by a Third Party (collectively, "Third Party IP Rights"), then Pfizer will have the sole right, but not the obligation, to negotiate and enter into a license or other agreement with such Third Party. The amounts payable under any such license or agreement with a Third Party will reduce Pfizer's royalty obligations under this Agreement as and to the extent provided in Section 3.5.3(a) or as otherwise agreed between the Parties.

7.3.6. Third Party Infringement Suits. Each of the Parties will promptly notify the other in the event that any Third Party files any suit or brings any other action alleging patent infringement by Pfizer or BioNTech or any of their respective Affiliates or Sublicensees with respect to the Development, Manufacture, Commercialization or use of any Candidate or Product or the practice of any BioNTech Technology or Research Program Technology (any such suit or other action referred to herein as an “Infringement Claim”). In the case of any Infringement Claim against Pfizer (including its Affiliates or Sublicensees) alone or against both Pfizer and BioNTech (including its Affiliates), Pfizer will have the right, but not the obligation, to control the defense of such Infringement Claim, including control over any related litigation, settlement, appeal or other disposition arising in connection therewith. BioNTech, upon request of Pfizer, agrees to cooperate with Pfizer at Pfizer’s expense. BioNTech will have the right to consult with Pfizer concerning any Infringement Claim and to participate in and be represented by independent counsel in any associated litigation in which BioNTech is a party at BioNTech’s own expense. If Pfizer elects to control the defense of any Infringement Claim and BioNTech is obligated under Section 11.3 to indemnify Pfizer (including any Pfizer Indemnified Party) with respect to such Infringement Claim, then (a) Pfizer will bear 50% of its own attorneys’ fees incurred in investigating, preparing or defending such Infringement Claim notwithstanding the provisions of Section 11.3 and (b) BioNTech will otherwise indemnify Pfizer and any applicable Pfizer Indemnified Parties to the full extent provided for under Section 11.3. In the case of any Infringement Claim against BioNTech alone, Pfizer will have the right to consult with BioNTech concerning such Infringement Claim and Pfizer, upon request of BioNTech, will reasonably cooperate with BioNTech at BioNTech’s expense. Neither Party will enter into any compromise or settlement in respect of an Infringement Claim admitting or implying that the Development, Manufacture, Commercialization or use of any Candidate or Product or the practice of any BioNTech Technology or Research Program Technology infringes Third Party patents without the other Party’s written consent.

7.4. Enforcement of Know-How.

7.4.1. Notification of Misappropriation. Each Party will promptly notify the other in the event of any actual, potential or suspected misappropriation of any BioNTech Know-How or Research Program Know-How in the Territory by any Third Party.

7.4.2. Pfizer Enforcement in the Field. As between Pfizer and BioNTech, Pfizer will have the sole right, but not the obligation, to institute litigation or take other steps to remedy misappropriation in the Territory in connection with any BioNTech Know-How (excluding BioNTech Know-How solely owned by Third Parties the subject of a Current Licence in so far as BioNTech has no enforcement rights in respect of the same) or Research Program Know-How in the Field, and any such litigation or steps will be at Pfizer’s expense including Pfizer indemnifying and holding harmless BioNTech and its Affiliates from and against any adverse cost award, where BioNTech or its Affiliates join any such Enforcement Action upon Pfizer’s request or where required by Law, subject to BioNTech’s obligation to indemnify Pfizer for such expenses pursuant to Section 11; *provided that* any infringement recoveries resulting from such litigation or steps relating to a claim of Third Party misappropriation, after deducting Pfizer’s out of pocket expenses (including counsel fees and expenses including any adverse cost award) in pursuing such claim, will be deemed Net Sales. BioNTech will have no obligation to cooperate with Pfizer in any such litigation except as set forth in this Section 7.4.2. Pfizer will not, without the prior written consent of BioNTech, enter into any compromise or settlement relating to such litigation or steps that (a) admits that all or any portion of the BioNTech Know-How or Research Program Know-how is not

protectable under relevant trade secret or confidentiality Laws or (b) requires Pfizer to abandon trade secret protection for any BioNTech Know-How or Research Program Know-how. In order to establish standing, BioNTech, upon request of Pfizer, agrees to timely commence or to join in any such litigation or steps, at Pfizer's expense, and in any event to cooperate with Pfizer in such litigation or steps at Pfizer's expense. BioNTech will have the right to consult with Pfizer about such litigation or steps and to participate in and be represented by independent counsel in such litigation or steps at BioNTech's own expense, and Pfizer shall take into account any reasonable comments provided by BioNTech in such litigation or steps.

7.4.3. **BioNTech Enforcement.** As between Pfizer and BioNTech, BioNTech will have the sole right, but not the obligation, to institute litigation or take other steps to remedy misappropriation in connection with any BioNTech Know-How or Research Program Know-how solely owned by BioNTech outside the Field, provided that any such Know-how does not lose its confidential status as part of or in consequence of any such litigation or steps, and any such litigation or steps will be at BioNTech's expense including BioNTech indemnifying and holding harmless Pfizer and its Affiliates from and against any adverse cost award, where Pfizer or its Affiliates join any such Enforcement Action upon BioNTech's request or where required by Law, and Pfizer will have no obligation to cooperate with BioNTech in any such litigation except as set forth in this Section 7.4.3. BioNTech will not, without the prior written consent of Pfizer, enter into any compromise or settlement relating to such litigation or steps that (a) admits that all or any portion of the BioNTech Know-How or Research Program Know-how is not protectable under relevant trade secret or confidentiality Laws or (b) requires BioNTech to abandon trade secret protection for any BioNTech Know-How or Research Program Know-How. In order to establish standing, Pfizer, upon request of BioNTech, agrees to timely commence or to join in any such litigation or steps at BioNTech's expense, and in any event to cooperate with BioNTech in such litigation or steps at BioNTech's expense. Pfizer will have the right to consult with BioNTech about such litigation or steps and to participate in and be represented by independent counsel in such litigation or steps at Pfizer's own expense, and BioNTech shall take into account any reasonable comments provided by Pfizer in such litigation or steps.

7.4.4. **Pfizer Know-How.** Subject to Section 7.4.2, Pfizer will have the sole right, but no obligation, to institute litigation or take other steps to remedy misappropriation in connection with any Know-How that it solely owns including any Pfizer Know-How.

8. **CONFIDENTIALITY**

8.1. Confidentiality. Except to the extent expressly authorized by this Agreement, the Parties agree that, during the Term and for [***] years thereafter (except to the extent a longer period is required by a Current License applicable for such Confidential Information disclosed pursuant to that Current License), each Party (the "Receiving Party") receiving any Confidential Information of the other Party (the "Disclosing Party") hereunder will: (a) keep the Disclosing Party's Confidential Information confidential; (b) not disclose, or permit the disclosure of, the Disclosing Party's Confidential Information; and (c) not use, or permit to be used, the Disclosing Party's Confidential Information for any purpose other than as expressly permitted under the terms of this Agreement (including under any license or right of use granted hereunder).

8.2. Authorized Disclosure.

8.2.1. **Disclosure to Party Representatives.** Notwithstanding the foregoing provisions of Section 8.1, the Receiving Party may disclose Confidential Information belonging to the Disclosing Party to the Receiving Party's Representatives who (a) have a need to know such Confidential Information in connection with the performance of the Receiving Party's obligations or the exercise of the Receiving Party's rights under this Agreement and (b) have agreed in writing to non-disclosure and non-use provisions with respect to such Confidential Information that are at least as restrictive as those set forth in this Section 8.

8.2.2. **Disclosure to Third Parties.** Notwithstanding the foregoing provisions of Section 8.1, each Party may disclose Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary:

(a) to Governmental Authorities (i), to the extent useful, to obtain or maintain INDs or Regulatory Approvals, in the case of Pfizer or its Affiliates, or any Regulatory Approvals related to the FIH Study, in the case of BioNTech or its Affiliates, for any Candidate or Product within the Territory, and (ii) in order to respond to inquiries, requests or investigations relating to Candidates or Products or this Agreement;

(b) to outside consultants (including any professional advisor), potential acquisition partners (including any potential successors in interest), private investors or financing sources, contractors, advisory boards, managed care organizations, and non-clinical and clinical investigators, in each case to the extent useful to develop, register or market any Candidate or Product; provided that the Receiving Party will obtain the same confidentiality obligations from such Third Parties as it obtains with respect to its own similar types of confidential information;

(c) in connection with filing or prosecuting Research Program Patent Rights or Trademark rights as permitted by this Agreement;

(d) in connection with any prosecution or litigation actions or defenses undertaken pursuant to Section 7 or any other litigation directly related to a Candidate or Product in the Field;

(e) subject to the provisions of Section 8.5.2, in connection with or included in scientific presentations and publications relating to Candidates or Products, including abstracts, posters, journal articles and the like, and posting results of and other information about clinical trials to clinicaltrials.gov or PhRMA websites;

(f) subject to the obligations in Section 2. 10. 3, by Pfizer in respect of Confidential Information belonging to BioNTech (including the terms of the Agreement) to any bona fide or potential sublicensee or manufacturer in respect of any Candidate or Product, or any co-development or co-promotion partner in the Field, in each case who has agreed in writing to non-disclosure and non-use provisions with respect to such Confidential Information that are at least as restrictive as those set forth in this Section 7.1; and

(g) to the extent necessary or useful in order to enforce its rights under this Agreement.

If a Party deems it reasonably necessary to disclose Confidential Information belonging to the other Party pursuant to clause (a) or any of clauses (c) through (e) of this Section 8.2.2, then the disclosing Party will to the extent possible give reasonable advance written notice of such disclosure to the other Party and take such measures to ensure confidential treatment of such information as is reasonably required by the other Party, at the other Party's expense.

8.3. **SEC Filings and Other Disclosures.** Either Party may disclose the terms of this Agreement and make any other public written disclosure regarding the existence of, or performance under, this Agreement, to the extent required, in the reasonable opinion of such Party's legal counsel, to comply with (a) applicable Law, including the rules and regulations promulgated by the United States Securities and Exchange Commission or (b) any equivalent Governmental Authority, securities exchange or securities regulator in any country in the Territory. Before disclosing this Agreement or any of the terms hereof pursuant to this Section 8.3, the Parties will consult with one another on the terms of this Agreement to be redacted in making any such disclosure, with the Party disclosing pursuant to this Section 8.3 providing as much advance notice as is feasible under the circumstances, and giving consideration to the comments of the other Party. Further, if a Party discloses this Agreement or any of the terms hereof in accordance with this Section 8.3, such Party will, at its own expense, seek such confidential treatment of confidential portions of this Agreement and such other terms, as may be reasonably requested by the other Party and limit its disclosure of such Confidential Information to only that required to comply with applicable Law.

8.4. **Residual Knowledge Exception.** Notwithstanding any provision of this Agreement to the contrary, Residual Knowledge will not be considered Confidential Information for purposes of this Section 8; provided that, for clarity, a Party's rights to Residual Knowledge hereunder shall not include the right to practice any Patent Right owned or Controlled by the other Party that claims such Residual Knowledge unless otherwise expressly granted in another provision of this Agreement or in another agreement between the Parties.

8.5. **Public Announcements; Publications.**

8.5.1. **Announcements.** Except as may be expressly permitted under Section 8.3, neither Party will make any public announcement regarding this Agreement without the prior written approval of the other Party. For the sake of clarity, nothing in this Agreement will prevent Pfizer from making any scientific publication or public announcement with respect to any Candidate or Product under this Agreement; *provided, however,* that, except as permitted under Section 8.2, Pfizer will not disclose any of BioNTech's Confidential Information in any such publication or announcement without obtaining BioNTech's prior written consent to do so. The Parties agree that the Parties will issue a mutually agreed upon joint press release regarding the signing of this Agreement following the Effective Date, but in any event no later than ten (10) days after HSR clearance or September 5, 2018 (whichever is later).

8.5.2. **BioNTech Publications.** During the Term, BioNTech will submit to Pfizer for review and approval any proposed academic, scientific and medical publication or public presentation which contains Confidential Information of Pfizer or its Representatives. In addition, BioNTech will submit to Pfizer for review and approval any proposed publication or public presentation proposed by BioNTech or its Affiliates or any of their respective Representatives that relates to the activities conducted under this Agreement, including the Research Plan, or otherwise relating to the BioNTech Technology, the Research Program Technology, the Pfizer Technology or any Candidate or Product in the Field. In both instances, such review and approval will be

conducted for the purposes of preserving the value of the BioNTech Technology, the Research Program Technology and the Pfizer Technology and the rights granted or to be granted to Pfizer hereunder and determining whether any portion of the proposed publication or presentation containing Pfizer's Confidential Information should be modified or deleted. Written copies of such proposed publication or presentation required to be submitted hereunder will be submitted to Pfizer no later than [***] days before submission for publication or presentation (the "Pfizer Review Period"). Pfizer will provide its comments with respect to such publications and presentations within [***] days of its receipt of such written copy. The Pfizer Review Period may be extended for an additional [***] days in the event Pfizer can, within ten days of receipt of the written copy, demonstrate reasonable need for such extension including for the preparation and filing of patent applications. BioNTech will comply with standard academic practice regarding authorship of scientific publications and recognition of contribution of other parties in any publication governed by this Section 8.5.2, including International Committee of Medical Journal Editors standards regarding authorship and contributions.

8.5.3. Pfizer Publications. During the Research Term, Pfizer will submit to BioNTech for review and approval any proposed academic, scientific and medical publication or public presentation which contains Confidential Information of BioNTech or its Representatives. Such review and approval will be conducted for the purposes of determining whether any portion of the proposed publication or presentation containing Confidential Information of BioNTech or its Representatives should be modified or deleted. Written copies of such proposed publication or presentation required to be submitted hereunder will be submitted to BioNTech no later than [***] days before submission for publication or presentation (the "BioNTech Review Period"). BioNTech will provide its comments with respect to such publications and presentations within [***] days of its receipt of such written copy. The BioNTech Review Period may be extended for an additional [***] days in the event BioNTech can, within ten days of receipt of the written copy, demonstrate reasonable need for such extension including for the preparation and filing of patent applications. Pfizer will comply with standard academic practice regarding authorship of scientific publications and recognition of contribution of other parties in any publication governed by this Section 8.5.3, including International Committee of Medical Journal Editors standards regarding authorship and contributions.

8.6. Obligations in Connection with Change of Control. If a Party is subject to a Change of Control ("Change of Control Party"), such Change of Control Party will, and it will cause its Representatives to, ensure that no Confidential Information of the other Party is released to (a) any Affiliate of the Change of Control Party that becomes an Affiliate of the Change of Control Party as a result of the Change of Control or (b) any other Representatives of the Change of Control Party (or of the relevant surviving entity of such Change of Control) who become Representatives of the Change of Control Party as a result of the Change of Control, unless such Affiliate or other Representatives, as applicable, have signed individual confidentiality agreements which include equivalent obligations to those set out in this Section 8. Upon occurrence of a Change of Control, the Change of Control Party will promptly notify the other Party, share with the other Party the policies, procedures and technical and organizational measures it plans to implement in order to protect the confidentiality of the other Party's Confidential Information prior to such implementation and make any adjustments to such policies and procedures that are reasonably requested by the other Party.

9. REPRESENTATIONS AND WARRANTIES

9.1. Mutual Representations and Warranties. Each of BioNTech and Pfizer hereby represents and warrants to the other Party that:

9.1.1. it is duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization;

9.1.2. the execution, delivery and performance of this Agreement by such Party has been duly authorized by all requisite action under the provisions of its charter, bylaws and other organizational documents, and does not require any action or approval by any of its shareholders or other holders of its voting securities or voting interests;

9.1.3. it has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder;

9.1.4. this Agreement has been duly executed and is a legal, valid and binding obligation on each Party, enforceable against such Party in accordance with its terms; and

9.1.5. the execution, delivery and performance by such Party of this Agreement and its compliance with the terms and provisions hereof does not and will not conflict with or result in a breach of or default under any Binding Obligation existing as of the Execution Date.

9.2. Mutual Covenants. In addition to the covenants made by the Parties elsewhere in this Agreement, each of BioNTech and Pfizer hereby covenants to the other Party that, from the Execution Date until expiration or termination of this Agreement it will perform its obligations under this Agreement in compliance with applicable Laws.

9.3. Representations and Warranties of BioNTech. BioNTech hereby represents and warrants to Pfizer that, unless otherwise disclosed in Schedule 9.3 (or otherwise as accepted to have been disclosed between BioNTech's external counsel and Pfizer's external counsel other than in writing), and provided that those provisions of the Current Licenses set forth in Schedule 9.6.3 shall be deemed disclosed against the representations and warranties given by BioNTech at sections 9.3.1, 9.3.2, 9.3.4, 9.3.11 and 9.3.12 of this Agreement:

9.3.1. as of the Execution Date, except with respect to BioNTech Technology Controlled by BioNTech pursuant to a Current License, BioNTech or its Affiliates are the sole and exclusive owner of the BioNTech Technology, and all BioNTech Technology is free and clear of any claims, liens, charges or encumbrances;

9.3.2. as of the Execution Date, BioNTech has, and to its knowledge will have, the full right, power and authority to (i) grant all of the right, title and interest in the licenses and other rights granted or to be granted to Pfizer, Pfizer's Affiliates or Pfizer's Sublicensees under this Agreement and (ii) perform its obligations under this Agreement;

9.3.3. Schedule 9.3.3 sets forth a true and complete list of all Candidates discovered or developed by BioNTech or its Affiliates on or prior to the Execution Date;

9.3.4. as of the Execution Date, (a) Schedule 9.3.4 sets forth a true and complete list of all Patent Rights (i) owned or otherwise Controlled by BioNTech or its Affiliates or (ii) to which BioNTech or its Affiliates have been granted or otherwise transferred any right to practice under, in each case of (i) and (ii), that relate to the Candidates, the Products, the BioNTech Technology, or the Parties' activities in the Research Program, (b) each such Patent Right is in full force and effect, (c) BioNTech or its Affiliates have timely paid, or caused the appropriate Third Parties to pay, all filing and renewal fees payable with respect to such Patent Rights; and (d) BioNTech Controls all Patent Rights listed in Schedule 9.3.4;

9.3.5. as of the Execution Date, BioNTech has disclosed to Pfizer all material scientific and technical information and all information relating to safety and efficacy or suitability for infectious disease arising from the application or use of the BioNTech Technology that are known to it or its Affiliates that relates to the Candidates or Products;

9.3.6. to BioNTech's knowledge as of the Execution Date, (a) the BioNTech Patent Rights issued as of the Execution Date are, valid and enforceable patents, (b) for the inventions that are the subject of BioNTech Patent Rights that are pending Patent Rights as of the Execution Date, there is no prior art or other facts or circumstances that BioNTech believes would preclude validity or enforceability of any Patent Rights issued from such pending Patent Rights and (c) as of the Execution Date, no Third Party (i) is infringing any BioNTech Patent Right or (ii) has challenged or threatened in writing to challenge the ownership, scope, validity or enforceability of, or BioNTech's or any Current Licensor's rights in or to, any BioNTech Patent Right (including, by way of example, through the institution or written threat of institution of interference, nullity or similar invalidity proceedings before the United States Patent and Trademark Office or any analogous foreign Governmental Authority);

9.3.7. as of the Execution Date, BioNTech and its Affiliates and, to BioNTech's knowledge, their Representatives and all Current Licensors have complied with all applicable Laws, including any disclosure requirements, in connection with the filing, prosecution and maintenance of the BioNTech Patent Rights;

9.3.8. as of the Execution Date, BioNTech has independently developed all BioNTech Know-How and BioNTech Materials or otherwise has a valid right to use, and to permit Pfizer, Pfizer's Affiliates and Pfizer's Sublicensees to use, the BioNTech Know-How and BioNTech Materials for all permitted purposes under this Agreement;

9.3.9. except with respect to BioNTech Technology Controlled by BioNTech pursuant to a Current License, BioNTech or its Affiliates have obtained from all inventors of BioNTech Technology existing as of the Execution Date, valid and enforceable agreements assigning to BioNTech or its Affiliates each such inventor's entire right, title and interest in and to all such BioNTech Technology (except to the extent applicable Law provides that all right, title and interest in and to such BioNTech Technology automatically vests in BioNTech or its Affiliates by operation of law);

9.3.10. in respect of BioNTech Technology solely or jointly owned by BioNTech existing as of the Execution Date, neither BioNTech nor its Affiliates are subject to any funding agreement with any government or Governmental Authority;

9.3.11. neither BioNTech nor any of its Affiliates are party to or otherwise subject to any agreement or arrangement which limits the ownership or licensed or sublicensed rights of Pfizer or its Affiliates with respect to, or limits the ability of Pfizer or its Affiliates to grant a license, sublicense or access, or provide or provide access or other rights in, to or under, any Intellectual Property Right or material (including any Patent Right, Know-How or other data or information), in each case, that would, but for such agreement or arrangement, be included in the rights licensed or assigned to Pfizer or its Affiliates pursuant to this Agreement;

9.3.12. as of the Execution Date (a) there are no BioNTech Third Party Agreements other than the Current Licenses set forth on Schedule 9.3.12, (b) true and complete copies of each Current License have been provided to Pfizer, (c) except as provided in the Current Licenses, no Third Party has any right, title or interest in or to, or any license under, any BioNTech Technology in the Field, (d) no rights granted by or to BioNTech or its Affiliates under any Current License conflict with any right or license granted to Pfizer or its Affiliates hereunder and (e) BioNTech and its Affiliates are in compliance in all material respects with all Current Licenses;

9.3.13. as of the Execution Date, to BioNTech's knowledge, the use by BioNTech or Pfizer (or their respective Affiliates or Sublicensees) of the BioNTech Technology in accordance with this Agreement, and the Development, Manufacture or Commercialization of those Candidates listed in Schedule 9.3.3 or Products incorporating such Candidates in accordance with this Agreement (a) does not and will not infringe any Patent Right of any Third Party or (b) will not infringe the claims of any published Third Party pending Patent Right when and if such claims issue;

9.3.14. as of the Execution Date, there is no (a) written claim, demand, suit, proceeding, arbitration, inquiry, investigation or other legal action of any nature, civil, criminal, regulatory or otherwise, pending or, to BioNTech's knowledge, made or threatened (irrespective of whether or not in writing) against BioNTech or any of its Affiliates or (b) judgment or settlement against or owed by BioNTech or any of its Affiliates, in each case in connection with the BioNTech Technology, the Current Licenses, any Candidate or Product or relating to the transactions contemplated by this Agreement;

9.3.15. except with respect to BioNTech Technology Controlled by BioNTech pursuant to a Current License, BioNTech has valid and enforceable agreements with all Persons acting by or on behalf of BioNTech or its Affiliates under this Agreement which require such Persons to assign to BioNTech their entire right, title and interest in and to all BioNTech Technology or Research Program Technology (except to the extent applicable Law provides that all right, title and interest in and to such BioNTech Technology or Research Program Technology automatically vests in BioNTech or its Affiliates by operation of law);

9.3.16. as of the Execution Date, BioNTech and its Affiliates have claimed and remunerated all employee inventions of their respective employees comprised within the GEIA Technology in accordance with the provisions of the GEIA;

9.3.17. as of the Execution Date, BioNTech and its Affiliates are entitled to unrestrictedly claim all rights to employee inventions of their employees comprised within the GEIA Technology;

9.3.18. as of the Execution Date, BioNTech has obtained all necessary assignment documents for the BioNTech Technology or Research Program Technology inventions in its files and maintains written track records of the proper claiming of any inventions made by employees of BioNTech, its Affiliates or Third Parties included in BioNTech Technology or Research Program Technology by the employer and/or the proper assignment of the inventors of their rights in the invention, including the right to claim priority to said invention, to the employer;

9.3.19. as of the Execution Date, BioNTech has no knowledge of (a) any inequitable conduct or fraud on any patent office with respect to any of the BioNTech Patent Rights or (b) any Person (other than Persons identified in the applicable patent applications or patents, as inventors of inventions disclosed in the BioNTech Patent Rights) who claims to be an inventor of an invention disclosed in the BioNTech Patent Rights;

9.3.20. as of the Execution Date, BioNTech and its Affiliates are not, and to BioNTech's knowledge, no Current Licensor or Representative of BioNTech (in each case, as applicable) is, debarred by any Regulatory Authority or the subject of debarment proceedings by any Regulatory Authority and, in the course of the discovery or pre-clinical development of any Candidate or Product, BioNTech and its Affiliates have not and, to the knowledge of BioNTech, no Current Licensor or Representative of BioNTech (in each case, as applicable) have used any employee or consultant that is debarred by any Regulatory Authority or, to the knowledge of BioNTech, is the subject of debarment proceedings by any Regulatory Authority;

9.3.21. BioNTech, its Affiliates, and to BioNTech's knowledge, all third parties and Representatives acting on BioNTech's behalf, have and will comply in all material respects with all applicable Law and accepted pharmaceutical industry business practices in connection with this Agreement, including, to the extent applicable, the FD&C Act (21 U.S.C. § 301, et seq.), the Anti-Kickback Statute (42 U.S.C. § 1320a-7b), Civil Monetary Penalty Statute (42 U.S.C. § 1320a-7a), the False Claims Act (31 U.S.C. § 3729 et seq.), comparable state statutes, the regulations promulgated under all such statutes, and the regulations issued by the FDA, consistent with the 'Compliance Program Guidance for Pharmaceutical Manufacturers' published by the Office of Inspector General, U.S. Department of Health and Human Services;

9.3.22. with respect to any Candidates, Products, or payments or services provided under this Agreement, BioNTech, its Affiliates, and to its knowledge all third parties and Representatives acting on BioNTech's behalf, have not taken and will not during the Term take any action directly or indirectly to offer, promise or pay, or authorize the offer or payment of, any money or anything of value in order to improperly or corruptly seek to influence any Government Official or any other person in order to gain an improper advantage, and has not accepted, and will not accept in the future such payment;

9.3.23. BioNTech, its Affiliates, and to its knowledge all third parties and Representatives acting on BioNTech's behalf, have and will continue to comply with the laws and regulations of the countries where it operates, including anti-bribery and anti-corruption laws, including, to the extent applicable, the U.S. Foreign Corrupt Practices Act of 1977 and the U.K. Bribery Act 2010, accounting and record keeping laws, and laws relating to interactions with healthcare professionals or healthcare providers (collectively, "HCPs") and Government Officials;

9.3.24. BioNTech has implemented or will implement within a reasonable period of time following the Effective Date of this Agreement (but in no event greater than March 30, 2020) policies and procedures, including but not limited to anti-corruption policies and procedures, commensurate with its current risk profile, and shall review said policies from time to time setting out rules governing interactions with HCPs and Government Officials, engagement of Third Parties, including, where appropriate, due diligence (“Policies”), and its Policies will mandate a robust set of internal controls, including accounting controls, designed to ensure the making and keeping of fair and accurate books, records and accounts, on its operations around the world and apply worldwide to all its employees, subsidiaries, and Third Parties acting on its behalf to provide reasonable assurance that BioNTech, its subsidiaries and such Third Parties will comply with Laws, including but not limited to Anti-Corruption Laws to the extent required by such Laws. BioNTech will reasonably monitor its operations and the operations of its Affiliates with the purpose of ensuring its Policies are effective at the reasonable assurance level and make necessary changes from time to time, in particular as its business activities expand;

9.3.25. BioNTech is, as between the Parties, solely responsible to ensure Compliance by it and its Affiliates; and

9.3.26. the Impf Group does not own or Control any Intellectual Property Rights used by BioNTech or that BioNTech may reasonably require or be useful to exploitation of any of the RNA Technology.

9.4. Accuracy of Representations and Warranties.

9.4.1. BioNTech will take no action which would render any representation or warranty made by BioNTech and contained in Section 9.1 or Section 9.2 inaccurate or untrue; provided that such covenant shall not apply to representations and warranties expressly given as of the Execution Date;

9.4.2. BioNTech will promptly notify Pfizer of any lawsuits, claims, administrative actions, regulatory inquiries or investigations, or other proceedings asserted or commenced against BioNTech or its Representatives involving in any material way the ability of BioNTech to deliver the rights, licenses and sublicenses granted herein; and

9.4.3. BioNTech will promptly notify Pfizer in writing of any facts or circumstances which come to its attention and which cause, or through the passage of time may cause, any of the representations and warranties contained in Section 9.1, Section 9.2, Section 12.11 or otherwise in this Agreement to be untrue or misleading in any material respect at any time during the Term; and in addition to the foregoing, with regard to any of the representations under Section 12.11, BioNTech will suspend all affected activities (including making any related payments) under this Agreement, unless and until Pfizer determines that such activities may be resumed; provided that such covenant shall not apply to representations and warranties expressly given as of the Execution Date.

9.5. BioNTech Covenants. In addition to the covenants made by BioNTech elsewhere in this Agreement, BioNTech hereby covenants to Pfizer that, from the Execution Date until expiration or termination of this Agreement:

9.5.1. BioNTech will not, and will cause its Affiliates not to (a) license, sell or assign (other than in a connection with a permitted assignment of this Agreement by BioNTech pursuant to Section 12.2) or otherwise transfer to any Person (other than Pfizer or its Affiliates or Sublicensees pursuant to the terms of this Agreement) any BioNTech Technology or Research Program Technology (or agree to do any of the foregoing) or (b) incur or permit to exist, with respect to any BioNTech Technology or Research Program Technology, any lien, encumbrance, charge, security interest, mortgage, liability, assignment, grant of license or other Binding Obligation, in each case of (a) and (b) that is inconsistent with the licenses and other rights granted (or that may be granted) to Pfizer or its Affiliates under this Agreement;

9.5.2. Except as explicitly permitted under this Agreement, BioNTech will not (a) take, or omit to take, any action that diminishes the rights under the BioNTech Technology or Research Program Technology granted (or that may be granted) to Pfizer or Pfizer's Affiliates under this Agreement or (b) take, or omit to take, any action that is reasonably necessary to avoid diminishing the rights under the BioNTech Technology or Research Program Technology granted (or that may be granted) to Pfizer or Pfizer's Affiliates under this Agreement (for the avoidance of doubt, BioNTech shall not be in breach of the covenants set forth in this Section 9.5.2 due to any reasonable act or position taken in connection with the filing, prosecution, maintenance, defense or enforcement of BioNTech Technology or Research Program Technology as permitted in Section 7);

9.5.3. BioNTech will (a) not enter into any BioNTech Third Party Agreement that adversely affects (i) the rights granted (or that may be granted) to Pfizer, Pfizer's Affiliates or Sublicensees hereunder or (ii) BioNTech's ability to fully perform its obligations hereunder; (b) not amend or otherwise modify any BioNTech Third Party Agreement (including any Current License) or consent or waive rights with respect thereto in any manner that (A) adversely affects the rights granted (or that may be granted) to Pfizer or Pfizer's Affiliates or Sublicensees hereunder or (B) BioNTech's ability to fully perform its obligations hereunder; (c) promptly furnish Pfizer with true and complete copies of all (1) amendments to the Current Licenses and (2) BioNTech Third Party Agreements and related amendments executed following the Execution Date (in each case with redactions only in respect of sensitive information which is not relevant for the purposes of this Agreement); (d) remain, and cause its Affiliates to remain, in compliance in all material respects with all BioNTech Third Party Agreements; and (e) furnish Pfizer with copies of all notices received by BioNTech or its Representatives relating to any alleged breach or default by BioNTech or its Representatives under any BioNTech Third Party Agreement within ten (10) Business Days after receipt thereof (in each case with redactions only in respect of sensitive information which is not relevant for the purposes of this Agreement); and

9.5.4. BioNTech will not enter into or otherwise allow itself or its Representatives to be subject to any agreement or arrangement, other than the Current Licenses, which limits the ownership or licensed rights of Pfizer or its Affiliates with respect to, or limits the ability of Pfizer or its Affiliates to grant a license, sublicense or access, or provide or provide access or other rights in, to or under, any Intellectual Property Right or material (including any Patent Right, Know-How or other data or information), in each case, that would, but for such agreement or arrangement, be included in the rights licensed or assigned (or that may be licensed or assigned) to Pfizer or its Affiliates pursuant to this Agreement

9.5.5. BioNTech and its Affiliates will maintain or obtain valid and enforceable agreements with or from all inventors of BioNTech Technology or Research Program Technology who are employed by or otherwise acting on behalf of BioNTech or its Affiliates assigning to BioNTech or its Affiliates each such inventor's entire right, title and interest in and to all such BioNTech Technology or Research Program Technology (except to the extent applicable Law provides that all right, title and interest in and to such BioNTech Technology or Research Program Technology automatically vests in BioNTech or its Affiliates by operation of law).

9.5.6. BioNTech will unrestrictedly claim and remunerate (and procure that its Affiliates will unrestrictedly claim and remunerate) all employee inventions of their respective employees comprised within the GEIA Technology in accordance with the provisions of the GEIA.

9.5.7. In respect of GEIA Technology created after the Effective Date to which Pfizer shall obtain a license hereunder, BioNTech will use Commercially Reasonable Efforts (and will procure that its Affiliates use Commercially Reasonable Efforts) to conclude agreements with BioNTech employee inventors regarding the respective inventions by which the respective inventors: (a) waive the employer's obligation to release the employee invention and to enable the employee inventor upon request to apply for foreign Intellectual Property Rights for such foreign countries in which it does not intend to apply for Intellectual Property Rights (Sec. 14 GEIA); and (b) waive the employer's obligation to notify the employee inventor and to transfer the right in the invention to the employee inventor at the latter's request and expense, if it does not intend to pursue the application for the grant on an Intellectual Property Right for the invention any further or if it does not want to maintain the Intellectual Property Right granted for the job-related invention (Sec. 16 GEIA); and (c) waive the employer's obligation to acknowledge protectability of the invention in case the employer decides not to file a registration, but to keep the invention secret (Sec. 17 GEIA);

9.5.8. To the extent BioNTech Technology or Research Program Technology is created after the Effective Date by inventors employed by or acting on behalf of BioNTech's or its Affiliates' Third Party subcontractors, BioNTech will use Commercially Reasonable Efforts (and will procure that its Affiliates use Commercially Reasonable Efforts) to obtain valid and enforceable agreements with their respective Third Party subcontractors imposing on their Third Party subcontractors the obligation to claim the rights in the invention in accordance with applicable law and to conclude agreements with its employee inventors assigning to the respective Third Party subcontractor each such inventor's entire right, title and interest in and to all such BioNTech Technology or Research Program Technology (except to the extent applicable Law provides that all right, title and interest in and to such BioNTech Technology or Research Program Technology automatically vests in the Third Party subcontractor by operation of law) and, to the extent GEIA applies to such BioNTech Technology or Research Program Technology, (ii) using Commercially Reasonable Efforts to obtain a waiver of inventor in his rights in Sec. 14, 16 and 17 GEIA;

9.5.9. with respect to any BioNTech Technology or Research Program Technology to which Pfizer shall obtain a license hereunder that is made after the Effective Date in the jurisdiction of the GEIA by an inventor on behalf of BioNTech or its Affiliates who is employed by a university pursuant to Sec. 42 GEIA (e.g. university professors, research assistants), BioNTech will use Commercially Reasonable Efforts (and will procure that its Affiliates use Commercially Reasonable Efforts) to obtain valid and enforceable trifold agreements with such inventor and the

respective university by which the university (a) waives its entire right, title and interest in and to that BioNTech Technology or Research Program Technology made by the inventor, (b) the inventor assigns its rights, title and interest in and to that BioNTech Technology or Research Program Technology to BioNTech or its Affiliates, (c) the inventor waives its rights pursuant to Sec. 14, 16 and 17 GEIA as well as (d) waives its negative publication right (Sec. 42 Nr. 2 GEIA) vis-a-vis BioNTech or its Affiliates;

9.5.10. with respect to animals used in conducting activities under this Agreement, BioNTech will, and will cause its Affiliates and permitted subcontractors to, comply with Pfizer's Corporate Policy regarding Animal Care and Use, attached hereto as Exhibit C (except where in conflict with applicable Law);

9.5.11. with respect to Human Material used, including collection or transfer, by BioNTech, its Affiliates or permitted subcontractors in conducting activities under this Agreement, (a) such use shall be in accordance with the Research Plan and FIH Studies and shall be within the scope of and consistent with its ethical approval policies, (b) BioNTech will, and will cause its Affiliates or permitted subcontractors to, handle and use the Human Material in accordance with all applicable Laws and the ICF, which shall permit Pfizer to use the Human Material for the research purposes contemplated by this Agreement, (c) BioNTech will provide the ICF to Pfizer upon request by Pfizer, (d) the Human Material will be used for research purposes only and not be used for treatment of or administration to humans and (e) if BioNTech procures any Human Material from a Third Party such as a sample bank, it will ensure that the collection and transfer of the Human Material and the use of the Human Material for purposes of the Research Plan is in accordance with all applicable Laws and recognized international standards for the protection of human research subjects; and

9.5.12. BioNTech has received a copy of and will comply with Pfizer's Anti-Bribery and Anti-Corruption Principles attached hereto as Exhibit B.

9.6. Pfizer Covenants. In addition to the covenants made by Pfizer elsewhere in this Agreement, Pfizer hereby covenants to BioNTech that, from the Execution Date until expiration or termination of this Agreement,

9.6.1. Pfizer and its Affiliates maintain or will obtain valid and enforceable agreements with or from all inventors of Pfizer Improvements, Research Program Technology, RNA Improvements or Reversion Technology who are employed by or otherwise acting on behalf of Pfizer or its Affiliates valid and enforceable agreements assigning to Pfizer or its Affiliates each such inventor's entire right, title and interest in and to all such Pfizer Improvements, Research Program Technology or RNA Improvements (except to the extent applicable Law provides that all right, title and interest in and to such Pfizer Improvements, Research Program Technology or RNA Improvements automatically vests in Pfizer or its Affiliates by operation of law), and Pfizer and its Affiliates have made or will make any payments owing to any such inventors in respect of any Pfizer Improvements, Research Program Technology or RNA Improvements or any other Person that is required in connection with the creation or exploitation of or transfer of rights to such Pfizer Improvements, Research Program Technology or RNA Improvements;

9.6.2. with respect to Human Material used, including collection or transfer, by Pfizer, its Affiliates or permitted subcontractors in conducting activities under this Agreement, (a) such use shall be within the scope of and consistent with its ethical approval policies, (b) Pfizer will, and will cause its Affiliates or permitted subcontractors to, handle and use the Human Material in accordance with all applicable Laws and the ICF, (c) Pfizer will provide the ICF to BioNTech upon request by BioNTech, (d) the Human Material will be used for research purposes only and not be used for treatment of or administration to humans and (e) if Pfizer procures any Human Material from a Third Party such as a sample bank, it will ensure that the collection and transfer of the Human Material and the use of the Human Material for purposes of the Research Plan is in accordance with all applicable Laws and recognized international standards for the protection of human research subjects; and

9.6.3. Pfizer will comply with the provisions of the Current Licenses set forth in Schedule 9.6.3 in respect of BioNTech Technology sublicensed to Pfizer under the respective Current Licenses insofar as Pfizer is using such BioNTech Technology.

9.7. Notifications. During the Term, BioNTech will promptly notify Pfizer in writing or orally in the event that it learns of:

9.7.1. any prior art or other facts that BioNTech believes would result in the invalidity or unenforceability of any of the claims included in any of the BioNTech Patent Rights or Research Program Patent Rights; or

9.7.2. any inequitable conduct or fraud on the patent office with respect to any of the BioNTech Patent Rights or Research Program Patent Rights; or

9.7.3. any Person (other than Persons identified as inventors of inventions disclosed in the BioNTech Patent Rights or Research Program Patent Rights) who claims to be an inventor of an invention disclosed in the BioNTech Patent Rights or Research Program Patent Rights; and

9.7.4. any lawsuits, claims, administrative actions, government inquiries or investigations, or other proceedings related to the activities contemplated under this Agreement.

9.8. Representation by Legal Counsel. Each Party hereto represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will exist or be implied against the Party which drafted such terms and provisions.

9.9. BioNTech's knowledge. All references in this Section 9 to BioNTech's knowledge (or equivalent) shall refer to the actual knowledge after reasonable internal inquiry of BioNTech's management comprising those individuals set forth in Schedule 9.9.

9.10. Disclaimer. THE FOREGOING REPRESENTATIONS AND WARRANTIES OF EACH PARTY ARE IN LIEU OF ANY OTHER REPRESENTATIONS AND WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR ANY IMPLIED WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE, ALL OF WHICH ARE HEREBY SPECIFICALLY EXCLUDED AND DISCLAIMED.

10. GOVERNMENT APPROVALS; TERM AND TERMINATION

10.1. Antitrust Filing. Each of BioNTech and Pfizer will, within [***] days after the Execution Date (or such later time as may be agreed to in writing by the Parties) make an appropriate filing under the HSR Act or any Foreign Antitrust Laws (the “Antitrust Filings”) if applicable in the reasonable opinion of either Party with respect to the transactions contemplated under this Agreement. The Parties will cooperate with one another to the extent necessary in the preparation of any such Antitrust Filings. BioNTech will not agree to any voluntary extension or delay of any statutory waiting period or withdraw any of its Antitrust Filings pursuant to the HSR Act or any Foreign Antitrust Laws unless Pfizer has given its prior written consent to such extension or delay. Each Party will be responsible for its own costs, expenses, and filing fees associated with any Antitrust Filing; *provided, however*, that Pfizer will be solely responsible for any fees (other than penalties that may be incurred as a result of actions or omissions on the part of BioNTech) required to be paid to any Governmental Authority in connection with submitting any such HSR Filing.

10.2. Termination Upon Antitrust Filing Denial. In the event that the Parties make an Antitrust Filing under Section 10.1, this Agreement will terminate (a) at Pfizer’s option, immediately upon notice to BioNTech, in the event that any Governmental Authority seeks a temporary restraining order, preliminary or permanent injunction or other legal restraint under the HSR Act or any Foreign Antitrust Laws against BioNTech and Pfizer to enjoin the transactions contemplated by this Agreement, (b) at the election of either Party, immediately upon notice to the other Party, in the event that any Governmental Authority obtains a temporary restraining order, preliminary or permanent injunction or other legal restraint under the HSR Act or any Foreign Antitrust Laws against BioNTech or Pfizer to enjoin the transactions contemplated by this Agreement or (c) at the election of either Party, immediately upon notice to the other Party, in the event that the Antitrust Clearance Date will not have occurred on or prior to 180 days after the effective date of any applicable Antitrust Filings.

10.3. Other Government Approvals. Each of BioNTech and Pfizer will cooperate with the other Party and to make all registrations, filings and applications, to give all notices and to obtain as soon as practicable all governmental or other consents, transfers, approvals, orders, qualifications authorizations, permits and waivers, if any, and to do all other things necessary or useful for the consummation of the transactions as contemplated hereby including the collection of Human Material.

10.4. Term. Except with respect to the provisions of Sections 10.1 and 10.2 and the provisions of Section 7.1, the term of this Agreement (the “Term”) will commence on the Effective Date and extend on a country-by-country basis (in the Territory), unless this Agreement is terminated earlier in accordance with this Section 10, until the last to expire of any Royalty Term for any Product in such country in the Territory. Notwithstanding any provision of this Agreement to the contrary, upon expiration of this Agreement, Pfizer will retain the fully paid-up, perpetual, irrevocable royalty-free license to each Product as set forth in Section 3.5.2.

10.5. Termination for Cause by BioNTech. BioNTech may terminate this Agreement for cause, at any time during the Term, by giving written notice to Pfizer in the event that Pfizer commits a material breach of its obligations under this Agreement and such material breach remains uncured (a) 90 days for a material breach that is a failure of Pfizer to make an undisputed payment owed to BioNTech under this Agreement and (b) 180 days for all other material breaches, in each case measured from the date written notice of such material breach is given to Pfizer; *provided, however*, that if any breach is not reasonably curable within 180 days and if Pfizer is making a bona fide effort/using Commercially Reasonable Efforts to cure such breach, such termination will be delayed for a time period to be agreed by both Parties in order to permit Pfizer a reasonable period of time to cure such breach. If the alleged material breach relates to non-payment of any amount due under this Agreement, the cure period will be tolled pending resolution of any bona fide dispute between the Parties as to whether such payment is due.

10.6. Termination by Pfizer.

10.6.1. **Termination for Convenience.** Upon at least [***] days' prior written notice to BioNTech, Pfizer may terminate this Agreement on a Product-by-Product and country-by-country basis, or in its entirety, without cause, for any or no reason.

10.6.2. **Termination for Cause.**

(a) *General.* Pfizer may terminate this Agreement for cause in its entirety, at any time during the Term, by giving written notice to BioNTech in the event that BioNTech commits a material breach of its obligations under this Agreement and such material breach remains uncured for [***] days, measured from the date written notice of such material breach is given to BioNTech; *provided, however*, that if any breach is not reasonably curable within [***] days and if BioNTech is making a bona fide effort/using its Commercially Reasonable Efforts to cure such breach, such termination will be delayed for a time period to be agreed by both Parties in order to permit BioNTech a reasonable period of time to cure such breach.

(b) Notwithstanding anything to the contrary in this Agreement, Pfizer may terminate this Agreement in whole, immediately and without regard to any cure period, if BioNTech or its Affiliates have committed a violation of Global Trade Control Laws in connection with this Agreement. Any such termination will be deemed for cause under Section 10.7.1(b) and Pfizer will not be responsible for any payments due relating to such violation of Global Trade Control Laws even if such activities have already occurred. BioNTech will be responsible for reimbursing Pfizer for any payments made to BioNTech or due to Pfizer under this Agreement that are blocked due to violation of Global Trade Control Laws.

10.6.3. **Termination for Law-related Breach.** Pfizer may terminate this Agreement if BioNTech breaches any of the representations and warranties set forth in Sections 9.3.21 through 9.3.23 or if Pfizer learns that improper payments are being or have been made to Government Officials by BioNTech with respect to services performed in connection with this Agreement. Further, in the event of such termination BioNTech shall be liable for damages or remedies as provided by Law.

10.7. Effects of Termination.

10.7.1. **Effect of Termination.**

(a) *Termination for Cause by BioNTech; Termination for Convenience by Pfizer.* In the event that BioNTech terminates this Agreement for cause pursuant to Section 10.5 or Pfizer terminates this Agreement for convenience pursuant to Section 10.6.1, the following will apply:

(i) Except as otherwise expressly provided herein, all rights and obligations of each Party hereunder will cease (including all rights and licenses and sublicenses granted by either Party to the other Party hereunder, and all sublicenses granted to Affiliates or Third Parties under the rights granted hereunder).

(ii) On BioNTech's written notice to Pfizer, which notice may only be delivered no later than [***] days following the effective date of termination:

(A) effective as of receipt of BioNTech's notice and subject to the remaining obligations of this Section 10.7.1(a), (1) Pfizer shall grant, and hereby grants, BioNTech a royalty-bearing, non-exclusive, sublicensable license under the Reversion Technology permitting BioNTech to continue to Develop, Commercialize and Manufacture any Product under this Agreement that is being Developed or Commercialized by Pfizer or its Affiliates at the time of termination, in the form in which such Product then exists (a "Continuation Product") and the other provisions of Schedule 10.7.1(a) shall apply; (2) BioNTech shall pay royalties to Pfizer in accordance with paragraphs 6 through 8 of Schedule 10.7.1(a), and (3) BioNTech and its Affiliates shall release and, upon Pfizer's receipt of such notice, hereby do release Pfizer, its Affiliates and sublicensees with respect to any and all claims of any nature that BioNTech or its Affiliates may have had against Pfizer relating to this Agreement that arose on or before the effective date of termination; and

(B) the Parties will negotiate in good faith for a period not to exceed [***] days regarding an agreement (x) governing the further terms of transition of the Continuation Product from Pfizer to BioNTech comprising at minimum the elements set forth in Schedule 10.7.1(a) and (y) for a license to such Continuation Product under the Pfizer Technology actually used by Pfizer or its Affiliates or Sublicensees before the effective date of termination; provided that if the Parties cannot reach an agreement within such [***] day period, then the provisions of Section 10.7.1(a)(ii)(C) and (D) shall apply;

(C) if the Parties cannot reach an agreement within such [***] day period set forth in of Section 10.7.1(a)(ii)(B) with respect to the terms of the transition of the Continuation Product or the license described in Section 10.7.1(a)(ii)(B), then the terms of such transition of the Continuation Product or license shall be determined, taking into account all then-relevant factors, by an independent Third Party expert knowledgeable in pharma licensing to be agreed between the Parties (and if the Parties cannot agree on such Third Party expert within [***] days of the expiration of the above negotiation period, the Third Party expert shall be independently appointed upon either Party's request by the International Chamber of Commerce). Each Party shall be obliged to submit its final proposal for the terms of such transition of or license to the Continuation Product to the Third Party expert, and such proposal shall remain confidential and shall not be disclosed to the other Party. The decision of the Third Party expert shall be final and binding on both Parties. The costs of the Third Party Expert shall be borne by both Parties at equal shares.

(D) for the period between the receipt of BioNTech' notice until an agreement is concluded in accordance with Section 10.7.1(a)(ii)(B) and (C) above, Pfizer hereby covenants not to sue (and to procure that its Affiliates will not sue) BioNTech or its Affiliates for infringement of the Pfizer Technology actually used by Pfizer or its Affiliates or Sublicensees before the effective date of termination.

(b) *Termination for Cause by Pfizer.*

(i) In the event that Pfizer terminates this Agreement pursuant to Section 10.6.2, all rights and obligations of each Party hereunder shall cease (including all non-perpetual, revocable rights and licenses granted by either Party to the other Party hereunder), except as otherwise expressly provided herein.

(ii) In the event that Pfizer has the right, but elects not, to terminate this Agreement pursuant to Section 10.7.1(b)(i) (after notice and failure of BioNTech to cure such breach as provided in Section 10.6.2), Pfizer shall notify BioNTech promptly and: (A) Pfizer's obligations to pay Development Milestones and Sales Milestones and royalties with respect to Net Sales of such Licensed Products shall be reduced by an amount equal to [***] of the amount that would otherwise have been payable under this Agreement such amount to be paid in accordance with and subject to the other terms of this Agreement, provided that any such reduction of royalty payments shall not result in any royalty rate that is below the royalty amount which BioNTech or its Affiliates have to pay under any BioNTech Third Party Agreement to Third Party licensors in connection with the relevant sale of Candidates or Products, and shall be offset against any damage claim of Pfizer in relation to such material breach; and (B) and at Pfizer's sole discretion Pfizer will have the right to offset, against any payments due to BioNTech under this Agreement, any damages finally awarded to Pfizer on account of such material breach. If, following Pfizer's exercise of the rights under this Section 10.7.1(b)(ii), a competent English court decides through final and binding decision that Pfizer was not entitled to exercise its rights hereunder, BioNTech shall be entitled to terminate this Agreement immediately without any option to cure for Pfizer.

10.7.2. **Accrued Rights.** Subject to the release granted pursuant to Section , expiration or termination of this Agreement for any reason will be without prejudice to any right which will have accrued to the benefit of either Party prior to such termination, including damages arising from any breach under this Agreement. Expiration or termination of this Agreement will not relieve either Party from any obligation which is expressly indicated to survive such expiration or termination.

10.7.3. Survival Period. The following sections, together with any sections that expressly survive (including any perpetual licenses and sublicenses granted hereunder), will survive expiration or termination of this Agreement for any reason: Sections 1 (Definitions), 3.6.3 (Royalty Statements and Payments) only in relation to any Calendar Quarter in which sales have occurred prior to the termination, 3.6.7 (Record Keeping), 3.6.8 (Audits), 3.6.9 (Underpayments/Overpayments), 3.6.10 (Confidentiality), 4.6.2 (Title to Pfizer Materials and BioNTech Materials), 4.6.4 (Return of Proprietary Materials), 7.2 (Ownership of Intellectual Property), 7.3.17.3.1(c) (Filing, Prosecution and Maintenance of Joint Patent Rights), 8 (Confidentiality), 10.7 (Effects of Termination), 10.8 (Provision for Insolvency), 11.1 (No Consequential Damages), 11.2 (Indemnification by Pfizer), 11.3 (Indemnification by BioNTech), 11.4 (Procedure), 12 (Miscellaneous) and, to the extent this Agreement expires or is terminated, either in whole or in part, for any reason except by BioNTech for cause pursuant to Section 10.5 or by Pfizer without cause pursuant to Section 10.6.1, Sections 7.2.4 (Patent Rights) and 7.4 (Enforcement and Defense of Know-How), and to the extent an Enforcement Action or Infringement Claim is active, live or pending at the time of expiry or termination Sections 7.3.2 or 7.3.6, as applicable.

10.8. Provision for Insolvency.

10.8.1. Termination Right. BioNTech will be deemed a “Debtor” under this Agreement if, at any time during the Term (a) a case is commenced by or against BioNTech under the Bankruptcy Code, (b) BioNTech files for or is subject to the institution of bankruptcy, reorganization, liquidation or receivership proceedings (other than a case under the Bankruptcy Code), (c) BioNTech assigns all or a substantial portion of its assets for the benefit of creditors, (d) a receiver or custodian is appointed for BioNTech’s business or (e) a substantial portion of BioNTech’s business is subject to attachment or similar process; *provided, however*, that in the case of any involuntary case under the Bankruptcy Code, BioNTech will not be deemed a Debtor if the case is dismissed within 60 days after the commencement thereof. If BioNTech is deemed a Debtor, then Pfizer may terminate this Agreement by providing written notice to BioNTech. If Pfizer terminates this Agreement pursuant this Section 10.8.1, then: (i) all licenses granted to Pfizer under this Agreement will become irrevocable and perpetual, and Pfizer will have no further obligations to BioNTech under this Agreement other than (A) those obligations that expressly survive termination in accordance with Section 10.7.3 and (B) an obligation to pay royalties with respect to Net Sales of Products in an amount equal to 100% of the amount that would otherwise have been payable under this Agreement, such amount to be paid in accordance with and subject to the other terms of this Agreement governing the payment of royalties; (ii) such termination will not be construed to limit BioNTech’s right to receive payments that accrued before the effective date of such termination; (iii) Pfizer will have the right to offset, against any payment owing to BioNTech as provided for under clause (i), above, any damages found or agreed by the Parties to be owed by BioNTech to Pfizer; and (iv) nothing in this Section 10.8.1 will limit any other remedy Pfizer may have for any breach by BioNTech of this Agreement.

10.8.2. Rights to Intellectual Property. All rights and licenses now or hereafter granted by BioNTech to Pfizer under or pursuant to any Section of this Agreement, including Sections 2.1, 2.2, 2.3.1, 2.7 and Section 7 hereof, are rights to “intellectual property” (as defined in the Bankruptcy Code). The Parties hereto acknowledge and agree that the payments provided for under Sections 3.1 through 3.4 and all other payments by Pfizer to BioNTech hereunder, other than royalty payments pursuant to Section 3.5, do not constitute royalties within the meaning of Section 365(n) of the Bankruptcy Code or relate to licenses of intellectual property hereunder. If (a) a case under the Bankruptcy Code is commenced by or against BioNTech, (b) this Agreement

is rejected as provided in the Bankruptcy Code and (c) Pfizer elects to retain its rights hereunder as provided in Section 365(n) of the Bankruptcy Code, then BioNTech (in any capacity, including debtor-in-possession) and its successors and assigns (including any trustee) will provide to Pfizer all intellectual property licensed hereunder, and agrees to grant and hereby grants to Pfizer and its Affiliates a right to access and to obtain possession of and to benefit from and, in the case of any chemical or biological material or other tangible item of which there is a fixed or limited quantity, to obtain a pro rata portion of, each of the following to the extent related to any Candidate or Product, or otherwise related to any right or license granted under or pursuant to this Agreement: (i) copies of pre-clinical and clinical research data and results; (ii) all of the following (to the extent that any of the following are so related): BioNTech Materials, cell lines, antibodies, assays, reagents and other biological materials; (iii) samples or Candidates and Products; (iv) BioNTech Technology and RNA Technology, (v) laboratory notes and notebooks; (vi) Candidate and Product data or filings, and (vii) Rights of Reference in respect of regulatory filings and approvals, all of which constitute "embodiments" of intellectual property pursuant to Section 365(n) of the Bankruptcy Code, and (viii) all other embodiments of such intellectual property, whether any of the foregoing are in BioNTech's possession or control or in the possession and control of any Third Party but which BioNTech has the right to access or benefit from and to make available to Pfizer. BioNTech will not interfere with the exercise by Pfizer or its Affiliates of rights and licenses to intellectual property licensed hereunder and embodiments thereof in accordance with this Agreement and agrees to use Commercially Reasonable Efforts to assist Pfizer and its Affiliates to obtain such intellectual property and embodiments thereof in the possession or control of Third Parties as reasonably necessary or useful for Pfizer or its Affiliates or Sublicensees to exercise such rights and licenses in accordance with this Agreement.

10.8.3. No Limitation of Rights. All rights, powers and remedies of Pfizer provided in this Section 10.8 are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at Law or in equity (including the Bankruptcy Code) in the event of the commencement of a case under the Bankruptcy Code involving BioNTech. To the extent equivalent rights exist under the Bankruptcy Code existing from time to time in the jurisdiction where BioNTech is established the foregoing provisions shall be interpreted in accordance with such equivalent rights, and where such equivalent rights do not exist Pfizer shall be entitled to avail of itself all remedies and rights available to it as a creditor and licensee of Intellectual Property Rights under such local Bankruptcy Code.

10.9. Change of Control of BioNTech. If a Change of Control of BioNTech by a Specified Person is consummated prior to the date Pfizer has paid the Development Milestone in row (v) of the table included in Section 3.3 ("Change of Control Term"), then Pfizer shall have the right to terminate the Research Plan (and BioNTech's involvement in performance of the Research Plan) in its entirety, as applicable, immediately upon written notice to BioNTech within [***] days after Pfizer receives notice from BioNTech of consummation of such Change of Control of BioNTech and, at Pfizer's option, it may request (which BioNTech shall deliver) a technology transfer under the Technology Transfer Plan as soon as reasonably practicable. Such termination of the Research Plan and/or BioNTech's involvement in its performance (a) shall not constitute termination of this Agreement, (b) shall not affect the Parties' rights and obligations under this Agreement other than those relating to such Research Plan including Pfizer's diligence obligations and (c) shall not relieve either Party of any obligation that arose prior to such termination. Following termination pursuant to this Section 10.9, Pfizer shall have no further obligations under Section 4.2.

10.10. **Effects of Change of Control.** In the event of a Change of Control of BioNTech by a Specified Person during the Change of Control Term, the following provisions of this Section 10.10 shall apply:

10.10.1. **BioNTech Intellectual Property.** All BioNTech Technology and Research Program Technology, Controlled by BioNTech immediately prior to such BioNTech Change of Control shall continue to be BioNTech Technology and Research Program Technology licensed to Pfizer for purposes of this Agreement.

10.10.2. **Existing Acquirer Intellectual Property.** Patent Rights and Know-How that were Controlled by the entity acquiring BioNTech or such entity's Affiliates that were not Affiliates of BioNTech prior to such BioNTech Change of Control (collectively, the "Acquirer") shall not be included within the licenses granted to Pfizer hereunder.

10.10.3. **Independent Intellectual Property.** Patent Rights and Know-How that, following such BioNTech Change of Control, are developed, made or otherwise acquired or Controlled by the Acquirer outside of the Research Plan and without use of Pfizer's Confidential Information or Research Program Technology, BioNTech Improvements or BioNTech Technology shall not be included within the Research Program Technology or BioNTech Technology or BioNTech Third Party Agreements (it being understood, however, for the avoidance of doubt, that all BioNTech Technology, Research Program Technology, and Intellectual Property Rights developed by BioNTech or the Acquirer in the course of, or used by BioNTech or the Acquirer under the Research Plan or used in the Manufacture of the Candidates or Products by BioNTech shall be licensed to Pfizer pursuant to the licenses set forth in this Agreement).

10.10.4. **Research Program Technology.** No Research Program Technology Controlled by Pfizer or RNA Improvements or Pfizer Improvements shall be licensed or sub-licensable to the Acquirer, and no Confidential Information of Pfizer or its Representatives shall be disclosed to the Acquirer, in each case without the prior written consent of Pfizer.

10.11. **Effect on Certain Agreement Provisions.** From and after the effective date of a BioNTech Change of Control by a Specified Person, the Acquirer shall not be considered an "Affiliate" for the purposes of this Agreement, provided that the Acquirer does not engage in any activities otherwise restricted under Section 10.10 using any Research Program Technology, Pfizer Technology, Pfizer Improvements or Confidential Information of Pfizer.

11. LIMITATION ON LIABILITY, INDEMNIFICATION AND INSURANCE

11.1. **No Consequential Damages.** Except with respect to liability arising from a breach of Sections 7 or 8, from any willful misconduct or intentionally wrongful act, or to the extent such Party may be required to indemnify the other Party under this Section 11, in no event will either Party or its Representatives be liable under this Agreement for any special (only as related to indirect, incidental or consequential damages), indirect, incidental, consequential or punitive damages, whether in contract, warranty, tort, negligence, strict liability or otherwise, including loss of indirect profits or revenue suffered by the other Party or any of its Representatives. Without limiting the generality of the foregoing, "consequential damages" will be deemed to include, and neither Party will be liable to the other Party or any of such other Party's Representatives or stockholders for any damages based on or measured by loss of projected or speculative future sales of the Products, any Development Payment due upon any unachieved Development Event under Section 3.3, any Sales Milestone Payment due upon any unachieved Total Annual Net Sales level under Section 3.4, any unearned royalties under Section 3.5 or any other unearned, speculative or otherwise contingent payments provided for in this Agreement.

11.2. Indemnification by Pfizer. Pfizer will indemnify, defend and hold harmless BioNTech, each of its Affiliates, and each of its and its Affiliates' employees, officers, directors and agents (each, a "BioNTech Indemnified Party") from and against any and all claims, causes, or allegations (whether threatened or pending), judgments, expenses, damages, liabilities, obligations, fees (including the reasonable fees of attorneys and other consulting or testifying professionals), costs and losses (collectively, "Liabilities") that the BioNTech Indemnified Party may be required to pay to one or more Third Parties resulting from or arising out of:

(a) (a) Development, Manufacture, Commercialization or use of any Product by, on behalf of, or under the authority of, Pfizer (other than by any BioNTech Indemnified Party), other than (i) claims by Third Parties relating to patent infringement arising out of the exercise of rights under the BioNTech Patent Rights, (ii) claims by Third Parties relating to misappropriation of trade secrets arising out of the exercise of rights under the BioNTech Know-How or (iii) claims for which BioNTech is required to indemnify Pfizer pursuant to Section 11.3; or

(b) (b) the material breach by Pfizer of any of its representations, warranties or covenants set forth in Section 4.6.1, 9.1 or 9.1.1;

except, in each case, to the extent caused by the negligence, recklessness or intentional acts of BioNTech or any BioNTech Indemnified Party.

11.3. Indemnification by BioNTech. BioNTech will indemnify, defend and hold harmless Pfizer, its Affiliates, Sublicensees, contractors, distributors and each of its and their respective employees, officers, directors and agents (each, a "Pfizer Indemnified Party") from and against any and all Liabilities that the Pfizer Indemnified Party may be required to pay to one or more Third Parties resulting from or arising out of (i) the FIH Study, (ii) use of the BioNTech name or logo pursuant to Section 6.4.2, (iii) rights or obligations under the GEIA relating to inventions made by employees of BioNTech or its Affiliates or Third Party Licensors in relation to BioNTech Technology or Research Program Technology used in any Candidate or Product; or (iv) the material breach by BioNTech or any of its Representatives of any of its representations, warranties or covenants set forth in Section 9.1, Section 9.1.1, Section 9. 2, Section 9.3, Section 9.4 or Section 9.5 except to the extent caused by the negligence, recklessness or intentional acts of Pfizer or any Pfizer Indemnified Party.

11.4. Procedure.

11.4.1. **Notice**. Each Party will notify the other Party in writing in the event it becomes aware of a claim for which indemnification may be sought hereunder. In the event that any Third Party asserts a claim or other proceeding (including any governmental investigation) with respect to any matter for which a Party (the "Indemnified Party") is entitled to indemnification hereunder (a "Third Party Claim"), then the Indemnified Party will promptly notify the Party obligated to indemnify the Indemnified Party (the "Indemnifying Party") thereof; *provided, however*, that no delay on the part of the Indemnified Party in notifying the Indemnifying Party will relieve the Indemnifying Party from any obligation hereunder unless (and then only to the extent that) the Indemnifying Party is prejudiced thereby.

11.4.2. **Control.** Subject to either Party's right to control any actions described in Section 7 (even where the other Party is the Indemnifying Party), the Indemnifying Party will have the right, exercisable by notice to the Indemnified Party within ten Business Days after receipt of notice from the Indemnified Party of the commencement of or assertion of any Third Party Claim, to assume direction and control of the defense, litigation, settlement, appeal or other disposition of the Third Party Claim (including the right to settle the claim solely for monetary consideration) with counsel selected by the Indemnifying Party and reasonably acceptable to the Indemnified Party; provided that (a) the Indemnifying Party has sufficient financial resources, in the reasonable judgment of the Indemnified Party, to satisfy the amount of any adverse monetary judgment that is sought, (b) the Third Party Claim seeks solely monetary damages and (c) the Indemnifying Party expressly agrees in writing that as between the Indemnifying Party and the Indemnified Party, the Indemnifying Party will be solely obligated to satisfy and discharge the Third Party Claim in full (the conditions set forth in clauses (a), (b) and (c) above are collectively referred to as the "Litigation Conditions"). Within ten Business Days after the Indemnifying Party has given notice to the Indemnified Party of its exercise of its right to defend a Third Party Claim, the Indemnified Party will give notice to the Indemnifying Party of any objection thereto based upon the Litigation Conditions. If the Indemnified Party reasonably so objects, the Indemnified Party will continue to defend the Third Party Claim, at the expense of the Indemnifying Party, until such time as such objection is withdrawn. If no such notice is given, or if any such objection is withdrawn, the Indemnifying Party will be entitled, at its sole cost and expense, to assume direction and control of such defense, with counsel selected by the Indemnifying Party and reasonably acceptable to the Indemnified Party. During such time as the Indemnifying Party is controlling the defense of such Third Party Claim, the Indemnified Party will cooperate, and will cause its Affiliates and agents to cooperate upon request of the Indemnifying Party, in the defense or prosecution of the Third Party Claim, including by furnishing such records, information and testimony and attending such conferences, discovery proceedings, hearings, trials or appeals as may reasonably be requested by the Indemnifying Party. In the event that the Indemnifying Party does not satisfy the Litigation Conditions or does not notify the Indemnified Party of the Indemnifying Party's intent to defend any Third Party Claim within ten Business Days after notice thereof, the Indemnified Party may (without further notice to the Indemnifying Party) undertake the defense thereof with counsel of its choice and at the Indemnifying Party's expense (including reasonable, out-of-pocket attorneys' fees and costs and expenses of enforcement or defense). The Indemnifying Party or the Indemnified Party, as the case may be, will have the right to join in (including the right to conduct discovery, interview and examine witnesses and participate in all settlement conferences), but not control, at its own expense, the defense of any Third Party Claim that the other party is defending as provided in this Agreement.

11.4.3. **Settlement.** The Indemnifying Party will not, without the prior written consent of the Indemnified Party, enter into any compromise or settlement that commits the Indemnified Party to take, or to forbear to take, any action. The Indemnified Party will have the sole and exclusive right to settle any Third Party Claim, on such terms and conditions as it deems reasonably appropriate, to the extent such Third Party Claim involves equitable or other non-monetary relief, but will not have the right to settle such Third Party Claim to the extent such Third Party Claim involves monetary damages without the prior written consent of the Indemnifying Party. Each of the Indemnifying Party and the Indemnified Party will not make any admission of liability in respect of any Third Party Claim without the prior written consent of the other party, and the Indemnified Party will use reasonable efforts to mitigate Liabilities arising from such Third Party Claim.

11.5. **Insurance.** Each Party further agrees to obtain and maintain, during the Term, commercial general liability insurance, including products liability insurance (or clinical trials insurance, if applicable), with minimum "A-" A.M. Best rated insurance carriers to cover its indemnification obligations under Section 11.2 or Section 11.3, as applicable, in each case with limits of not less than \$5,000,000 (Five Million U.S. Dollars) per occurrence and in the aggregate. All deductibles and retentions will be the responsibility of the named insured. Within [***] days of the Effective Date, BioNTech will amend its existing insurance policies in such a way that (i) Pfizer Inc. and its Affiliates will be indemnified as principal on BioNTech's commercial general liability and products liability policies (or clinical trials insurance, if applicable) and (ii) Pfizer Inc. and its Affiliates will be provided a waiver of subrogation on BioNTech's commercial general liability and products liability policies (or clinical trials insurance, if applicable). For U.S. exposures, additional insured status on BioNTech's commercial general liability and products liability policies shall be via form CG20101185 or its equivalent. Products liability coverage shall be maintained for three years following termination of this Agreement. To the extent of its culpability or negligence, all coverages of BioNTech will be primary and non-contributing with any similar insurance, carried by Pfizer. Notwithstanding any provision of this Section 11.5 to the contrary, Pfizer may meet its obligations under this Section 11.5 through self-insurance. Neither Party's insurance will be construed to create a limit of liability with respect to its indemnification obligations under this Section 11.

12. **MISCELLANEOUS**

12.1. **BioNTech AG.** BioNTech AG and BioNTech RNA shall each be jointly and severally liable to Pfizer with respect to this Agreement and their obligations hereunder.

12.2. **Assignment.** Neither this Agreement nor any interest hereunder will be assignable by a Party without the prior written consent of the other Party, except as follows: (a) subject to the provisions of this Agreement in respect of Change of Control, as applicable, a Party may assign its rights and obligations under this Agreement by way of sale of itself or the sale of the portion of its business to which this Agreement relates, through merger, sale of assets and/or sale of stock or ownership interest, *provided that* the assignee will expressly agree to be bound by such Party's obligations under this Agreement and that such sale is not primarily for the benefit of its creditors, (b) such Party may assign its rights and obligations under this Agreement to any of its Affiliates, *provided that* the assignee will expressly agree to be bound by such Party's obligations under this Agreement and that such Party will remain liable for all of its rights and obligations under this Agreement. In addition, Pfizer may assign its rights and obligations under this Agreement to a Third Party where Pfizer or its Affiliate is required, or makes a good faith determination based on advice of counsel, to divest a Product in order to comply with Law or the order of any Governmental Authority as a result of a merger or acquisition, *provided that* the assignee will expressly agree to be bound by Pfizer's obligations under this Agreement. Each Party will promptly notify the other Party of any assignment or transfer under the provisions of this Section 12.2. This Agreement will be binding upon the successors and permitted assigns of the Parties and the name of a Party appearing herein will be deemed to include the names of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Agreement. Any assignment not in accordance with this Section 12.2 will be void.

12.3. Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of the Agreement.

12.4. Force Majeure. Each Party will be excused from the performance of its obligations under this Agreement to the extent that such performance is prevented by force majeure (defined below) and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse will be continued so long as the condition constituting force majeure continues and the nonperforming Party takes Commercially Reasonable Efforts to remove the condition. For purposes of this Agreement, “force majeure” will include conditions beyond the control of the Parties, including an act of God, voluntary or involuntary compliance with any regulation, Law or order of any government, war, act of terror, civil commotion, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe.

12.5. Interpretation. Except where the context expressly requires otherwise, (a) the use of any gender herein will be deemed to encompass references to either or both genders, and the use of the singular will be deemed to include the plural (and vice versa), (b) the words “include”, “includes” and “including” will be deemed to be followed by the phrase “without limitation”, (c) the word “will” will be construed to have the same meaning and effect as the word “shall”, (d) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any Person will be construed to include the Person’s successors and assigns, (f) the words “herein”, “hereof” and “hereunder”, and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Sections, Exhibits or Schedules will be construed to refer to Sections, Exhibits or Schedules of this Agreement, and references to this Agreement include all Exhibits and Schedules hereto, (h) the word “notice” means notice in writing (whether or not specifically stated) and will include notices, consents, approvals and other written communications contemplated under this Agreement, (i) provisions that require that a Party, the Parties or any committee hereunder “agree,” “consent” or “approve” or the like will require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (excluding e-mail or instant messaging, but a signed PDF document being acceptable), (j) references to any specific law, rule or regulation, or article, section or other division thereof, will be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, and (k) the term “or” will be interpreted in the inclusive sense commonly associated with the term “and/or”.

12.6. Notices. Any notice or notification required or permitted to be provided pursuant to the terms and conditions of this Agreement (including any notice of force majeure, breach, termination, change of address, etc.) will be in writing and will be deemed given upon receipt if delivered personally or by facsimile transmission (receipt verified), and upon delivery if mailed by registered or certified mail or courier. Where delivery occurs outside normal working hours, notice will be deemed given at the start of normal working hours on the next Business Day. Notice shall be given to the Parties at the following addresses or facsimile numbers (or at such other address or facsimile number for a Party as will be specified by like notice, *provided, however*, that notices of a change of address will be effective only upon receipt thereof):

All correspondence to Pfizer will be addressed as follows:

Pfizer Inc.
Notices: R&D Business Development
235 East 42nd Street
New York, NY 10017
Attention: Attn.: R&DBD Contract Notice
Fax: +1-646-563-9619

with a copy to:

Pfizer Inc.
Notices: Pfizer Legal Division
235 East 42nd Street
New York, NY 10017
Attn.: Chief Counsel, R&D
Fax: +1-646-563-9619

To help expedite Pfizer's awareness and response, copies of notices may be provided to Pfizer by email but must be supplemented by one of the following methods: (a) personal delivery, (b) first class certified mail with return receipt requested, or (c) next-day delivery by major international courier, with confirmation of delivery. Electronic copies may be sent via email to [***].

All correspondence to BioNTech will be addressed as follows:

BioNTech AG
An der Goldgrube 12
D-55131
Mainz, Germany
Attn: Vice President, Legal and Intellectual Property
Fax: +49-6131-576-270-28

12.7. Amendment. No amendment, modification or supplement of any provision of this Agreement will be valid or effective unless made in writing and signed by a duly authorized officer of each Party.

12.8. Waiver. No provision of this Agreement will be waived by any act, omission or knowledge of a Party or its agents or employees except by an instrument in writing expressly waiving such provision and signed by a duly authorized officer of the waiving Party. The waiver by either of the Parties of any breach of any provision hereof by the other Party will not be construed to be a waiver of any succeeding breach of such provision or a waiver of the provision itself.

12.9. Severability. If any clause or portion thereof in this Agreement is for any reason held to be invalid, illegal or unenforceable, the same will not affect any other portion of this Agreement, as it is the intent of the Parties that this Agreement will be construed in such fashion as to maintain its existence, validity and enforceability to the greatest extent possible. In any such event, this Agreement will be construed as if such clause or portion thereof had never been contained in this Agreement, and there will be deemed substituted therefor such provision as will most nearly carry out the intent of the Parties as expressed in this Agreement to the fullest extent permitted by applicable Law.

12.10. Descriptive Headings. The descriptive headings of this Agreement are for convenience only and will be of no force or effect in construing or interpreting any of the provisions of this Agreement.

12.11. Global Trade Control Laws. The Parties acknowledge that certain activities covered by or performed under this Agreement may be subject to laws, regulations or orders regarding economic sanctions, import controls or export controls ("Global Trade Control Laws"). Each of the Parties will perform all activities under this Agreement in compliance with all applicable Global Trade Control Laws. Furthermore, with respect to the activities performed under this Agreement, each of the Parties represents, warrants and covenants that:

12.11.1. Each Party will not, for activities under this Agreement, (i) engage in any such activities in a Restricted Market; (ii) involve individuals ordinarily resident in a Restricted Market; or (iii) include companies, organizations, or Governmental Authorities from or located in a Restricted Market. "Restricted Market" for purposes of this Agreement means the Crimean Peninsula, Cuba, the Donbass Region, Iran, North Korea, Sudan, and Syria, or any other country or region sanctioned by the United States or European Union.

12.11.2. Each Party represents and warrants that it is not a Restricted Party and is not owned or controlled by a Restricted Party. With respect to activities performed under this Agreement, neither Party will engage or delegate to any Restricted Parties for any activities under this Agreement. Each Party will screen all relevant Third Parties involved by such Party in the activities under this Agreement under the relevant Restricted Party Lists. "Restricted Parties" for purposes of this Agreement means any individual or entity on any of the following "Restricted Party Lists": the list of sanctioned entities maintained by the United Nations; the Specially Designated Nationals List and the Sectoral Sanctions Identifications List of the U.S. Treasury Department's Office of Foreign Assets Control; the U.S. Denied Persons List, the U.S. Entity List, and the U.S. Unverified List of the U.S. Department of Commerce; entities subject to restrictive measures and the Consolidated List of Persons, Groups and Entities Subject to E.U. Financial Sanctions, as implemented by the E.U. Common Foreign & Security Policy; the List of Excluded Individuals / Entities published by the U.S. Health and Human Services' Office of Inspector General; any lists of prohibited or debarred parties established under the U.S. Federal Food Drug and Cosmetic Act; the list of parties suspended or debarred from contracting with the U.S. government; and similar lists of restricted parties maintained by the Governmental Authorities of the countries that have jurisdiction over the activities conducted under this Agreement.

12.11.3. Neither Party will knowingly transfer to the other Party any goods, software, technology or services that are (i) controlled under the U.S. International Traffic in Arms Regulations or at a level other than EAR99 under the U.S. Export Administration Regulations; or (ii) specifically identified as an E.U. Dual Use Item or on an applicable export control list of another country.

12.12. Dispute Resolution. If any dispute or disagreement arises between Pfizer and BioNTech in respect of this Agreement, they will follow the following procedures in an attempt to resolve the dispute or disagreement:

12.12.1. The Party claiming that such a dispute exists will give notice in writing ("Notice of Dispute") to the other Party of the nature of the dispute.

12.12.2. Within 30 days of receipt of a Notice of Dispute and in advance of any meeting pursuant to Section 12.12.3, the receiving Party will provide a written response to the other Party's claims regarding the dispute.

12.12.3. Within 45 days of receipt of a Notice of Dispute, the Chief Scientific Officer, Vaccine Research and Development of Pfizer and the Chief Scientific Officer of BioNTech AG will meet at a mutually agreed-upon time and location for the purpose of resolving such dispute to discuss the dispute or disagreement.

Notwithstanding any provision of this Agreement to the contrary, either Party may immediately initiate litigation in any court of competent jurisdiction seeking any remedy at law or in equity, including the issuance of a preliminary, temporary or permanent injunction, to preserve or enforce its rights under this Agreement. The provisions of this Section 12.12 will survive for five years from the date of termination or expiration of this Agreement.

12.13. Governing Law. This Agreement is governed by, and all disputes arising under or in connection with this Agreement shall be resolved in accordance with, laws of England and Wales, without regard to conflict of law principles thereof.

12.14. Consent to Jurisdiction and Venue. The Parties irrevocably submit to the exclusive jurisdiction of the courts of England and Wales as regards any claim, dispute or matter (whether contractual or non-contractual) arising out of or in connection with this Agreement (including its formation). Notwithstanding the foregoing, this clause shall not prevent either Party from being entitled to seek urgent interim or emergency relief (such as a preliminary injunction) before any other court of competent jurisdiction in respect of any claim, dispute or matter (whether contractual or non-contractual) arising out of or in connection with this Agreement (including its formation).

12.15. Entire Agreement. This Agreement constitutes and contains the complete, final and exclusive understanding and agreement of the Parties and cancels and supersedes any and all prior negotiations, correspondence, understandings and agreements, whether oral or written, between the Parties respecting the subject matter hereof and thereof, including that certain Confidential-Disclosure Agreement between the Parties dated [***] which is hereby terminated effective as of the Execution Date, *provided that* such Confidential Disclosure Agreement will continue to govern the treatment of Confidential Information disclosed by the Parties prior to the Execution Date in accordance with its terms.

12.16. Independent Contractors. Both Parties are independent contractors under this Agreement. Nothing herein contained will be deemed to create an employment, agency, joint venture or partnership relationship between the Parties hereto or any of their agents or employees, or any other legal arrangement that would impose liability upon one Party for the act or failure to act of the other Party. Neither Party will have any express or implied power to enter into any contracts or commitments or to incur any liabilities in the name of, or on behalf of, the other Party, or to bind the other Party in any respect whatsoever.

12.17. Counterparts. This Agreement may be executed in two (2) counterparts, each of which will be an original and both of which will constitute together the same document. Counterparts may be signed and delivered by facsimile or digital (e.g., PDF) file, each of which will be binding when received by the applicable Party.

12.18. No Third Party Rights or Obligations. No provision of this Agreement will be deemed or construed in any way to result in the creation of any rights or obligation in any Person not a Party to this Agreement, and this Agreement does not give rise to any rights under the Contracts (Rights of Third Parties) Act 1999 to enforce any term of this Agreement. However, Pfizer may decide, in its sole discretion, to use one or more of its Affiliates to perform its obligations and duties hereunder, *provided that* Pfizer will remain liable hereunder for the performance by any such Affiliates of any such obligations.

(Signature page follows.)

IN WITNESS WHEREOF, authorized representatives of the Parties have duly executed this Agreement as of the Execution Date to be effective as of the Effective Date.

PFIZER INC.

By: [***]

Name: [***]

Title: [***]

**BIONTECH RNA
PHARMAECEUTICALS GmbH**

By: [***]

Name: [***]

Title: [***]

BIONTECH AG

By: [***]

Name: [***]

Title: [***]

Exhibit A
Research Plan

Title: BioNTech-Pfizer RNA Flu Vaccine Research Plan

BioNTech Lead: [***]

Pfizer Lead: [***]

Brief Rational/Background:

[***]

Objectives, Milestones and Time Frame for Completion:

Work Plan:

Detailed descriptions of experiments to be produced jointly by BioNTech and Pfizer during the kick-off meeting after deal closure and in ongoing consultations, with review of experimental designs by the JSC.

Materials: The materials to be transferred are detailed below.

[***]

Equipment and Facilities:

[***]

[*]:**

[***]

Human Tissue Samples:

[***]

Subcontractors:

[***]

Work Plan Timeline:

[***]

Exhibit B

PFIZER ANTI-BRIBERY AND ANTI-CORRUPTION PRINCIPLES

Pfizer has a longstanding corporate policy that prohibits colleagues or anyone acting on our behalf from providing any payment or benefit to any person or entity in order to improperly influence a government official or to gain an unfair business advantage. Pfizer is committed to performing with integrity, and acting ethically and legally in accordance with all applicable laws and regulations, including, but not limited to, anti-bribery and anti-corruption laws. We expect the same commitment from the consultants, agents, representatives or other companies and individuals acting on our behalf (“Business Associates”), as well as those acting on behalf of Business Associates, in connection with work for Pfizer.

Bribery of Government Officials

Most countries have laws that forbid making, offering or promising any payment or anything of value (directly or indirectly) to a government official when the payment is intended to influence an official act or decision to award or retain business. Under Pfizer’s policies, “government official” is broadly interpreted and includes: (i) any elected or appointed government official (e.g., a member of a ministry of health); (ii) any employee or person acting for or on behalf of a government official, agency, or enterprise performing a governmental function; (iii) any political party, candidate for public office, officer, employee, or person acting for or on behalf of a political party or candidate for public office; or (iv) an employee or person acting for or on behalf of a public international organization (e.g., the United Nations). “Government” is meant to include all levels and subdivisions of governments (i.e., local, regional, or national and administrative, legislative, or executive). Because this definition of “government official” is so broad, it is likely that Business Associates will interact with a government official in the ordinary course of their business on behalf of Pfizer. For example, doctors employed by government-owned hospitals would be considered “government officials” under Pfizer’s policies.

The U.S. Foreign Corrupt Practices Act of 1977 (the “FCPA”) prohibits making, promising, or authorizing the making of a payment or providing anything of value to a non-U.S. government official to improperly or corruptly induce that official to make any governmental act or decision to assist a company in obtaining or retaining business, or to otherwise obtain an improper advantage. The FCPA also prohibits a company or person from using another company or individual to engage in any of the foregoing activities. As a U.S. company, Pfizer must comply with the FCPA and could be held liable as a result of acts committed anywhere in the world by a Business Associate.

Anti-Bribery and Anti-Corruption Principles Governing Interactions with Governments and Government Officials

Business Associates must communicate and abide by the following principles with regard to their interactions with governments and government officials:

- Business Associates, and those acting on their behalf in connection with work for Pfizer, may not directly or indirectly make, promise, or authorize the making of a corrupt payment or provide anything of value to any government official to induce that government official to make any governmental act or decision to help Pfizer obtain or retain business. Business Associates, and those acting on their behalf in connection with work for Pfizer, may never make a payment to or offer a government official any item or benefit, regardless of value, as an improper inducement for such government official to approve, reimburse, prescribe, or purchase a Pfizer product, to influence the outcome of a clinical trial, or otherwise improperly to benefit Pfizer’s business activities.
- Business Associates, and those acting on their behalf in connection with work for Pfizer, need to understand whether local laws, regulations, or operating procedures (including requirements imposed by government entities such as government-owned hospitals or research institutions) impose any limits, restrictions, or disclosure requirements on compensation, financial support, donations, or gifts that may be provided to government officials. Business Associates, and those acting on their behalf in connection with work for Pfizer, must take into account and comply with any applicable restrictions in conducting their Pfizer-related activities. If a Business Associate is uncertain as to the meaning or applicability of any identified limits, restrictions, or disclosure requirements with respect to interactions with government officials, that Business Associate should consult with his or her primary Pfizer contact before undertaking their activities.

- Business Associates, and those acting on their behalf in connection with work for Pfizer, are not permitted to offer facilitation payments. A “facilitation payment” is a nominal, unofficial payment to a government official for the purpose of securing or expediting the performance of a routine, non-discretionary governmental action. Examples of facilitation payments include payments to expedite the processing of licenses, permits or visas for which all paperwork is in order. In the event that a Business Associate, or someone acting on their behalf in connection with work for Pfizer, receives or becomes aware of a request or demand for a facilitation payment or bribe in connection with work for Pfizer, the Business Associate shall report such request or demand promptly to his or her primary Pfizer contact before taking any further action.

Commercial Bribery

Bribery and corruption can also occur in non-government, business to business relationships. Most countries have laws which prohibit offering, promising, giving, requesting, receiving, accepting, or agreeing to accept money or anything of value in exchange for an improper business advantage. Examples of prohibited conduct could include, but are not limited to, the provision of inappropriate gifts or hospitality, kickbacks, or investment opportunities offered to improperly induce the purchase of goods or services. Pfizer colleagues are not permitted to offer, give, solicit or accept bribes, and we expect our Business Associates, and those acting on their behalf in connection with work for Pfizer, to abide by the same principles.

Anti-Bribery and Anti-Corruption Principles Governing Interactions with Private Parties and Pfizer Colleagues

Business Associates must communicate and abide by the following principles with regard to their interactions with private parties and Pfizer colleagues:

- Business Associates, and those acting on their behalf in connection with work for Pfizer, may not directly or indirectly make, promise, or authorize the making of a corrupt payment or provide anything of value to any person to induce that person to provide an unlawful business advantage for Pfizer.
- Business Associates, and those acting on their behalf in connection with work for Pfizer, may not directly or indirectly, solicit, agree to accept, or receive a payment or anything of value as an improper inducement in connection with their business activities performed for Pfizer.
- Pfizer colleagues are not permitted to receive gifts, services, perks, entertainment, or other items of more than token or nominal monetary value from Business Associates, and those acting on their behalf in connection with work for Pfizer. Moreover, gifts of nominal value are only permitted if they are received on an infrequent basis and only at appropriate occasions.

Reporting Suspected or Actual Violations

Business Associates, and those acting on behalf in connection with work for Pfizer, are expected to raise concerns related to potential violations of these International Anti-Bribery and Anti-Corruption Principles or the law. Such reports can be made to a Business Associate’s primary point of contact at Pfizer, or if an Associate prefers, to Pfizer’s Compliance Group, by e-mail at corporate.compliance@pfizer.com or by phone at 1-212-733-3026.

Pfizer's Corporate Policy regarding Animal Care and Use (v. 1.2, June 18, 2017)

BACKGROUND

Pfizer is dedicated to helping people and animals live longer, healthier lives through the discovery and development of breakthrough medicines and therapies. Animal-based biomedical research in the pharmaceutical industry remains a vital component of the discovery, evaluation and regulatory processes, which lead to the development of products that save or improve human lives throughout the world. Pfizer's Animal Care and Use policy reflects our absolute commitment that all animals used by our business are treated humanely. This means that any research involving animals is conducted only after appropriate ethical consideration and review. This review ensures that we provide a high level of care to all animals used, and that a scientifically appropriate and validated alternative to the use of animals is not available.

Why We Conduct Animal-based Biomedical Research

Pfizer is ethically and legally obliged to rigorously evaluate potential new medicines and therapies. Many of these evaluations can be, and are, accomplished by techniques that do not require the use of animals. However, given the present state of scientific knowledge, testing potential new medicines and therapies in animals is frequently critical to their evaluation, and is required by regulatory authorities worldwide to ensure the quality, efficacy and safety of the medicines we discover.

Pfizer's Commitment to Ethical and Humane Treatment of Animals

Pfizer accepts its responsibility to use animals in a humane and ethical manner and expects all Colleagues to treat animals with respect. We approach the use of animals in our business with a high level of humane and ethical concern for those animals. All use is carefully planned and conducted in such a way as to minimize or avoid pain, distress, or discomfort to the animals. Every proposed use is thoroughly evaluated before being undertaken as the health and well-being of all animals under our care is a primary concern. Similarly, we expect any Third Party organization we engage to conduct animal-based research on our behalf to adhere to this Policy and to comply with all applicable laws and regulations.

Pfizer's Commitment to Alternatives to Animal-based Biomedical Research

Pfizer is fully committed to the development and use of scientifically validated alternative testing methods that are acceptable to regulatory authorities and do not compromise patient safety or the effectiveness of our medicines. Pfizer continues to engage and lead cross-industry efforts aimed at developing and refining new in-vitro testing and predictive informatics-based systems that hold promise for future reduction of animal usage. Pfizer works directly with regulators and through pharmaceutical trade organizations to increase the recognition and acceptance of alternative models where such alternatives can be used appropriately.

POLICY

For as long as it remains necessary to use animals in the discovery, development, evaluation and production of new medicines, we commit to maintaining high standards in the humane treatment of these animals. Significantly, we embrace the principles known as the "3Rs" of animal research first proposed in 1959 by Russell and Burch to describe the use of alternatives in animal research. These are:

Replacement of animal experiments with non-animal experiments such as mathematical models, computer simulations, and in-vitro biological systems wherever appropriate; and where animals must be used;

Reduction of the numbers of animals used in each study, and of the number of studies involving animals, to the absolute minimum necessary to obtain valid results and achieve our research objectives; and

Refinement of procedures involving animals to minimize the potential for pain and distress.

In addition to the 3R's, and to further assure we maintain high standards for our animals, we have adopted the following guidelines:

- When animal experimentation is necessary, great care is taken to choose the most appropriate animal species for the research and to optimize the study design to ensure that the results will be as meaningful as possible.
- Non-human primates will only be used when scientifically justified, for example in cases where other species will not provide sufficiently close analogues to the biological pathways and responses expected in humans.
- All studies are carefully designed to gain the maximum information from the fewest number of animals possible.
- Each proposed use of animals is reviewed and approved by a panel of objective experts prior to performing any experiments to ensure that the use of the animals is consistent with sound scientific practices and ethical considerations.
- Our standards of animal care and welfare meet or exceed those required by applicable local, national, or international laws and regulations.
- We regularly monitor our animals for signs of ill health or distress and take prompt action wherever appropriate. We make veterinary care available to our animals at all times.
- Our veterinarians and scientists evaluate every proposed animal procedure with an emphasis on eliminating or minimizing any potential for pain or distress which may be experienced by the animals.
- We train all Colleagues involved in the care, welfare and use of animals to ensure (a) that they are competent in the care of the animals and in the procedures required to complete the proposed work; (b) that they are aware of the ethical issues involved in the use of animals; and (c) that they demonstrate respect and humane treatment towards the animals in their care.
- We expect our contract research organizations, collaborators and vendors to maintain similar high standards. Parties conducting animal based research for Pfizer at their facilities are required to adhere to this Policy and to comply with all applicable laws and regulations. We perform welfare audits of Third Party facilities in accordance with our quality assurance policies.
- Because respect is a key tenant in our use of animals, we have also established standards regarding the use of animals in the marketing of Pfizer products. If advertisements featuring animals are used, any animal shown should be healthy and in a natural or appropriate setting. Non-human primates should not be used in the advertising of Pfizer products, and other wild animals will also not be used unless they are shown in their natural setting or portrayed through animation or computer-generated graphics.

This Policy represents Pfizer's commitment to high-quality animal care and welfare throughout our business, and to the replacement, reduction and refinement of the use of animals in research. We are equally committed to bringing important and safe new medicines to patients.

Exhibit D

Manufacturing Technology Transfer Plan

[***]

Schedule 1.15

Pfizer's CAN Criteria in Effect as of the Effective Date

[***]

Schedule 1.111
Specified Persons

Schedule 3.5.1

Marginal Royalty Rate Calculation Example

Schedule 4.2.2
Approved Subcontractors

Supply Agreement Terms

DEFINITIONS

[***]

MANUFACTURE OF CLINICAL TRIAL MATERIAL

[***]

FINANCIAL TERMS

[***]

Exceptions to BioNTech's Representations and Warranties

Schedule 9.3.3

Candidates Existing as of the Execution Date

[***]

BioNTech Patent Rights Existing as of the Execution Date

Schedule 9.3.12

Current Licenses

[***]

Schedule 9.6.3

Certain Terms of Current Licenses

Schedule 9.9

BioNTech's Knowledge

[***]

Effects of Reversion Rights in case of Termination for Cause by BioNTech or Termination for Convenience by Pfizer

In the event BioNTech notifies Pfizer pursuant to Section 10.7.1(a)(ii) that it desires a license to the Continuation Product, the following terms and conditions shall apply:

1. Within the time periods set forth in Section 10.7.1(a)(ii), if requested by BioNTech, the Parties will, subject to the terms of the license described in Section 10.7.1(a)(ii)(C), mutually agree upon a transition plan to effect an orderly and timely transition to BioNTech of all Development, Manufacture and Commercialization activities and responsibilities with respect to Continuation Products (a "Transition Plan"). Any and all support provided by Pfizer with respect to the Transition Plan shall be at the BioNTech's cost and expense.
2. To the extent permitted by Law and requested by BioNTech, assignment and transfer by Pfizer to BioNTech of all Regulatory Materials Controlled by Pfizer solely relating to the Continuation Products in the Territory, and not relating to any other product. If Pfizer is restricted from assigning or transferring ownership of any of the foregoing items to BioNTech, and in respect of Regulatory Materials Controlled by Pfizer and necessary or useful for the Development, Manufacturing or Commercialization of the Continuation Products in the Territory, Pfizer shall use its Commercially Reasonable Efforts to grant BioNTech (or its designee) a right of reference or use to such item and Pfizer shall take reasonable actions that are reasonably necessary to effect such assignment and transfer or grant of right of reference or use to BioNTech (or its designee), at BioNTech's sole expense, including by making such filings as may be reasonably required with Regulatory Authorities in the Territory that may be necessary to record such assignment or effect such transfer and, at BioNTech's written request complete any pending regulatory filings with respect to all Continuation Products. For purposes of this Schedule 10.7.1(a), "Regulatory Materials" means all regulatory registrations, applications, authorizations and approvals (including approvals of BLAs, supplements and amendments, pre- and post-approvals, pricing and Third Party reimbursement approvals, and labeling approvals), Regulatory Approvals or other submissions made to or with any Regulatory Authority necessary for the Development (including the conduct of clinical studies), Manufacture or Commercialization of a Continuation Product in a regulatory jurisdiction, together with all related correspondence to or from any Regulatory Authority and all documents referenced in the complete regulatory chronology for each BLA, including all INDs, clinical trial applications and foreign equivalents of any of the foregoing.
3. Upon BioNTech's written request, assignment and transfer by Pfizer to BioNTech of its entire right, title, and interest in and to all pharmacological, toxicological and clinical test data and results, research data, reports and batch records, safety data and all other data Controlled by Pfizer and reasonably in its possession as of the effective date of termination and generated in the Development, Manufacture or Commercialization of Continuation Products, at BioNTech's sole expense, subject to a retained non-exclusive right by Pfizer to use such data for research purposes and to continue prosecution of any Patent Rights Controlled by Pfizer and its Affiliates in the course of conducting its activities under this Agreement.
4. Any supply agreement entered into by the Parties pursuant to the Agreement shall terminate. If Pfizer has, at such time of termination, established its own supply and is capable of supplying the Continuation Product without breaching applicable Law and to the extent not prevented by technical or force majeure

(as defined in Section 12.4 of the Agreement) conditions, and if BioNTech so requests, the Parties shall negotiate in good faith as soon as reasonably possible (with a target date of [***] days from the termination effective date) a supply agreement under which Pfizer would supply BioNTech with transitional supply of such Continuation Product at [***] and on commercially reasonable terms for a commercially reasonable period of time of up to [***] months. During the negotiation period, Pfizer will provide a continued supply of the Continuation Product to BioNTech for BioNTech's demand of Continuation Product for BioNTech's or its Affiliates Development or Commercialization of the Product at [***] (provided that such demand does not exceed Pfizer's anticipated forecasts (prior to termination of this Agreement). The transfer of the applicable Manufacturing process from Pfizer to BioNTech or its designee will be part of the transition planning pursuant to Section 1 above.

5. BioNTech shall have the first right to file, prosecute, maintain, defend and enforce any Product Patent Rights included in the Reversion Technology; provided, however, that if Pfizer requests, Pfizer shall be granted the right to review and comment on such Product Patent Rights.

6. Pfizer shall receive the following percentage of the royalties set forth in the table in Section 3.5.1 of the Agreement in respect of Continuation Product Net Sales during the Continuation Product Royalty Term:

[***]

(A) "Continuation Product Net Sales" shall be on the same basis as if BioNTech was Pfizer in the definition of Net Sales.

(B) "Continuation Product Royalty Term" shall be on the same basis as if BioNTech was Pfizer in the definition of Royalty Term (or defined terms used in that definition).

7. Pfizer shall have the same reporting, audit and other rights with respect to the royalties to be paid by BioNTech to Pfizer under this Schedule 10.7.1(a) as are afforded by Pfizer to BioNTech under the Agreement.

8. Section 3.5.3 of the Agreement would apply *mutatis mutandis* to BioNTech with respect to the Continuation Product, provided, however that:

(A) BioNTech shall maintain its books and records in accordance with IFRS, as consistently applied by BioNTech with respect to sales of the Product, rather than GAAP;

(B) Pfizer shall not be obliged to share or be responsible for any payments to any Third Party in respect of the Candidates or Products under any royalty stacking provisions or Third Party Patents, and BioNTech shall be responsible for all Third Party payment obligations and responsibilities concerning Third Party Patents; and

-
- (C) BioNTech shall be responsible for and indemnify Pfizer for any breach or liability arising under any agreement between Pfizer and a Third Party concerning Patent Rights licensed in by Pfizer in connection with any Candidate or Product.

THE SYMBOL “[*]” DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED**

COLLABORATION & LICENSE AGREEMENT

DATED AS OF OCTOBER 9th, 2018

BY AND BETWEEN

THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA

AND

BIONTECH RNA PHARMACEUTICALS GMBH

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COLLABORATION & LICENSE AGREEMENT

This Collaboration & License Agreement (this “**Agreement**”) is dated as of October 9th 2018 (the “**Effective Date**”) by and between The Trustees of the University of Pennsylvania, a Pennsylvania nonprofit corporation (“**Penn**”), and BioNTech RNA Pharmaceuticals GmbH, a German corporation having its principal office at An der Goldgrube 12, 55131 Mainz, Germany (“**Licensee**”). Penn and Licensee may be referred to herein as a “**Party**” or, collectively, as “**Parties**”.

RECITALS:

WHEREAS, Licensee is a biopharmaceutical company with expertise in the development, manufacture and commercialization of mRNA vaccines, including RNA synthesis, formulation and GMP manufacturing;

WHEREAS, Penn, through Dr. Drew Weissman and the Weissman Laboratory, have technology and expertise in RNA synthesis and purification, immunogen discovery and development, and the use of mRNA as prophylactic vaccines against infectious diseases; and

WHEREAS, the Research Program contemplated by this Agreement is of mutual interest to Licensee and Penn and furthers the educational, scholarship and research objectives of Penn as a nonprofit, tax-exempt, educational institution, and may benefit Licensee and Penn through the creation or discovery of new inventions and the development and commercialization of Products (as defined below).

NOW, THEREFORE, in consideration of the various promises and undertakings set forth herein, the Parties agree as follows:

ARTICLE 1 DEFINITIONS

Unless otherwise specifically provided herein, the following terms shall have the following meanings:

- 1.1 “**Acceptance Criteria**” means the target criteria set forth in the Research Plan with respect to the development of any Product; provided that on an Indication-by-Indication basis these criteria shall be deemed to have been achieved no later than upon completion of an IND-ready data package for such Product for such Indication.
- 1.2 “**Accounting Standards**” means the United States generally accepted accounting principles applied on a consistent basis (GAAP) or the International Financial Reporting Standards (IFRS).
- 1.3 “**Affiliate**” means a Person that controls, is controlled by or is under common control with a Party, but only for so long as such control exists. For the purposes of this Section 1.2, the word “control” (including, with correlative meaning, the terms “controlled by” or “under the common control with”) means the actual power, either directly or indirectly through one or more intermediaries, to direct the management and policies of such Person or entity, whether by the ownership of more than fifty percent (50%) of the voting securities of such entity, or by contract or otherwise.
- 1.4 “**Arbitration Rules**” has the meaning as set forth in Section 11.10(b).
- 1.5 “**BioNTech Background IP**” means the BioNTech Background Patents and the BioNTech Background Know-How.

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- 1.6 “**BioNTech Background Know-How**” means Know-How that (i) is Controlled by Licensee and/or its Affiliates as of the Effective Date or thereafter during the Research Term and (ii) is necessary or reasonably useful for the research, development, manufacturing, use or exploitation of any Product.
- 1.7 “**BioNTech Background Patents**” means the Patent Rights that are listed on Exhibit A, and any Patent Rights issuing therefrom.
- 1.8 “**BioNTech Foreground IP**” means the BioNTech Foreground Patents and the BioNTech Foreground Know-How.
- 1.9 “**BioNTech Foreground Patents**” means any Patent Rights solely conceived or conceived and reduced to practice by Licensee or its subcontractors under the Research Program.
- 1.10 “**BioNTech Foreground Know-How**” means Know-How solely developed by Licensee or its subcontractors under the Research Program.
- 1.11 “**BioNTech Materials**” means any biological or chemical materials Controlled by Licensee and provided to Penn under this Agreement.
- 1.12 “**BioNTech Patent Family**” means Patent Rights that (i) are related to each other through priority claims, (ii) claim or cover one or more Licensed Product or the manufacturing or use thereof, (iii) are Controlled by Licensee and (iv) excludes Penn Patent Rights.
- 1.13 “**BLA**” means an application submitted to a Regulatory Authority for marketing approval of a product, including (a) a Biologics License Application or New Drug Application submitted to the FDA, (b) a Marketing Authorization Application (“**MAA**”) in the European Union, (c) any equivalent or comparable application, registration or certification in any other country or region, or (d) any successor applications or procedures, supplements or amendments that may be submitted with respect to the foregoing.
- 1.14 “**Calendar Quarter**” mean the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31 of each Calendar Year.
- 1.15 “**Calendar Year**” means each successive period of twelve (12) months commencing on January 1 and ending on December 31.
- 1.16 “**cGLP**” means the current good laboratory practice regulations promulgated by the FDA, published at 21 C.F.R. § 58, and all applicable FDA rules, regulations, orders and guidances and equivalent or comparable non-United States regulations, rules, orders, guidances and standards in the Territory, as applicable, as such current laboratory practices, rules, regulations, orders, guidances and standards may be amended from time to time.
- 1.17 “**cGMP**” means those current good manufacturing practices promulgated by the FDA, published at 21 C.F.R §§ 210 and 211, and all applicable FDA rules, regulations, orders and guidances, and the requirements with respect to current good manufacturing practices prescribed by the European Community under provisions of “The Rules Governing Medicinal Products in the European Community, Volume 4, Good Manufacturing Practices, Annex 13, Manufacture of Investigational Medicinal Products, July 2003”, as such practices, rules, orders, guidances, guidelines, regulations and standards may be amended from time to time.
- 1.18 “**Clinical Trial**” means a human clinical trial conducted on human subjects that is designed to (a) evaluate whether a pharmaceutical product is reasonably safe for continued testing, (b) investigate the safety and efficacy of the pharmaceutical product for its intended use, and to define warnings, precautions and adverse reactions that may be associated with the pharmaceutical product in the dosage range to be prescribed or (c) support Regulatory Approval of such pharmaceutical product or label expansion of such pharmaceutical product.

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- 1.19 “**Combination Product**” means any Product containing a) at least one Licensed Product and b) at least one additional therapeutically active ingredient that is not a Product; in each case where the foregoing is co-formulated, co-packaged or sold under one price (whether payment of such price is paid to the same or more than one seller). For the avoidance of doubt, adjuvants, including molecular adjuvants or lipid nanoparticles, are not considered therapeutically active ingredients for the purposes of this definition regardless of whether or not such adjuvant or lipid nanoparticle is co-packaged with a Licensed Product.
- 1.20 “**Commercially Reasonable Efforts**” means the efforts and resources that a similarly situated biopharmaceutical company or research institution, as applicable, would use for its own internally discovered technology of similar commercial potential and similar stage of development, taking into consideration the likely timing of the technology’s entry into the market, any patent and other proprietary position and issues of safety and efficacy. For clarity, Commercially Reasonable Efforts will not mean that a Party guarantees that it will actually accomplish the applicable task or objective.
- 1.21 “**Companion Diagnostic**” means an *ex vivo* medical test used as a companion to a Licensed Product in the Field for diagnosis, screening, or evaluation of a disease, or the progress of, or response to, treatment in the Field.
- 1.22 “**Controlled**” means, with respect to intellectual property rights, that a Party or one of its Affiliates owns or has a license or sublicense to such intellectual property rights and has the ability to provide to, grant a license or sublicense to, or assign its right, title and interest in and to, such intellectual property rights as provided for in this Agreement without violating the terms of any agreement or other arrangement with any Third Party.
- 1.23 “**Development Candidate**” means any Product developed under the Research Plan that meets the Acceptance Criteria, and/or for which Licensee decides to enter into the clinical development and file an IND.
- 1.24 “**Distributor**” means any Third Party that: [***].
- 1.25 “**Distributor Fees**” means, with respect to a Licensed Product, any consideration received by Licensee or its Affiliates or Sublicensees from a Distributor that is allocable to such Licensed Product [***].
- 1.26 “**EMA**” means the European Medicines Agency and any successor entity thereto.
- 1.27 “**FDA**” means the United States Food and Drug Administration and any successor entity thereto.
- 1.28 “**FD&C Act**” means the United States Federal Food, Drug and Cosmetic Act, as amended.
- 1.29 “**Field**” means mRNA vaccines and mRNA diagnostics for the diagnosis, detection, evaluation, prophylaxis and treatment of infectious diseases in humans and animals.
- 1.30 “**First Commercial Sale**” means, on a country-by-country basis, the first Sale of a Licensed Product in such country to a Third Party by Licensee, or any of its Affiliates or Sublicensees, in each case, after all Governmental Approvals have been obtained for such country.
- 1.31 “**Foreground IP**” means the BioNTech Foreground IP, the Joint Foreground IP, the Penn Foreground IP, and all Research Results.

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- 1.32 **“Foreground Patents”** means any Patent Rights covering any Foreground IP.
- 1.33 **“Governmental Approval”** means, with respect to a Licensed Product in a country or region, all approvals, licenses, registrations and authorizations of the relevant Governmental Body, if applicable, required for the commercialization of such Licensed Product in such country.
- 1.34 **“Governmental Body”** means any: (a) nation, principality, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, provincial, state, local, municipal, foreign or other government; (c) governmental or quasi-governmental authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, board, instrumentality, officer, official, representative, organization, unit, body or entity and any court or other tribunal); (d) multi-national or supranational organization or body; or (e) individual, entity, or body exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military or taxing authority or power of any nature.
- 1.35 **“IND”** means an Investigational New Drug Application as defined in the FD&C Act and the regulations promulgated thereunder, or (b) the equivalent application to the equivalent regulatory authority in any other regulatory jurisdiction, including a Clinical Trial Authorization (“CTA”) to the European Medicines Agency, the filing of which is necessary to initiate or conduct clinical testing of a pharmaceutical product in humans in such jurisdiction.
- 1.36 **“Indication”** means, with respect to the Field, a distinct disease or disorder; in each case regardless of the severity, frequency or route of any treatment. One Indication shall be distinguished from another Indication by reference to the then current World Health Organization (WHO) International Classification of Diseases at the time such Indication is selected for inclusion in the Research Program, as agreed upon by the Parties. Indication consists of Licensed Indications and Research Indications, which shall be listed in Exhibits D and E.
- 1.37 **“Joint Foreground IP”** means the Joint Foreground Patents and the Joint Foreground Know-How.
- 1.38 **“Joint Foreground Know-How”** means Know-How that is Controlled by the Parties and developed jointly by Licensee and Penn in the Weissman Laboratory during the Research Term under the Research Program.
- 1.39 **“Joint Foreground Patents”** means any Patent Rights Controlled by the Parties and conceived or conceived and reduced to practice jointly by Licensee and Penn (or their relevant subcontractors) under the Research Program.
- 1.40 **“Know-How”** means proprietary and confidential intellectual property, data, results, pre-clinical and clinical protocols and study data, chemical structures, chemical sequences, information, inventions, formulas, trade secrets, techniques, methods, processes, procedures and developments, and regulatory documentation, whether or not patentable; except that “Know-How” does not include Patent Rights claiming any of the foregoing (for as long as such Patent Rights exist).
- 1.41 **“Law”** or **“Laws”** means all applicable laws, statutes, rules, regulations, ordinances and other pronouncements having the binding effect of law of any Governmental Body.
- 1.42 **“Licensed Indication”** means an Indication for which a Product has achieved the Acceptance Criteria as determined by the JSC and/or formal notice is provided to Penn as set forth in Section 2.7. Licensed Indications shall be listed in Exhibit D, which exhibit shall be updated by the Parties as new Licensed Indications are added or removed.

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- 1.43 “**Licensed Product**” means any Product for an Indication covered by a Valid Penn Claim or whose manufacture, import, use, offer for sale or sale would, absent the License, constitute an infringement, inducement of infringement or contributory infringement of any Valid Penn Claim.
- 1.44 “**MHLW**” means the Ministry of Health, Labor and Welfare of Japan.
- 1.45 “**Net Revenue**” means the gross monetary consideration received by Penn for a sublicense to a Product developed under this Agreement directed against a terminated Licensed Indication in accordance with the provisions of Section 5.5.4 of this Agreement that would meet the definition of Product if licensed to Licensee under this Agreement less (a) payments made to Penn under sponsored research agreements or research awards, grants and contracts, (b) accrued interest, (c) reimbursement for intellectual property or legal expenses, and (d) reimbursement for research and development costs [***].
- 1.46 “**Net Sales**” means the gross consideration invoiced or received by Licensee or any of its Affiliates or Sublicensees for Sales of Licensed Product (including any cash amounts plus the fair market value of any other forms of consideration), less the following deductions (to the extent included in and not already deducted from the gross amounts invoiced or otherwise charged) to the extent reasonable and customary and solely related to the sale of the Licensed Product:
- (a) trade discounts, including trade, cash and quantity discounts or rebates, credits or refunds;
 - (b) allowances or credits granted upon claims, returns or rejections of products, including recalls, regardless of the party requesting such recall;
 - (c) charges included in the gross sales price for freight, insurance, transportation, postage, handling and any other charges relating to the sale, transportation, delivery or return of such Licensed Product;
 - (d) customs duties, sales, excise and use taxes and any other governmental charges (including value added tax) actually paid in connection with the transportation, distribution, use or sale of such Licensed Product (but excluding what is commonly known as income taxes);
 - (e) rebates and chargebacks or retroactive price reductions made to federal, state or local governments (or their agencies), or any Third Party payor, administrator or contractor, including managed health organizations; and
 - (f) payments required by law to be made under Medicaid, Medicare or other government special medical assistance programs (including, but not limited to, payments made under the new “Medicare Part D Coverage Gap Discount Program” and the “Annual Fee on Branded Pharmaceutical Manufacturers”, specific to the Licensed Product for which the deduction is taken).

Even if there is overlap between any of deductions described above, each individual item shall only be deducted once in the overall Net Sales calculation. Each of the above deductions to Net Sales shall be calculated in accordance with the Accounting Standards (with the applicable Accounting Standard used clearly indicated on any reports).

In the event that the Licensed Product is sold as a Combination Product, Net Sales will be determined by multiplying Net Sales of such Combination Product by the fraction $A/(A+B)$, where A is the invoice price of the Licensed Product, when sold separately, and B is the invoice

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price of any other therapeutically active ingredient(s) in the combination, when sold separately, in each case in the same country and similar class, purity and dosage as in the Combination Product. If, on a country-by-country basis, the Licensed Product or the other therapeutically active ingredient that is not a Product in the Combination Product is/are not sold separately in such country, Net Sales shall be determined by multiplying actual Net Sales of such Combination Product by the fraction $C/(C+D)$, where C is the fair market value of the Licensed Product portion of such combination and D is the fair market value of the other therapeutically active ingredient that is not a Product (such fair market value is to be determined by mutual agreement of the Parties or, in the absence of such mutual agreement, by a neutral Third Party).

- 1.47 **“Option Patents”** means the Patent Rights Controlled by Penn that are listed on [Exhibit F](#), and any Patent Rights issuing therefrom.
- 1.48 **“Patent Rights”** means patents and patent applications, together with any unlisted patents and patent applications claiming priority thereto, and any continuations, continuations-in-part (to the extent related directly to the subject matter of the parent application or containing new information developed pursuant to the Research Program), reissues, reexamination certificates, substitutions, divisionals, supplementary protection certificates, renewals, registrations, extensions including all confirmations, revalidations, patents of addition, PCTs, and pediatric exclusivity periods and all foreign counterparts thereof, and any patents issued or issuing with respect to any of the foregoing.
- 1.49 **“Penn Background IP”** means the Penn Background Patents and the Penn Background Know-How.
- 1.50 **“Penn Background Know-How”** means Know-How that (i) is Controlled by Penn and a) existing in the Weissman Laboratory as of the Effective Date or b) developed by Penn in the Weissman Laboratory thereafter during the Research Term but outside of the Research Program and (ii) is necessary or reasonably useful for the research, development, manufacturing, use or exploitation of any Product in the Field (excluding Penn Foreground Know-How).
- 1.51 **“Penn Background Patents”** means the Patent Rights Controlled by Penn that are listed on [Exhibit B](#), and any Patent Rights issuing therefrom.
- 1.52 **“Penn Foreground IP”** means the Penn Foreground Patents and the Penn Foreground Know How.
- 1.53 **“Penn Foreground Know-How”** means Know-How that (i) is Controlled by Penn and developed by Penn in the Weissman Laboratory during the Research Term under the Research Program and (ii) is necessary or reasonably useful for the research, development, manufacturing, use or exploitation of any Product in the Field.
- 1.54 **“Penn Foreground Patents”** means any Patent Rights Controlled by Penn and solely conceived or conceived and reduced to practice by Penn or its subcontractors under the Research Program.
- 1.55 **“Penn Know-How”** means (a) the Penn Background Know-How, (b) the Penn Foreground Know-How, and (c) Penn’s interest in the Joint Foreground Know-How.
- 1.56 **“Penn Materials”** means any biological or chemical materials Controlled by Penn and provided to Licensee under this Agreement, including any progeny or unmodified derivatives thereof, including without limitation, portions and sequence information, made, used or developed by or on behalf of Licensee.

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- 1.57 “**Penn Patent Family**” means Penn Patent Rights that (i) are related to each other through priority claims, and (ii) claim or cover one or more Licensed Product or the manufacturing or use thereof.
- 1.58 “**Penn Patent Rights**” means (a) the Penn Background Patents, (b) the Penn Foreground Patents, (c) the Joint Foreground Patents and (d) Third Party Patents.
- 1.59 “**Person**” means any natural person, corporation, firm, business trust, joint venture, association, organization, company, partnership or other business entity, or any government or agency or political subdivision thereof.
- 1.60 “**Phase 1 Study**” means a Clinical Trial of a Licensed Product in patients with the primary objective of characterizing its safety, tolerability, and pharmacokinetics and identifying a recommended dose and regimen for future studies as described in 21 C.F.R. § 312.21(a), or a comparable Clinical Trial prescribed by the relevant regulatory authority in a country other than the United States. The Licensed Product can be administered to patients as a single agent or in combination with other investigational or marketed agents.
- 1.61 “**Phase 1/2 Study**” means a Clinical Trial of a Licensed Product in diseased patients that satisfies the requirements of a Phase 1 Study and a Phase 2 Study.
- 1.62 “**Phase 2 Study**” means a Clinical Trial of a Licensed Product in patients with the primary objective of characterizing its activity in a specific disease state as well as generating more detailed safety, tolerability, and pharmacokinetics information as described in 21 C.F.R. § 312.21(b), or a comparable Clinical Trial prescribed by the relevant regulatory authority in a country other than the United States including a human Clinical Trial that is also designed to satisfy the requirements of 21 C.F.R. § 312.21(a) or corresponding foreign regulations and is subsequently optimized or expanded to satisfy the requirements of 21 C.F.R. § 312.21(b) (or corresponding foreign regulations) or otherwise to enable a Phase 3 Study (e.g., a phase 1/2 trial). The relevant Licensed Product may be administered to patients as a single agent or in combination with other investigational or marketed agents.
- 1.63 “**Phase 2/3 Study**” means a Clinical Trial of a Licensed Product in diseased patients that satisfies the requirements of a Phase 2 Study and a Phase 3 Study.
- 1.64 “**Phase 3 Study**” means a Clinical Trial of a Licensed Product in patients that incorporates accepted endpoints for confirmation of statistical significance of efficacy and safety with the aim to obtain regulatory approval in any country as described in 21 C.F.R. § 312.21(c), or a comparable Clinical Trial prescribed by the relevant regulatory authority in a country other than the United States. The relevant Licensed Product may be administered to patients as a single agent or in combination with other investigational or marketed agents.
- 1.65 “**Product**” means any article, composition, substance, or any other material identified, discovered or developed under the Research Program that incorporates, consists of, is made through use of, or otherwise uses a formulated mRNA or a defined combination of formulated mRNAs encoding one or more immunogens for applications in the Field.
- 1.66 “**Program Data**” means the data resulting from the performance of the Research Program.
- 1.67 “**Regulatory Approval**” means, with respect to a product in any regulatory jurisdiction, approval from the applicable Regulatory Authority sufficient for the manufacture, commercialization, use, marketing and sale of such pharmaceutical product in such jurisdiction in accordance with Laws. “Regulatory Approval” does not include authorization by a Regulatory Authority to conduct named patient, compassionate use or other similar activities.

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- 1.68 **“Regulatory Authority”** means any Governmental Authority, including the FDA, EMA or MHLW, or any successor agency thereto, that has responsibility for granting any licenses or approvals or granting pricing or reimbursement approvals necessary for the marketing and sale of a pharmaceutical product in any country.
- 1.69 **“Research Indication”** means an Indication for which Products are being developed under the Research Program prior to achievement of the Acceptance Criteria. The initial Research Indications are listed in Exhibit E attached hereto, which shall be updated by the Parties as Research Indications are added or removed.
- 1.70 **“Research Plan”** means the research plan setting forth the Parties’ roles and responsibilities for the Research Program as set forth in Exhibit C hereto, respectively, and as may be agreed upon by the JSC and amended from time to time by the JSC.
- 1.71 **“Research Program”** means the research and development program of Products in the Field funded by Licensee and to be conducted by the Parties hereunder in accordance with the Research Plan.
- 1.72 **“Research Results”** means all any and all information, inventions, developments, animate and inanimate materials, including live animals, discoveries, software, know-how, methods, techniques, formulae, data, software, processes, methodologies, techniques, biological materials, software and works of authorship, whether patentable or copyrightable, that are first conceived, discovered, developed or reduced to practice, or generated in the performance of the Research Program, including any unpatentable inventions discovered, developed or conceived in the conduct of the Research Program. Research Results expressly exclude any Foreground Patents.
- 1.73 **“Sale”** means any transaction for which consideration is received or expected by Licensee, its Affiliates or Sublicensees for sale, use, lease, transfer or other disposition of a Licensed Product to or for the benefit of a third party. For clarity, sale, use, lease, transfer or other disposition of a Licensed Product by Licensee or any of its Affiliates or Sublicensees to another of these entities for resale by such entity to a third party shall not be deemed a Sale. For the avoidance of doubt, the provision of a Licensed Product for clinical studies, named patient or similar programs or compassionate use prior to the grant of a Governmental Approval shall not be regarded as First Commercial Sale.
- 1.74 **“Sublicense”** means any sublicense granted by Licensee to another Person, in whole or in part, under its rights received under the License, as permitted under Section 3.4, but excluding any Person acting solely as a contract manufacturer or contract research organization on behalf of Licensee or its Affiliates or Sublicensees and for clarity not marketing or selling Licensed Product. The term Sublicense shall include any grant of rights under the License by a Sublicensee to any downstream Third Party, and such applicable downstream Third Party shall be considered a Sublicensee for purposes of this Agreement.
- 1.75 **“Sublicensee”** means a Person (including any Affiliate) to which a Sublicense is granted pursuant to the terms of Section 3.4.
- 1.76 **“Sublicense Documents”** means any and all agreements, amendments or written understandings entered into with a Sublicensee or any of its Affiliates pertaining to a Sublicense.
- 1.77 **“Sublicense Income”** means income received by Licensee or its Affiliates in consideration for a Sublicense granted to a Third Party. Sublicense Income includes income received from a Third Party Sublicensee in the form of license issue fees, milestone payments and the like but specifically excludes [***].

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- 1.78 “**Tax**” means all taxes, duties, fees, premiums, assessments, imposts, levies, rates, withholdings, dues, government contributions and other charges of any kind whatsoever, whether direct or indirect, together with all interest, penalties, fines, additions to tax or other additional amounts, imposed by any Governmental Body.
- 1.79 “**Territory**” means worldwide.
- 1.80 “**Third Party**” means any Person other than Penn, Licensee or any of their respective Affiliates.
- 1.81 “**Third Party Patents**” means Third Party Patent Rights in the Field directly related to the Research Program or any Licensed Product that are in-licensed by Penn pursuant to Section 2.2.7 during the Research Term, to the extent Controlled by Penn and added to the Agreement as Exhibit K. For clarity, Third Party Patent Rights under this Agreement does not include any Patent Rights that are jointly owned by Penn and a Third Party.
- 1.82 “**United States**” or “**US**” means the United States of America, its territories and possessions.
- 1.83 “**USD**” or “**\$**” means the lawful currency of the United States of America.
- 1.84 “**Valid Claim**” means a claim of (i) a good faith patent application pending for less than [***] from the filing date of such patent application, or (ii) an issued patent, in each case of (i) and (ii) which has not expired or lapsed, or been cancelled, abandoned or dedicated to the public and which has not been disclaimed, cancelled, or held invalid or unenforceable by a court or administrative agency of competent jurisdiction from which no further appeal can be taken or was timely taken.
- 1.85 “**Valid Penn Claim**” means a Valid Claim in any of the Penn Patent Rights but excluding a Valid Claim in a Third Party Patent.
- 1.86 “**Weissman Laboratory**” means all individuals within the Weissman Laboratory at Penn that report directly to or are under the direct supervision or control of Drew Weissman, MD or any successor.
- 1.87 **Other Terms.** The definition of each of the following terms is set forth in the section of the Agreement indicated below:

<u>Defined Term</u>	<u>Section</u>
Advance Payment	6.3.3
Agreement	Introductory Clause
Alliance Management Fee	4.2
Arbitration Rules	11.10
BioNTech/mRT License	4.3.1
Cellscript	4.3.1
Commercial Milestone	4.3.3(a)
Commercial Milestone Payment	4.3.3(a)
Confidential Information	7.1
CTA	1.35
Development Milestone	4.3.2(a)
Development Milestone Payment	4.3.2(a)

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Disclosing Party	7.1
Effective Date	Introductory Clause
Infringement Notice	6.4.1
Joint IP Sub-Committee	2.6.2
Joint Steering Committee (“JSC”)	2.6.1(a)
License	3.1
License Fee Report	4.7
Licensee	Introductory Clause
MAA	1.13
mRT	4.3.1
mRT Offset	4.3.1
mRT Payment	4.3.1
Observer Period	5.4.2
Ongoing Patent Costs	6.3.2
Party or Parties	Introductory Clause
Patent Costs	6.3.1
Penn	Introductory Clause
Penn/mRT License	4.3.1
Penn Patent Counsel	6.2.1(a)
Penn Indemnities	9.1.1
Penn Sublicense Income Share	4.5.3
Permitted Assignment	11.6.2
Progress Report	5.6.1
Quarterly Budget Amount	2.3.2
Quarterly Financial Report	2.3.3
Receiving Party	7.1
Reduction License	4.4.4
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Royalty	4.4.1
Royalty Term	4.4.2
SDR Report	3.4.4
Sublicense Income A	4.5.1
Sublicense Income B	4.5.2
Term	10.1
Third Party License	2.2.7

ARTICLE 2
COLLABORATION PROGRAMS; GOVERNANCE

- 2.1 **Overall Project.** The Parties desire to collaborate with respect to the research and development of Products, as set forth in more detail in this Article 2, within the Field, with the goal of identifying one or more Development Candidates for clinical development and commercialization in the Field.
- 2.2 **Research.**
- 2.2.1 Under the Research Program, the Parties will use Commercially Reasonable Efforts to develop Products that meet the Acceptance Criteria for up to ten (10) Indications in the Field. The Research Program will be performed in accordance with the Research Plan and the other terms and conditions of this Agreement. Unless otherwise agreed in the Research Plan, Penn will be responsible for the conduct of the Research Plan for the research and development work up to completion of IND enabling studies, including animal model development, and IND supporting preclinical work (toxicology and pharmacokinetics) of Products within the Field, and Licensee shall be responsible for the manufacture of mRNA amounts in excess [***] to support pre-clinical studies and IND-enabling studies.
- 2.2.2 The Research Program shall begin on the Effective Date and continue for a period of [***] years, unless otherwise mutually agreed by the Parties (“**Research Term**”). Notwithstanding the foregoing, the Research Term shall end immediately upon termination or conclusion of funding provided by Licensee to Penn to conduct the Research Program.
- 2.2.3 All personnel, contractors and others who participate in the conduct of the Research Program on behalf of either Party shall be bound by confidentiality obligations that are at least as restrictive as the confidentiality obligations set forth in this Agreement and are consistent with the intellectual property assignment provisions set forth in this Agreement during the Research Term. For all researchers working on the Research Program in the Weissman Laboratory, such confidentiality obligations shall be agreed in writing.
- 2.2.4 The JSC shall review the Research Plan (i) within [***] of the Effective Date, and (ii) thereafter at least once per Calendar Year or upon request by either Party in accordance with Section 2.3.1. The JSC may discuss and approve amendments the Research Plan at any time, including amendments to include further activities, including corresponding revisions to the budget.
- 2.2.5 Each Party shall maintain records of its activities and any results obtained under the Research Program in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes to properly reflect all work done and results achieved. Upon reasonable request of Licensee during the Research Term and [***] thereafter, Penn shall provide to Licensee copies of any such records or results (including nonclinical data (*in vitro* and *in vivo*) and mRNA development data and results) generated or obtained under the Research Program. Notwithstanding the above, within [***] days after the conclusion of each year of the Research Program, Penn will provide Licensee with a written report setting forth the research conducted and results obtained. For a period of [***] months after delivery of such written report, and at Licensee’s sole cost and expense, Penn shall, through the Weissman Laboratory, provide reasonable technical assistance as Licensee may reasonably request to assist Licensee

in connection with questions arising from such written report; provided, however, that such assistance shall not include performance of any additional activities that are not set forth in the Research Plan.

- 2.2.6 Through the JSC, during the performance of activities under the applicable Research Plan, the Parties will discuss potential Development Candidates arising out of the applicable Research Program.
- 2.2.7 In addition to the Research Plan, Penn shall provide to Licensee through the JSC the proposed constructs for a Product such that the Parties may consider known freedom-to-operate issues related thereto. For clarity, this Section 2.2.7 will not change the governance of the Research Program and does not require that Penn engage in a freedom-to-operate analysis with respect to any technology or intellectual property relating to a Product or Penn's performance of the Research Plan. If the Parties identify additional intellectual property owned or controlled by a Third Party that is necessary to develop Products, the JSC will decide which Party, if any, will enter into a license with such Third Party (the "**Third Party License**"). If the Parties agree that the Third Party License shall be concluded by Penn and sublicensed to Licensee hereunder, Licensee shall reimburse to Penn all costs which relate to the license rights sublicensed to Licensee hereunder, provided that Licensee has given its prior written consent to such costs. In all other cases, Licensee will bear all Third Party License costs necessary to achieve freedom-to-operate for any Product. If the Parties cannot agree on which Party shall enter into a Third Party License, Licensee shall have the first right to enter into such Third Party License.
- 2.2.8 The Parties hereby acknowledge that there are inherent uncertainties involved in the research and development of Products and such uncertainties form part of the business risk involved in undertaking the Research Program. Accordingly, in the event that, at any time during the Research Term and on an Indication-by-Indication basis, the JSC determines that the Parties are not able to develop or identify a suitable Product to propose as a Development Candidate in such Indication, then the JSC may decide to terminate the Research Program with respect to such Indication and such Indication shall immediately be excluded from the license grants to Licensee set forth in Section 3.1 of this Agreement.
- 2.2.9 Each Party will have the right to engage Third Party subcontractors to perform certain of its obligations under this Agreement; provided that Penn's right to engage commercial Third Party subcontractors is subject to Licensee's prior written consent, which shall not be unreasonably withheld. Any subcontractor to be engaged by either Party to perform a Party's obligations set forth in this Agreement shall meet the qualifications typically required by such Party for the performance of work similar in scope and complexity to the subcontracted activity and will enter into such Party's standard agreement for such activity consistent with such Party's standard practices, subject to modifications to ensure that such agreement shall be as least as protective as the nondisclosure obligations and consistent with the assignment of intellectual property rights set forth herein. Any Party engaging a subcontractor hereunder will remain responsible and obligated for such activities and will not grant rights to such subcontractor that interfere with the rights of the other Party under this Agreement.

2.3 Funding of the Research Program.

- 2.3.1 During the initial Research Term, Licensee intends to provide funding of Twenty Million United States Dollars (\$20,000,000) to Penn as a research funding commitment to fund research activities under the Research Program (the "**Research Funding**")

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Commitment). The activities to be performed by Penn under the Research Program shall be funded in their entirety by Licensee. All such activities shall be charged at cost. [***]

- 2.3.2 On the Effective Date, Licensee shall pay to Penn an upfront one-time non-refundable research payment of Five Million United States Dollars (\$5,000,000) to start work on the initial development programs under the Research Plan selected by the JSC. Prior to the beginning of each Calendar Year, the Parties, via the JSC, shall estimate, on a per Calendar Quarter basis, what additional funds are required for Penn to perform its activities planned such Calendar Year under the Research Plan (each such amount a “**Quarterly Budget Amount**”). [***]
- 2.3.3 Penn shall maintain records of the use of the funds provided by Licensee under this Agreement and shall make such records available to Licensee in accordance with the terms of this Agreement including Section 4.10.2. In addition, within [***] days following the end of each Calendar Quarter, Penn shall provide to Licensee a detailed report of all costs incurred by Penn under the Research Plan in the respective previous Calendar Quarter (each such report a “**Quarterly Financial Report**”). [***].
- 2.3.4 Unless otherwise determined by the JSC, title to any equipment, laboratory animals, or any other tangible materials made or acquired (in whole or in part) with funds provided under this Agreement will vest in Penn, and such equipment, animals, or tangible materials will remain the property of Penn following termination or expiration of this Agreement (but subject to any license grants to Licensee hereunder).
- 2.3.5 Licensee will be responsible, at its sole cost and expense, for the manufacture of mRNA in amounts in excess of [***].
- 2.4 **Unavailability of Dr. Drew Weissman.** If Drew Weissman, MD becomes unavailable to oversee and support the performance of the activities under the Research Plan for any reason, Penn may propose another member of its faculty to oversee the performance of the Research Program whom Licensee may accept nor not in its sole discretion. If a substitute faculty member acceptable to Licensee has not been agreed upon within [***] days after Drew Weissman, MD is no longer available to oversee and support the performance of the Research Plan, Licensee may terminate this Agreement upon written notice thereof to Penn, subject to the provisions of Article 10.
- 2.5 **Transfer of Materials.** Upon reasonable request of Licensee, Penn shall transfer to Licensee a portion or sample of any materials generated or obtained under the Research Program. All Penn Materials and BioNTech Materials shall be transferred by the Parties pursuant to a material transfer protocol to be executed by both Parties and the terms set forth in this Agreement and the terms of material transfer set forth on [Exhibit H](#). The use of such Penn Materials shall be limited to the rights granted to Licensee herein and in Exhibit H and the use of such BioNTech Materials shall be limited to Penn’s performance of the Research Program.
- 2.6 **Governance.**
- 2.6.1 **Joint Steering Committee.**
- (a) Formation; Composition. Within [***] days of the Effective Date, the Parties will establish a joint steering committee (the “**Joint Steering Committee**” or “**JSC**”) comprised of a minimum of two (2) representatives from each Party with sufficient

seniority within the applicable Party to make decisions arising within the scope of the JSC's responsibilities. The Penn JSC will include a representative from the Penn Center for Innovation and the Penn principal investigator. The JSC may change its size from time to time by mutual consent of its members, provided that the JSC will consist at all times of an equal number of representatives of each of Penn and Licensee. Each Party may replace its JSC representatives at any time upon written notice to the other Party.

- (b) Specific Responsibilities. The JSC will:
- (i) oversee the Research Program;
 - (ii) determine the Acceptance Criteria;
 - (iii) determine whether a Product for an Indication satisfies the Acceptance Criteria for such Indication;
 - (iv) determine whether the development of Products in relation to a specific Research Indication shall be terminated in accordance with Section 2.2.8;
 - (v) review freedom-to-operate issues related to proposed constructs of Products;
 - (vi) on or before October 1 of each year, approve an updated budget, including capital expenditures, in accordance with Section 2.3.1;
 - (vii) determine and monitor the Quarterly Budget Amounts in accordance with Section 2.3.2,
 - (viii) consider and decide on any amendments to the Research Plan;
 - (ix) resolve any disagreement between the Parties relating to the Research Program or Research Plan;
 - (x) discuss and decide on the use of any Patent Rights in connection with the Research Program or any Product (including any Penn Patent Rights);
 - (xi) designate patent representatives from each Party to consider, and resolve as necessary to the extent possible, any intellectual property matters;
 - (xii) oversee, manage, coordinate and integrate the activities of the Parties under the Research Plan;
 - (xiii) make key decisions during the progress of the Research Plan;
 - (xiv) address any issues identified by Licensee with respect to Third Party intellectual property rights necessary for the performance of the Research Program, including Licensee's analysis of whether a license is required from such Third Party for the exploitation of a Product;
 - (xv) decide which Party, if any, will enter into a license with a Third Party to secure rights necessary to develop Products;
 - (xvi) establish such additional subcommittees as it deems necessary to achieve the objectives and intent of the Research Program; and
 - (xvii) perform such other functions as appropriate, and as agreed in writing by the parties.

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- (c) **Reporting.** Each Party shall keep the JSC informed on the progress of the activities under the Research Program then currently ongoing under the Research Plan, including delivering quarterly written updates of its progress under the Research Plan to the JSC at least one (1) week in advance of each JSC meeting.
 - (d) **Meetings.** During the performance of the Research Plan, the JSC will meet quarterly. Following the completion of the performance under the Research Plan, the Parties may agree to meet to discuss items previously addressed by the JSC. The JSC may meet in person, by videoconference or by teleconference. Notwithstanding the foregoing, at least two (2) meetings per Calendar Year will be in person unless the parties mutually agree in writing to waive such requirement. In-person JSC meetings will be held at locations alternately selected by Penn and by Licensee. Meetings of the JSC will be effective only if all representatives of each Party are present or participating in such meeting, and each Party shall use Commercially Reasonable Efforts to ensure that all representatives of each Party are present and participate in every meeting. The JSC shall keep accurate minutes of its deliberations which shall record all proposed decisions and all actions recommended or taken. The secretary of the JSC (as appointed by the Licensee) shall be responsible for the preparation of draft minutes. Draft minutes shall be sent to all members of the JSC within [***] working days after each meeting and shall be approved, if appropriate, at the next meeting. All records of the JSC shall at all times be available to both Penn and Licensee.
 - (e) **Decision-Making.** The representatives from each Party on the JSC will have, collectively, one (1) vote on behalf of that Party, and all decision making will be by unanimous consent of both Parties. If the JSC is unable to reach agreement on any issue or matter for which it is responsible, such disputed matter will be escalated to Licensee's Chief Executive Officer and Penn's Associate Vice Provost for Research or his/her designee, for discussion in good faith. In the event that after escalation the Parties are unable to reach agreement with respect to the disputed matter within [***] days, then Licensee shall have the final decision-making authority; provided that Penn and the Weissman Laboratory cannot be forced to conduct work or other activities that it believes to be unsafe or not legally permissible. [***]
- 2.6.2 **Joint IP Sub-Committee.** The Parties will establish a joint intellectual property sub-committee (the "**Joint IP Sub-Committee**") consisting of an equal number of members from each Party, and such Joint IP Sub-Committee will oversee and steer intellectual property filings, prosecution, management and freedom-to-operate analysis; however, the Joint IP Sub-Committee shall have no authority to make financial decisions. The representatives from each Party on the Joint IP Sub-Committee will have, collectively, one (1) vote on behalf of that Party, and all decision making will be by unanimous consent by the Parties. Disputes at the Joint IP Sub-Committee will be referred to the JSC for resolution.
- 2.7 **Licensed Indication Election.** During the Research Term, on a Research Indication-by-Research Indication basis, the JSC shall determine if the Acceptance Criteria have been achieved for a Product for such Research Indication. Upon achievement of the Acceptance Criteria for a Product for a specific Research Indication, Licensee may elect, by providing Penn with formal written notice, to convert such Research Indication to a Licensed Indication within [***], provided, however, that Licensee shall not be obligated to make an election decision for more than one (1) Research Indication in any [***] time period following the achievement of the Acceptance Criteria for the first Product as determined by the JSC [***].

ARTICLE 3
LICENSES AND OTHER RIGHTS

- 3.1 **Grant of License to Licensee.** Subject to the terms and conditions of this Agreement, Penn hereby grants to Licensee and its Affiliates (the “Licensee”):
- 3.1.1 an exclusive (even as to Penn but subject to Section 3.2), worldwide, royalty-bearing right and license (with the right to sublicense (through multiple tiers) as provided in, and subject to, the provisions of Section 3.4) under Penn’s interest in the Penn Patent Rights which are necessary or useful, to research, develop, make, have made, use, sell, offer for sale, commercialize and import Products in the Field in the Territory for the Licensed Indications during the Term;
 - 3.1.2 a non-exclusive, worldwide, royalty-bearing right and license (with the right to sublicense (through multiple tiers) as provided in, and subject to, the provisions of Section 3.4) under Penn Know-How and Penn Materials to the extent necessary or useful to research, develop, make, have made, use, sell, offer for sale, commercialize and import Products in the Field in the Territory for the Licensed Indications during the Term; and
 - 3.1.3 an exclusive (even as to Penn but subject to Section 3.2), worldwide right and license (without the right to sublicense) under Penn’s interest in the Penn Patent Rights and a non-exclusive, worldwide right and license (without the right to sublicense) under Penn Know-How and Penn Materials, in each case which are necessary or useful, to research and develop Products in the Field in the Territory for the Research Indications during the Research Term.
- 3.2 **Retained Rights and Grant of License to Penn.** Notwithstanding the License set forth in Section 3.1, Penn retains the right under the Penn Patent Rights and the Foreground IP (including Penn Materials which have been generated under the Research Program) to: (a) conduct educational, research and patient care activities itself and (b) authorize non-commercial Third Parties to conduct educational, research and patient care activities. For clarity, the foregoing retained rights of Penn are in all fields (including the Field). Licensee hereby grants to Penn a non-exclusive license to Licensee’s interest in BioNTech Foreground IP and Joint Foreground IP to conduct educational, research and patient care activities at Penn. Notwithstanding anything in this Section 3.2 to the contrary, the foregoing patient care activities shall not include the use of any Product in the Field outside the conduct of the Research Program.
- 3.3 **U.S. Government Rights.** The License is expressly subject to all applicable provisions of any license to the United States Government executed by Penn and is subject to any overriding obligations to the United States Federal Government under 35 U.S.C. §§200-212 or applicable governmental implementing regulations or guidelines, including the requirement that products that result from intellectual property funded by the United States Federal Government that are sold in the United States be substantially manufactured in the United States. In the event that Licensee believes in good faith that substantial manufacture of such product is not commercially feasible in the United States and makes a request to Penn in writing to assist in obtaining a waiver of such requirement from the United States Government, then Penn shall, at the expense of Licensee with respect to Penn’s documented out-of-pocket expenses, use reasonable efforts to assist in obtaining such waiver.

3.4 Grant of Sublicense by Licensee.

- 3.4.1 Penn grants to Licensee the right to grant Sublicenses (through multiple tiers), in whole or in part, under the License in Sections 3.1.1 and 3.1.2 subject to the terms and conditions of this Agreement and specifically this Section 3.4.
- 3.4.2 All Sublicenses will be (a) issued in writing, (b) to the extent applicable, include all of the retained rights of Penn and the U.S. Government pursuant to Section 3.2 and 3.3 and (c) shall explicitly list all Products, and include no less than the following terms and conditions, and in each such instance shall be consistent with the provisions applicable to Licensee under this Agreement:
- (i) Reasonable record keeping, audit and reporting obligations sufficient to enable Licensee to reasonably verify the payments due to Licensee under such Sublicense and to reasonably monitor such Sublicensee's progress in developing and/or commercializing Product, provided that such obligations shall be no less stringent than those provided in this Agreement for Licensee.
 - (ii) Infringement and enforcement provisions that do not conflict with the restrictions and procedural requirements imposed on Licensee and do not provide greater rights to Sublicensee than as provided in Section 6.4.
 - (iii) Confidentiality provisions with respect to Confidential Information of Penn consistent with the restrictions on Licensee in Article 7 of this Agreement.
 - (iv) Covenants by Sublicensee that are equivalent to those made by Licensee in Section 8.3.
 - (v) A requirement of indemnification of Penn by Sublicensee that is equivalent to the indemnification of Penn by Licensee under Section 9.1 of this Agreement.
 - (vi) A requirement of obtaining and maintaining commercially reasonable insurance by Sublicensee.
 - (vii) Restriction on use of Penn's names etc. consistent with Section 11.4 of this Agreement.

Any Sublicense that does not include all of the terms and conditions set forth in this Section 3.4.2 or which is not issued in accordance with the terms and conditions set forth in this Section 3.4, shall be considered null and void with no further notice from Penn.

- 3.4.3 Within [***] after the execution of a Sublicense Document, Licensee shall provide a complete and accurate copy of such Sublicense Document to Penn (which copy may be redacted solely to remove confidential information of Licensee that is not applicable to determining compliance with this Agreement and confidential information of such Sublicensee), in the English Language, and such copies will be the Confidential Information of Licensee and may only be used to determine Licensee's compliance with this Agreement. Penn's receipt of a Sublicense Document, however, will constitute neither an approval nor disapproval of the Sublicense Document nor a waiver of any right of Penn or obligation of Licensee under this Agreement. In the event Penn cannot, in its reasonable discretion, interpret the Sublicense Document due to the redacted information, Penn may request, and Licensee shall be obligated to provide to Penn counsel a copy of the unredacted Sublicense Document (other than any research and development plans included as an exhibit to such Sublicense Document).

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- 3.4.4 Licensee shall provide an annual Sublicense Development Report on or before December 1 of each year during the Term (“**SDR Report**”), which shall contain the information set forth on Exhibit I attached hereto.
- 3.5 **No Implied License.** Each Party acknowledges that the rights and licenses granted in this Agreement are limited to the scope expressly granted. Accordingly, except for the rights expressly granted under this Agreement, no right, title, or interest of any nature whatsoever is granted whether by implication, estoppel, reliance, or otherwise, by either Party to the other Party. All rights with respect to any know-how, patent or other intellectual property right rights that are not specifically granted herein are reserved to the owner thereof.
- 3.6 **Additional Weissman Patent Rights.** [***].
- 3.7 **Covenants of Penn.**
- 3.7.1 During the Research Term, Penn shall not directly (or indirectly through license grant from Penn to a non-commercial Third Party that is sub-licensable or transferrable to a commercial Third Party) grant a license to any commercial Third Party to use any Penn Foreground IP or Joint Foreground IP for development, manufacture, use or exploitation of any Product in the Field without the prior written permission of Licensee. [***].
- 3.7.2 [***].
- 3.7.3 [***].
- 3.7.4 [***].
- 3.8 **Time-Limited Option.** Subject to the terms and conditions of this Agreement, Penn hereby grants an option to Licensee for [***] months after the Effective Date, exercisable through written notice to Penn, to obtain a license under Penn’s interest in the Option Patent Rights set forth in Exhibit E to research, develop, make, have made, use, sell, offer for sale, commercialize and import Products in the Field in the Territory for the Licensed Indications during the Term (the “**Option**”). Upon exercise of such Option, the Option Patents shall become Penn Background Patents under this Agreement. During the term of the Option, Licensee shall be responsible for reimbursing Penn for Historical and Ongoing Patent Costs associated with the Option Patents in accordance with Sections 6.3.1 and 6.3.2 of this Agreement. The Option shall terminate immediately if the Agreement is terminated for any reason prior to Licensee’s exercise of such Option.

ARTICLE 4 FINANCIAL PROVISIONS

- 4.1 **Research Funding.** The research funding to be provided by Licensee to Penn in connection with the performance of the Research Program is set forth in Section 2.3.
- 4.2 **Alliance Management Fee.** During the Research Term, Licensee shall pay Penn an active alliance management fee of [***] to cover all alliance management activities at the Penn Center for Innovation related to managing and overseeing the intellectual property and contractual obligations of Penn under this Agreement (including managing permitted subcontractors and

attending JSC meetings) (“**Alliance Management Fee**”). Such Alliance Management Fee shall be payable to Penn in advance on the Effective Date and each one year anniversary thereafter during the Research Term per contract year to cover all alliance management activities at the Penn Center for Innovation related to managing and overseeing the intellectual property and contractual obligations of Penn under this Agreement (including managing permitted subcontractors and attending JSC meetings). For the avoidance of doubt, the Alliance Management Fee shall be in addition to, and shall not reduce, the Research Funding Commitment. [***] of all Alliance Management Fees paid by Licensee shall be [***].

4.3 **Milestone Payments.**

4.3.1 [***]

4.3.2 **Development Milestones.**

(a) As consideration for the License, [***] Licensee will pay Penn each of the following milestone payments (each, a “**Development Milestone Payment**”) upon the first, second and third achievement of the corresponding milestone by any Licensed Product (assessed on a milestone-by-milestone basis) irrespective of the Licensed Product for which such milestone has been achieved (each, a “**Development Milestone**”), whether achieved by Licensee or an Affiliate or Sublicensee. For the avoidance of doubt, no Development Milestone Payment shall be due upon the fourth, fifth or any subsequent achievement of any of the below milestones in this Section 4.3.2(a). Licensee shall promptly notify Penn in writing of the achievement of any such Development Milestone and Licensee shall pay Penn in full the corresponding Development Milestone Payment within forty-five (45) days of such achievement. For clarity, each Development Milestone Payment is non-refundable, is not an advance against Royalties due to Penn or any other amounts due to Penn. For further clarity, the maximum cumulative amount of Development Milestone Payments potentially payable under this Agreement is [***].

<u>Development Milestone</u>	<u>Milestone Payment (in U.S. dollars, each payable up to three (3) times)</u>	<u>Maximum mRT Offset</u>
Initiation of Phase 1 Study (as defined by the enrollment of the 3 rd patient)	[***]	[***]
Initiation of Phase 2 or Phase 1/2 Study (as defined by the enrollment of the 5 th patient)	[***]	[***]
Initiation of Phase 3 or Phase 2/3 Study (as defined by the enrollment of the 5 th patient)	[***]	[***]
Approval of first BLA	[***]	[***]
Approval of second BLA	[***]	[***]
Approval of third BLA	[***]	[***]

(b) Each time a Development Milestone is achieved for any Licensed Product, then any other Development Milestone Payments with respect to earlier Development Milestones for the same Licensed Product that have not yet been paid will be due and payable together with the Development Milestone Payment for the Development Milestone that is achieved.

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- (c) Each Development Milestone in the Table above will be payable for the first three (3) Licensed Products to achieve such Development Milestone and for no Licensed Product thereafter.

4.3.3 Commercial Milestone Payments.

- (a) As additional consideration for the License [***] Licensee will pay Penn the following commercial milestone payments (each, a “**Commercial Milestone Payment**”) on a Licensed Product-per-Licensed Product basis upon the achievement of the corresponding milestone (each, a “**Commercial Milestone**”), whether achieved by Licensee or an Affiliate, or a combination of Licensee and/or an Affiliate. Licensee shall promptly notify Penn in writing of the achievement of any such Commercial Milestone and Licensee shall pay Penn in full the corresponding Commercial Milestone Payment within forty-five (45) days of such achievement. For clarity, each Commercial Milestone Payment is non-refundable and is not an advance against Royalties due to Penn or any other amounts due to Penn.

<u>Commercial Milestone Event</u>	<u>Milestone Payment (U.S. Dollars, each payable once per Licensed Product)</u>	<u>Maximum mRT Offset</u>
Worldwide annual Net Sales of a Licensed Product by Licensee and/or Affiliates equal or exceed [***] US Dollars	[***]	[***]
Worldwide annual Net Sales of a Licensed Product by Licensee and/or Affiliates equal or exceed [***] US Dollars	[***]	[***]
Worldwide annual Net Sales of a Licensed Product by Licensee and/or Affiliates equal or exceed [***] US Dollars	[***]	[***]

- (b) For clarity, each of the foregoing Commercial Milestone Payments shall only be due once per Licensed Product and Net Sales made by any Third Party Sublicensee shall be disregarded in the calculation of the Commercial Milestone event.

4.4 Royalties.

- 4.4.1 **Royalty.** As further consideration for the License [***] during the Royalty Term, Licensee shall pay to Penn a non-refundable, non-creditable royalty of [***] on worldwide annual Net Sales for all Licensed Products sold by Licensee, its Affiliates, or Sublicensees (“**Royalty**”).
- 4.4.2 **Royalty Term.** Licensee’s obligations to pay Penn the Royalty will continue on a country-by country and Licensed Product-by-Licensed Product basis from the date of the First Commercial Sale of such Licensed Product in such country until the expiration or abandonment of the last Valid Penn Claim within the Penn Patent Rights in the country in which such Licensed Product is made, used, imported, or sold (such term, the “**Royalty Term**”).

4.4.3 **Licensed Products for Animal Health, Diagnostics and Companion Diagnostics.**

- (a) Licensed Products developed and sold solely (i) for animal health applications or (ii) as diagnostic tests shall not be subject to the Development Milestones and Commercial Milestones set forth in Section 4.3 and shall only be subject to the Royalty payment to Penn as set forth in Section 4.4.1 above.
- (b) Licensed Products that are developed and sold solely as Companion Diagnostics shall not be subject to Development Milestones, Commercial Milestones or Royalty payments.

4.4.4 **Reductions for Third Party Licenses.** If Licensee determines upon the advice of independent intellectual property counsel that a license to Patent Rights from a Third Party is necessary to develop, make, have made, use, sell, offer for sale, commercialize or import a Licensed Product, Licensee may obtain such a Third Party license to such Patent Rights. Licensee may deduct from any Royalty payments due to Penn under Section 4.4.1 of this Agreement an amount equal to [***] of any royalty paid by Licensee to a Third Party on Sales of a particular Licensed Product in a particular country under a Third Party license obtained by Licensee pursuant to this Section 4.4.4 (“**Reduction License**”); provided that the royalty deductions shall not reduce the Royalty payable to Penn to less than [***].

4.4.5 **Distributor Fees.** With respect to any Distributor Fees received by Licensee or its Affiliates or Sublicensees with respect to a Licensed Product in any Calendar Quarter, Licensee shall pay to Penn [***] of all such Distributor Fee [***].

4.4.7 **Calculations.** Licensee must pay Royalties owed to Penn on a Calendar Quarter basis on or before the following dates:

- (a) February 28 for any Sales that took place on or before the last day of the Calendar Quarter ending December 31, of the prior year;
- (b) May 31 for any Sales that took place on or before the last day of the Calendar Quarter ending March 31 of such calendar year;
- (c) August 31 for any Sales that took place on or before the last day of the Calendar Quarter ending June 30 of such calendar year; and
- (d) November 30 for any Sales that took place on or before the last day of the Calendar Quarter ending September 30 of such calendar year; or
- (e) In case of Royalties on Sublicense Income, on or before the dates specified in Section 4.5.5.

4.5 **Penn Sublicense Income.**

4.5.1 **Sublicense Income A.** As further consideration for the License, Penn will receive a percentage of all Sublicense Income assessed on a Licensed Product-by-Licensed Product basis for the [***] Licensed Products sublicensed to any Third Party Sublicensee (including, for clarity, commercial sales milestones), tiered according to the schedule set forth in Section 4.5.3 below (“**Sublicense Income A**”). [***]. Any payments made by Licensee to Penn under Section 4.5.1 shall be credited towards future Development Milestone payments under Section 4.3.2. [***].

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- 4.5.2 **Sublicense Income B.** As further consideration for the License, Penn will receive a percentage of Sublicense Income from commercial sales milestones assessed on a Licensed Product-by-Licensed Product basis for the [***] Licensed Product sublicensed to any Third Party Sublicensee, tiered according to Section 4.5.3 below (“**Sublicense Income B**”). [***].
- 4.5.3 Subject to the respective caps and other stipulations in Sections 4.5.1 and 4.5.2 above, Licensee will pay to Penn the following percentage of Sublicense Income A and Sublicense Income B received by Licensee (the “**Penn Sublicense Income Share**”), on a Licensed Product-by-Licensed Product basis:
- [***]
- 4.5.4 When multiple products are being licensed under a Sublicense, [***], the relative value of the sublicensed products will be based on the stage of development of each product at the time of Sublicensing, and weighted in accordance with the following chart:
- [***]
- 4.5.5 Licensee will make such payment to Penn on or before the following dates:
- (a) February 28 for any Sublicense Income received by Licensee on or before the last day of the Calendar Quarter ending December 31, of the prior year;
 - (b) May 31 for any Sublicense Income received by Licensee on or before the last day of the Calendar Quarter ending March 31 of such calendar year;
 - (c) August 31 for any Sublicense Income received by Licensee on or before the last day of the Calendar Quarter ending June 30 of such calendar year; and
 - (d) November 30 for any Sublicense Income received by Licensee on or before the last day of the Calendar Quarter ending September 30 of such calendar year.
- 4.6 **Mode of Payment and Currency.** All payments to Penn hereunder shall be made by deposit of USD in the requisite amount to the “The Trustees of the University of Pennsylvania” and will be made by delivery to any one of the following:

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For funding of the performance of the Research Program by Penn:

By ACH/Wire:

[***]

For all other payments to Penn under this Agreement:

By ACH/Wire:

[***]

By Check (lockbox):

[***]

All payments owed to Penn by Licensee will be invoiced by Penn in the format provided in [Exhibit L](#). Payments under this Agreement shall be made in USD. All Royalties, Commercial Milestones, and Penn Sublicense Income Share payable shall be calculated first in the currency of the jurisdiction in which payment was made, and if not in the United States, then converted into USD. The exchange rate for such conversion shall be the average of the rate quoted in The Wall Street Journal for the last business day of each month in the Calendar Quarter for such Royalty payment made.

- 4.7 **Royalty and Sublicense Income Reports.** Within sixty (60) days after the end of each Calendar Quarter, Licensee shall deliver to Penn a report (“**License Fee Report**”) setting out all details necessary to calculate the Royalty and the Penn Sublicense Income Share due under this Article 4 for such Calendar Quarter, including:
- 4.7.1 Number of the Licensed Products Sold by Licensee, its Affiliates and Sublicensees in each country and the corresponding name of each such Licensed Product;
 - 4.7.2 Gross sales, Net Sales of each Licensed Product made by Licensee, its Affiliates and Sublicensees;
 - 4.7.3 Royalties (including calculation of any applicable mRT Offset) or (only if applicable) the [***].
 - 4.7.4 Distributor Fees for Licensed Product;
 - 4.7.5 Sublicense Income and the calculation of the Penn Sublicense Income Share broken down by Sublicense Income A and Sublicense Income B, the respective caps on such Sublicense Income and any credits being applied to unpaid Development Milestones based on the Penn Sublicense Income Share paid to Penn;

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- 4.7.6 The method and currency exchange rates (if any) used to calculate the Royalties and the Penn Sublicense Income Share;
- 4.7.7 A specification of all deductions and their dollar value that were taken to calculate Net Sales;
- 4.7.8 A list of all countries in which Licensed Product is being manufactured (on a product by product basis); and
- 4.7.9 Date of First Commercial Sale in the United States (this needs only to be reported in the first royalty report following such First Commercial Sale in the United States).

Each License Fee Report shall be substantially in the form of the sample report attached hereto as Exhibit J.

- 4.8 **Late Payments.** In addition to any other remedies available to Penn, including the right to terminate this Agreement, any failure by Licensee to make an undisputed (in good faith) payment within [***] days after the date when due shall obligate Licensee to pay computed interest, the interest period commencing on the due date and ending on the actual payment date, to Penn at a rate per annum equal to [***].
- 4.9 **Accounting.** Each Party shall calculate all amounts, and perform other accounting procedures required, under this Agreement and applicable to it in accordance with Accounting Standards.
- 4.10 **Books and Records.**
 - 4.10.1 Licensee will keep accurate books and records of all Licensed Products developed, manufactured or sold and all Sublicenses entered into by Licensee that involve Penn Patent Rights. Licensee will preserve these books and records for at least [***] years from the date to which they pertain.
 - 4.10.2 Penn will keep accurate books and records of all work performed under the Research Program. Penn will preserve these books and records for at least [***] from the date to which they pertain.
- 4.11 **Audits.**
 - 4.11.1 Penn, at its own cost, through an independent auditor reasonably acceptable to Licensee (and who has executed an appropriate confidentiality agreement reasonably acceptable to Licensee that requires the auditor to keep any information learned by it confidential except as needed to report its audit conclusions to Penn), may inspect and audit only the relevant records of Licensee pertaining to the calculation of any Milestones, Royalties and Penn Sublicense Income Share due to Penn under this Agreement. Licensee shall provide such auditors with reasonable access to the records during reasonable business hours and at mutually agreed upon times. Such access need not be given to any such set of records more often than once each year, not more frequently than once with respect to records covering any specific period of time and not more than [***] years after the date of any report to be audited. Penn shall provide Licensee

with written notice of its election to inspect and audit the records related to the Milestones, Royalties and Penn Sublicense Income Share due hereunder not less than [***] days prior to the proposed date of review of Licensee's records by Penn's auditors. Should the auditor find any underpayment of Milestones, Royalties or Penn Sublicense Income Share by Licensee, Licensee shall (a) promptly pay Penn the amount of such underpayment; and (b) reimburse Penn for the cost of the audit, if such underpayment equals or exceeds [***] of the total Milestones, Royalties and Penn Sublicense Income Share paid during the time period audited. If the auditor finds overpayment by Licensee, then Licensee shall have the right to deduct the overpayment from any future Milestones, Royalties or Penn Sublicense Income Share due to Penn by Licensee or, if no such future Milestones, Royalties or Penn Sublicense Income Share are payable, then Penn shall refund the overpayment to Licensee within [***] days after Penn receives the audit report. Licensee may designate competitively sensitive information which such auditor may see and review but which it may not disclose to Penn; provided, however, that such designation shall not restrict the auditor's investigation or conclusions.

4.11.2 Licensee, at its own cost, through an independent auditor reasonably acceptable to Penn (and who has executed an appropriate confidentiality agreement reasonably acceptable to Penn that requires the auditor to keep any information learned by it confidential except as needed to report its audit conclusions to Licensee), may inspect and audit only the relevant records of Penn pertaining to the costs and expenses incurred by and reduction of Royalties due to Penn under this Agreement. Penn shall provide such auditors with reasonable access to the records during reasonable business hours at mutually agreed upon times. Such access need not be given to any such set of records more often than once each year, not more frequently than once with respect to records covering any specific period of time and not more than [***] years after the date of any report to be audited. Licensee shall provide Penn with written notice of its election to inspect and audit such records not less than [***] days prior to the proposed date of review of Penn's records by Licensee's auditors. Should the auditor find any over reporting of costs and expenses or underreporting of reduction of Royalties, then Penn shall promptly issue to Licensee a credit against future payments due or, in the case that no future payments are expected, issue a refund, in each case, in the amount of such overpayment. If the auditor finds underpayment by Licensee to Penn, then Licensee shall pay the difference between the underpayment and the actual payment made for the relevant time period to Penn within [***] days after Licensee receives the audit report. Penn may designate competitively sensitive information which such auditor may see and review but which it may not disclose to Licensee; provided, however, that such designation shall not restrict the auditor's investigation or conclusions.

4.12 Withholdings.

4.12.1 Licensee may withhold from payments due to Penn amounts for payment of any withholding tax that is required by Law to be paid to any taxing authority with respect to such payments. Licensee will provide Penn all relevant documents and correspondence, and will also provide to Penn any other cooperation or assistance on a reasonable basis as may be necessary to enable Penn to claim exemption from such withholding taxes and to receive a refund of such withholding tax or claim a foreign tax credit. Licensee will give proper evidence from time to time as to the payment of any such tax. The Parties will cooperate with each other in seeking deductions under any double taxation or other similar treaty or agreement from time to time in force.

4.12.2 Apart from any such permitted withholding and those deductions expressly included in the definition of Net Sales, the amounts payable hereunder will not be reduced on account of any taxes, charges, duties or other levies.

ARTICLE 5

MANUFACTURING, CLINICAL DEVELOPMENT, REGULATORY AFFAIRS; COMMERCIALIZATION

- 5.1 **Clinical Development.** Licensee will have sole responsibility for and sole decision making over the clinical development of any Product arising from the Research Program in the Field. Notwithstanding the foregoing, if Licensee wishes to conduct clinical development of a Development Candidate at Penn and Penn has the clinical expertise, interest and ability to run such a trial as assessed at Penn's sole discretion, such a study will be conducted under a separate Clinical Trial Agreement to be negotiated by the Parties prior to initiation of such study. Such separate clinical trial agreement will include a detailed clinical development plan, including costs and time lines for conducting the Clinical Trial.
- 5.2 **Commercialization.** Licensee will have sole responsibility for and sole decision making over all commercialization activities of Products arising from the Research Program in the Field, and will be solely responsible for the associated costs of such commercialization activities.
- 5.3 **Manufacturing.** Except as otherwise provided in this Agreement or in the Research Plan, Licensee will be responsible for all manufacturing activities and associated costs to support the clinical development (including GMP manufacturing for Clinical Trials) of the Products developed under the Research Program, and commercialization of the Products for Licensed Indications arising from the Research Program. Any transfer of materials in support of the manufacturing activities will be managed in accordance with Section 2.5 of this Agreement. Any manufacturing activities conducted under this Agreement (including manufacturing activities conducted by or on behalf of Licensee, or Licensee's fully-owned Affiliate, BioNTech Innovative Manufacturing Services GmbH) will be done at Licensee's sole cost and expense.
- 5.4 **Regulatory.**
- 5.4.1 It is anticipated that Licensee (or any Sublicensee) will be the regulatory sponsor for Clinical Trials, and in such instance Licensee (or any Sublicensee) will: (a) have responsibility for all regulatory activities for the Products arising from the Research Program in the Field; (b) have the right to conduct all communications with Regulatory Authorities, including all meetings, conferences and discussions (including advisory committee meetings), with regard to Products arising from the Research Program in the Field; (c) lead and have control over preparing and submitting all regulatory filings related to the Products arising from the Research Program in the Field, including all applications for Regulatory Approval (provided, however, that Licensee shall provide Penn with copies of all such applications made by Licensee prior to submission; for the avoidance of doubt, this bracket shall not apply to applications made by Sublicensees); and (d) own any and all applications for Regulatory Approvals (including INDs), Regulatory Approvals, and other regulatory filings related to the Product arising from the Research Program in the Field which will be held in the name of Licensee or its designees. Notwithstanding any of the foregoing, for Clinical Trials conducted at and solely by Penn, the JSC may decide that the applications for Regulatory Approvals (including INDs), Regulatory Approvals, and other regulatory filings related to the Product arising from the Research Program will be owned by, and held in the name of, Penn.

5.4.2 At the discretion of Licensee, Penn shall have the right to participate as an observer in all material meetings, conferences, and discussions by Licensee with Regulatory Authorities pertaining to Development of the corresponding Products and Regulatory Approvals, provided that such right shall expire with respect to each Product upon the submission of an IND for such Product (the period of time during which Penn may participate in such meetings, conferences and discussions, the “**Observer Period**”). During the Observer Period, Licensee shall provide Penn with reasonable advance notice of all such meetings and other contact and shall provide advance copies of all related documents and other relevant information relating to such meetings or other contact, including any documents that Licensee proposes to submit to any Regulatory Authority. During any meetings with Regulatory Authorities, which shall be at Licensee’s expense, Penn shall not initiate any interactions with any Regulatory Authority and will only communicate with a Regulatory Authority if (a) such Regulatory Authority asks a question of Penn or (b) Licensee instructs Penn to communicate with such Regulatory Authority. For the avoidance of doubt, this Section 5.4.2 shall not apply to any regulatory activities of any Sublicensee.

5.5 General Diligence.

5.5.1 **General Diligence.** Licensee will use Commercially Reasonable Efforts to clinically develop, obtain Regulatory Approval and commercialize at least one (1) Product for each Licensed Indication selected by Licensee pursuant to Section 2.7 (“**General Diligence**”).

5.5.2 **Diligence Events.** Licensee, itself and/or through its Affiliates, Sublicensees or Third Party subcontractors, shall achieve each Diligence Event set forth in the table below by the corresponding Achievement Date (each a “**Diligence Event**”) for the first Product for each Licensed Indication. [***]

Diligence Event for each Licensed Indication, on a Licensed Indication-by-Licensed Indication basis	Achievement Date
[***]	[***]

5.5.3 Penn’s sole and exclusive remedy with respect to Licensee’s failure to comply with its obligations under this Section 5.5 shall be its right to terminate this Agreement on an Indication-by-Indication basis with respect to the Licensed Indication for which a Diligence Event or General Diligence has not been achieved, upon written notice to Licensee.

5.5.4 Returned Indications

(a) [***]

(b) If Licensee exercises its option to enter into such collaboration and/or license with Penn, the financial terms of this Agreement shall apply to such collaboration or license, provided that each Development Milestone in Section 4.3.2 shall be increased by [***]. In addition, the Royalty under Section 4.4.1 shall be increased by [***] provided that at least [***] patients have been dosed in a Phase 1 Study that has been initiated for the Product. In addition, Licensee shall pay Penn [***] of the development costs for the

development of the Product for the Indication incurred by Penn since the termination of the license for such Indication pursuant to Section 5.5.3 or the decision by Licensee not to elect such Indication as a Licensed Indication pursuant to Section 2.7.

- (c) If Licensee does not exercise its option, Penn shall be free to enter into any agreement with a Third Party regarding such Product for the Indication. For agreements entered into by Penn within the first [***] after an Indication becomes a Returned Indication, Penn will pay Licensee [***] of the Net Revenue Penn receives in such sublicensing transaction for any Product for such Returned Indication.

5.6 **Progress Reports.**

5.6.1 Licensee, on an annual basis, but in no event later than December 1st of each Calendar Year, shall submit to Penn a progress report (each, a “**Progress Report**”) covering Licensee’s (and any Affiliates’ and Sublicensees’) activities related to the development of all Products and the obtaining of Governmental Approvals necessary for commercialization of Products.

5.6.2 Each Progress Report must include all of the following for each annual period:

- (a) Summary of work completed;
- (b) Summary of work in progress;
- (c) Current schedule of anticipated events or milestones;
- (d) An updated SDR report listing of any and all Third Party Sublicenses granted by Licensee; and
- (e) The names and addresses of all Sublicensees, and a current and valid phone number and e-mail address for a principal point of contact at each such Sublicensee who is responsible for administering the Sublicensee.

ARTICLE 6 **INTELLECTUAL PROPERTY**

6.1 **Ownership and Inventorship.**

6.1.1 **Penn Intellectual Property.** Penn will be the sole owner of all Penn Foreground IP and will retain all right, title and interest in and to the Penn Background IP, Penn Foreground IP and Penn Materials, subject to the rights and licenses granted to Licensee set forth herein.

6.1.2 **Licensee Intellectual Property.** Licensee will be the sole owner of all BioNTech Foreground IP and will retain all right, title and interest in and to all BioNTech Background IP, BioNTech Foreground IP and BioNTech Materials, subject to the rights and licenses granted to Penn set forth herein.

6.1.3 **Joint Intellectual Property.** All Joint Foreground IP will be jointly owned by the Parties.

6.1.4 **Inventorship.** Inventorship shall be determined in accordance with United States patent laws with ownership following inventorship.

6.2 **Patent Filing Prosecution and Maintenance.**

6.2.1 **Penn Background Patents and Penn Foreground Patents.** Penn Background Patents and Penn Foreground Patents will be held in the name of Penn. Penn shall have the first right, but not the obligation, to control the preparation, filing, prosecution and maintenance of Penn Background Patents and Penn Foreground Patents subject to the provisions of this Section 6.2.1:

- (a) The filing, prosecution and maintenance of any Penn Background Patents and Penn Foreground Patents shall be made by a qualified patent counsel selected by Penn and reasonably acceptable to Licensee, taking also the costs into account ("**Penn Patent Counsel**").
- (b) Penn shall (through the Penn Patent Counsel) (i) provide Licensee with written notice as early as possible in advance of undertaking to prepare, file, prosecute and maintain any Patent Rights for any Penn Background Patents or Penn Foreground Patents, (ii) provide Licensee with any draft patent application to be filed by Penn as early as reasonably possible in advance of filing and use reasonable efforts to incorporate all reasonable comments by Licensee thereon; (iii) provide Licensee with any patent application filed by Penn after such filing; (iv) provide Licensee with copies of all substantive communications received from or filed in patent office(s) with respect to such filings and use reasonable efforts to incorporate all reasonable comments by Licensee thereon; (v) notify Licensee of any interference, opposition, reexamination request, nullity proceeding, appeal or other interparty action, review it with Licensee as reasonably requested, and use reasonable efforts to incorporate all reasonable comments by Licensee thereon; and (vi) provide Licensee with written notice at least [***] days prior to abandoning or forfeiting any such Patent Rights, to permit Licensee to undertake such filing, prosecution and/or maintenance without a loss of rights.
- (c) In the event that Penn provides Licensee with the written notice described in sub-section (b)(vi) above, prior to abandoning or forfeiting any such Patent Rights, Licensee shall have the option, exercisable by delivery to Penn of written notice thereof within [***] days thereafter, to assume the right (but not the obligation), at its sole expense and sole discretion, to control the preparation, filing, prosecution and maintenance of such Patent Rights. If Licensee timely exercises such option, then with respect to such Patent Rights, (i) Licensee shall thereafter assume the rights and obligations attributed to Penn under sub-section (b) above, and (ii) Penn shall thereafter assume the rights and obligations attributed to Licensee under sub-section (b) above.

6.2.2 **Joint Foreground Patents.** Licensee shall have the first right, but not the obligation, to control the preparation, filing, prosecution and maintenance of any Joint Foreground Patents subject to the provisions of this Section 6.2.2:

- (a) The filing, prosecution and maintenance of any Joint Foreground Patents shall be made by a qualified patent counsel selected by Licensee and reasonably acceptable to Penn ("**Licensee Patent Counsel**").
- (b) Licensee shall (through Licensee Patent Counsel) (i) provide Penn with written notice as early as possible in advance of undertaking to prepare, file, prosecute and maintain any Patent Rights for any Joint Foreground Patents, (ii) provide Penn with any draft of patent application to be filed by Licensee as early as reasonably possible in advance of

filing and incorporate all reasonable comments by Penn thereon; (iii) provide Penn with any patent application filed by Licensee after such filing; (iv) provide Penn with copies of all substantive communications received from or filed in patent office(s) with respect to such filings and incorporate all reasonable comments by Penn thereon; (v) notify Penn of any interference, opposition, reexamination request, nullity proceeding, appeal or other interparty action, review it with Penn as reasonably requested, and incorporate all reasonable comments by Penn thereon; and (vi) provide Penn with written notice at least [***] days prior to abandoning or forfeiting such Patent Rights, sufficiently in advance to permit Penn to undertake such filing, prosecution and/or maintenance without a loss of rights.

- (c) In the event that Licensee provides Penn with the written notice described in sub-section (b)(vi) above, prior to abandoning, or forfeiting any such Patent Rights, Penn shall have the option, exercisable by delivery to Licensee of written notice thereof within thirty (30) days thereafter, to assume the right (but not the obligation), at its sole expense and sole discretion, to control the preparation, filing, prosecution and maintenance of such Patent Rights. If Penn timely exercises such option, then with respect to such Patent Rights, the License to such Patent Rights will terminate, and Licensee shall have no rights, and Penn shall have no obligations, with respect to such Patent Rights.
- 6.2.3 **BioNTech Background Patents and BioNTech Foreground Patents.** Licensee shall have the sole right, but not the obligation, to control the preparation, filing, prosecution and maintenance of BioNTech Background Patents and BioNTech Foreground Patents at its sole cost and expense and at its sole discretion.
- 6.2.4 **Clarification.** For the purposes of Section 6.2.1 to 6.2.3, “maintenance” of Patent Rights includes interference proceedings, re-examinations, inter parties patent review proceedings before the USPTO or a similar patent administration outside the US (including opposition proceedings at the EPO). For further clarity, validity challenges raised in infringement litigation will be handled per Section 6.4.
- 6.2.5 **Patent Term Extensions.** Penn will have the exclusive right to decide whether to elect and file for patent term restoration or extension, supplemental protection certificate or any of their equivalents with respect to Penn Background Patents and Penn Foreground Patents in the Territory where Licensee is not the only licensee for such Penn Background Patents or Penn Foreground Patents, and Licensee will have the exclusive right to decide whether to elect and file for patent term restoration or extension, supplemental protection certificate or any of their equivalents with respect to Penn Background Patents and Penn Foreground Patents in the Territory where Licensee is the only licensee for such Penn Patent Rights as well as any Joint Foreground Patents and shall, if required, direct Penn regarding such filings with respect to such Patent Rights. Penn will cooperate and follow all instructions received from Licensee with respect to electing and filing for such restoration or extension, supplemental protection certificate or the equivalent of any of the foregoing for Penn Background Patents and Penn Foreground Patents where Licensee is the only licensee as well as any Joint Foreground Patents.

6.3 Patent Costs.

- 6.3.1 **Historic Patent Costs.** Within [***] days of the Effective Date, Licensee will reimburse Penn an amount of [***] all unreimbursed out-of-pocket costs for the filing, prosecution and maintenance of Penn Background Patents and Option Patents, including all accrued attorney fees, expenses, official and filing fees (“**Patent Costs**”)

incurred prior to the Effective Date; provided, however, that if the Parties agree to include any additional Patent Rights to Exhibit B after the Effective Date, Licensee will reimburse Penn for all unreimbursed Patent Costs that have been incurred by Penn as of the date that such additional Patent Rights are added to Exhibit B. If additional Penn Background Patents are added at a later time during the Term, Licensee will reimburse Penn for Patent Costs incurred by Penn prior to the date such additional Background Patents are added to the Agreement.

- 6.3.2 **Ongoing Patent Costs.** During the Term of this Agreement, Licensee will bear all Patent Costs incurred by either Penn or Licensee in connection with the preparation, filing, maintenance or prosecution of any Patent Rights under Section 6.2 and the Option Patents except for the Patent Costs incurred by Penn after Licensee has notified Penn of its abandonment or forfeiture of such Penn Foreground Patent or Joint Foreground Patent and the [***] day notice period has expired pursuant to Section 6.2.2(b)(vi) or Patent Costs incurred by Penn after expiration of the term of an unexercised Option for the Option Patents (“**Ongoing Patent Costs**”). Licensee will reimburse Penn for all Ongoing Patent Costs incurred by Penn in relation to Penn Background Patents and Penn Foreground Patents pursuant to Section 6.2.1 within [***] days of receipt of an invoice for such costs. In the event that Penn licenses any Penn Patent Right in a field separate from the Field to a Third Party, then, upon execution of such Third Party license agreement, Licensee’s Ongoing Patent Costs obligation will be a pro-rata portion of such Ongoing Patent Costs.
- 6.3.3 **Advance Payments.** At any time, at Penn’s request, Licensee shall pay in advance the Penn Patent Counsel’s estimated costs for undertaking material patent actions in relation to Penn Background Patents and Penn Foreground Patents before Penn authorizes the Penn Patent Counsel to proceed (“**Advance Payment**”). Notwithstanding whether Licensee makes an Advance Payment for any patent action, Licensee shall bear all Ongoing Patent Costs incurred during the Term in accordance with Section 6.3.2.
- 6.3.4 [***].

6.4 **Infringement.**

- 6.4.1 **Infringement Notice.** If either Party believes that an infringement by a Third Party with respect to any Penn Background Patents or any Foreground Patents is occurring or may potentially occur, the knowledgeable Party will provide the other Party with (a) written notice of such infringement or potential infringement (if enforcement action is intended, reasonably in advance of taking such enforcement action), and (b) evidence of such infringement or potential infringement (the “**Infringement Notice**”).
- 6.4.2 **Enforcement in the Field.** As between the Parties, Licensee will have the first right, under its sole control and at its sole expense, to institute suit against an infringer asserting patent infringement of any Penn Background Patent, any Penn Foreground Patents and any Joint Foreground Patents in the Field, provided that Penn has been appropriately notified in advance, and Penn has determined that Licensee is the sole licensee for such Patent Rights at the time when such enforcement action is to be initiated. If required by Law, Penn will permit any action under this Section 6.4.2 to be brought in its name, including being joined as a party-plaintiff, provided that Licensee will reimburse Penn for its documented out-of-pocket costs incurred in connection with such action. Licensee will have the right to settle any such action with Penn’s consent (such consent not to be unreasonably withheld or delayed). In the event that Penn provides an Infringement Notice to Licensee regarding an infringement of a Penn

Background Patent or Penn Foreground Patent in the Field and Licensee does not within [***] days of receipt of such notice abate the infringement or file suit to enforce such Penn Background Patent or Penn Foreground Patent, then Penn shall have the right to take any action reasonably appropriate to enforce such Penn Background Patent or Penn Foreground Patent, provided that (i) all such actions shall be closely coordinated with Licensee and (ii) Penn shall have no enforcement step-in right with respect to such Penn Background Patent or Penn Foreground Patent in the event that Licensee notifies Penn in advance of such enforcement action that Licensee does not wish to enforce such Penn Background Patent or Penn Foreground Patent for strategic reasons. If Penn has determined that Licensee is not the sole licensee for such Patent Rights at the time when such enforcement action is to be initiated, Penn shall have the first right, under its sole control and at its sole expense, to institute suit against an infringer asserting patent infringement of such Patent Rights, provided that all such enforcement actions shall be closely coordinated with Licensee.

- 6.4.3 **Enforcement of Penn Background Patents and Penn Foreground Patents outside the Field.** As between the Parties, Penn will have the first right, under its sole control and at its sole expense, to institute suit against an infringer asserting patent infringement of any Penn Background Patent and any Penn Foreground Patent outside the Field, provided that Licensee has been appropriately notified in advance and Licensee's reasonable comments have been taken into account by Penn. All such enforcement actions shall be reasonably coordinated with Licensee.
- 6.4.4 **Recoveries.** Any recovery or settlement received in connection with any suit will first be shared by Penn and Licensee equally to cover any litigation costs each incurred and next shall be paid to Penn or Licensee to cover any litigation costs it incurred in excess of the litigation costs of the other. Any remaining recoveries shall be allocated as follows:
- (a) for any suit that is initiated by Licensee with respect to infringement of any Penn Patent Right in the Field, Penn shall receive [***] (other than amounts attributable to enhanced damages for willful infringement) and the Licensee shall receive the remainder;
 - (b) for any suit that is initiated by Penn with respect to infringement of any Penn Patent Right, Penn shall receive [***] of the recovery; and
 - (c) for any portion of the recovery or settlement paid as enhanced damages for willful infringement, (a) for a suit that is initiated by a Party and the other Party voluntarily joins such suit, then the Parties shall share equally the enhanced damages, and (b) for any suit that is initiated by Licensee and Penn is not a party to the litigation, Penn shall receive [***] and Licensee shall receive the remainder.
- 6.4.5 **Cooperation.** Each Party will reasonably cooperate and assist with the other in litigation proceedings instituted hereunder but the Party who initiated the suit shall reimburse the cooperating Party for documented out-of-pocket expenses with respect to such cooperation. For clarity, such requirement does not require a Party to join a suit unless otherwise specifically required under this Agreement. If Penn is subjected to third party discovery related to the Penn Patent Rights or Licensed Products, Licensee will pay Penn's reasonable, documented out-of-pocket expenses with respect to same.
- 6.5 **Patent Marking.** Licensee shall place in a conspicuous location on any Licensed Product (or its packaging where appropriate and practicable) made or sold under this Agreement a patent notice in accordance with the Laws concerning the marking of patented articles where such Licensed Product is made or sold, as applicable.

ARTICLE 7
CONFIDENTIALITY & PUBLICATION

- 7.1 **Confidential Information.** Each Party shall use reasonable efforts to limit the disclosure of Confidential Information hereunder to the information that is required to be disclosed pursuant to the terms of this Agreement and that is reasonably necessary for either Party to fulfill its obligations and exercise its rights under this Agreement. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, the Parties agree that, during the Term and for [***] years thereafter, the receiving Party (the “**Receiving Party**”) and its Affiliates will keep confidential and will not publish or otherwise disclose or use for any purpose, other than as necessary to satisfy obligations or exercise rights under this Agreement, any confidential or proprietary information or materials, patentable or otherwise, in any form (written, oral, photographic, electronic, magnetic, or otherwise), including trade secrets, Know-How, inventions or discoveries, proprietary information, formulae, processes, techniques and information relating to the past, present and future marketing, financial, and research and development activities of any product or potential product or useful technology of the Disclosing Party or its Affiliates and the pricing thereof (collectively, “**Confidential Information**”), which is disclosed by or on behalf of such Party (the “**Disclosing Party**”) to the Receiving Party or its Affiliates or otherwise received or accessed by a Receiving Party in the course of performing its obligations or exercising its rights under this Agreement. The Parties agree that all Research Results generated under the Research Program solely by Licensee shall be regarded as Confidential Information of Licensee and treated by Penn accordingly. All other Research Results shall be treated as confidential by Penn and Licensee until publication in accordance with Section 7.4 below.
- 7.2 **Exceptions to Confidentiality.** “Confidential Information” does not include information that the Receiving Party can show (a) was in the lawful knowledge and possession of the Receiving Party or its Affiliates prior to the time it was disclosed to, or learned by, the Receiving Party or its Affiliates, or was otherwise developed independently by the Receiving Party or its Affiliates, as evidenced by written records kept in the ordinary course of business, or other documentary proof of actual use by the Receiving Party or its Affiliates; (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party or its Affiliates, as evidenced by written records of the Receiving Party or its Affiliates; (c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the Receiving Party or its Affiliates in breach of this Agreement; or (d) was disclosed to the Receiving Party or its Affiliates, other than under an obligation of confidentiality, by a Third Party who had no obligation to the Disclosing Party or its Affiliates not to disclose such information to others. In the event a Party is required to make a disclosure under Law or regulation, the order of a court of competent jurisdiction, or the rules of the U.S. Securities and Exchange Commission or any foreign equivalent (including by reason of any securities offering by Licensee), any stock exchange or listing entity, the Receiving Party shall be entitled to make such disclosure, provided that it provides prompt prior written notice to the Disclosing Party and takes all reasonable steps (including cooperating with the Disclosing Party in seeking to secure confidential treatment of, or otherwise limit, such Confidential Information required to be disclosed) to limit the extent of the disclosure and obtain confidential treatment for any remaining required disclosure.

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- 7.3 **Penn Intellectual Property.** In order to preserve the patentability of intellectual property and to preserve Penn's publication rights, each Party shall maintain Penn Patent Rights Foreground IP, BioNTech Background IP, Penn Background IP, Research Results and information provided pursuant to the Research Program (whether oral or written) as confidential and shall not disclose such information to any Third Party until the earlier of (i) publication of such information pursuant to the terms of this Agreement or (ii) with respect to intellectual property or Patent Rights Controlled by a Party pursuant to the terms of this Agreement, such Party's written confirmation that all desirable patentable inventions relating to such information have been protected.
- 7.4 **Publications.**
- 7.4.1 **Alignment of Publications in JSC.** The Parties will use commercially reasonable efforts to agree upon publications of Research Results or other information and material resulting from the Research Program in the JSC.
- 7.4.2 **Coordination of Publications.** Notwithstanding the above, Penn shall have the first right to publish Research Results generated by Penn. If either Party wishes to publish, present or otherwise disclose Research Results or other information and material resulting from the Research Program for any purpose, such Party shall furnish the other Party with a copy of any proposed publication, presentation or other disclosure at least [***] days in advance of the date of such presentation or disclosure or the submission of said proposed publication in order for the other Party to review and comment on said proposed publication, disclosure or presentation to (a) determine whether such contains any Confidential Information of the other Party and (b) enable the other Party to identify any intellectual property that it wishes to file patent applications on or to seek other intellectual property protection for. If within the [***] day review period (i) the other Party notifies publishing Party that it requires deletion from the publication, disclosure or presentation of its Confidential Information, the Parties will cooperate to modify the disclosure to ensure that Confidential Information of the other Party is not disclosed or (ii) if the other Party requests that publication or presentation be delayed to allow for patent filings or other intellectual property protection on certain items in the proposed publication, disclosure or presentation, the publishing Party shall delay the publication or presentation for up to [***] days, subject to reasonable extension as mutually agreed upon by the Parties, to allow for the filing of patent applications or other intellectual property protection.
- 7.4.3 **Naming of Other Party.** Either Party shall name the other Party as collaboration partner in accordance with good scientific practice in all of its publications, presentations or other disclosures relating to any Research Results or other information and material resulting from the Research Program.
- 7.5 **Other Permitted Disclosures.** Notwithstanding anything herein to the contrary, either Party may disclose Confidential Information of the other Party to (a) its Affiliates, and to its and their directors, employees, consultants, agents, licensees, sublicensees, collaborators, subcontractors, potential or actual investors, acquirers or merger partners (each a "**Representative**") in each case who have a need to know such Confidential Information, are bound by commercially reasonable obligations of confidentiality and such Party remains liable for any breach by such Representative of the non-disclosure and restrictions on use set forth in this Agreement and (b) the extent such disclosure is required to file or prosecute patent applications, prosecute or defend litigation, or to submit filings to Regulatory Authorities, provided, however, that in each case in this subsection (b), the prosecuting or filing Party shall provide to the other Party prior written notice of such disclosure.

ARTICLE 8
REPRESENTATIONS, WARRANTIES AND COVENANTS

- 8.1 **Mutual Representations and Warranties.** Each Party represents and warrants to the other Party that, as of the Effective Date:
- 8.1.1 such Party is duly organized and validly existing under the Laws of the jurisdiction of its incorporation or organization;
 - 8.1.2 such Party has taken all action necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement;
 - 8.1.3 this Agreement is a legal and valid obligation of such Party, binding upon such Party and enforceable against such Party in accordance with the terms of this Agreement, except as enforcement may be limited by applicable bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other laws relating to or affecting creditors' rights generally and by general equitable principles; and
 - 8.1.4 such Party has all right, power and authority to enter into this Agreement and to perform its obligations under this Agreement without violating any prior agreements or legal obligations.
- 8.2 **Penn Representations.** Penn represents to Licensee that, as of the Effective Date:
- 8.2.1 it has not granted any commercial license to any Third Party under any of the Penn Background Patents in the Field;
 - 8.2.2 to the knowledge of the current staff of the Penn Center for Innovation, Penn has not received any claim in writing from any Third Party contesting the validity, enforceability, licensability, use, or ownership of any Penn Background Patents;
 - 8.2.3 [***]; and
 - 8.2.4 [***].
- 8.3 **Disclaimer of Representations and Warranties.**
- 8.3.1 Other than the representations and warranties provided in Sections 8.1 and 8.2 above, NEITHER PENN NOR LICENSEE MAKES ANY REPRESENTATIONS OR WARRANTIES, WHETHER EXPRESS OR IMPLIED, AND PENN AND LICENSEE EACH EXPLICITLY DISCLAIMS ANY REPRESENTATION AND WARRANTY, INCLUDING WITH RESPECT TO ANY ACCURACY, COMPLETENESS, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, COMMERCIAL UTILITY, NON-INFRINGEMENT OR TITLE FOR THE INTELLECTUAL PROPERTY, PATENT RIGHTS, LICENSE AND ANY LICENSED PRODUCT.
 - 8.3.2 Furthermore, nothing in this Agreement will be construed as:
 - (a) A representation or warranty by Penn as to the validity or scope of any Penn Patent Right;

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- (b) A representation or warranty that anything made, used, sold or otherwise disposed of under the License is or will be free from infringement of patents, copyrights, trademarks or any other forms of intellectual property rights or tangible property rights of Third Parties;
- (c) Obligating Penn to bring or prosecute actions or suits against Third Parties for patent, copyright or trademark infringement; and
- (d) Conferring by implication, estoppel or otherwise any license or rights under any Patent Rights of Penn other than Penn Patent Rights as defined herein, regardless of whether such Patent Rights are dominant or subordinate to Penn Patent Rights.

8.4 Mutual Covenants.

- 8.4.1 Licensee and its Affiliates will not, directly or indirectly (including where such is done by a Third Party on behalf of Licensee or its Affiliates, at the urging of Licensee or its Affiliates or with the assistance of the Licensee or its Affiliates) challenge the validity, scope, or enforceability of or otherwise oppose any Penn Patent Right, [***].
- 8.4.2 Both Parties will comply with all Laws that apply to its activities or obligations under this Agreement. For example, both Parties will comply with applicable United States export laws and regulations. The transfer of certain technical data and commodities may require a license from the applicable agency of the United States government and/or written assurances by the relevant Party that such Party will not export data or commodities to certain foreign countries without prior approval of the agency.
- 8.4.3 Licensee will not grant a security interest in the License or this Agreement without Penn's prior written consent. [***].

ARTICLE 9

INDEMNIFICATION; INSURANCE AND LIMITATION OF LIABILITY

9.1 Indemnification.

- 9.1.1 **Indemnification by Licensee.** Licensee shall defend, indemnify and hold Penn and its respective trustees, officers, faculty, students, employees, contractors and agents (the "**Penn Indemnitees**") harmless from and against any and all liability, damage, loss, cost or expense (including reasonable attorneys' fees), including, without limitation, bodily injury, risk of bodily injury, death and property damage to the extent arising out of Third Party claims or suits related to:
 - (a) the gross negligence, recklessness or wrongful intentional acts or omissions of Licensee, its Affiliates or Sublicensees and its or their respective directors, officers, employees and agents, in connection with Licensee's performance of its obligations or exercise of its rights under this Agreement;
 - (b) any breach of this Agreement by Licensee (including violation of the representations and warranties set forth in Section 8.1); or
 - (c) any violation of Law by Licensee or its Affiliates or Sublicensees; or

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- (d) the development, manufacturing or commercialization (including commercial manufacturing, packaging and labeling of Products, and all product liability losses) of a Product by or on behalf of Licensee or its Affiliates or Sublicensees; or
- (e) the use of licensed Penn Know-How or Penn Materials in the development, manufacturing or commercialization (including commercial manufacturing, packaging and labeling of Products) by or on behalf of Licensee or its Affiliates or Sublicensees; or
- (f) the use of BioNTech Background IP, Penn Background IP, any Foreground IP or Research Results by or on behalf of Licensee or its Affiliates or Sublicensees; or
- (g) any enforcement action or suit brought by Licensee against a Third Party for infringement of Penn Patent Rights or any Joint Foreground Patent;

provided that Licensee's obligations pursuant to this Section 9.1 shall not apply to the extent such claims or suits result from the gross negligence or willful misconduct of any of Penn Indemnitees.

- 9.1.2 As a condition to a Penn Indemnitee's right to receive indemnification under this Section 9.1, Penn shall: (a) promptly notify Licensee as soon as it becomes aware of a claim or suit for which indemnification may be sought pursuant hereto; (b) reasonably cooperate, and cause the individual Penn Indemnitees to reasonably cooperate, with Licensee in the defense, settlement or compromise of such claim or suit; and (c) permit the Licensee to control the defense, settlement or compromise of such claim or suit, including the right to select defense counsel. In no event, however, may Licensee compromise or settle any claim or suit in a manner which (i) admits fault or negligence on the part of Penn or any other Penn Indemnitee; (ii) commits Penn or any other Penn Indemnitee to take, or forbear to take, any action, without the prior written consent of Penn, or (iii) grant any rights under the Penn Patent Rights except for Sublicenses permitted under Article 3. Penn shall reasonably cooperate with Licensee and its counsel in the course of the defense of any such suit, claim or demand, such cooperation to include without limitation using reasonable efforts to provide or make available documents, information and witnesses.
- 9.1.3 Notwithstanding Section 9.1.2 above, in the event that Penn believes in good faith that a bona fide conflict exists between Licensee and Penn or any other Penn Indemnitee with respect to a claim or suit subject to indemnification hereunder, then Penn or any other Penn Indemnitee shall have the right to defend against any such claim or suit itself at its own expense, including by selecting its own counsel.

9.2 Insurance.

- 9.2.1 Licensee, at its sole cost and expense, must insure its activities in connection with the exercise of its rights under this Agreement and obtain, and keep in force and maintain Commercial Form General Liability Insurance (contractual liability included) with limits as follows:

- (a) Each occurrence [***]
- (b) General aggregate [***]

Prior to the commencement of Clinical Trials, if applicable, involving Product:

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- (c) Clinical trials liability insurance [***]

Prior to the First Commercial Sale of a Product:

- (d) Products liability insurance [***]

The Parties may review periodically the adequacy of the minimum amounts of insurance for each coverage required by this Section 9.2.1, and adjust the limits in the Parties' reasonable discretion but in no event will Licensee be required to increase such limits beyond the limits of insurance carried by similarly-situated companies.

- 9.2.2 Licensee expressly understands that the coverages and limits in Section 9.2.1 do not in any way limit Licensee's liability of indemnification obligations.

- 9.2.3 Upon request by Penn but not to exceed once per year, Licensee must furnish to Penn with valid certificate of insurance evidencing compliance with all requirements of this Agreement.

- 9.3 **LIMITATION OF LIABILITY.** IN NO EVENT SHALL EITHER PARTY OR ANY OF ITS AFFILIATES BE LIABLE TO THE OTHER PARTY OR ANY OF ITS AFFILIATES FOR SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, INCLUDING LOSS OF PROFITS, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE ARISING OUT OF OR RELATING TO THIS AGREEMENT, THE TRANSACTIONS CONTEMPLATED HEREIN OR ANY BREACH HEREOF. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS AGREEMENT SHALL LIMIT EITHER PARTY'S INDEMNIFICATION OBLIGATIONS UNDER SECTION 9.1 ABOVE.

ARTICLE 10 TERM AND TERMINATION

- 10.1 **Term.** The term of this Agreement (the "**Term**") shall commence on the Effective Date and, unless terminated sooner as provided below, shall continue in full force and effect until the expiration or abandonment of the last Penn Patent Right covering any Development Candidate or Licensed Product in the Field. [***].
- 10.2 **Termination of the Agreement for Convenience.** At any time during the Term beginning [***] months after the Effective Date, Licensee may, at its convenience, terminate this Agreement, entirely or in relation to one or more Indications only, upon providing at least [***] days prior written notice to Penn of such intention to terminate, and provided that Licensee ceases using the License or making, using, or selling Products in relation to the Indications that have been terminated.
- 10.3 **Termination For Cause.**
- 10.3.1 If either Party materially breaches any of its material obligations under this Agreement, the non-breaching Party may give to the breaching Party a written notice specifying the nature of the default, requiring the breaching Party to cure such breach, and stating the non-breaching Party's intention to terminate this Agreement. If such breach is not cured within ninety (90) days of such notice, such termination shall become effective with respect to the relevant Indication(s) upon a notice of termination by the terminating Party thereafter.

10.3.2 Either Party may terminate this Agreement, upon written notice, with immediate effect if, at any time, the other Party is unable to pay its debts, including any debts related to exclusive sublicensees, when they come due, or files in any court or agency pursuant to any statute or regulation of any state, country or jurisdiction, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of the other Party or of its assets, or if the other Party proposes a written agreement of composition or extension of its debts, or if the other Party is served with an involuntary petition against it, filed in any insolvency proceeding, and such petition is not dismissed within ninety (90) days after the filing thereof, or if the other Party proposes or is a party to any dissolution or liquidation, or if the other Party makes an assignment for the benefit of its creditors of all or substantially all its assets.

10.4 Effects of Termination.

10.4.1 In the event of any expiration of this Agreement pursuant to Section 10.1, the following provisions shall survive: [***] All other provisions set forth in this Agreement shall terminate upon expiration of this Agreement.

10.4.2 In the event of any termination by Licensee pursuant to Section 10.2 or by Penn pursuant to Section 10.3, the following provisions shall survive: [***] All other provisions set forth in this Agreement shall terminate upon termination of this Agreement.

10.4.3 In the event of any termination of this Agreement by Licensee pursuant to Section 10.3, the following provisions shall survive: Sections [***] All other provisions set forth in this Agreement shall terminate upon termination of this Agreement.

10.4.4 Termination or expiration of this Agreement shall not relieve the Parties of any obligation or liability that, at the time of termination or expiration, has already accrued hereunder, or which is attributable to a period prior to the effective date of such termination or expiration. Termination or expiration of this Agreement shall not preclude either Party from pursuing all rights and remedies it may have hereunder or at Law or in equity with respect to any breach of this Agreement nor prejudice either Party's right to obtain performance of any obligation.

10.4.5 If this Agreement is terminated for any reason, all outstanding Sublicenses (including all Sublicense Documents for each Sublicense) not in default will be assigned by Licensee to Penn, and such assignment will be accepted by Penn. Each assigned Sublicense will remain in full force and effect with Penn as the licensor or sublicensor instead of Licensee, but the duties and obligations of Penn under the assigned Sublicenses will not be greater than the duties of Penn under this Agreement, and the rights of Penn under the assigned Sublicenses will not be less than the rights of Penn under this Agreement, including all financial consideration and other rights of Penn. Penn may, at its sole discretion, amend such outstanding Sublicenses to contain the terms and conditions found in this Agreement.

10.4.6 Within [***] days of termination of this Agreement by Licensee pursuant to pursuant to Section 10.2 with respect to any Indication(s), Licensee shall pay Penn all costs not previously paid and attributable solely to the terminated Indication(s) through the effective termination date per the budget of the Research Plan for services performed by, or on behalf of, Penn, as well as all commitments related to the performance of the

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Research Plan for such Indication(s) that are reflected in the budget (i.e., all costs or non-cancellable commitments incurred prior to the receipt, or issuance, by Penn of the notice of termination, and the cost of each employee, student and faculty member supported under the Research Plan for such Indication until the earlier of (a) [***] days of termination of this Agreement and (b) reassignment of such employee, student and faculty member supported under the Research Plan; and subject to Penn's written notification to Licensee and Licensee's acknowledgement of all costs and non-cancellable commitments as they arise) incurred by Penn under this Agreement for the terminated Indication(s), as applicable.

10.4.7 Upon termination pursuant to Section 10.2 or Section 10.3, Licensee and its Affiliates will promptly cease selling the Product(s) in the Indications subject to such termination. Each Party will return (or destroy, as directed by the other Party) all data, files, records and other materials containing or comprising the other Party's Confidential Information with respect to Product(s) in the Indications subject to such termination, except to the extent such Confidential Information is necessary or useful to conduct activities in connection with surviving portions of this Agreement. Notwithstanding the foregoing, the Parties will be permitted to retain one copy of such data, files, records, and other materials for archival and legal compliance purposes.

10.5 **Tolling.** [***].

ARTICLE 11 ADDITIONAL PROVISIONS

11.1 **Relationship of the Parties.** Nothing in this Agreement is intended or shall be deemed, for financial, tax, legal or other purposes, to constitute a partnership, agency, joint venture or employer-employee relationship between the Parties. The Parties are independent contractors and at no time will either Party make commitments or incur any charges or expenses for or on behalf of the other Party.

11.2 **Expenses.** Except as otherwise provided in this Agreement, each Party shall pay its own expenses and costs incidental to the preparation of this Agreement and to the consummation of the transactions contemplated hereby

11.3 **Third Party Beneficiary.** The Parties agree that each Sublicensee is a third party beneficiary of this Agreement with respect to Section 10.4.4.

11.4 **Use of Names.**

11.4.1 Licensee, its Affiliates and Sublicensees may not use the name, logo, seal, trademark, or service mark (including any adaptation of them) of Penn or any Penn school, organization, employee, student or representative, without the prior written consent of Penn. Notwithstanding the foregoing, Licensee may use the name of Penn in a non-misleading and factual manner solely in (a) executive summaries, business plans, offering memoranda and other similar documents used by Licensee for the purpose of raising financing for the operations of Licensee, or entering into commercial contracts with Third Parties, but in such case only to the extent necessary to inform a reader that the Penn Patent Rights have been licensed by Licensee from Penn, and to inform a

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reader of the identity and published credentials of inventors of intellectual property, and (b) any securities reports required to be filed with the US Securities and Exchange Commission or any foreign equivalent.

- 11.4.2 Penn will not use Licensee's name without Licensee's prior written consent except that Penn may (a) acknowledge Licensee's funding of the Research Program, (b) use Licensee's name in connection with any scientific contributions in scientific publications and in listings of sponsored research projects as well as required under Section 7.4.3, (c) use Licensee's name as required by Law, and (d) use Licensee's name in connection with institutional compliance policies; provided that, Penn shall not use Licensee's name for publicity purposes without Licensee's prior written consent.
- 11.5 **No Discrimination.** Neither Penn nor Licensee will discriminate against any employee or applicant for employment because of race, color, sex, sexual or affectional preference, age, religion, national or ethnic origin, handicap, or veteran status.
- 11.6 **Successors and Assignment.**
- 11.6.1 The terms and provisions hereof shall inure to the benefit of, and be binding upon, the Parties and their respective successors and permitted assigns.
- 11.6.2 Neither Party may not assign or transfer this Agreement or any of its rights or obligations created hereunder, by operation of law or otherwise, without the prior written consent of the other Party, provided that the other Party shall not unreasonably withhold, condition or delay its consent; provided, however, that each Party may assign this Agreement to any Affiliate of such Party or to any entity with which such Party merges or consolidates, or to which it sells or transfers all of its stock or all or substantially all of its assets to which this Agreement relates without the other Party's consent ("**Permitted Assignment**"). For any Permitted Assignment, the assigning Party will provide the other Party with notice of such assignment containing at minimum the contact information of the assignee within [***] days after closing of such Permitted Assignment, and such Permitted Assignment shall be in accordance with this Section 11.6.
- 11.6.3 Any assignment not in accordance with this Section 11.6 shall be void.
- 11.7 **Further Actions.** Each Party agrees to execute, acknowledge and deliver such further instruments and to do all such other acts as may be necessary in order to carry out the purposes and intent of this Agreement.
- 11.8 **Entire Agreement of the Parties; Amendments.** This Agreement and the Exhibits and Appendices or Schedules hereto constitute and contain the entire understanding and agreement of the Parties respecting the subject matter hereof and cancel and supersede any and all prior negotiations, correspondence, understandings and agreements between the Parties, whether oral or written, regarding such subject matter. No waiver, modification or amendment of any provision of this Agreement shall be valid or effective unless made in a writing referencing this Agreement and signed by a duly authorized officer of each Party.

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- 11.9 **Governing Law.** This Agreement shall be governed by and interpreted in accordance with the laws of the [***], excluding application of any conflict of laws principles that would require application of the law of a jurisdiction outside of the [***].
- 11.10 **Dispute Resolution.** If a dispute arises between the Parties concerning this Agreement, then the Parties will confer, as soon as practicable, in an attempt to resolve the dispute.
- (a) The Parties shall attempt in good faith to resolve any dispute arising out of or relating to this Agreement promptly by negotiation between senior individuals who have the authority to settle the controversy. Either Party may give the other Party written notice of a dispute not resolved in the normal course of business. If the matter has not been resolved by these persons within [***] days of a disputing Party's notice, the dispute shall be referred to a more senior individual of the Parties with the decision-making authority for resolution. If the dispute is not resolved within [***] days from the referral to a more senior individual the parties will have no further obligation under this Section 11.10(a).
- (b) With respect to any claim or controversy that has not been resolved under 11.10(a), the Parties will consider in good faith whether to enter into an agreement to resolve any such claim or controversy by mediation under the International Institute for Conflict Prevention & Resolution ("CPR") Mediation Procedure then currently in effect. Unless otherwise mutually agreed, any such mediation shall be held in New York City. Such agreement may provide that (a) the mediator would be selected from the CPR Panels of Distinguished Neutrals and (b) if any such claim or controversy remains unresolved [***] days after the appointment of a mediator or [***] days after good faith efforts by either Party to proceed to mediation, the Parties shall discuss in good faith whether to submit the dispute to binding arbitration in accordance with the arbitration rules of the International Chamber of Commerce (ICC) ("**Arbitration Rules**"). In such case, the arbitration shall be conducted in the English language in London, United Kingdom, by one arbitrator appointed in accordance with the Arbitration Rules. The arbitrator, by accepting appointment, undertakes to exert their best efforts to conduct the process so as to issue an award within [***] of the appointment of the arbitrator. The arbitrator shall decide the dispute in accordance with the law governing this Agreement. The procedural rules of the seat of the arbitration tribunal shall not apply; no discovery proceedings shall take place, unless the Parties otherwise agree in writing.
- (c) However, absent a separate agreement concerning mediation and/or an agreement of the Parties to submit any dispute to binding arbitration, each Party shall remain free to enforce its rights in a court of law, and the Parties agree that such dispute shall be litigated in the United States District Court for the Southern District of New York, or in the state courts of the State of New York, New York County, and each Party hereby irrevocably submits to the exclusive jurisdiction of such courts for all purposes with respect to any such legal action or proceeding in connection with this Agreement and subject to this Section 11.10.
- 11.11 **Injunctive Relief.** Notwithstanding anything herein to the contrary, in the event of an actual or threatened breach of this Agreement, the aggrieved Party may seek provisional equitable relief (including restraining orders, specific performance or other injunctive relief).
- 11.12 **Notices and Deliveries.** Any notice, request, approval or consent required or permitted to be given under this Agreement shall be in writing and directed to a Party at its address shown below or such other address as such Party shall have last given by notice to the other Party. A

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notice will be deemed received: if delivered personally, on the date of delivery; if mailed, five (5) days after deposit in the United States mail or if sent via courier, one (1) business day after deposit with the courier service.

For Penn
[***]

with a copy to:
[***]

- 11.13 **Waiver.** A waiver by either Party of any of the terms and conditions of this Agreement in any instance shall not be deemed or construed to be a waiver of such term or condition for the future, or of any other term or condition hereof. All rights, remedies, undertakings, obligations and agreements contained in this Agreement shall be cumulative and none of them shall be in limitation of any other remedy, right, undertaking, obligation or agreement of either Party.
- 11.14 **Severability.** When possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under law, but if any provision of this Agreement is held to be prohibited by or invalid under law, such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement. The Parties shall make a good faith effort to replace the invalid or unenforceable provision with a valid one which in its economic effect is most consistent with the invalid or unenforceable provision.
- 11.15 **Interpretation.** The words “include,” “includes” and “including” shall be deemed to be followed by the phrase “without limitation”. All references herein to Articles, Sections, Schedules and Exhibits shall be deemed references to Articles and Sections of, Schedules and Exhibits to, this Agreement unless the context shall otherwise require. “Herein,” “hereby,” “hereunder,” “hereof” and other equivalent words refer to this Agreement as an entirety and not solely to the particular portion of this Agreement in which any such word is used. The term “or” means “and/or” hereunder. All definitions set forth herein will be deemed applicable whether the words defined are used herein in the singular or the plural. Except as otherwise expressly provided herein, all terms of an accounting or financial nature shall be construed in accordance with Accounting Standards, as in effect from time to time. Unless the context otherwise requires, countries shall include territories. References to any specific Law or article, section or other division thereof, shall be deemed to include the then-current amendments or any replacement Law thereto.
- 11.16 **Counterparts.** This Agreement may be executed in counterparts, each of which will be deemed an original, and all of which together will be deemed to be one and the same instrument. A facsimile or a portable document format (PDF) copy of this Agreement, including the signature pages, will be deemed an original.

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11.17 **Force Majeure.** Neither Party will be liable for any failure to perform as required by this Agreement to the extent such failure to perform is due to circumstances reasonably beyond such Party's control, including, without limitation, labor disturbances or labor disputes of any kind, accidents, failure of any governmental approval required for full performance, civil disorders or commotions, terrorism, acts of aggression, acts of God, energy or other conservation measures imposed by law or regulation, explosions, failure of utilities, mechanical breakdowns, material shortages, disease, or other such occurrences.

[SIGNATURE PAGE FOLLOWS]

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IN WITNESS WHEREOF, duly authorized representatives of the Parties have executed this Agreement as of the Effective Date.

THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA

BIONTECH RNA PHARMACEUTICALS GmbH

By: [***]
Name: [***]
Title: [***]

By: [***]
Name: [***]
Title: [***]

**Read and Acknowledged by
Dr. Drew Weissman:**

[***]_____

[Signature Page to Collaboration & License Agreement]

Exhibit A
BioNTech Background Patents

[***]

Exhibit B
Penn Background Patents

[***]

Exhibit C
Research Program

Penn-BioNTech Vaccine Development Alliance Program

Initial Research Plan

General points that should be considered in plans:

- I am assuming that all vaccines will pass through toxicity testing without incident, based on macaque studies, use of similar lipids in Phase 3 trials, and physiologic nature of mRNA.
- We do not know the optimal dosing interval. This may need to be incorporated into each macaque study or could be done as a single study, whose results are used for all vaccines. Potentially, some of the vaccines could be a single injection.
- All of the Year 1 studies are underfunded, due to the limitation of 5 million dollars total, but all are currently ongoing with good potential to move into clinical trials. We would not want to delay any of them.
- The remaining 4 vaccines have not been selected. Discussions with BioNTech scientists and business advisors, as well as, the potential addition of a pharmaceutical partner, are needed.
- I believe a human experimental phase 1 clinical trial of LNPs, 3-5, empty or poly(C) containing, should be part of the selection criteria for LNPs to use for vaccination for all vaccine studies. While expensive, it would likely increase the success and reduce the toxicity observed in all vaccine trials that follow.

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Estimated timeline for vaccine development

[***]

* Potential pathogens for vaccine development but not included in initial Research Indications.

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[**]

Year 1

[**]

Year 2

[**]

Year 3

[**]

[Table of Contents](#)

[**]

Year 1

[**]

Year 2

[**]

Year 3

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[Table of Contents](#)

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Year 1

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Year 2

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Year 3

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Table of Contents

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Year 1

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Year 2

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Year 3

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[Table of Contents](#)

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Year 1

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Year 2

[**]

Year 3

[**]

Table of Contents

[**]

Year 2

[**]

Year 3

[**]

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Other potential programs need to be discussed with BioNTech to identify desired targets through the JSC. Potential pathogens may include:

[***]

Additional pathogens – many of these are currently under investigation with academic collaborators. Positive vaccine results would move them to the active investigation list either replacing a pathogen whose vaccine is not performing well or bumping a pathogen to later study.

Other potential pathogens that can be considered for vaccine development. Some studies are ongoing:

[***]

Exhibit D
Licensed Indications

None as of the Effective Date

Exhibit E
Research Indications

The initial Research Indications under the Agreement are:

[***]

Exhibit F
Option Patents

[***]

Exhibit G
Research Program Budget

Exhibit H
Material Transfer Terms

Penn agrees to provide certain Penn Materials to Licensee, and Licensee agrees to provide certain BioNTech Materials to Penn, under the following conditions:

1. The Penn Materials and the BioNTech Materials are considered proprietary to the providing Party. The providing Party shall be free, in its sole discretion, to distribute its proprietary Materials to others and to use such Materials for its own purposes, unless otherwise stated in the Agreement.
2. Materials provided by a Party may only be utilized for research by the receiving Party at the receiving Party's facility and the facility of any permitted third party. The receiving Party shall not distribute or release the other Party's Materials to any person other than laboratory personnel under the receiving Party's direct supervision, or other personnel and third parties permitted by the Agreement. The receiving Party shall ensure that no one will be allowed to take or send Materials received from the providing Party to any location in violation of the Agreement.
3. The transfer of Materials are for the receiving Party's use of the Materials solely for the performance of the Research Program, subject to the terms of the Agreement. Each Party agrees that nothing herein shall be deemed to grant any additional rights under any Patent Rights except to those contained in the Agreement and to the extent provided therein. Materials received from the providing Party will not be used by or on behalf of the receiving Party in research that is subject to consulting or licensing obligations to any Third Party, other than obligations to the U.S. government resulting from research that is funded by the U.S. government.
4. Each Party agrees to use Materials received from the providing Party in compliance with all laws and regulations, including current EPA, FDA, USDA, and NIH guidelines. All Materials are supplied solely for research purposes.
5. Neither Party shall have rights in the Materials received from the providing Party other than as provided in this Agreement, and at the request of the providing Party, the receiving Party will return all unused Materials received from the providing Party. It is understood that any and all proprietary rights, including Patent Rights, trademarks, and proprietary rights, in and to the Materials and replications or derivatives of the Materials shall be and remain in the providing Party, subject to the rights granted herein.
6. Materials will be considered Confidential Information of the providing Party, and subject to the terms of Article 7 of the Agreement.
7. Each Party acknowledges that Materials received from the providing Party are experimental in nature and they are provided WITHOUT WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER WARRANTY, EXPRESS OR IMPLIED. THE PROVIDING PARTY MAKES NO REPRESENTATION OR WARRANTY THAT THE USE OF THE MATERIALS WILL NOT INFRINGE ANY PATENT OR OTHER PROPRIETARY RIGHTS.
8. For clarity, the terms of this Exhibit H shall not be interpreted to limit any rights granted, or to grant any rights other than those granted, elsewhere in the body Agreement. The terms set forth in the body of the Agreement shall prevail in the event of a conflict between this Exhibit H and any term set forth in the body of the Agreement.

Exhibit I

Information to be provided in SDR Report

Summary of work completed by each Third Party Sublicensee;

Summary of work in progress by each Third Party Sublicensee; and

Current schedule of anticipated events or milestone with respect to each Third Party Sublicensee

Exhibit K
Third Party Patents

None as of the Effective Date.

Exhibit L

Format of Invoice

To be discussed and agreed to by the Parties.

THE SYMBOL “[*]” DENOTES PLACES WHERE CERTAIN IDENTIFIED
INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i)
NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE
COMPANY IF PUBLICLY DISCLOSED**

This document is an English translation of a document prepared in German. In preparing this document, an attempt has been made to translate as literally as possible without jeopardizing the overall continuity of the text. Inevitably, however, differences may occur in translation and if they do, the German text will govern by law.

In this translation, German legal concepts are expressed in English terms and not in their original German terms. The concepts concerned may not be identical to concepts described by the English terms as such terms may be understood under the laws of other jurisdictions.

SUBLEASE AGREEMENT

The following sublease agreement is entered into

between:

University Medical Centre of the Johannes Gutenberg University of Mainz,
55131 Mainz, Langenbeckstraße 1,
represented by
the chairman of the executive board and the Medical Director, [***],
the Scientific Director, [***], as well as
the Commercial Director [***]
(hereafter referred to “Unimedizin”)

and

BioNTech AG
55131 Mainz, Hölderlinstraße 8
represented by
the director
[***] (German business degree)
(hereafter referred to the subtenant).

Preamble

SANIPharma GmbH has acquired the plot “An der Goldgrube”, 55131 Mainz (GFZ barracks facility; district Mainz, plot 21, no. 450/5) and intends to erect a building with laboratory and office areas on this land by the 4th quarter of 2013. Unimedizin intends to lease the building to ensure future space requirements are met and to transfer the same to third parties, such as Ganymed Pharmaceuticals AG and BioNTech AG, by way of subletting the use of part areas.

The contract partners agree that the subtenant will take over the lease areas described in more detail below for commercial purposes to carry out research, development and the marketing of products and services within the biotechnological / medical sector in line with this agreement. The contract partners have individually negotiated all regulations of the sublease agreement in detail. The following regulations summarise the verbal agreements made in writing.

In principle, the property shall be managed by SANIPharma for the term of this agreement unless a third party becomes the subtenant of the building in question in place of Ganymed Pharmaceuticals AG. Details regarding this are regulated in Section 6 no. 4 of the sublease agreement.

Section 1 Leased object

Lease areas:

The probable extent of the leased areas of this agreement and the number of parking spaces for the contractual leased object are:

1.

Office areas	approx. 1,012 m ²
Laboratory areas	approx. 2,632 m ²
Archive and storage areas	approx. 365 m ²
Animal accommodation areas	approx. 331 m ²
Conference rooms	approx. 68 m ²
Shared rental areas	approx. 339 m ²
Parking spaces	approx. 50 spaces

The useable area (**Appendix 1**) has been calculated on the basis of the current plan status in line with planning approval as well as the guideline for calculating the lease area of commercial facilities (MF-G gif e.V.), status 01.11.2004 (**Appendix 2**, calculation and guideline). The parties agree that the object will be measured in a way that is binding for both sides as soon as the building status allows this. Once these measurements are available the final useable areas will be recorded in an addendum and added as a tabular list of the lease areas. Should the area change from the one listed under Section 1 no. 1 the rent according to Section 6 no. 1 will change accordingly.

2. The leased object is clear from the plans enclosed with this lease agreement as **Appendices 3, 5 and 6**.
3. The fit-out standard is laid down in the building specification enclosed as **Appendix 4**. Should special requests by the subtenant necessitate changes to the fixed fit-out standard, the parties will confirm these together with SANIPharma GmbH in an addendum to the main lease agreement or the sublease agreement by mutual consent. Any additional costs incurred due to this will be borne by the subtenant in the form of a construction cost surcharge. The owner, namely SANIPharma GmbH, assures the future building status of the rental premises in line with the building specification (**Appendix 4**) under the conditions of the planned building quality.

Changes to this functional building specification (**Appendix 4**) by the owner, namely SANIPharma GmbH, are admissible as long as material of the same quality and grade is used and the justified interests of the subtenant are adequately taken into consideration.

4. With regard to the technical laboratory equipment (cost groups 300 and 400) the facilities serve as a reference object for Ganymed Pharmaceuticals GmbH, Freilingrathstraße 12 in Mainz. Permanently fitted office furniture (cost group 600) will be installed on the basis of the plans (**Appendix 3**). Moveable laboratory objects and laboratory furniture will not be part of the lease agreement. The subtenant itself will acquire these objects. Changes with regard to technology and/or laboratory furniture made by SANIPharma GmbH in the building plans will be recorded in the final plans and added to the property management contract between SANIPharma GmbH and the subtenant as an addendum.
5. With regard to the equipment and building services to be supplied only the building specification enclosed as **Appendix 4** applies. Illustrations that deviate from the same, for example in the planning documentation of the architects or the building contractor, are not binding for Unimedizin. The subtenant will not be able to make claims from this.

The leased object will be completed and handed over as a turn-key project in line with accepted technical rules, bearing in mind all currently valid public law provisions and official stipulations. Regulations already agreed and published that will however come into force only within six months from approval application must also be taken into consideration, as these may lead to subsequent object-related stipulations. If higher requirements are defined in the building specification these are considered to be owed.

Deviations from the documents enclosed as **Appendices 3 and 4** due to building law or technical requirements or official stipulations are admissible as long as the contractual serviceability of the leased object is not substantially affected and the justified interests of the subtenant are adequately taken into consideration.

Possible deviations must be notified to the subtenant within at least 28 days from Unimedizin becoming aware of the same.

Section 2

Leasing purpose

1. The subtenant intends to use the leased areas for operating a laboratory (S1, S2 and animal laboratory) as well as an office area.

2. Any change to the type of business operated at the lease facility, the use or the profession carried out there, requires the prior written approval of Unimedizin.
3. The subtenant is solely responsible for obtaining and maintaining other official non-object related approvals that may be required for the business operation of the subtenant at its own cost and its risk. If approvals required for the business operation within the meaning of Section 2 no. 1 are granted only under specific stipulations the subtenant is obliged to comply with the same at its own cost. In the case of a final refusal of the initial operating approval the subtenant will have the right to withdraw from this agreement according to sections 346 et seq. BGB if the refusal is based on a non-compliance with building and/or technical requirements.

The subtenant will comply with official instructions and stipulations relating to the use of the leased object passed following handover within the meaning of Section 3 at its own cost. If such instructions or stipulations are object (building) related or will necessitate object related measures the subtenant will implement these in agreement with Unimedizin. Should such object related stipulations or measures require investments of more than one total annual net rent p.a. the parties will endeavour to agree a regulation concerning the covering of additional costs.

The issue of official instructions, stipulations or other provisions will not grant the subtenant a withdrawal, termination or performance refusal right as long as operating approval still exists and the reason for this is not the fault of Unimedizin. The same applies for impairments of the commercial use of the leased object due to external circumstances such as traffic diversions, excavations, road closures, noise, odour and dust nuisance etc.

Section 3 Handover of the leased object

1. The subtenant will inform Unimedizin in good time prior to handover of the leased object, who will implement this for the subtenant.
2. A protocol documenting the handover will be generated and signed by both contract partners. Defects found will be included in the protocol. If the leased object contains defects the obligation of Unimedizin will initially be limited to rectifying the same. Should this fail or is not likely to be successful, a claim to rent reduction and/or compensation or withdrawal will exist in line with statutory provisions. If the contractual parties cannot agree, any rectifications may have to be implemented following a corresponding expert report.

3. As construction progresses, SANIPharma GmbH will carry out a so-called technical inspection - possibly also for spatially or technically separate part areas - prior to handover to the subtenant together with individual companies participating in the construction. SANIPharma GmbH undertakes to inform the subtenant of the date of the technical inspection three weeks prior to the same.
4. Following timely notification of the date, the subtenant shall attend and cooperate in the technical inspection.
5. If recognisable defects or the non-contractual condition of the leased object are not claimed in the handover protocol, defects will be considered not to exist and the leased object as contractually compliant in this regard. Hidden defects are excluded from this. SANIPharma GmbH will send the subtenant protocols of the building planning meetings.

Section 4 Lease period and termination

1. The lease relationship begins upon handover, provisionally during the 4th quarter of 2013.
2. If the leased object cannot be handed over on the date listed under point 1 - irrespective of the reason - the handover date and the start of the lease relationship will be postponed accordingly for up to nine months. There will be no possibility for the subtenant to withdraw in this case. Reference is made to the right of termination without notice (Section 5 para. 2).
3. The sublease relationship is limited to a period of ten years. The parties will set a start and end date of the fixed term in an addendum to the sublease agreement immediately after handover according to Section 3. The subtenant will have the option to extend the lease agreement three times by a further 5 years. Exercise of the option must be declared in writing at least 18 months prior to expiry of the (possibly extended) lease agreement in writing in each case. The receipt of the declaration by the landlord is crucial for compliance with this deadline.

If Ganymed Pharmaceuticals AG vacates the leased object in the future, the remaining subtenant will be granted preferential lease rights to also lease the facilities of Ganymed Pharmaceuticals AG about to become vacant under the conditions of this sublease agreement for a period yet to be agreed by the parties. Exercising the preferential lease right must then be declared by the subtenant within four weeks from service of the request to Unimedizin in writing. Following expiry of the deadline without a written declaration exercising the preferential lease right, the said preferential lease right will lapse.

The subtenant further has no preferential lease right for the period that exceeds the 25-year term of the main lease agreement of Unimedizin or an earlier end of the main lease agreement of Unimedizin.

Should the tax authorities revise the economic tax allocation of the leased object such that the subtenant is deemed to be the economic owner, the contractual parties and SANIPharma shall negotiate a regulation that will not lead to disadvantages or advantages for the contractual parties.

4. If the subtenant continues to use the leased object once the lease period has expired the lease relationship will be considered to have been extended. Section 545 BGB will therefore not apply.
5. Splits, mergers or conversions under company law by the subtenant will not lead to an end of the lease agreement and will not grant special termination rights. The subtenant will inform Unimedizin of the legal entity who is the successor on the side of the subtenant. The liquidity of the subtenant may not be negatively affected by this.

Section 5 Extraordinary termination

1. The right to an extraordinary termination without notice shall be based on the statutory provisions and this must be declared in writing unless agreed otherwise below. Unimedizin may terminate the sublease relationship with immediate effect and without complying with a notice period,
 - a) if the subtenant is in default with payment of the rent for two consecutive rent payment dates or with payment of a not insubstantial part of the rent, or has defaulted on payment of the rent for an amount that totals the rent for two months during a period that extends over more than two payment dates;
 - b) if the subtenant continues using the leased object contrary to the agreement irrespective of a written reminder by Unimedizin, in particular sub-lets the same without approval;
 - c) if the subtenant violates its obligations to such an extent that Unimedizin cannot be expected to continue the sublease relationship, in particular continues to make late payments (of total or part amounts) despite written reminders by Unimedizin;
 - d) for another important reason.

2. If the leased object is not ready for occupation, or not on the agreed date, and is not ready for occupation within the extended completion period listed under Section 4 paragraph 2 above, or if the leased object is found to have defects that will void its suitability for the contractually agreed occupation, the subtenant has the right to set Unimedizin a suitable deadline that does not need to be longer than three months, and to terminate without notice upon expiry of this deadline.

Excluded from this are: force majeure, strike, insolvency of the builder(s); in these cases the contractual parties will agree a suitable further deadline.

Compensation claims are excluded unless Unimedizin has acted with intent or gross negligence or if they relate to injuries to life, body or health.

Section 6 Rent and security deposit

The total rent amount for the building including installations and parking spaces will be set according to Section 1 para. 1 and in line with the respective usage areas at the following prices per m² and per month, plus VAT at the respective statutory rate.

1. The monthly rent at the time of completing the agreement is therefore:

<u>Utilisation units</u>	<u>Price/ m²</u>	<u>Area in m²</u>	<u>Price per utilisation area</u>
Office areas	€ 12.50	1,012	€ 12,650.00
Laboratory areas	€ 24.00	2,632	€ 63,168.00
Archive and storage areas	€ 12.50	365	€ 4,562.50
Animal accommodation areas	€ 52.00	331	€ 17,212.00
Conference rooms	€ 12.50	68	€ 850.00
Shared rental areas or traffic areas	€ 12.50	339	€ 4,237.50
Parking spaces	€ 30.00	50 spaces	€ 1,500.00
Sub-total			€ 104,180.00
Surcharge 1%			€ 1,041.80
Total			€ 105,221.80

2. SANIPharma GmbH has claimed input tax deduction for the costs of purchasing and equipping the leased object. For this reason, the subtenant may use the leased object only for realising income that will not exclude the deduction of input tax by SANIPharma GmbH and Unimedizin.

The subtenant is aware that only income liable to VAT allows this VAT option in principle and that the financial authorities and courts will accept other income that rules out an input tax deduction only within very strict and low limits. The subtenant must provide Unimedizin with all information required by Unimedizin for enforcing and maintaining the VAT option. It undertakes upon request by Unimedizin to provide Unimedizin and SANIPharma GmbH or the responsible tax office with corresponding documents. This regulation also applies for the case of a possible subletting where this is permitted in this agreement. The subtenant will be required to reimburse any damage incurred or apparent in cases of violation.

3. The rent according to point 1 is set on the basis of the consumer price index for the cost of living of all private households in Germany (published by the Federal Office for Statistics in Wiesbaden) at the time of signing the agreement (base year 2005 = 100). If the status of this index changes by more than 7.5 points either up or down 12 months after the start of the contract or at the time of the last rent adjustment, the rent (excluding auxiliary costs and VAT) will change at a corresponding ratio with effect from the month following the change without requiring a special declaration of either of the contractual parties or another contractual amendment. The percentage of the rent adjustment will be converted by means of the formula $([\text{index status new} \times 100] : \text{index status old}) - 100 = \text{rent adjustment in percent}$. If the index should not be continued in its present form it will be replaced with the statistics recorded by the Federal Office for Statistics that come as close as possible to the same with a new base year.
4. The subtenant undertakes to complete a property management contract with SANIPharma GmbH, the owner of the plot, for the entire term of the sublease agreement, unless a third party replaces Ganymed as subtenant, in which measures and operating costs invoices according to Sections 7 and 10 are regulated where these are not provided by the subtenant itself at its own cost or paid directly to the service providers, or where these are not provided by the subtenant at its own cost or paid directly to the service providers.

The subtenant thus agrees to SANIPharma GmbH commissioning a third party for the fulfilment of the property management contract.

The subtenant agrees to a future property management by Unimedizin when the property management by SANIPharma GmbH ends. Property management includes all measures and operating cost statements according to Sections 7 and 10 unless this is not provided by the subtenant itself at its own cost or paid directly to the service providers, details of which with regard to the operating costs to be invoiced and the distribution principles to be applied are regulated in Section 7a.

Section 7
Operation and use of the leased object

1. The subtenant shall implement all measures and bear all costs necessary for the use of the leased object. These include in particular, but not exclusively:
 - all public safety obligations with regard to the leased object;
 - cleaning responsibilities for paths bordering the leased object where this exists on the basis of corresponding local statutes;
 - completion of supply contracts with the respective suppliers (electricity, gas, water, drainage, heating, chimney sweeping, road cleaning and waste disposal) and corresponding statements;
 - operation, monitoring and maintenance of the heating system including exhaust gas system and the regular inspection of operational readiness and safety, including adjustments to be carried out by a professional, cleaning of the system and the equipment room, implementation of necessary measures in line with the Federal Emission Protection Act, implementation of calibrations;
 - operation of a passenger or freight lift including supervision, operation, monitoring and maintenance of the system, regular inspection of operational readiness and safety including adjustments to be carried out by a professional and cleaning of the system;
 - cleaning of the building and pest control, including the external cleaning of windows;
 - operation, maintenance and upkeep of all technical and mechanical building components;
 - maintenance of fire extinguishers as well as obtaining official test certificates;
 - testing, maintenance and upkeep of fire and safety-technical equipment. This for example includes fault and fire alarm systems with auxiliary equipment, sprinkler systems, smoke and heat extraction systems, hydrants;
 - maintenance, upkeep and regular inspection of lighting protection system as well as roof vegetation and roof drainage;
 - garden maintenance including the replacement of plants and bushes as well as the upkeep of open spaces, access paths and access roads that do not serve the general public;
 - supply of traffic areas, equipment spaces and facilities with water, electricity, heat etc., including the acquisition of lighting equipment;
 - operation of an antenna system or a broadband cable network;
 - implementation of cosmetic repairs in public areas;

If the (prior) agreement of SANIPharma GmbH is required for implementing these measures such agreement must be obtained.

2. Costs charged directly to SANIPharma GmbH or Unimedizin, such as for example ongoing public charges, namely property taxes or other costs, will be borne by the subtenant. These costs will be invoiced annually by the 31.08. at the latest. The same applies for the cost of insurances taken out by SANIPharma GmbH or Unimedizin according to Section 15. The subtenant must inform Unimedizin of any objections at least 6 weeks after receipt of the invoice. The subtenant will no longer be able to object to an invoice after this deadline has expired.

Section 7a **Property management by Unimedizin**

For the case of a termination of property management activities by SANIPharma GmbH the parties will agree the following in a supplementary agreement to this sublease agreement:

1. The subtenant will pay the operating costs resulting from Sections 7 and 10 of the sublease agreement, the respective valid operating cost regulations and from property management activities to Unimedizin where these are not provided by the subtenant himself at its own cost or paid for directly to the service providers.

A copy of the currently valid operating cost regulations is enclosed as **Appendix 7** and form the object of this agreement.

Monthly advance payments will be paid for the aforementioned costs and auxiliary costs charged according to Section 7 no. 1 as follows:

a) for heating and hot water supplies	€
b) for all other operating costs	€
c) for administration costs	€
Total monthly ancillary cost advance payment	€

2. Distribution ratios:

- a) Heating and hot water supply costs will be distributed in line with the allocation principle specified under no. 5.
- b) Costs for hot water supplies will be invoiced depending on the consumption for the whole building/ the economic unit where corresponding measuring equipment is available. Failing this they will be distributed in line with the following allocation principle:

- c) Drainage costs will be distributed proportionate to the water supply.
 - d) Lift costs will be charged in line with the conversion code specified under no. 6.
 - e) All other operating costs and administration costs will be distributed in line with the ratio of usage area to total area of the building / the economic unit unless the following conversion ratio is agreed: _____
 - f) If Unimedizin incurs specific costs as a consequence of the usage type of the object (for example surcharge for fire insurance, additional waste containers), these amounts will be passed on to the subtenant in full.
 - g) Unimedizin may change the conversion ratios at its discretion if reasons for a correct upkeep of the building / the economic unit demand this.
3. An invoice for the prepayments shall be issued annually by 31 August at the latest. Unimedizin may change the invoice period for reasons of expedience. The subtenant must inform Unimedizin of any objections at least 6 weeks from receipt of the invoice. The subtenant may no longer submit objections against the invoice following expiry of this deadline. In the case of an increase or reduction in ancillary costs Unimedizin will have the right to review advance payments with effect from the month following the annual statement. Unimedizin may demand appropriate advance payments from the date of notification of newly incurred ancillary costs, in particular operating costs.
4. If increases in operating costs occur, Unimedizin will have the right to distribute such increases proportionally to the subtenant by means of a written declaration; the reason for the conversion must be stated and explained in the declaration. In a case of retrospective increases in operating costs the declaration of Unimedizin will apply from the date of the increase. This also applies if new operating costs as defined in the operating costs regulations are incurred or arise following completion of the sublease agreement.
- If operating costs fall, they will be reduced accordingly from the date of the fall.
5. Heating and hot water supply
- a) Unimedizin will maintain the shared hot water system for respective use throughout the year to the usual extent. The hot water supply system will be operational at all times.
 - b) Heating costs to be paid by means of allocation include:
the cost of fuels used and their delivery, the cost of operating currents, the cost of operating, monitoring and maintaining the heating system including the exhaust gas system, the regular inspection of its operational readiness and operational safety including adjustments to be carried out by a professional, the cleaning of the system including the tank and

equipment room, the cost of measurements in line with the Federal Emissions Protection Act, the cost of leasing or other types of transfer of use of equipment for consumption recording as well as the cost of using equipment for consumption recording including calculation and distribution costs.

The above regulations apply correspondingly for the costs of hot water supply systems of the building / the economic unit.

- c) Heating and hot water costs will be allocated as follows:

Hot water consumption will be recorded with a heat meter and invoiced in line with actual consumption. Heating costs will be distributed at the ratio of usage area to total area of the building or the economic unit.

Unimedizin will be entitled to change invoicing ratios at its discretion within the legally admissible scope if justified interests necessitate this for a correct maintenance of the building / the economic unit.

It is clear from the technical calculations of **Appendix 8** that an exception from the application of sections 3 to 7 Heating Costs Ordinance with regard to the supply of heat and hot water according to section 11 para. 1 no. 1 lit. b and para. 2 Heating Costs Ordinance exists, so that the aforementioned stipulations of the Heating Costs Ordinance do not apply.

6. Lift

- a) The lift costs to be allocated for the operation of a passenger and/or freight lift include:

the costs for operating electricity, supervision costs, the cost of operating, monitoring and upkeep of the system, the regular inspection of its operational readiness and operational safety including adjustments to be carried out by a professional as well as the costs of cleaning the system.

- b) Lift costs will be allocated according to the ratio of usage area to total area of the building or the economic unit or according to the following allocation principle:

-
- c) Unimedizin reserves the right to change the allocation principle at its discretion if reasons for the correct maintenance of the building / the economic unit necessitate this.

Section 8
Payment of rent

1. Rent plus VAT must be paid to Unimedizin monthly in advance, by the fourth of every month at the latest, free of charge, with a releasing effect only to the following account:
Account holder: [***] Sort code: [***]
Account number: [***] Bank: [***]
Unimedizin will provide the debtor number as a payment reference.
2. The timeliness of the payment will depend not on the transfer, but on the receipt of the money.
3. Late payment of rent will entitle Unimedizin to charge interest on appears from their due date until the date when payment is received according to section 288 BGB. The claiming of higher interest charges is not ruled out by this. Irrespective of this further compensation claims and the statutory or contractually agreed termination rights of Unimedizin remain unaffected.

Section 9
Reduction, set-off, right of retention, compensation claims

1. A reduction or retention of rent and set-off against claims of Unimedizin are excluded if circumstances outside of Unimedizin's control (for example road closures, construction work on neighbouring buildings, changes to or cessation of the delivery of supply media which Unimedizin is unable to influence etc.) affect the use of the facilities. Unimedizin will assign corresponding claims against third parties to the subtenant in this regard.
2. Apart from this the subtenant may set off counterclaims against rent demand claims or exercise a right of reduction or retention only if the counterclaim is undisputed or has been legally confirmed.

Section 10
Maintenance and use of the leased object

1. The subtenant undertakes to maintain and repair the leased object including other facilities and equipment also let at its own cost. Not included in the maintenance obligation of the subtenant are the underlying construction components (work on roof and the building shell), although the moveable parts of doors and windows are. The same applies if a case of force majeure exists or if maintenance or repair become necessary due to a construction defect. Costs may not exceed a total charge of 10% of the annual rent per year. Any costs exceeding this will be borne

by SANIPharma GmbH. VAT will not be included, i.e. only net amounts will be included in the calculation of limit values where the parties to the lease agreement are entitled to withhold input tax. Work on installations and objects, in particular on technical systems that affect the entire building (air-conditioning shafts, water and heating pipes) must be agreed with SANIPharma GmbH in advance.

2. The subtenant undertakes to carry out ongoing cosmetic repairs at its own cost as appropriate as soon as the degree of wear requires this for the type of commercial operation or the contractual use. Cosmetic repairs include all internal painting, wallpapering, whitewashing and the painting of walls and ceilings, the painting or gloss painting of radiators, heating pipes, internal doors, windows and the insides of external doors. The subtenant undertakes to have existing floor coverings including skirting boards treated by a qualified tradesperson if necessary.
3. The subtenant undertakes to treat the leased object including all components as well as the common facilities (yard areas, vestibules, stairwells, lifts etc.) with care and consideration.
4. The subtenant must request information about admissible load limits of respective story ceilings from SANIPharma GmbH prior to erecting machines, heavy apparatus and safes in the lease facility and must obtain the latter's written approval. The subtenant is liable for damage caused through disregarding this provision. If machines have a negative effect on the building, for example due to vibration, cracks etc., SANIPharma GmbH may revoke any approvals granted.

5. Damage caused to and inside the lease as well as to the rental premises must be notified to Unimedizin or SANIPharma GmbH as soon as the subtenant becomes aware of it and must be rectified by the subtenant in line with the above obligations as well as according to the obligations of Section 7. Should the subtenant not comply with this obligation within an appropriate period of time even following a written reminder, Unimedizin or SANIPharma GmbH may have necessary work carried out at the cost of the subtenant. If a risk of further damage exists the written reminder and the setting of a deadline are not required.
6. If the subtenant is not subject to a rectification obligation it will nevertheless be liable towards Unimedizin for damage culpably caused by itself through violation of its obligatory duty of care. The same applies if corresponding damage is culpably caused by employees, family members, vicarious agents, lodgers, visitors, suppliers, customers and tradesmen etc. of the subtenant who do not have a rectification obligation.

Section 11 **Repairs and construction changes**

1. Unimedizin or SANIPharma GmbH may carry out repairs, improvements, modernisations or other construction changes necessary or expedient for the upkeep, operation or for the development of the building or the rental premises or for preventing anticipated danger or rectifying damage without agreement of the subtenant. Unimedizin undertakes to inform the subtenant of the measures in good time prior to the start of the same without having to comply to the form, scope and deadline requirements of section 554 para. 3 BGB. If rental premises are affected, access to the same for the subtenant must be retained wherever possible. The subtenant must not obstruct or delay such work. A right of the subtenant to terminate for a special reason due to work that has to be tolerated is excluded. The possible construction of a further building wing will be tolerated by the subtenant without compensation.
2. Unimedizin or SANIPharma GmbH may not compromise the operational processes of the subtenant unduly. The subtenant will have rent reduction claims because of such measures only if the measure lasts longer than two weeks and the subtenant is severely affected. Claims under tort remain unaffected by this.
3. If such measures result in the improved value of the rental premises, Unimedizin will have the right to increase the rent by an appropriate value improvement surcharge, which will come into effect on the first of the month following the corresponding written declaration by Unimedizin. If the subtenant objects to the increase within a period of one month from receipt of the increase request, an expert appointed by the responsible Chamber of Commerce will decide as an arbitrator. The costs of the arbitrator will be borne by the unsuccessful contract party.

Section 12
Installations and conversions by the subtenant as well as advertising
and special operating equipment

1. The subtenant requires the written approval of Unimedizin for installations and conversions in the rental premises including any changes to technical equipment, for which suitable plans must be submitted upon request. The same applies for the fitting of other special operating equipment (for example automats, awnings, antennae) outside of the rental premises, Unimedizin may make any approval dependent on proof of safety measures against risks posed by such equipment and demand the removal of such equipment if an important reasons exists for the same (retrospectively ascertained harmful effects on the building, building components or other object users). A right to the granting of approval does not exist.
2. The obtaining of official approvals that may be required as well as the costs connected with this (also for the compliance with stipulations) are the responsibility of the subtenant, who must also regularly check the safety of installations. The subtenant is liable for compliance with inspectorate stipulations and all damage caused during installation or conversion work, irrespective of the type. Costs for the fitting, the operation and the upkeep of the equipment will also be borne by the subtenant.
3. The subtenant is liable for all damage caused in connection with installing and/or operating the equipment provided by itself or at its request by a third party or by Unimedizin. It will release Unimedizin from third party claims. The subtenant will further notify all intended changes in or to the leased object, and in particular all changes to the risk assessment in the sense of the fire prevention regulations of Unimedizin. If surcharges are applied to insurance premiums on the basis of such changes the subtenant will reimburse Unimedizin for the corresponding amount upon request.

Section 13
Subletting

The subtenant is not permitted to sublet the facilities without the prior written approval of Unimedizin.

Section 14
Destruction of the leased object

In a case of a complete destruction or the destruction of most of the leased object due to an event that is outside of the control of Unimedizin (for example fire etc.), Unimedizin is not liable to reinstate the leased object. It may declare the end of the lease relationship with effect from the date of the destruction of the leased object irrespective of whether the rental premises are to be reinstated at a later date or not. Upon reinstatement of the rental premises the subtenant will have priority rights regarding the completion of a new lease agreement over other applicants.

Section 15
Insurance policies

1. SANIPharma GmbH will take out the following insurance policies:

- fire insurance for the building,
- insurance against storm and damage to water supply,
- occupiers and building liability insurance.

and will invoice the subtenant directly as part of the property management contract, failing which Unimedizin will forward the invoice to the subtenant, who is then liable for a proportional payment to Unimedizin according to Section 7 no. 2 to the account listed in Section 8 no. 1.

2. The subtenant will take out operational liability insurance to the normal extent of the industry section at its own cost as well as all normal insurances for its operation including fire, furniture, glass breakage and business disruption insurance with adequate sums insured, maintain the same and pay premiums on time. Claims against Unimedizin are excluded where the subtenant receives payments from the aforementioned insurances or is no insurance cover exists in a case where he has failed to adequately insure such risks or has not paid insurance premiums or has notified any damage too late. The liability of Unimedizin for intent and gross negligence or for injuries to life, body and health remain unaffected.

Section 16
End of the lease relationship

1. The subtenant will return the leased object completely empty and in a clean condition with all keys - also those obtained by the subtenant - to Unimedizin when the lease relationship ends. The return must be notified with an appropriate notice period and must take place on the last working day prior to the end of the lease period at the latest. Upon return the subtenant will also return all accessories and equipment components provided by Unimedizin in a clean condition ready for use. The subtenant undertakes to rectify all damage to the leased object caused through use that exceeds the consequences of normal wear during the lease period prior to its return.

2. Unless specifically agreed otherwise as part of the landlord's approval (Section 12) the subtenant undertakes to remove installations, removals and conversions as well as installations it has carried out in or on the leased object, and to return the condition in which the leased object was upon handover to itself where reinstatement liability exists and no takeover by Unimedizin will take place.

Section 17
Plurality of persons

If several persons act as a contract partner, they will be liable as joint debtors for all liabilities arising from this agreement.

Section 18
Access to the leased object

The subtenant must guarantee that Unimedizin, an authorised expert or interested parties are able to inspect the leased object during normal business hours for the purpose of ascertaining its state of repair. In cases of risk access must be permitted at any time of the day or night.

Section 19
House rules

Possible house rules yet to be compiled will become part of this agreement. They will apply in their respective valid version. SANIPharma GmbH will expect all subtenants to comply with the house rules as part of the property management contract and will provide them with a current copy, **Appendix 9**.

Section 20
Miscellaneous agreements

1. Unimedizin has the right to transfer the lease agreement with all rights and duties to a group company. The subtenant agrees to such a transfer.

2. The subtenant undertakes to provide a rent security deposit for three months, namely a total of € [***] (in words: [***]). This amount must be transferred to the account listed in Section 8 para. 1 within 14 days from the start of the sublease agreement at the latest.

The rent deposit will be held in a savings account for the period of the sublease agreement by Unimedizin. Interest will be paid into this account.

The subtenant may optionally provide an absolute, irrevocable and unconditional bank guarantee for € [***] from a major bank or public saving bank based on the above period according to **Appendix 10**.

If the subtenant does not comply with its lease contract obligations during the sublease period Unimedizin will have the right but is not obliged to satisfy these claims from the bank guarantee. If Unimedizin makes use of the bank guarantee to fulfil lease contractual obligations of the subtenant during the term of the sublease agreement the subtenant undertakes upon request by Unimedizin to provide the same with further securities up to a height of the security deposit due to a subsequently reduced available security deposit. The same applies for the rent deposit.

In a case of a valid exercising of an extension option for the sublease agreement the preferential lease right according to Section 4 no. 3 the parties undertake to adjust the size of the security deposit acc. to Section 20 para. 2 to the current sum of three months' rent.

Section 21

Closing provisions

1. Other agreements, in particular additional verbal agreements, do not exist. All contract amendments and additions require the written form.
2. All appendices listed in this agreement become a major part of this agreement upon inclusion or approval of the same.
3. Declarations of intent to be issued to the other contract partner require the written form to become effective.
4. Should a provision of this agreement be or become invalid or unenforceable this will not affect the validity of the remaining provisions. The invalid provision will be replaced one that comes closest to the intention of the invalid provision in a legally admissible way. The contractual parties undertake to amend the agreement according to sections 242, 313 BGB in exceptional circumstances, such as for example a currency change or inflation that will endanger the existence of the contract.

5. This agreement consists of 23 pages and the appendices.
6. Each party will receive one copy of this agreement including the appendices.
7. The place of jurisdiction is Mainz.
8. The law of the Federal Republic of Germany applies.

Appendices

- Appendix 1 - Summary of lease areas according to MF-G
- Appendix 2 - Lease area calculation and guideline (MF-G)
- Appendix 3 - Installation status plans
- Appendix 4 - Building specification
- Appendix 5 - Open space layout
- Appendix 6 - Section drawing
- Appendix 7 - Operating cost regulations
- Appendix 8 - Expert report regarding exceptions from the Heating Costs Ordinance (to be submitted by SANIPharma GmbH upon handover of the leased object in the autumn of 2013 latest)
- Appendix 9 - House rules
(to be submitted by SANIPharma GmbH upon handover of the leased object in the autumn of 2013 latest)
- Appendix 10 - Bank guarantee form

Mainz, on 12.12.12

Mainz, on 14.01.2013

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Subtenant

University Medical Centre of the
Johannes Gutenberg University of Mainz

[signature]

[signature]

[***]

Chairman

[***]

Chairman of the executive board

[signature]

[***]

Scientific Director

[signature]

[***]

Commercial Director

Approved by the owner of the plot and building, SANIPharma GmbH, Haidgraben 5, 85521 Ottobrun:

[signature]

[***]

Managing Director

[stamp - Sanipharma GmbH

Haidgraben 5

85521 Ottobrun]

Calculation of lease areas according to GIF (status 11/2004)

Project:	New construction of administration and laboratory building in Mainz Project no. 606 2	Key Bfl.Gany Bfl.BioN	Ganymed office area BioNTech office area
Client:	SANIPharma GmbH Haidgraben 5 85521 Ottobrun	Lfl.Gany Lfl.BioN Fl.TL Fl.Konf.	Ganymed laboratory area BioNTech laboratory area Animal laboratory area Conference rooms
User:	Ganymed Pharmaceuticals AG Freiligrathstraße 12, 55131 Mainz	AfluLfl.G AfluLfl.B gg Mfl.	Ganymed archive & storage area BioNTech archive & storage area Common use lease area
	BioNTech AG Hölderlinstraße 8, 55131 Mainz	gg Mfl.L gg Mfl.AL	Common use laboratory lease area Common use archive & storage lease area

Areas are CAD calculated

MF - G1	Ganymed lease area
MF - G2	BioNTech lease area
MF - G	General lease area
MF - 0	No lease area

Cellar

Area type	Division	Room number	Room description	NF (m ²)	VF (m ²)	TF (m ²)
MF-G	ggMfl	-1-010	Stairwell 1		5.01	
MF-0		-1-004	Lift 1		3.33	
MF-G	Fl.TL	-1-003	Corridor		27.65	
MF-G	Fl.TL		Autoclave	8.67		
MF-G	Fl.TL		MAT H202	4.51		
MF-G	Fl.TL	-1-114	Material entry access	13.47		
MF-G	Fl.TL	-1-102	Personal entry access "unclean"	5.95		
MF-G	Fl.TL	-1-103	Shower	3.64		
MF-G	Fl.TL	-1-104	Personal entry access "clean"	5.70		
MF-G	Fl.TL	-1-101	Corridor "clean"		56.97	
MF-G	Fl.TL	-1-113	Corridor "unclean"		49.89	
MF-G	Fl.TL	-1-112	Laboratory 1	10.60		
MF-G	Fl.TL	-1-111	Laboratory 2	10.70		
MF-G	Fl.TL	-1-110	Laboratory 3	10.63		
MF-G	Fl.TL	-1-105	Experiment 1	21.62		
MF-G	Fl.TL	-1-106	Experiment 2	21.78		
MF-G	Fl.TL	-1-107	Experiment 3	21.72		
MF-G	Fl.TL	-1-108	Breeding	32.52		
MF-G	Fl.TL	-1-109	Ventilation centre animal laboratory			100.14
MF-G	Fl.TL	-1-001	Corridor		30.55	
MF-G	Fl.TL	-1-011	Animal keeper changing room, female	8.69		
MF-G	Fl.TL	-1-007	Animal keeper changing room, male	8.67		
MF-G	Fl.TL	-1-012	Toilet, female	3.57		
MF-G	Fl.TL	-1-008	Toilet, male	3.57		
MF-G	Fl.TL	-1-009	Shower	2.08		
MF-G	Fl.TL	-1-014	Animal keepers store	88.06		
MF-G	Fl.TL	-1-006	Transition point IT/animal keeping			15.11
MF-G	Fl.TL	-1-017	Kitchen	61.57		
MF-G	Fl.TL	-1-015	Animal laboratory storage room, litter waste disposal	26.11		
MF-G	Fl. TL	-1-016	Carcass room	7.13		
MF-G	ggMfl	-1-003	Corridor 1		33.81	
MF-G1	AfluLfl.G	-1-018	Goods storage	40.75		
MF-G	ggMfl.L	-1-020	Lock	5.37		
MF-G	ggMfl.L	-1-021	Isotope laboratory	27.19		
MF-G1	Lfl.Gany	-1-022	Server room 1	26.83		
MF-0		-1-019	SiBe			8.79
MF-G	ggMfl.AL	-1-024	Nitrogen store. -80C (celcius) refrigerators	73.24		
MF-G	ggMfl	-1-038	Corridor 2		65.87	
MF-G	ggMfl	-1-040	Stairwell 2		4.83	
MF-0		-1-039	Shaft 2			8.28

MF-0		-1-043	Shaft 3						8.70
MF-0		-1-046	Shaft 4						8.70
MF-0		-1-042	Shaft 5						8.28
MF-0		-1-044	List 2				6.98		
MF-0		-1-041	BMA						8.97
MF-0		-1-051	NSHV						25.10
MF-G2	Lfl.BioN	-1-053	Server room 2			27.71			
MF-G2	AfluLfl.B	-1-055	Central goods store			66.29			
MF-0		-1-058	Building technology 1						62.97
MF-0		-1-056	Building technology 2						51.38
MF-0		-1-057	Waste water neutralization						15.79
MF-0		-1-059	Building technology 3						146.97
MF-G	ggMfl	-1-052	Corridor 3					51.58	
MF-G	ggMfl	-1-038	Stairwell 3					4.63	
MF-G	ggMfl	-1-083	Corridor 4					19.77	
MF-0		-1-040	Lift 3					3.33	
MF-G	ggMfl.AL	-1-035	Disposal room			120.24			
MF-G	ggMfl.AL	-1-036	Liquid waste store			9.18			
MG-0		-1-034	Lift 4					5.53	
MF-G	ggMfl	-1-204	Corridor 5					52.52	
MF-0		-1-202	Building technology 4						77.80
MF-G2	AfluLfl.B	-1-203	Archive QA			37.27			
MF-G2	AfluLfl.B	-1-204	Archive IP			39.16			
MF-G1	AfluLfl.G	-1-205	Archive 1			39.16			
MF-G1	AfluLfl.G	-1-207	Archive 2			39.44			
MF-G	ggMfl.AL	-1-208	Archive 3			39.14			
MF-G2	AfluLfl.B	-1-206	Archive General			38.87			
MF-G1/2	Subtotal Cellar					1010.80	403.08	115.25	1529.13
MF-0	Subtotal Cellar					0.00	19.17	431.73	450.90

Ground floor

Area type	Division	Room number	Room description	NF (m ²)	VF (m ²)	TF (m ²)
MF-G	ggMfl	0-119	Porch		13.40	
MF-G	ggMfl	0-118	Foyer/reception		42.51	
MF-G1	Bfl.Gany	0-101	Corridor 1		62.96	
MF-G1	Bfl.Gany	0-102	Combination zone	27.33		
MF-G1	Bfl.Gany	0-103	Office 01	29.62		
MF-G1	Bfl.Gany	0-104	Office 02	11.53		
MF-G1	Bfl.Gany	0-105	Office 03	17.31		
MF-G1	Bfl.Gany	0-106	Office 04	17.29		
MF-G1	Bfl.Gany	0-107	Office 05	24.91		
MF-G1	Bfl.Gany	0-108	Office 06	15.12		
MF-G1	Bfl.Gany	0-109	Office 07	29.20		
MF-G1	Bfl.Gany	0-110	Office 08	17.29		
MF-G1	Bfl.Gany	0-111	Office 09	17.31		
MF-G1	Bfl.Gany	0-112	Office 10	11.53		
MF-G1	Bfl.Gany	0-113	Office 11	29.62		
MF-0			E-UV			0.56
MF-G	ggMfl	0-001	Corridor 2		17.77	
MF-G	ggMfl	0-010	Stairwell 1		18.39	
MF-0		0-004	Lift 1		3.33	
MF-0		0-006	E-/EDV-UV 1			7.24
MF-0		0-005	Shaft 1			5.83
MF-G1	Bfl.Gany	0-007	Vestibule toilet, male	3.90		
MF-G1	Bfl.Gany	0-008	Toilet, male	5.06		
MF-G1	Bfl.Gany	0-011	Vestibule toilet, female	3.90		
MF-G1	Bfl.Gany	0-012	Toilet, female	5.06		
MF-G1	Bfl.Gany	0-003	Disabled toilet	5.81		
MF-G	Fl.Konf	0-013	Meeting room 1	80.61		
MF-G	Fl.Konf	0-014	Meeting room 2	40.50		
MF-G	Fl.Konf	0-009	Chair storage	14.30		
MF-G	ggMfl		Communication zone		43.58	

MF-G1	Bfl.Gany	0-002	Corridor 3			33.79		
MF-G2	Bfl.BioN	0-015	Office, animal cages 1 (BioNTech)		21.87			
MF-G1	Bfl.Gany	0-016	Office, animal cages 2 (Ganymed)		21.85			
MF-G1	Bfl.Gany	0-018	Meetings (Ganymed)		29.13			
MF-G1	Bfl.Gany	0-021	Typing pool 1		21.85			
MF-G1	Bfl.Gany	0-022	Typing pool 2		21.07			
MF-G1	Bfl.Gany	0-017	Social area		43.20			
MF-G1	Bfl.Gany	0-019	Copy room		6.26			
MF-G	ggMfl.AL	0-020	Purchasing office		31.87			
MF-G	ggMfl.AL	0-023	Temporary goods storage		33.72			
MF-G	ggMfl	0-038	Corridor 4			62.08		
MF-G	ggMfl	0-040	Stairwell 2			18.01		
MF-0		0-044	Lift 2			6.98		
MF-0		0-039	Shaft 2				8.28	
MF-0		0-043	Shaft 3				8.70	
MF-0		0-046	Shaft 4				8.70	
MF-0		0-042	Shaft 5				8.28	
MF-G	ggMfl	0-035	Corridor 5			26.59		
MF-G	ggMfl.AL	0-033	Goods-in (liquid nitrogen tank)				43.33	
MF-G	ggMfl.AL	0-036	Gas bottle store				15.22	
MF-0		0-034	Lift 4			5.53		
MF-0			Air supply opening, waste disposal room				1.13	
MF-G1	Lfl.Gany	0-051	Lock			5.42		
MF-G1	Lfl.Gany	0-047	Changing room, female		15.70			
MF-G1	Lfl.Gany	0-048	Washroom, female		5.70			
MF-G1	Lfl.Gany	0-049	Changing room, male		11.98			
MF-G1	Lfl.Gany	0-050	Washroom, male		5.56			
MF-G1	Lfl.Gany	0-058	Corridor 6			57.89		
MG-G1	Lfl.Gany	0-058	Electrophoresis		21.30			
MF-G1	Lfl.Gany	0-056	Centrifuge		9.01			
MF-G1	Lfl.Gany	0-053	Microscopy		9.23			
MF-G1	Lfl.Gany	0-054	Copy room		6.16			
MF-G1	Lfl.Gany	0-055	Storage		8.35			
MF-G1	Lfl.Gany	0-061	Typing pool		17.57			
MF-G1	Lfl.Gany	0-062	Typing pool		13.45			
MF-G1	Lfl.Gany	0-060	RNA laboratory		15.49			
MF-G1	Lfl.Gany	0-059	pre PCR		14.82			
MF-G1	Lfl.Gany	0-063	post PCR		21.69			
MF-G1	Lfl.Gany	0-064	Typing pool		8.94			
MF-G1	Lfl.Gany	0-065	Plasma preparation		21.34			
MF-G1	Lfl.Gany	0-066	Typing pool		14.35			
MF-G1	Lfl.Gany	0-067	Kitchen		9.08			
MF-G1	Bfl.Gany	0-081	Vestibule toilet, female		3.90			
MF-G1	Bfl.Gany	0-082	Toilet, female		5.06			
MF-G1	Bfl.Gany	0-087	Vestibule toilet, male		3.90			
MF-G1	Bfl.Gany	0-088	Toilet, male		5.06			
MF-G1	Lfl.Gany	0-079	Corridor 7			30.50		
MF-G1	Lfl.Gany	0-068	Histology laboratory		44.40			
MF-G1	Lfl.Gany	0-069	Histology equipment		17.28			
MF-G1	Lfl.Gany	0-070	Typing pool histology		21.27			
MF-G1	Lfl.Gany	0-071	Histology documents		12.69			
MF-0		0-085	Shaft 6				5.83	
MF-0		0-086	E-EDV-UV 2				7.24	
MF-0		0-084	Lift 3			3.33		
MF-G	ggMfl	0-080	Stairwell 3			18.39		
MF-G1	Bfl.Gany	0-083	Corridor 8			18.23		
MF-G1/2	Subtotal Ground Floor				981.30	469.51	58.55	1509.36
MF-0	Subtotal Ground Floor				0.00	19.17	61.79	80.96

1st Floor

Area type	Division	Room number	Room description	NF (m ²)	VF (m ²)	TF (m ²)
MF-G1	Bfl.Gany	1-101	Corridor 1		59.48	
MF-G1	Bfl.Gany	1-102	Combination zone	35.89		
MF-G1	Bfl.Gany	1-103	Storage	7.93		
MF-G1	Bfl.Gany	1-104	Office 01	23.02		
MF-G1	Bfl.Gany	1-105	Office 02	17.29		
MF-G1	Bfl.Gany	1-106	Office 03	17.32		
MF-G1	Bfl.Gany	1-107	Office 04	17.29		
MF-G1	Bfl.Gany	1-108	Office 05	24.00		
MF-G1	Bfl.Gany	1-109	Office 06	14.54		
MF-G1	Bfl.Gany	1-110	Office 07	24.91		
MF-G1	Bfl.Gany	1-111	Office 08	11.52		
MF-G1	Bfl.Gany	1-112	Office 09	11.55		
MF-G1	Bfl.Gany	1-113	Office 10	11.53		
MF-G1	Bfl.Gany	1-114	Office 11	11.53		
MF-G1	Bfl.Gany	1-115	Office 12	23.02		
MF-0			E-UV			0.56
MF-G1	Bfl.Gany	1-119	Meeting room	22.32		
MF-G1	Bfl.Gany	1-120	Social area	22.37		
MF-G1	Bfl.Gany	1-118	Corridor 2		15.98	
MF-G1	Bfl.Gany	1-001	Corridor 3		18.26	
MF-G	ggMfl	1-010	Stairwell 1		4.98	
MF-0		1-004	Lift 1		3.33	
MF-0		1-006	E-/EDV-UV 1			7.24
MF-0		1-005	Shaft 1			5.83
MF-G1	Lfl.Gany		Communication zone		9.49	
MF-G1	Lfl.Gany	1-002	Corridor 4		53.84	
MF-G1	Lfl.Gany		Communication zone		7.07	
MF-G1	Lfl.Gany	1-003	Darkroom	13.35		
MF-G1	Lfl.Gany	1-009	Lock	8.66		
MF-G1	Lfl.Gany	1-013	Cell development	60.84		
MF-G1	Bfl.Gany	1-014	Typing pool	8.17		
MF-G1	Lfl.Gany	1-015	Typing pool	8.34		
MF-G1	Lfl.Gany	1-016	Cell development process	59.76		
MF-G1	Bfl.Gany	0-007	Vestibule toilet, male	3.90		
MF-G1	Bfl.Gany	0-008	Toilet, male	5.06		
MF-G1	Bfl.Gany	0-011	Vestibule toilet, female	3.90		
MF-G1	Bfl.Gany	0-012	Toilet, female	5.06		
MF-G1	Lfl.Gany	1-017	Cell culture 4	30.30		
MF-G1	Lfl.Gany	1-019	Cell culture 3	30.39		
MF-G1	Lfl.Gany	1-021	Cell culture 2	30.39		
MF-G1	Lfl.Gany	1-024	Cell culture 1	59.85		
MF-G1	Lfl.Gany	1-018	Typing pool	19.32		
MF-G1	Lfl.Gany	1-020	Typing pool	17.57		
MF-G1	Lfl.Gany	1-023	Typing pool	17.52		
MF-G1	Lfl.Gany	1-022	Copy room	4.72		
MF-G1	Lfl.Gany	1-025	Storage	8.81		
MF-G1	Lfl.Gany	1-026	Refrigerator room	8.14		
MF-G1	Lfl.Gany	1-038	Corridor 5		44.27	
MF-0		1-036	Electro UV3			7.02
MF-G	ggMfl.	1-040	Stairwell 2		5.18	
MF-G1	Lfl.Gany	1-037	Washroom	4.68		
MF-G1	Lfl.Gany	1-041	PuMi	4.65		
MF-G1	Lfl.Gany	1-045	Freezer room	15.32		
MF-0		1-044	Lift 2		6.98	
MF-0		1-039	Shaft 2			8.28
MF-0		1-043	Shaft 3			8.70
MF-0		1-046	Shaft 4			8.70
MF-0		1-042	Shaft 5			8.28
MF-G1	Lfl.Gany	1-052	Corridor 6		18.42	
MF-G1	Lfl.Gany		Communication zone	6.10		
MF-G1	Lfl.Gany	1-047	Changing room, female	15.70		
MF-G1	Lfl.Gany	1-048	Washroom, female	5.70		
MF-G1	Lfl.Gany	1-049	Changing room, male	11.98		
MF-G1	Lfl.Gany	1-050	Washroom, male	5.56		
MF-G1	Lfl.Gany	1-051	Copy room	6.16		
MF-G1	Lfl.Gany	1-055	Typing pool	29.29		

MF-G1	Lfl.Gany	1-058	Storage	10.13			
MF-G1	Lfl.Gany	1-059	Freezer room	9.18			
MF-G1	Lfl.Gany	1-060	Refrigerator room	8.91			
MF-G1	Lfl.Gany	1-053	Chemical storage/scales	21.97			
MF-G1	Lfl.Gany	1-054	Kitchen/autoclave	38.72			
MF-G1	Lfl.Gany	1-056	Biochemical laboratory function room	44.25			
MF-G1	Lfl.Gany	1-057	Typing pool	16.82			
MF-G1	Lfl.Gany	1-064	Protein biochemical analysis	35.76			
MF-G1	Lfl.Gany	1-065	Typing pool	13.78			
MF-G1	Lfl.Gany	1-062	Protein biochemical cleaning	36.37			
MF-G1	Lfl.Gany	1-063	Typing pool	14.04			
MF-G1	Lfl.Gany	1-061	FACS	27.61			
MF-G1	Bfl.Gany	1-081	Vestibule toilet, female	3.90			
MF-G1	Bfl.Gany	1-082	Toilet, female	5.06			
MF-G1	Bfl.Gany	1-087	Vestibule toilet, male	3.90			
MF-G1	Bfl.Gany	1-088	Toilet, male	5.06			
MF-0		1-085	Shaft 6			5.83	
MF-0		1-086	E-EDV UV 2			7.24	
MF-G1	Lfl.Gany	1-079	Corridor 7	56.24			
MF-G1	Bfl.Gany	1-083	Corridor 8	18.26			
MF-G	ggMfl	1-080	Stairwell 3	4.98			
MF-0		1-084	Lift 3	3.33			
MF-G1/2 Subtotal First Floor				1100.68	316.45	0.00	1417.13
MF-0 Subtotal First Floor				0.00	13.64	67.68	81.32

2nd Floor

Area type	Division	Room number	Room description	NF (m ²)	VF (m ²)	TF (m ²)
MF-G2	Bfl.BioN	2-101	Corridor 1		59.28	
MF-G2	Bfl.BioN	2-102	Combination zone	16.33		
MF-G2	Bfl.BioN	2-103	Storage	7.72		
MF-G2	Bfl.BioN	2-104	Copy room	6.99		
MF-G2	Bfl.BioN	2-105	Office 01	29.62		
MF-G2	Bfl.BioN	2-106	Office 02	11.53		
MF-G2	Bfl.BioN	2-107	Office 03	11.53		
MF-G2	Bfl.BioN	2-108	Office 04	11.55		
MF-G2	Bfl.BioN	2-109	Office 05	11.51		
MF-G2	Bfl.BioN	2-110	Office 06	24.91		
MF-G2	Bfl.BioN	2-111	Archive	19.40		
MF-G2	Bfl.BioN	2-112	Office 07	24.91		
MF-G2	Bfl.BioN	2-113	Office 08	17.29		
MF-G2	Bfl.BioN	2-114	Office 09	11.55		
MF-G2	Bfl.BioN	2-115	Office 10	17.29		
MF-G2	Bfl.BioN	2-116	Office 11	29.62		
MF-0			E-UV			0.39
MF-G2	Bfl.BioN	2-119	Meeting room	22.32		
MF-G2	Bfl.BioN	2-120	Social area	22.37		
MF-G2	Bfl.BioN	2-118	Corridor 2		15.98	
MF-G2	Bfl.BioN	2-001	Corridor 3		18.26	
MF-G	ggMfl	2-010	Stairwell 1		4.98	
MF-0		2-004	Lift 1		3.33	
MF-0		2-006	E-/EDV-UV 1			7.24
MF-0		2-005	Shaft 1			5.83
MF-G2	Lfl.BioN	2-002	Corridor 4		60.97	
MF-G2	Lfl.BioN	2-009	Communication zone	22.30		
MF-G2	Lfl.BioN	2-016	Pre-clinical	32.82		
MF-G2	Lfl.BioN	2-003	Typing pool	20.33		
MF-G2	Lfl.BioN	2-014	Typing pool	14.56		
MF-G2	Lfl.BioN	2-015	Typing pool	21.83		
MF-G2	Lfl.BioN	2-017	Typing pool	21.30		
MF-G2	Bfl.BioN	2-007	Vestibule toilet, male	3.90		
MF-G2	Bfl.BioN	2-008	Toilet, male	5.06		

MF-G2	Bfl.BioN	2-011	Vestibule toilet, female	3.90			
MF-G2	Bfl.BioN	2-012	Toilet, female	5.06			
MF-G2	Lfl.BioN	2-013	Corridor 5		28.32		
MF-G2	Lfl.BioN	2-019	Tea kitchen	19.32			
MF-G2	Lfl.BioN	2-021	Typing pool	17.57			
MF-G2	Lfl.BioN	2-022	Typing pool	17.57			
MF-G2	Lfl.BioN	2-024	Storage	17.85			
MF-G2	Lfl.BioN	2-018	Analytics	40.50			
MF-G2	Lfl.BioN	2-020	Laboratory DSP	50.62			
MF-G2	Lfl.BioN	2-026	Microscopy room	10.84			
MF-G2	Lfl.BioN	2-023	Laboratory USP	40.46			
MF-G2	Lfl.BioN	2-025	Kitchen/autoclave	29.46			
MF-G2	ggMfl	2-038	Corridor 6		44.27		
MF-G2	ggMfl	2-040	Stairwell 2		5.18		
MF-0		2-036	Electro UV3			7.02	
MF-G2	Lfl.BioN	2-037	Washroom	4.68			
MF-G2	Lfl.BioN	2-041	PuMi	4.65			
MF-G	ggMfl.L	2-045	Pipette calibration	15.32			
MF-0		2-044	Lift 2		6.98		
MF-0		2-039	Shaft 2			8.28	
MF-0		2-043	Shaft 3			8.70	
MF-0		2-046	Shaft 4			8.70	
MF-0		2-042	Shaft 5			8.28	
MF-G2	Lfl.BioN	2-052	Corridor 7		18.42		
MF-G2	Lfl.BioN	2-047	Changing room, female	15.70			
MF-G2	Lfl.BioN	2-048	Washroom, female	5.70			
MF-G	Lfl.BioN	2-049	Changing room, male	11.98			
MF-G2	Lfl.BioN	2-050	Washroom, male	5.56			
MF-G2	Lfl.BioN	2-051	Copy room	6.16			
MF-G2	Lfl.BioN	2-054	Typing pool	17.59			
MF-G2	Lfl.BioN	2-056	Typing pool	17.57			
MF-G2	Lfl.BioN	2-058	Refrigerator room	13.45			
MF-G2	Lfl.BioN	2-053	Testing laboratory	30.30			
MF-G2	Lfl.BioN	2-055	Kitchen/autoclave	30.39			
MF-G2	Lfl.BioN	2-057	Laboratory ELISA	30.39			
MF-G2	Lfl.BioN	2-059	Laboratory Luminex	30.68			
MF-G2	Lfl.BioN	2-060	Laboratory Pre-PCR	29.73			
MF-G2	Lfl.BioN	2-061	Laboratory Post-PCR	20.14			
MF-G2	Lfl.BioN	2-065	Typing pool	14.67			
MF-G2	Lfl.BioN	2-064	Typing pool	14.04			
MF-G2	Lfl.BioN	2-063	IHC	51.35			
MF-G2	Lfl.BioN	2-062	Chemical storage	12.64			
MF-G2	Lfl.BioN	2-079	Corridor 8		56.24		
MF-G2	Bfl.BioN	2-081	Vestibule toilet, female	3.90			
MF-G	Bfl.BioN	2-082	Toilet, female	5.06			
MF-G2	Bfl.BioN	2-087	Vestibule toilet, male	3.90			
MF-G	Bfl.BioN	2-088	Toilet, male	5.06			
MF-0		2-085	Shaft 6			5.83	
MF-0		2-086	E-EDV UV 2			7.24	
MF-G2	Bfl.BioN	2-083	Corridor 9		18.26		
MF-G	ggMfl	2-080	Stairwell 3		4.98		
MF-0		2-084	Lift 3		3.33		
MF-G1/2	Subtotal Second Floor			1092.30	335.14	0.00	1427.44
MF-0	Subtotal Second Floor			0.00	13.64	67.51	81.15

3rd Floor

Area type	Division	Room number	Room description	NF (m ²)	VF (m ²)	TF (m ²)
MF-G2	Bfl.BioN	3-101	Corridor 1		59.488	
MF-G2	Bfl.BioN	3-102	Combination zone	29.34		
MF-G2	Bfl.BioN	3-103	Storage	7.22		
MF-G2	Bfl.BioN	3-104	Copy room	6.99		
MF-G2	Bfl.BioN	3-105	Office 01	17.24		
MF-G2	Bfl.BioN	3-106	Office 02	17.31		
MF-G2	Bfl.BioN	3-107	Office 03	11.53		
MF-G2	Bfl.BioN	3-108	Office 04	11.55		
MF-G2	Bfl.BioN	3-109	Office 05	11.52		
MF-G2	Bfl.BioN	3-110	Office 06	24.91		
MF-G2	Bfl.BioN	3-111	Office 07	9.72		
MF-G2	Bfl.BioN	3-112	Office 08	9.68		
MF-G2	Bfl.BioN	3-113	Office 09	24.91		
MF-G2	Bfl.BioN	3-114	Office 10	17.29		
MF-G2	Bfl.BioN	3-115	Office 11	17.31		
MF-G2	Bfl.BioN	3-116	Office 12	17.31		
MF-G2	Bfl.BioN	3-117	Office 13	17.24		
MF-0			E-UV			0.39
MF-G2	Bfl.BioN	3-119	CliFo function room/meetings	22.32		
MF-G2	Bfl.BioN	3-120	Social area	22.37		
MF-G2	Bfl.BioN	3-118	Corridor 2		15.98	
MF-G2	Bfl.BioN	3-001	Corridor 3		18.26	
MF-G	ggMfl	3-010	Stairwell 1		4.98	
MF-0		3-004	Lift 1		3.33	
MF-0		3-006	E-/EDV-UV 1			7.24
MF-0		3-005	Shaft 1			5.83
MF-G2	Lfl.BioN	3-002	Corridor 4		51.22	
MF-G2	Bfl.BioN	3-007	Vestibule toilet, male	3.90		
MF-G2	Bfl.BioN	3-008	Toilet, male	5.06		
MF-G2	Bfl.BioN	3-011	Vestibule toilet, female	3.90		
MF-G2	Bfl.BioN	3-012	Toilet, female	5.06		
MF-G2	Lfl.BioN	3-015	FACS	21.46		
MF-G2	Lfl.BioN	3-009	FACS	22.15		
MF-G2	Lfl.BioN	3-017	MolBio 2	20.93		
MF-G2	Lfl.BioN	3-003	MolBio 1	27.61		
MF-G2	Lfl.BioN	3-014	Functional laboratory 1	29.11		
MF-G2	Lfl.BioN	3-016	Functional laboratory 2	21.30		
MF-G2	Lfl.BioN	3-018	Lock	5.65		
MF-G2	Lfl.BioN	3-019	Cell culture 1	35.18		
MF-G2	Lfl.BioN	3-021	Cell culture 2	40.46		
MF-G2	Lfl.BioN	3-024	Cell culture 3	29.10		
MF-G2	Lfl.BioN	3-025	Typing pool	11.37		
MF-G2	Lfl.BioN	3-028	Cell culture 4	39.62		
MF-G2	Lfl.BioN	3-013	Corridor 5		28.32	
MF-G2	Lfl.BioN	3-027	Kitchen/autoclave	22.82		
MF-G2	Lfl.BioN	3-026	Cool room	11.72		
MF-G2	Lfl.BioN	3-023	Storage	17.59		
MF-G2	Lfl.BioN	3-022	Typing pool	17.57		
MF-G2	Lfl.BioN	3-020	Typing pool	13.45		
MF-G2	Lfl.BioN	3-038	Corridor 6		44.27	
MF-G	ggMfl	3-040	Stairwell 2		5.18	
MF-0		3-036	Electro UV 3			7.02
MF-G2	Lfl.BioN	3-037	Washroom	4.65		
MF-G2	Lfl.BioN	3-041	PuMi	4.68		
MF-G2	Lfl.BioN	3-045	Nitrogen store	15.32		
MF-0		3-044	Lift 2		6.98	
MF-0		3-039	Shaft 2			8.28
MF-0		3-043	Shaft 3			8.70
MF-0		3-046	Shaft 4			8.70
MF-0		3-042	Shaft 5			8.28
MF-G2	Lfl.BioN	3-052	Corridor 7		18.42	
MF-G2	Lfl.BioN	3-047	Changing room female	15.70		
MF-G2	Lfl.BioN	3-048	Washroom, female	5.70		
MF-G2	Lfl.BioN	3-049	Changing room, male	11.98		
MF-G2	Lfl.BioN	3-050	Washroom, male	5.56		
MF-G2	Lfl.BioN	3-051	Copy room	6.16		
MF-G2	Bfl.BioN	3-056	Secretarial	11.72		
MF-G2	Bfl.BioN	3-053	Office managing director	36.88		
MF-G	ggMfl	3-079	Corridor 8		56.24	
MF-G2	Lfl.BioN	3-054	Staff stay	91.08		
MF-G	ggMfl.L	3-057	Chemical laboratory	30.68		

MF-G1	Lfl.Gany	3-059	Storage	12.61			
MF-G1	Lfl.Gany	3-060	Storage GxP analytics	44.11			
MF-G1	Lfl.Gany	3-061	Typing pool	21.30			
MF-G1	Lfl.Gany	3-058	Standard laboratory	43.61			
MF-G1	Lfl.Gany	3-062	Meeting room	20.93			
MF-G2	Bfl.BioN	3-081	Vestibule toilet, female	3.90			
MF-G2	Bfl.BioN	3-081	Toilet, female	5.06			
MF-G2	Bfl.BioN	3-087	Vestibule toilet, male	3.90			
MF-G2	Bfl.BioN	3-088	Toilet, male	5.06			
MF-0		3-085	Shaft 6				5.83
MF-0		3-086	E-EDV UV 2				7.24
MF-G	ggMfl	3-083	Corridor 9			18.26	
MF-G	ggMfl	3-080	Stairwell 3			4.98	
MF-0		3-084	Lift 3			3.33	
MF-G1/2 Subtotal Third Floor				1101.36	325.59	0.00	1426.95
MF-0 Subtotal Third Floor				0.00	13.64	67.51	81.15

Attic floor / penthouse

Area type	Division	Room number	Room description	NF (m ²)	VF (m ²)	TF (m ²)	
MF-G2	Bfl.BioN	4-001	Corridor 1		18.26		
MF-G	ggMfl	4-010	Stairwell 1		4.65		
MF-0		4-004	Lift 1		3.33		
MF-0		4-006	E-/EDV-UV 1			7.24	
MF-0		4-005	Shaft 1			5.83	
MF-G2	Lfl.BioN	4-002	Corridor 2		65.38		
MF-G2	Bfl.BioN	4-007	Vestibule toilet, male	3.90			
MF-G2	Bfl.BioN	4-008	Toilet, male	5.06			
MF-G2	Bfl.BioN	4-011	Vestibule toilet, female	3.90			
MF-G2	Bfl.BioN	4-012	Toilet, female	5.06			
MF-G2	Lfl.BioN	4-003	Storage	12.64			
MF-G2	Lfl.BioN	4-014	Typing pool	15.24			
MF-G2	Lfl.BioN	4-015	Typing pool	14.29			
MF-G2	Lfl.BioN	4-016	Typing pool	12.38			
MF-G2	Lfl.BioN	4-017	Typing pool	12.65			
MF-G2	Lfl.BioN	4-018	Typing pool	12.69			
MF-G2	Lfl.BioN	4-019	Typing pool	12.49			
MF-G2	Lfl.BioN	4-009	Meeting room	20.96			
MF-G2	Lfl.BioN	4-020	Quiet room	12.75			
MF-G2	Lfl.BioN	4-013	Corridor 3		39.28		
MF-G2	Lfl.BioN	4-021	Pre PCR	30.47			
MF-G2	Lfl.BioN	4-023	Post PCR	30.39			
MF-G2	Lfl.BioN	4-029	Molbio	43.03			
MF-G2	Lfl.BioN	4-027	Cycler	8.89			
MF-G2	Lfl.BioN	4-025	Chemical storage	8.90			
MF-G2	Lfl.BioN	4-030	Plasmide	31.05			
MF-G2	Lfl.BioN	4-022	Typing pool	13.45			
MF-G2	Lfl.BioN	4-024	Typing pool	17.57			
MF-G2	Lfl.BioN	4-026	Typing pool	17.59			
MF-G2	Lfl.BioN	4-028	Typing pool	17.59			
MF-G2	Lfl.BioN	4-031	Tea kitchen	16.95			
MF-G2	Lfl.BioN	4-038	Corridor 4		44.27		
MF-G	ggMfl	4-040	Stairwell 2		5.18		
MF-G2	Lfl.BioN	4-037	Washroom	7.02			
MF-G2		4-041	MSR-technical			9.33	
MF-G2	Lfl.BioN	4-045	Nitrogen store	15.32			
MF-0		4-044	Lift 2		6.98		
MF-0		4-039	Shaft 2			8.28	
MF-0		4-043	Shaft 3			8.70	
MF-0		4-046	Shaft 4			8.70	
MF-0		4-042	Shaft 5			8.28	

MF-G2	Lfl.BioN	4-052	Corridor 5		18.42			
MF-G2	Lfl.BioN	4-047	Changing room, female	15.70				
MF-G2	Lfl.BioN	4-048	Washroom female	5.70				
MF-G2	Lfl.BioN	4-049	Changing room, male	11.98				
MF-G2	Lfl.BioN	4-050	Washroom male	5.56				
MF-G2	Lfl.BioN	4-051	Copy room	6.16				
MF-G2	Lfl.BioN	4-053	Kitchen/autoclave	30.30				
MF-0	Lfl.BioN	4-055	HPLC laboratory	30.39				
MF-G2	Lfl.BioN	4-079	Corridor 6		56.28			
MF-G	Lfl.BioN	4-059	Spectroscopy	17.18				
MF-0	Lfl.BioN	4-058	Laboratory formulation	43.89				
MF-G2	Lfl.BioN	4-054	Storage	11.72				
MF-G2	Lfl.BioN	4-056	Typing pool	23.44				
MF-G2	Lfl.BioN	4-057	Refrigerators	13.45				
MF-G2	Lfl.BioN	4-061	Laboratory RNA cleaning analysis	20.33				
MF-G2	Lfl.BioN	4-062	Laboratory RNA cleaning analysis	21.83				
MF-G2	Lfl.BioN	4-060	Laboratory RNA synthesis	43.91				
MF-G2	Lfl.BioN	4-064	Typing pool	20.63				
MF-G2	Lfl.BioN	4-063	Process development	35.89				
MF-G2	Bfl.BioN	4-081	Vestibule toilet, female	3.90				
MF-G2	Bfl.BioN	4-082	Toilet, female	5.06				
MF-G2	Bfl.BioN	4-087	Vestibule toilet, male	3.90				
MF-G2	Bfl.BioN	4-088	Toilet, male	5.06				
MF-0		4-085	Shaft 6			5.83		
MF-0		4-086	E-/EDV-UV 2			7.24		
MF-G2	Bfl.BioN	4-083	Corridor 7		18.26			
MF-G	ggMfl	4-080	Stairwell 3		4.66			
MF-G		4-084	Lift 3		3.33			
MF-G1/2 Subtotal Attic Floor				778.21	274.64	0.00		1052.85
MF-0 Subtotal Attic Floor				0.00	13.64	69.43		83.07

[Floor plans attached to original lease follow]

Society of Property
Researchers, Germany

Wilhelmstraße 12
D-65185 Wiesbaden

Telephone (0611) 3 34 49 70
Fax (0611) 3 34 49 75

E-mail info@gif-ev.de
Internet <http://ww.gif-ev.de>

Guideline
for the calculation
of
lease areas for commercial properties
(MF-G)

1 November 2004

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Immobilienwirtschaftliche
Forschung e.V.
Working group
Area Definition

in agreement with

DIN
Construction Standards Committee
DIN 277

Supported by
RICS Germany, [illegible] Germany and GFFMA Germany

Members of the gif working group Area Definition, guideline MF-G

[***]

This guideline was generated by the gif working group Area Definition and approved by gif e.V. It represents an approach that is considered correct by the members of gif e.V. This guideline is a source of knowledge for the correct conduct under normal conditions. Individuals must decide at their own responsibility whether application of the guideline is correct in a specific case and whether it will lead to a correct result.

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PREAMBLE

When a lease relationship is created in connection with a property, the lease area plays a crucial role. This is the case in particular because a legally binding definition of the lease area does not currently exist for commercially used objects. It has therefore always been of particular interest to deal not only with the rent aspect, but also with the definition of what constitutes the lease area.

Depending on the market and interest position, the area set constituting the lease area was extended more or less on each occasion. This lease area did not reflect the actual serviceability of the area of the object in question very reliably.

The guideline for calculating the rental area of commercial facilities (MF-G) formulates a set of rules that sees the lease area as a single entity to be deduced directly from the object characteristics. It is therefore no longer subject to regional customs or to building typology. In the same way it no longer knows variation tolerances for one and the same object.

Gif is providing market participants with a set of rules designed to achieve the following aims as defined in the sense of its working hypothesis *Definition and improvement of professional standards in the property industry with the Guideline MF-G*:

- Increased planning security during the development, realisation and utilisation phases
- Increased significance and comparability of lease area information
- Reduction of cases in which a re-calculation of the lease area becomes necessary

Guideline MF-G defines the lease area of commercially leased or used buildings. It complies with the terminology and features of DIN 277 *Floor space and volume capacities of structural engineering buildings*. The guideline is market-related but independent, and ensures that calculations can be completed consistently clearly and reproducibly.

This guideline serves for area calculations only and is not suitable for a monetary value assessment of areas.

APPLICATION AND LIMITATIONS

Guideline MF-G is a summary, harmonisation and further development of the guidelines introduced since 1996 (MF-B) and 1997 (MF-H) for lease area calculations for office and commercial properties. Upon publication of the guideline MF-G the same replaces its two predecessors. It means that this guideline applies to all leased or utilised buildings.

Guideline MF-G builds on the definition resources of DIN 277. For this reason, knowledge of DIN 277 is essential for the user of the guideline. DIN 277 is not a lease area definition. It deals with statements regarding the systemisation of floor space and volumes of building construction. Guideline MF-G exceeds this in that it determines which of these areas are part of the lease area and which are not. The proportional allocation of common use areas is also regulated. For this reason, we differentiate between exclusively and jointly used areas.

Guideline MF-G refers to DIN 277 in the version valid from 2005. The main usage area (HNF) and the additional usage area (NNF) are summarised into one usage area (NF) there. Functional areas (FF) are described as technical functional areas (TF). DIN 277, 1987, continues to apply for the transition period until DIN 277, 2005 is published.

According to guideline MF-G the lease area is normally smaller than the gross floor space (BGF) of DIN 277, as certain areas that form part of BGF are not part of the lease area.

In an individual case it may transpire that an area forms part of the lease area even though it makes sense not to include it from a monetary point of view.

Areas not delimited to the required extent in DIN 277 or not forming part of BGF, which can however be rented out as leased objects, are listed in chapter Other Leased objects. Such leased objects must be specifically listed and calculated separately from the MF-G.

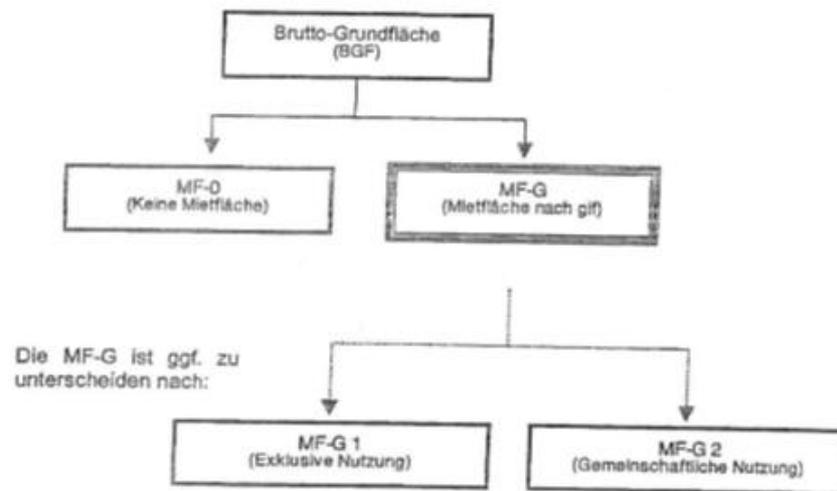
Guideline MF-G specifies that a change in the sizing of lease units within a building has no effect on the total lease area of the object. Measure requiring planning approval will however mostly result in changes to the total lease area.

Part areas leading to the lease area should be systematically and clearly recorded in a lease area log, which must be detailed to such a degree that all major qualitative differentiation criteria are recognisable from the same. The lease area calculation should be part of the lease agreement or a supplementary agreement.

The guideline should only be used in its entirety. If use of the same deviates in individual points this must be stated in summary with direct reference to guideline MF-G. In all other cases a reference to guideline MF-G must be omitted.

1 GIF AREA TYPES

The area types of this guideline are divided into MF-D (no lease area) and MF-G (lease area according to gif) based on the gross floor space according to the following structure model.



Brutto-Grundfläche (BGF)

= gross floor space (BGF)

MF-O (Keine Mietfläche)

= MF-D (no lease area)

MF-G (Mietfläche nach gif)

= MF-G (lease area according to gif)

Die MF-G ist ggf. zu unterscheiden nach:

= the MF-G may have to be differentiated according to:

MF-G 1 (Exklusive Nutzung)

= MF-G 1 (exclusive use)

MF-G 2 (Gemeinschaftliche Nutzung)

= MF-G 2 (common use)

The allocation of building floor space to MF-O and MF-G is obvious and simply object-dependent. It can normally change only following a measure requiring planning approval.

The factitive case of several tenants occupying the building is assumed for calculating MF-O for just one tenant or user.

Differentiation between the lease areas according to exclusive usage right (MF-G 1) and common usage right (MF-G 2) is realised according to an assumed lease situation during the planning and construction phase. The actual situation must be illustrated during the usage phase.

Classification as an area with exclusive usage right (MF-G 1) is typically characterised by:

- the right to exclude other users
- the right to occupy the area with personnel and/or objects

The ratio of MF-G 1 to MF-G 2 may change for a new lease situation within a building.

1.1 MF-O, no lease area

Areas that are not lease areas are called MF-O.

None of the following floor space types of DIN 277 are lease areas:

1.1.1 Technical function areas (TF)

a All technical function areas

1.1.2 Public areas (VF)

b fixed and moveable staircases and ramps and their interim plinths (exception landing plinths), list shaft floor space per stopping point

c vehicle traffic areas

d paths, stairs and balconies, the main purpose of which serves for escape and rescue

e in shopping centres: entry halls, shopping malls and atriums

1.1.3 Basic construction areas (KGF)

f external walls

g floor space of upright construction components such as walls and supports, necessary for the structural, i.e. supporting and/or reinforcing room construction of a building

h floor space of enclosing walls, technical function and traffic areas forming part of MF-O

I floor space of installation channels and shafts, chimneys as well as crawl spaces representing construction floor space according to DIN 277

All three of the floor space types listed here are lease areas if they are the consequence of an individual lease requirement. This will be the case where they are specifically agreed between landlord and tenant.

1.2 MF-G lease area according to gif

1.2.1 MF-G

A floor space forming part of the gross floor space and not classified as MF-O is a lease area and is called MF-G.

The floor space of a lease area separation wall that is not classified as MF-O is allocated to neighbouring tenants at half each.

Vehicle parking areas are not classified as MF-G, but can be leased objects (see chapter 4).

All areas of MF-G with a clear room height of 1.50 m and less must be identified as such.

1.2.2 MF-G and MF-G 2

Depending on the lease situation the lease area MF-G can be divided into lease areas with an exclusive usage right and those with common usage rights:

MF-G 1 Lease area with exclusive usage right

MF-G areas found inside buildings are classified as exclusive lease areas when they can normally be allocated to one tenant.

They are called exclusive lease areas (MF-G 1).

MF-G 1 Lease area with common usage right

MF-G areas found inside buildings are classified as a common usage area when it is typically allocated to several or all tenants.

These should be allocated to all tenants proportionally (see chapter 3.2).

They are called common usage areas (MF-G 2).

2 LEASE AREA LAYOUT

<u>DIN 277</u>	<u>gif area types *</u>	
<u>SGF</u>	<u>MF-O</u>	<u>MF-G</u>
	Vehicle parking areas (parking spaces)	Common rooms, rest rooms, social areas, waiting rooms, dining rooms, detention areas, office facilities, open-plan offices, meeting rooms, construction rooms, ticket offices, operating rooms monitoring rooms, office technology rooms works halls, workshops, laboratories, rooms for keeping animals and plant propagation kitchens, special work rooms storage rooms, archives, collection rooms, cool rooms goods-in and goods despatch rooms sales and exhibition rooms differential steps (max. 3 steps) teaching and training rooms, library rooms, sports room, meeting rooms stages, studio rooms, display rooms, religious rooms rooms with medical equipment for operations, diagnostics and therapy, bedrooms sanitary rooms, wardrobes, storage closets rooms for central supply technology (for example power stations, radio centres) protective spaces loggias, balconies, covered building floor space useable roof areas
TF	Wastewater treatment and disposal water supply heating and grey water heating fuel storage gases and fluids electricity supply telecommunications technology ventilation technical systems lift and transport system machine rooms switching areas house connection and installation, waste incineration	Technical systems with individual tenant requirement
VF	Paths, stairs and balconies serving mainly escape and rescue purposes Areas without individual tenant requirement: fixed and moveable stairs and ramps and their interim plinths lift shafts, disposal shafts (each per floor) vehicle traffic areas	Corridors, entry halls, foyers (except in shopping centres) Storey plinths of stairwells areas with individual tenant requirement: fixed and moveable stairs and ramps and their interim plinths lift shafts, disposal shafts (each per floor) Loading ramps, platforms
KGF	External walls and supports internal walls and supports necessary for construction (supporting or reinforcing) purposes enclosure walls MF-Os surrounding TFs, VFs	Light separation walls or other moveable or changeable constructions lease area separation walls between MF-G areas KGFs necessary on the basis of tenant requirements

* The examples show some typical usage scenarios without claim to completeness. The regulations of the guideline text precede this lease area plan in cases of doubt.

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3 RULES FOR CALCULATION AND ILLUSTRATION

3.1 Measuring points for area calculation

In principle floor space is recorded directly above the floor inside the completed surfaces. Skirting boards, guard rails and facing formwork that is not of ceiling height as well as installations will not be included.

In principle, measurements should extend right up to all room-delimiting components including formwork of ceiling height.

Curtain walls with floor-level horizontal support profiles should be measured up to the inside of any glazing. Vertical fascia profiles are disregarded in the floor plan.

3.2 Allocation of jointly used lease area

MF-G 2 should be allocated to participating parties. The type of allocation must be stated. The calculation must be comprehensible.

3.2.1 Division into sections

Depending on the lease situation of a property a sectional division must be defined. Sections can include entire properties, individual buildings, storeys, construction sections or components.

3.2.2 Calculation within a section

Commonly used areas within such sections are added up and allocated to the parties proportionally at the ratio of MF-G 1.

3.3 Illustration and proof

The calculation of MF-G and the listing of other leased objects (chapter 4) will be according to plans, CAD data or to local measurements. The calculation basis must be stated.

The above areas will be confirmed by means of tables and plans.

3.3.1 Table

The lease area calculation must be compiled in table form. The following areas should be identified separately:

- Division into sections according to chapter 3.2.1; by storey, construction section etc.
- Lease areas;
- gif area types (MF-O, MF-G and possibly MF-G 1, MF-G 2);
- Area types according to DIN 277, part 1, point 3, separated into different usage and area types recorded as areas b or c in line with DIN 277, part 1, point 4;
- Areas with a clear room height of 1.50m and less

3.3.2 Layouts

The various gif area types (MF-O, MF-G and possibly MF-G 1, MF-G 2) must be illustrated on lease area layouts to be graphically distinguishable.

Each continuous lease area must be equipped with a lease area stamp that will allow the same to be identified in the table.

The dimensional specifications of DIN 1356 apply; a minimum scale of 1:100 shall be used as a basis unless specified otherwise.

4 OTHER LEASED OBJECTS

Areas which can be leased objects are listed below, whilst the underlying areas of the same cannot be classified as a MF-G lease area. These leased objects are subject to individual tenant requirements and must then be agreed separately.

4.1 Vehicle parking areas

Vehicle parking areas (parking spaces) within parking areas. They will be identified by numbers.

4.2 Display windows

The area difference between the inner edge of the fascia alignment and the MF-G area of the sales room at the width of the fascia opening, measured at floor height. The floor space of all display window components are included. Green areas near upright components of the fascia are not part of the leased object.

4.3 Customer service zones

Customer service zones up to a depth of 1.00 m and a width of the clear sales opening, where these are located outside of a MF-G area and on the land of the landlord.

4.4 Ceiling apertures

Large-format opening in storey ceilings are not floor space according to DIN 277 unless they lie inside an exclusive lease area.

4.5 Gastronomy zones

Gastronomy or bar areas (outside or inside of general areas) in their actual expansion, where they lie on the land of the landlord.

4.6 Event zones, market stalls

Zones in malls or shopping arcades of shopping centres for temporary campaigns, events or other use.

4.7 Stacked staircases

The additional floor space of staircases inside of exclusive lease areas in a case where these are larger than the simple projection onto the storey above.

4.8 Covered building areas

Covered building areas, where these are envisaged for the exclusive or common use by tenants (for example external sales areas of garden centres, shopping trolley parking areas etc.)

5 GRAPHIC EXPLANATIONS

5.1 MF-G in context MF-0, MF-G 1 and MF-G 2

Floor plan A shows a storey with two lease areas, reached via a common stairwell and a common lift vestibule.

[***]

Mieter = tenant

The external wall is firstly designed as a punctuated fascias (top) and secondly as a strip-structured fascia (bottom). The strip-structured fascia consists of a glazed area arranged above a parapet. The lease area separation results from a fixed wall and a light separation wall, which is to simplify the variation of the lease area layout.

[***]

Mieter = tenant

MF-O: The lift shaft area, the stairs with interim plinth, the shafts required for operating the building reinforcing construction components and the wall that enclose the MF-O areas.

[***]

Mieter = tenant

MF-G 1: The exclusive lease areas of tenants 1 and 2

MF-G 2: The common lease area (lift vestibule/ storey plinth)

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5.2 Lease area limits near fascias

The drawings show sections of a punctuated (B) and a strip-structured fascia (C).

Floor plan B

Floor plan C

[***]

Section B

Section C

[***]

The floor space is measured at the height of the completed floor up to the room delimiting component, i.e.

up to the inner edge of the external wall up to the inner edge of the glazing

5.3 Allocation of partition walls

The drawings show sanitary areas in which light separation walls are used as room dividers.

Floor plan D

Floor plan E

[***]

Section D

Section E

[***]

The area of the installation shaft and the floor space of the light separation walls surrounding the same are no lease areas.

The floor space of the light separation wall and the primary walling that is not of room height are lease areas.

THE SYMBOL “[*]” DENOTES PLACES WHERE CERTAIN IDENTIFIED
INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i)
NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE
COMPANY IF PUBLICLY DISCLOSED**

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1st Additional Agreement

to the

Sublease of 12.12.2012/14.01.2013

between

University Medical Center of Johannes Gutenberg-Universität Mainz,

55131 Mainz, Langenbeckstraße 1,

represented by

the Chairperson and Medical Chairperson [***],

the Academic Chairperson, (Univ.) [***], and

the Commercial Chairperson [***]

(hereinafter referred to as “Unimedizin”)

and

BioNTech AG,

55131 Mainz, An der Goldgrube 12,

represented by

the Chairperson [***] (with German business degree)

(hereinafter referred to as “Sublessee”)

concerning

Laboratory and administrative premises “An der Goldgrube 12” in 55131 Mainz.

Following interim completion of the rental property with the address “An der Goldgrube 12” in “55131 Mainz”, the parties agree to amend the Sublease 12.12.2012/14.01.2013 as follows:

1. In compliance with Section 4 Point 1 of the Sublease the sub-lease relationship commences on 1 June 2014 and ends on 31 May 2024.
2. The actual leased area within the meaning of Section 1 Point 1 of the lease comprises in the period from 1 June 2014 to 31 July 2014: The laboratory areas are reduced during the above time period to in aggregate 907 square meters (2nd upper floor 467 square meters; 3rd upper floor 440 square meters).

Office spaces	1,001m ²
Laboratory spaces	
• Special laboratory animals	33m ²
• Laboratory shared	59m ²
• Laboratory spaces	1,795m ²
Filing and storage spaces	182m ²
Filing and storage spaces shared	172m ²
Stable spaces	463m ²
Conference rooms	81m ²
Shared rental and circulation areas	441m ²
Parking spaces	48 spaces

3. The rent pursuant to Section 6 Point 1 of the Sublease in connection with paragraph 2 of this 1st Additional Agreement is:

<u>Utilisation units</u>	<u>Price/m²</u>	<u>Area in m²</u>	<u>Price per utilisation unit</u>
Office spaces	€ [***]	1,001m ²	€ [***]
Laboratory spaces			
• Special laboratory animals (100%)	€ [***]	33m ²	€ [***]
• Laboratory shared (60%)	€ [***]	59m ²	€ [***]
• Laboratory spaces	€ [***]	1,795m ²	€ [***]
Filing and storage spaces	€ [***]	182m ²	€ [***]
Filing and storage spaces shared (60%)	€ [***]	172m ²	€ [***]
Stable spaces (70%)	€ [***]	463m ²	€ [***]
Conference rooms (60%)	€ [***]	81m ²	€ [***]
Shared rental and circulation areas (60%)	€ [***]	441m ²	€ [***]
Parking spaces	€ [***]	48 spaces	€ [***]
Subtotal			€ [***]
Surcharge 1%			€ [***]
Total monthly rent			€ [***]

4. The actual leased areas within the meaning of Section 1 Point 1 of the lease from 1 August 2014 consists of:

Office spaces	1,001m ²
Laboratory spaces	
• Special laboratory animals	33m ²
• Laboratory shared	59m ²
• Laboratory spaces	2,702m ²
Filing and storage spaces	182m ²
Filing and storage spaces shared	172m ²
Stable spaces	463m ²
Conference rooms	81m ²
Shared rental and circulation areas	441m ²
Parking spaces	48 spaces

The calculation of the dimensions and the leased areas according to GIF drawn up by the Architecture firm Ries and Ries from 13 February 2014 are appended as **Appendix 1a and 1b** and form part of the lease. The calculation of the lease is determined according to GIF (Section 1 Point 1 of the Sublease).

5. The rent pursuant to Section 6 Point 1 of the Sublease from 1 August 2014 is:

<u>Utilisation units</u>	<u>Price/m²</u>	<u>Area in m²</u>	<u>Price per utilisation unit</u>
Office spaces	€ [***]	1,001m ²	€ [***]
Laboratory spaces			
• Special laboratory animals (100%)	€ [***]	33m ²	€ [***]
• Laboratory shared (60%)	€ [***]	59m ²	€ [***]
• Laboratory spaces	€ [***]	2,702m ²	€ [***]
Filing and storage spaces	€ [***]	182m ²	€ [***]
Filing and storage spaces shared (60%)	€ [***]	172m ²	€ [***]
Stable spaces (70%)	€ [***]	463m ²	€ [***]
Conference rooms (60%)	€ [***]	81m ²	€ [***]
Shared rental and circulation areas (60%)	€ [***]	441m ²	€ [***]
Parking spaces	€ [***]	48 spaces	€ [***]
Subtotal			€ [***]
Surcharge 1%			€ [***]
Total monthly rent			€ [***]

6. The authorized bank account pursuant to Section 8 Point 1 of the lease is:

Account name: [***]
 Account number: [***]
 IBAN: [***]

Sort code: [***]
 Bank: [***]
 BIC: [***]

- The handover protocol (Appendix 2) of 05. June 2014 was handed over at the handover meeting and forms a part of the Sublease.
7. The expert report in respect of the exemption from the Heating Costs Ordinary (previously Appendix 8) is attached in **Appendix 3** and forms a part of the Sublease.
 8. The room book contains the built-in laboratory equipment and substantiates Appendix 3 of the Sublease. It is attached as **Appendix 4 (CD)** of the 1st Additional Agreement and forms a part of the Sublease.
 9. The previous Appendix 5 of the Sublease in relation to the free areas is replaced by the attached **Appendix 5** and forms a part of the Sublease.
 10. To comply with Section 15 Point 1 of the lease, **Appendix 6** will apply as the insurance policies from 1 March 2014 for
 - fire insurance for the building
 - insurance against storm and damage to the water supply as well as
 - building and property liability insurance.at the time of handover of the building.
 11. The house rules from 1 March 2014 (previously Appendix 9) is attached as **Appendix 7** and forms part of the the Sublease.
 12. Apart from the above, the provisions of the Sublease and the 1st Additional Agreement shall remain unchanged.

- Signature page follows -

Mainz, the 5 July 2014

Sublessee:

[signature]

Name: [***] (with German business degree)

Management Board

Unimedizin:

of Johannes Gutenberg-Universität Mainz
- Public Corporation –

[signature]

Name: [***]

Chairperson and Medical Chairperson

[signature]

Name: [***]

Commercial Chairperson

Approved by the owner of the property and building, SANIPharma GmbH, Haidgraben 5, 85521 Ottobrunn:

[signature]

[***]

Managing Director

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2nd Additional Agreement

to the

Sublease of 12.12.2012/14.01.2013

(hereinafter referred to as the “2nd Additional Agreement”)

between

University Medical Center of Johannes Gutenberg-Universität Mainz,

55131 Mainz, Langenbeckstraße 1,

represented by

the Chairperson and Medical Chairperson [***],

the Academic Chairperson, (Univ.) [***], and

the Commercial Chairperson [***]

(hereinafter referred to as “Unimedizin”)

and

BioNTech AG,

55131 Mainz, An der Goldgrube 12,

represented by

the Chairperson [***]

(hereinafter referred to as “Sublessee” or “Biontech”)

(Unimedizin and the Sublessee are hereinafter also

referred to as the “Contracting Party” or the “Contracting Parties”)

concerning

Laboratory and administrative premises “An der Goldgrube 12” in 55131 Mainz.

On 12 December 2012/14 January 2013, Unimedizin and the Sublessee entered into a sublease concerning premises in the rental property with the address “An der Goldgrube 12” in “55131 Mainz” (hereinafter referred to as the “Sublease”).

In order to ascertain some lease agreements in the Sublease, on 09.07.2014 the Contracting Parties entered into a "1st Additional Agreement to the Sublease of 12.12.2012/14.01.2013" (hereinafter referred to as the "1st Additional Agreement").

Moreover, Ganymed Pharmaceuticals AG (hereinafter referred to as "Ganymed"), which is also a sublessee of premises in the aforementioned rental property, with the consent of Unimedizin, sublet two of the spaces which it had rented from Unimedizin, by means of the "Sublease for Commercial Premises between Ganymed Pharmaceuticals AG and BioNTech AG" dated 27.01.2015 (hereinafter referred to as "GM – Biontech Sublease") to the Sublessee/Biontech. The premises are Room No. 3-059 (surface area 12.61m²) and Room No. 3-062 (surface area 20.93m²).

In consultation with Unimedizin, the Sublessee/Biontech and Ganymed planned for further spaces in the aforementioned property currently rented by Ganymed to be rented to the Sublessee/Biontech. For this purpose, both the Sublessee (Biontech) and Ganymed shall adjust their respective subleases directly with Unimedizin. The two aforementioned premises (Room No. 3-059 and Room No. 3-062), subject of the Ganymed – Biontech Sublease, shall be rented directly to the Sublessee (Biontech) by Unimedizin at the same time as the adjustment of this Sublease and removed in the sublease between Unimedizin and Ganymed correspondingly. The Ganymed – Biontech Sublease shall automatically end at the time of the handover of the additional rental spaces to Biontech, which in turn takes place through the contract adjustment of the respective subleases of Ganymed and the Sublessee in relation to Unimedizin.

With this proviso, Unimedizin and the Sublessee, by means of this 2nd Additional Agreement, would like to change and respectively adjust the spaces and premises rented by the Sublessee in the aforementioned rental property as well as the rental cost, as agreed in the Sublease and in the 1st Additional Agreement, as of 01 May 2015.

1. The actual rental spaces rented by the Sublessee within the meaning of Section 1 Point 1 of the Sublease, last modified by Points 2 and 4 respectively of the 1st Additional Agreement, shall henceforth, as of **01 May 2015**, amount to:

Office spaces	1,037.00m ²
Laboratory spaces	
• Laboratory shared	85.00m ²
• Laboratory spaces	3,044.00m ²
• Special laboratory animals	33.00m ³
Filing and storage spaces	182.00m ²
Filing and storage spaces shared	193.00m ²
Stable spaces	471.00m ²
Conference rooms	91.00m ²
Shared rental and circulation areas	496.00m ²
Parking spaces	48 spaces

The calculation of the rental spaces and the utilisation units of the rental space are derived from the “Area Overview (following amendment from May 2015)” drawn up by [***] (Ganymed) (appended to this Agreement as **Appendix 1**), and from the “Area Overview (grouped utilisation units ID) (following amendment from May 2015)”, also drawn up by [***] (appended to this Agreement as **Appendix 2**).

2. Following an amendment to the extent of the rental spaces in accordance with Point 1 above, the monthly rental cost shall be calculated in accordance with Section 6 Point 1 of the Sublease, last modified by Point 3 and respectively Point 5 of the 1st Additional Agreement as of **01 May 2015** as follows:

<u>Utilisation units</u>	<u>Price/m²</u>	<u>Area in m²</u>	<u>Price per utilisation unit</u>
Office spaces	[***]	1,037.00m ²	[***]
Laboratory spaces			
• Laboratory shared	[***]	85.00m ²	[***]
• Laboratory spaces	[***]	3,044.00m ²	[***]

• Special laboratory animals	[***]	33.00m ²	[***]
Filing and storage spaces	[***]	182.00m ²	[***]
Filing and storage spaces shared	[***]	193.00m ²	[***]
Stable spaces	[***]	471.00m ²	[***]
Conference rooms	[***]	91.00m ²	[***]
Shared rental and circulation areas	[***]	496.00m ²	[***]
Parking spaces	[***]	48 spaces	[***]
Subtotal			[***]
Surcharge 1%			[***]
Total monthly rent			[***]

3. In accordance with Section 3 No. 2 of the Sublease, a report is to be drawn up concerning the handover and signed by both Contracting Parties. Given the fact that Ganymed is releasing rental space and premises to Unimedizin and Unimedizin is in turn directly handing these over to the Sublessee, the Contracting Parties agree that the rental space and premises shall be directly handed over to the Sublessee by Ganymed. The Sublessee shall draw up a handover report with Ganymed in this respect. The areas and premises rented to the Sublessee shall be listed in the handover report and any established defects shall be documented in the said report. For the handover of the premises, as well as the drafting of the handover report, either a representative of Unimedizin or, in consultation with Unimedizin, a representative of SANIPharma GmbH (owner of the rental property), shall be involved.

The Sublessee shall verify the defects in the rental object in its current condition listed in the handover report of 05.06.2014 (this is appended to the 1st Additional Agreement as Appendix 2 and both Contracting Parties have a copy thereof) concerning the handover of the rental object from Unimedizin to the Sublessee (Biontech) upon the handover of the relevant rental space and premises to the Sublessee (Biontech) and shall document them in the report correspondingly.

The handover report shall be appended to this 2nd Additional Agreement as **Appendix 3** following the handover date.

Unimedizin shall include a provision corresponding to the above in the additional agreement or supplementary agreement between it and Ganymed.

4. Apart from the above, the provisions of the Sublease and the 1st Additional Agreement shall remain unchanged.

Appendices:

Appendix 1: Area Overview (following amendment of May 2015)

Appendix 2: Area Overview (grouped utilisation units ID) (following amendment of May 2015)

Appendix 3: Handover Report (to be provided later after handover date).

- Signature page follows -

Mainz, June 8, 2015

Sublessee:

BioNTech AG
Mainz

[signature]

Name: [***]

Title: Managing Director, CFO

Mainz, 11.06.15

Unimedizin:

Universitätsmedizin
of Johannes Gutenberg-Universität Mainz
- Public Corporation –

[signature]

Name: [***]

Title: Director service centre purchasing and
logistics

[signature]

Name: [***]

Title: Director department central services

Approved by the owner of the property and building, SANIPharma GmbH, Haidgraben 5, 85521 Ottobrunn:

Mainz
~~Ottobrunn~~, 02.06.2015

P.p. [signature]
[***] [illegible]
Managing Director

...

[***]

DE	EN
Berechnung der Mietkosten mit gerundeten Flächenangaben	Calculation of the rent costs with rounded surface area information
Angaben Mietvertrag	Lease information
Nutzungseinheiten	Utilisation units
Kosten/QM	Costs/m ²
Summe von Fläche	Total surface area
Summe von Fläche Ganymed	Total surface area Ganymed
Summe von Summe Kosten Ganymed	Total of total costs Ganymed
Summe von Fläche BioNTech (QM)	Total surface area BioNTech (m ²)
Summe von Summe Kosten BioNTech	Total of total costs BioNTech
Büroflächen	Office spaces
Ergebnis	Result
Labor Gemeinschaftlich	Laboratory shared
Laborflächen	Laboratory spaces
Speziallabor Tiere	Special laboratory animals
Archiv und Lagerflächen	Filing room and storage spaces
Archiv und Lagerflächen Gemeinsam	Filing room and storage spaces shared
Tierstallflächen	Stable spaces

Konferenzräume

Conference rooms

Gemeinschaftl. Mietflächen bzw. Verkehrsflä[chen]

Shared rental surface area and circulation areas

Gesamtergebnis

Total result

zzgl. Parkplätze

Plus parking spaces

Zwischensumme

Subtotal

zzgl.1% Zuschlag

Plus 1% surcharge

Monatsmiete Gesamt (nach Flächenänderung)

Monthly rent total (after area variation)

Stellplätze

Parking spaces

Building "An der Goldgrube 12, Mainz"

Area Overview (grouped utilisation units ID)
(following amendment of May 2015)

by Dirk Brinkhus (Ganymed)

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

THE SYMBOL “[*]” DENOTES PLACES WHERE CERTAIN IDENTIFIED
INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i)
NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE
COMPANY IF PUBLICLY DISCLOSED**

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**3rd Supplemental Agreement
of
Sublease Agreement from 12.12.2012/14.01.2013**

between

University Medical Center of the Johannes Gutenberg University of Mainz,
55131 Mainz, Langenbeckstraße 1,
represented by
the chairman of the executive board and the Medical Director, [***]
the Scientific Director, [***] as well as
the Commercial Director [***]
(hereafter called “Unimedizin”)

and

BioNTech AG
An der Goldgrube 12
55131 Mainz
(hereafter called “Biontech”)

regarding

the building, with laboratory and administration facilities, at An der Goldgrube 12 in 55131 Mainz

The contract parties agree to supplement the sublease agreement from 12.12.2012/ 14.01.2013, last amended with the 1st supplementary agreement from 09.07.2014 and the 2nd supplementary agreement from 02.06.2015/ 08.06.2015 (hereafter together called "sublease agreement") with the following:

The owner of the building, Santo Service GmbH, formerly SANIPharma GmbH, has erected a four-storey extension (ground floor to 3rd floor) in a second building section on the basement of the east wing already erected in the first building section. As per the existing and approved planning application this extension consists of a laboratory and office facilities. The development of access roads and the supply of media such as electricity, heat, water etc. is realised via the existing building section. Unimedizin intends to additionally lease these new lease areas from Santo Services GmbH and to sublet these to Biontech with this addendum.

Ganymed Pharmaceuticals GmbH, formerly Ganymed Pharmaceuticals AG (hereafter called "Ganymed") as well as Unimedizin and Biontech have also agreed in a termination agreement with effect from 01.11.2017 that the sublease agreement between Ganymed and Unimed will end on 01.11.2017 and Biontech will take over the facilities sublet by Ganymed. Unimedizin therefore intends to sublet all areas currently leased by Ganymed to Biontech with this addendum as well, so that Biontech is the sole subtenant for the building with laboratory and administration facilities at An der Goldgrube 12 in 55131 Mainz.

The parties wish to agree the subletting period anew for the entire lease object with this addendum.

1. The regulations stipulated in the sublease agreement continue to apply without limitation with the exception of the newly agreed term according to point 2 below. Apart from that this addendum extends the sublease agreement by the newly added lease areas.
2. Section 4 no. 3 of the sublease agreement is herewith replaced as follows:

The sublease relationship is limited to a period of ten years starting from 01.11.2017. Biontech is granted the option to extend the sublease agreement three times, twice by a respective 5 years each, and a third option ending on 20.04.2039. Exercising the option must be declared in writing at least 18 months prior to expiry of the (possibly extended) lease agreement in writing in each case. The receipt of the declaration by Unimedizin is crucial for compliance with this deadline.

Section 4 para. 2 of the sublease agreement is deleted without replacement by ending the lease agreement between Ganymed and Unimedizin.

Should the financial managers revise the economic allocation of the lease object for taxation purposes in such a way that Biontech is considered the economic owner, the contract partners and Santo Services GmbH are bound to negotiate a regulation that will not lead to disadvantages or advantages for the contract parties.

3. The lease areas in the sense of Section 1 point 1 of the sublease agreement, last amended with the 2nd supplementary agreement from 02.06.2015/ 08.06.2015, apply as follows from 01.11.2017:

Office areas	1,863 m ²
Laboratory areas	4,194 m ²
Archive and storage areas	379 m ²
Animal accommodation areas	679 m ²
Specialist laboratories and animal laboratories	1,304 m ²
Conference rooms	132 m ²
Common lease facilities and traffic areas	865 m ²
Parking spaces	76 spaces

The calculation of the provisional lease areas is carried out according to the plans generated by Architekturbüro Ries und Ries, enclosed as **Appendix 1.1**. Following completion of the building the actual lease areas will be calculated exactly by an officially appointed surveyor according to GIF (Section 1 no. 1 lease agreement) and submitted.

4. The rent according to Section 6 no. 1 of the sublease agreement, last amended with the with the [sic] 2nd supplementary agreement from 02.06.2015/ 08.06.2015, will now be, from 01.11.2017:

<u>Utilisation units</u>	<u>Price/ m²</u>	<u>Area in m²</u>	<u>Price per utilisation area</u>
Office areas	[***]	1,863 m ²	[***]
Laboratory areas	[***]	4,194 m ²	[***]
Archive and storage areas	[***]	379 m ²	[***]
Animal accommodation areas	[***]	679 m ²	[***]
Specialist laboratories and animal laboratories	[***]	1,304 m ²	[***]
Conference rooms	[***]	132 m ²	[***]
Common lease facilities and traffic areas	[***]	865 m ²	[***]
Parking spaces	[***]	76 spaces	[***]
Sub-total			[***]
Surcharge 1%			[***]
Total monthly rent			[***]

5. The size of the security deposit according to Section 20 para. 2 of the sublease agreement is adjusted to the sum of 3 monthly rent payments of the currently agreed monthly rent listed under point 5.
6. The 2nd building section will be completed in August 2017.
7. Handover of the rooms of the east wing will take place following completion and will be recorded in a handover protocol. The date of the handover will be agreed at least 3 weeks in advance. **Appendix 1.2.**

Handover of the areas currently leased by Ganymed to Biontech will also be recorded in a handover protocol. Against the background of the fact that Ganymed will concede lease areas to Unimedizin, and Unimedizin will hand the same over to Biontech immediately following this, the contract parties agree that the handover of the lease areas or facilities will take place directly from Ganymed to Biontech. Biontech [sic] will produce a handover protocol to record this together with Ganymed.
8. The respective room books and plans for the facilities of the east wing will be handed over during said handover. **Appendix 1.3.**
9. The current Appendix 5 of the lease agreement concerning open spaces is replaced with the enclosed **Appendix 1.4.**

Mainz,

Landlord

Universitätsmedizin
of the Johannes Gutenberg University of Mainz
- Public Corporation -

[signature]

Chairman of the executive board
Medical Director

[signature]

Scientific Director

[signature]

Commercial Director

Tenant

BioNTech

[signature]

Director

Approved by the owner of the plot and the building, Santo Services GmbH, Steinstrasse 72, 81667 Munich.

18.01.17 [signature]

[***]

Managing Director

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Lease for Commercial Premises

Contract No.: _____ Date: 17.8.2011

The lease is concluded between the following contracting parties:

Lessor:

Wolfram Richter
Kupferbergterrasse 15, 17-19
55116 Mainz
Tel. : [***]; Fax [***]
Lessor's tax number: [***]

Lessee:

BioNTech AG
Represented by its chairperson, [***] (with German business degree)
Hölderlinstraße 8
D-55131 Mainz
registered in the Commercial Register of the District Court of Mainz, register number: HRB 41865

The Lessor guarantees that he has full representation authorisation to conclude the agreement. The Lessor has opted for value-added tax. For this reason, the Lessee confirms that it is entitled to the deduction of input tax and will only use the rental property for dealings which do not exclude the deduction of input tax. The Lessee undertakes to inform the Lessor immediately in the event that it is no longer entitled to the deduction of input tax.

Section 1 Rental Property

The following shall be rented on the property: Kupferbergterrasse 15, 17-19, 55116 Mainz

- Front building 2nd floor (upper floor) ca. 256m²
- Front building 3rd floor (top floor) ca. 244m²
- Original building 2nd floor (upper floor) ca. 146m²
- Adjacent areas ca. 95m² (then verify)

Moreover, the Lessee shall receive an option on a section in the brick building 2nd floor and commercial building (laboratories) 2nd floor.

The rental spaces are listed in Appendix I with the aforementioned descriptions in the floor plan.

Total rented space ca. 741m², including 646m² for offices, and 95m² for other use. Ca. 741m² of the total space is heated.

Also rented therewith are eight (8) parking spaces on the same property, as well as 7 parking spaces on the bastion property. It shall also be possible to rent further parking spaces.

Section 2 Purpose of Use of the Rental Property

The Lessee shall use the rental property as offices. The option space as appropriate also as laboratories.

The Lessor is aware that this use must be structurally possible and permissible in accordance with public law, insofar as structural conditions and those of the co-rented facilities respectively are concerned.

These conditions must be adhered to for the entire term of the lease by the Lessor.

These conditions must be adhered to for the entire term of the lease by the Lessor. All other conditions, in particular those within the personal or operational circumstances of the Lessee, shall fall within the Lessee's scope of responsibility. In the event that the Lessee fails to adhere to the conditions for which it is responsible, the Lessee shall not be able to invoke the frustration of purpose.

Section 3 Rental Term

1. Contractual term
The tenancy shall begin on 15.09.2011 and end on 14.09.2013.
It shall be extended respectively by two (2) years if neither party objects to the extension in writing in compliance with a six-month notice period.
2. Termination, objection to the extension of the tenancy and the assertion of an agreed extension option must be in writing. Timeliness shall not be determined by the sending of the declaration, but the other party's receipt thereof.
3. At the end of the tenancy, a tacit contractual extension in accordance with Section 545 BGB [Civil Code] shall not come into consideration. Thus, if the Lessee continues to use the rental property after the rental period has expired, the tenancy shall not be extended indefinitely. A declaration against a tacit extension is therefore not necessary.

Section 4 Extraordinary Termination Right of the Lessor

1. The Lessor may terminate the lease with immediate effect without adhering to a notice period,
 - a) if the Lessee is in default with the payment of the rent or a non-insignificant part thereof for two payment deadlines in a row, or in a period covering more than two payment deadlines, is in default with the payment of the rent for an amount which amounts to two months' rent;
 - b) if the Lessee, in spite of a written warning from the Lessor, continues to use the rental property in a way that does not comply with the lease, in particular if it uses the rental property without the Lessor's written consent in a way which is prohibited by Section 2 or in the case of an agreement of a specific commercial use, in ways other than those stated in Section 2, namely in the case of a modification to or significant expansion of the type of operation, business purpose or an agreed product range, or in the case of unauthorised subletting, other usage transfers to third parties, including the unauthorised change of business owner or legal form, and the Lessee hereby infringes the Lessor's rights to a considerable extent (see Section 13 Paragraph 4);
 - c) if the Lessee breaches its obligations in such a way that the Lessor cannot reasonably be expected to continue the tenancy, in particular, in spite of a written warning from the Lessor, it continues to make the rental payments late (collectively or only partial amounts);
 - d) otherwise for cause.

2. Termination must be notified in writing.

Section 5 Rent and Breakdown of the Rent

The monthly rent consists of the following:

Term: 15.09.2011 until 14.09.2013

1. Base rents:

- a) for the office spaces front building 2nd floor, ca. 256m², €[***]m² EUR [***]
- b) for the office spaces original building 2nd floor, ca. 146m², €[***]m² EUR [***]
- c) for other uses ca. 71m², €[***]/m² EUR [***]
- d) for the parking spaces 15 at €[***]each EUR [***]

Net rent:	EUR[***]
Advance payments on the operating costs for ca. 473m² at €[***]/m²	EUR [***]
Net rent including advance payment on operating costs:	EUR [***]
Value-added tax currently 19% VAT	EUR [***]
Gross rent	EUR[***]

From 01.10.2011 the following spaces shall be added:

Term: 01.10.2011 until 31.08.2013

2. Base rents:

- a) for the office spaces front building 3rd floor (top floor) ca. 244m², €[***]/m²: EUR [***]
- b) for other uses ca. 24m², €[***]/m² EUR [***]

Net rent:	EUR[***]
Advance payments on the operating costs for ca. 248m² at €[***]/m²	EUR [***]
Net rent including advance payment on operating costs:	EUR [***]
Value-added tax currently 19% VAT	EUR [***]
Gross rent	EUR[***]

The total rent from 01.10.2011 amounts to:

Net rent including advance payment on operating costs: EUR [***]

Value-added tax currently 19% VAT EUR [***]

Gross rent:	EUR[***]
--------------------	-----------------

Section 6 Operating Costs

Together with the base rent, the Lessee shall bear the operating costs for all rented spaces within the meaning of the Operating Costs Regulations, as amended. In particular, these may include the following cost types. (The list is purely an example and does not oblige the Lessor to make corresponding facilities available):

1. Public charges, e.g.

- Land tax water supply costs, including calibration costs of water meters

- Drainage costs, in particular sewerage and surface drainage
- Costs for operating and maintaining the central heating system, including floor heating
- Costs for operating the central hot water supply system
- Costs for operating the lift equipment
- Street cleaning costs
- Rubbish removal costs
- Building cleaning and pest removal costs
- Garden care costs
- Lighting and shared electricity costs
- Chimney cleaning costs
- Property and liability insurance costs
- Caretaker costs

- Costs for maintaining fire extinguishing units (including the replacement of extinguishing agents) - the following other operating costs:

Gutter cleaning, maintenance of exhaust disposal devices of garages, Maintenance of garages/underground car park doors, Maintenance of alarm installations, video surveillance, intercom and door-opening systems, Costs for monitoring e.g. property security company, doorman costs, etc.

- Management costs, these are the costs for the workforce and facilities necessary for managing the building or the business entity, surveillance costs as well as the value of the management work personally provided by the Lessor. The costs for the statutory or voluntary examination of the annual financial statements and management are also included in the management costs.

2. The Lessee undertakes to register the electricity of the rented premises (not the shared electricity costs) and the following operating costs during the rental period itself with the appropriate provider on its own behalf and at its own expense and maintain this for the rental period, inasmuch as the maintenance of the supply is necessary for the proper performance of the contract.

3. Property and labour services of the Lessor may be set up to the amount of the saved costs for equivalent third-party services.

4. Distribution criteria

Costs which may be specifically assigned to the rental property are to be allocated to this alone. For the distribution of the other costs, which cannot be separated from the costs of the whole property, the following shall apply:

- a) The heating and hot water supply costs shall be distributed in accordance with the allocation principles set out in Section 11.
- b) The water supply costs shall be calculated in accordance with the rental property's use, insofar as corresponding measuring instruments are available. Otherwise, they shall be distributed in accordance with the following allocation principles:

741m² office spaces in accordance with Section 1 Paragraph 1 in proportion to the m² of the entire property.

- c) The sewerage costs shall be allocated in accordance with the water supply costs. If separate fees are calculated for surface drainage, this division shall be carried out in the proportion of the living spaces/usable areas, provided that the fee does not arise for spaces which may be used by the Lessee alone. The fee for spaces usable by the Lessee alone shall be exclusively borne by the Lessee alone.

- d) The costs for rubbish removal shall be specifically allocated, inasmuch as the Lessee uses its own rubbish containers which only it is entitled to use. Otherwise, the costs shall be distributed in accordance with the following allocation principles:

741m² office spaces in accordance with Section 1 Paragraph 1 in proportion to the m² of the entire property.

- e) All other operating costs shall be distributed in accordance with the proportion of the surface area of the entire building, unless another allocation principle has been agreed.
- f) If specific allocation principles have not been agreed, the Lessor shall be responsible for the determination within the framework of the first invoicing at its reasonable discretion.
- g) If, as a result of the usage type of the property, the Lessor incurs special costs (e.g. surcharge for fire insurance, additional rubbish containers), the full amount of these costs shall be allocated to the Lessee.
- h) The Lessor shall be entitled to undertake advance distributions of operating costs, if this makes sense or is necessary owing to the cost types, the property or its use.

6. The Lessor may modify the allocation principle at its reasonable discretion if this is provided for by law or this is required or appears to make sense for reasons relating to the proper management of the building.

7. The following shall apply for the invoicing of the operating costs:

- a) As a rule, advance payments shall be invoiced on a yearly basis. The Lessor may modify the invoice period for reasons of expediency. For this purpose, as an exception, invoice periods which fall short of the usual twelve-month invoicing shall also be possible. No more than twelve months may be invoiced per invoice.

If, following receipt of the operating cost invoice, the Lessee has not expressed its objection to the operating cost invoice within four weeks, the operating cost invoice shall be deemed to have been accepted, objections to the operating cost invoice shall then be excluded.
- b) The invoice amount shall be paid to the contracting partner within four weeks following receipt of the invoice. If the Lessee raises objections to individual invoice items of the operating cost invoice, the Lessee shall have to settle the balance of the operating cost invoice, which does not take into account the items against which objections have been raised.
- c) In the event of increases or reductions in the operating costs, the Lessor shall be entitled to revise the advance payments with effect from the month following the notice of increase. This declaration may be made at any time with the provision of proof of the reason for the change.
- d) The Lessee must bear operating costs within the meaning of Section 6 which arise after the end of the contract from the point at which notice is received from the Lessor. Notice must be made in writing and contain the cost type, reason for the subsequent occurrence of the costs, total costs for the property and/or the business entity, distribution of the costs and the Lessee's share.
- e) For newly-arising operating costs, the Lessor may request appropriate advance payments from when it is informed thereof.

8. If changes to operating costs occur retroactively, the Lessor shall be entitled to allocate them proportionally to the Lessee by notifying it thereof in writing. The statement shall indicate the reason for the apportionment and explain this. In the event of retroactive increases in the operating costs, the Lessor's statement shall have retroactive effect to the time of the increase. If the operating costs decrease, then they shall be reduced accordingly from the time of the decrease.

Section 7 Change in the Rent

1. Payment of value-added tax shall be agreed in the applicable statutory amount. Changes shall apply at the time of the statutory increase.
2. Future changes to the base rent (see Section 5 Paragraph 1) shall be determined by the following agreement:

Index clause, automatic guaranteed value

If the German consumer price index (basis 2000 = 100 points) determined by the Federal Statistical Office changes (increase or decrease) in the future compared with what it was at the time the contract was concluded by at least five percent, then there shall be a corresponding change in the rental amount in the same proportion from the start of the month following this change.

This provision shall apply correspondingly on a repeat basis if the above conditions are met, based on the date of the immediately preceding change in rent in each case. Rental increases arising after the conclusion of the contract in accordance with Paragraph 3 for value-enhancing measures of the Lessor shall be taken into account as follows when applying the guaranteed value clause: The necessary change in the price index shall be based on the status at which the rent increase in accordance with Paragraph 3 becomes effective. For the change in the rent owing to a change in the price index which has arisen since this point in time, the increased rent in accordance with Paragraph 3 shall be taken as a basis.

3. Value-enhancing measures

If the Lessor incurs expenses for modernisation measures within the meaning of Section 559 BGB and other suitable measures or measures for which he is not responsible within the meaning of Section 19 Paragraph 1 b, including development and expansion measures for circulation areas of the property, supply and waste pipelines including the utilities of such facilities or for connections to the broadband cable network, then the Lessor may request an increase in the yearly rent by 11% of the costs attributable to the rental property. The Lessee shall pay the increased rent from the start of the month following the receipt of the written rent increase statement from the Lessor, but not earlier than the start of the month following the completion of the measure.

Section 8 Security Deposit

1. The Lessee undertakes to irrevocably pay a security deposit for all of the Lessor's claims in the amount of [***]EUROS (in words: [***]EUROS) as an absolute, irrevocable, unrestricted and unconditional guarantee (e.g. of a major bank or public savings bank or of a shareholder, general partner or other

third party). The guarantee shall be provided by (exact name of the institute or person including address):

BioNTech AG:

[***]

Sort Code [***]

Account [***]

2. The Lessee shall deliver the written guarantee commitment to the Lessor in the month in which the rental property is handed over. If, in spite of a reminder, the Lessee fails to fulfil this obligation, then the Lessor shall be entitled to withdraw from the contract.
3. The Lessor shall be entitled to set-off, even with lapsed compensation claims, as a result of changes in or deterioration of the rental property, against the Lessee's claim to the repayment of the deposit, even if he has not settled the deposit provided upon termination of the tenancy.

Section 9 Payment of the Rent

1. The total monthly payment amount in accordance with Section 5 shall be paid monthly in advance, but no later than the 3rd working day of the month, to the Lessor's rent account:
Account No. [***]
with [***]
Sort Code: [***]
2. The first rent instalment shall be paid before the rental premises is handed over. Failure to pay, in spite of a reminder, shall mean that the Lessor is entitled to withdraw from the contract.
3. At the Lessor's request, the Lessee shall pay the rent by direct debit.
4. Timeliness of payment shall not be determined by the sending of the amount, but the receipt or crediting thereof. The Lessee may not derive any right to late payment of the rent from multiple non-timely payments. Late payments shall entitle the Lessor to levy reminder fees and default interest and terminate the tenancy where necessary.
5. The Lessor may, at his discretion, credit all payments of the Lessee to base rents, operating costs, other rental components, costs of any legal action including reminder costs and procedural interest, rent arrears and current rent, if the Lessee does not make an effective designation.

If the Lessee owes interest and costs in addition to a main payment (e.g. rent, reimbursement of expenses, compensation or other), its repayment arrangement shall only be effective if the payment is initially credited to the costs, then the interest and finally to the main payment. If the Lessee determines a different imputation, then the Lessor may refuse to accept the payment.

Section 10 Reduction, Set-off, Right of Retention.

1. The Lessee may neither offset nor exercise a right of retention against the rent, nor reduce the rent. The Lessee's claims for compensation for non-fulfilment or reimbursement of expenses as a result of an initial or subsequent defect in the rental property, for which the Lessor is responsible as a result of intent or gross negligence, and other claims derived from the tenancy, insofar as they are undisputed, legally established, or ready for decision, are excluded herefrom. Set-off or the exercise of the right of retention is only permitted if the Lessee has informed the Lessor of its intention in writing at least one month before the rent is due.
2. The reimbursement of any counterclaims from the tenancy asserted by the Lessee by way of set-off shall be made in monthly partial instalments which may not exceed 30% of the respective monthly rent.
3. Set-off against operating costs by the Lessee is not permitted.

Section 11 Heating and Hot Water Supply

1. The rental property has a central heating system, which supplies other building sections of the property with heating in addition to the rental property. The Lessor undertakes to keep the heating system in operation between 1 October and 30 April to the usual extent. Outside of the heating period, the Lessor shall decide on this at its reasonable discretion. The hot water supply system shall remain in operation constantly.
2. The heating costs to be covered as operating costs in accordance with Section 6 include, in particular: Costs of the fuel used and its delivery, costs of the electricity for the heating system, costs for the operation, monitoring and care of the system, the regular inspection of its operational readiness and operational safety including setup by a professional, cleaning of the system including the tank and service room, costs of measurements in accordance with the Federal Pollution Control Act, costs of rental or other kinds of usage transfer of metering equipment as well as the costs for using metering equipment including calibration costs as well as calculation and division. At the start and end of the tenancy, the Lessor, where applicable, proportionally, shall bear the costs for an interim meter reading, unless the start or end of the lease coincides with the start or end of the heating cost accounting period. The above provisions shall apply for the costs of the building's hot water supply system correspondingly.
3. The heating and hot water costs shall be allocated as follows:

At 50%—70% in accordance with the reading of the calorimeters or heat cost allocators and respectively water meters or water cost allocators and at 30%—50% in accordance with the usable or commercial space of the building. If no allocation principles sets are recorded, then these costs shall be ascertained by the Lessor within the framework of the Heating Costs Ordinance with the first invoice.

The Lessor shall be entitled to modify the invoicing criteria at his reasonable discretion within the legally permissible limits if justified interests require this for the proper management of the building.
4. If the rental property is connected to a central heating system, the Lessor shall operate the system himself or shall obtain the required heating from an independent heating provider.
5. Switching between self-supply and heating supply (heating contracting) does not require the Lessee's consent. If the heating is obtained from an independent heating supplier, the Lessor shall only be liable for the absence of the heating supply if breakdowns occur as a result of the Lessor's own in-house

supply lines. In the event of heating contracting, the Lessor may request that the costs of the heating supply be billed by the Lessee directly with the heating supplier. In this case, the Lessor shall not owe any heating cost or hot water bills. An invoice for these costs shall be issued exclusively by the heating supplier without the Lessor's involvement. The allocation of cost shall be determined by the ordinance on the consumption-dependent invoicing of heating and hot water costs (Heating Costs Ordinance) and where applicable the ordinance on general conditions for tele-heating supply (AVBFernwärmeV).

Section 12 Use of the Rental property

1. The Lessee shall be given the following keys for a period of one week from the start of the rental period: **in accordance with the Handover Record of**

The Lessee must immediately inform the Lessor in each case if it loses or acquires keys. The keys provided must be returned upon expiry of the two weeks. At the same time, the Lessee must hand over keys, which it had cut additionally at its own expense, to the Lessor free-of-charge, or must prove destruction thereof. For reasons relating to the safety of the entire property, the Lessor shall be entitled, in the event of the loss of keys provided to the Lessee or those which the Lessee acquired itself, to have the required number of keys and new keys cut at the Lessee's expense. This provision shall apply correspondingly for a central locking system of the property. The Lessee shall not have to reimburse costs if it is able to prove that there is no concrete security risk. In the one-week transition period, the Lessee shall install its own locking system in the respective doors of the rental property. The Lessee shall therefore itself be responsible for the security of the rented premises; the Lessor's liability is hereby excluded.

2. The Lessee undertakes to treat the rental property and shared building sections, facilities and installations considerately and with care. Within the framework of the contractual use of the rental property, the Lessee must exercise consideration.
3. The Lessee must not make use of anything which has not been rented to it through the lease or special agreements.
4. Any changes to or significant expansion of the type of business, branch of business or an agreed product range, inasmuch as a corresponding agreement has been reached, as well as sub-letting and other partial or full transfer of use of the rented premises to third parties are prohibited without the Lessor's prior consent. This shall also apply for a change of firm owner or legal form of the Lessee negatively impacting on the Lessor's rights. If the Lessor does not grant its consent, this shall not mean that the Lessee has the right to terminate the tenancy, unless the Lessor's refusal is arbitrary.

Consent to sublet or grant permission to use the rental property shall apply on a case-by-case basis and may be revoked by the Lessor at any time for good reason. Upon request, the Lessee shall be obliged to assign its claims against the sublessee. The Lessee shall be liable for the conduct of the sublessee or the third party to which it has granted permission to use the rental property.

Section 13 Cleaning Obligations and Rubbish Service

1. The Lessee must clean the rental property properly on a regular basis. This shall also apply for outside units such as window frames and shutters from the outside, inasmuch as this is possible for the Lessee without any special expenditure (scaffolds, etc.) according to the construction. The cleaning obligation shall also apply for advertising structures. The Lessee must clean these on a regular basis at its own expense and create the necessary conditions (ladders, scaffolding, hoists) at its own expense. The cleaning obligation aims to maintain a good impression of the entire property in order to keep it attractive to customers, also to the benefit of the Lessee.
2. The Lessee shall wet-clean the part of the corridor leading to its rental property and the stairs if necessary, however at least once a week and also keep it clean on the other days. If the Lessee is unable to do this, it must have someone else do it at its own expense.
3. The Lessee shall keep the rental property including facilities and areas, customer parking spaces, garage entrances, accesses, and the traffic areas in front of the rental property, rented along with the rental property, safe for traffic at all times. It must remove any contamination produced as a result of its operations. The parking of vehicles (e.g. cars, vans, motorcycles) which are not registered, but which must be registered, is not permitted.
4. The Lessee shall assume responsibility for the cleaning of the public spaces for which the Lessor, as owner, has to comply with public-law cleaning obligations, in particular the pavement. When icy, it must be gritted with slippage-preventing agents, repeatedly if necessary. De-icing salt and de-icing agents may not be used. Snow must be removed in accordance with the local bylaws, in any case immediately after snow has finished falling. Upon the Lessee's request, the local bylaws must be provided to it by the Landlord in the applicable version in force. In the event of ice formation, this should be gritted immediately. Ice formation, which cannot be sufficiently counteracted by gritting, must be removed. If the Lessee is unable to do this, the Lessee must ensure that someone else does so in its place. Insofar as the costs of these obligations are allocated to the Lessee as operating costs, the Lessee shall not be responsible for complying with the obligations.

On the basis of the Lessee's declaration of commitment, the Lessor shall be entitled to request his release from his public-law duty to maintain safety. The Lessee shall also remove the snow and black ice from the site areas, customer parking spaces, garage entrances and accesses rented with the rental property at its own expense. Within the framework of its statutory and contractual duty to maintain public safety, the Lessee shall indemnify the Lessor from all liability, unless the Lessor is guilty of intentional or grossly negligent contributory fault in individual cases.

Section 14 Maintenance and Care

1. The Lessee shall be responsible for the maintenance of the rental property, including facilities and installations rented therewith, as outlined below:
 - a. The Lessee shall heat the rental property with the available equipment to the necessary extent.
 - b. The Lessee shall sufficiently ventilate the rental property. Correct ventilation requires regular transverse ventilation (draught). Tilting the windows to let air in is not a correct method of ventilation and entails the risk of moisture damage and mould formation.
 - c. The Lessee shall also contribute to the costs of small maintenance and repair works ("small repairs") to any items that are subject to its immediate access, such as installation items for

electricity, water and gas, the heating and cooking facilities, the window and door latches, the closers of window shutters and parts of shutters. Small repairs are those not exceeding the amount of 300.00 EUROS at the start of the rental period on a case-by-case basis. Since small repairs are essentially wage-dependent, this amount increases in the same proportion as the German consumer price index, basis 2000 = 100 increases relative to the start of the rental period. This increase shall however only increase the cost for small repairs if there is an increase in the base rent. The Lessee shall contribute 300.00 EUROS to these small repairs per individual repair irrespective of the actual invoice amount, but no more than the proven invoiced amount. Per year, the total costs for small repairs shall be limited to 6% of the annual base rent in accordance with Section 5 Paragraph 1. This provision is a merely a cost-bearing provision. The Lessee must inform the Lessor of the defects immediately, so that the Lessor can arrange for the repairs to be carried out. Inasmuch as the Lessee has the works carried out itself at its own expense, there shall be no reimbursement of costs from the Lessor.

2. The Lessee undertakes, as a rule and to the extent required by the actual condition of the rental property, to have wooden floors subjected to professional basic treatment every ten years, calculated from the handover of the rental property. For parquet, this shall require sanding and re-treatment of the surface either by sealing, waxing or oiling. The re-treatment must be carried out in the design available at the start of the rental period, unless agreed otherwise. Sealed parquet surfaces must also be resealed.

Section 15 Cosmetic Repairs by the Lessor

The Lessor shall not be obliged to carry out regular cosmetic repairs.

Section 16 Cosmetic Repairs by the Lessee

The following has been agreed concerning the execution of cosmetic repairs by the Lessee:

Since a contractual term of at least ten years is possible, agreed option rights taken into account, without the Lessor being able to terminate the tenancy, irrespective of notice of termination provided by the Lessee, it is agreed that the Lessee shall not have to carry out regular cosmetic repairs. However, since after such a long rental period, a complete optical deterioration of the objects concerned by the cosmetic repairs regularly occurs, it is agreed that the Lessee must return the rental property fully renovated. Inasmuch as the Lessee has carried out cosmetic repairs during the term of the tenancy, it shall still be responsible for proving that cosmetic repairs are now not due. In this case, to the extent that the condition of the rental property corresponds to a like-new performance of cosmetic repairs, it shall be released from the final renovation obligation. Otherwise, it shall, at its own expense, professionally re-renovate or have renovated the rental property, or reimburse the Lessor for the costs corresponding to the deterioration of the rental property until the end of the rental period.

Section 17 Lessor's Liability

The Lessor shall only be liable for the damages to the Lessee's property and assets in the event of intent or gross negligence, insofar as the defect is attributable to the rental property and is a risk not typically associated with the contract. He shall also only be liable for the conduct of his representative or vicarious agent in the event of intent or gross negligence. The Lessee's claims for performance as well as its statutory right to termination

without notice shall not be affected thereby. The exclusion of liability may only be invoked if the Lessor has specifically guaranteed a particular characteristic of the rental property or has fraudulently concealed a defect. It shall not apply in the event of injury to life, limb or health of the Lessee, based on the Lessor's negligent breach of duty or an intentional or grossly negligent breach of obligation of a legal representative or vicarious agent of the Lessor; insofar as the damage is based on a breach of a "cardinal duty", i.e. a breach of contractual obligations which enable the proper performance of the contract in the first place, and in whose fulfilment the Lessee therefore has trust; as well as for damage for which the Lessor has insurance, e.g. home and property liability insurance or building insurance.

Section 18 Structural Modifications and other Measures

1. Lessor's measures

- a. The Lessee must tolerate structural modifications necessary for preserving the rental property, the building, or in order to prevent imminent danger or to eliminate damage.
- b. The Lessee must also tolerate all beneficial or appropriate measures or measures for which the Lessor is not responsible, in particular modernisation measures, e.g. heating and soundproofing measures, and the improvement of installations.
- b) This provision shall apply correspondingly for improvement and expansion measures to traffic areas, supply and removal systems including the utilities of such facilities as well as connections to the broadband cable network.
- c) For measures in accordance with Letters a) and b), the Lessee must keep the premises in question accessible, pursuant to prior arrangement, and may not obstruct or delay the performance of the works. In the event of culpable behaviour, it must pay for the resulting additional costs and damage.
- d) Claims for compensation of the Lessee shall be excluded because of tolerable measures, unless the Lessor is responsible because of intent or gross negligence.
- e) The agreement under Section 7 Paragraph 6 shall apply to the rental increase due to the Lessor's expenses for measures in accordance with Letter b).

2. Lessee's measures

The Lessee shall only be entitled to carry out structural and other modifications and create new facilities with the Lessor's prior consent. Without the Lessor's consent, the Lessee must remove any measures undertaken at its own expense immediately at the Lessor's request and restore the rental property to its previous condition. The Lessor's right to request the restoration of the rental property to its previous state at the end of the lease at the Lessee's expense shall not be excluded by his consenting to a structural modification by the Lessee. The Lessee shall be liable for all damage that it has caused.

Section 19 Liability of the Lessee

1. The Lessee shall be liable to the Lessor for damage to the rental premises and the building as well as to the facilities and installations belonging to the rental premises or to the building, caused by it, persons

belonging to its household, staff, employees, visitors, customers, suppliers and craftsmen and similar persons appointed by it, insofar as it is answerable for the same. If the Lessee pays the Lessor damages, then the Lessor must assign the Lessee any claims he may have against the person who caused the damage. The Lessor must prove the objective breach of duty. The Lessee shall have the burden to prove that there was no culpable conduct, insofar as premises, installations and facilities are entrusted to its care. The Lessee shall not be liable for unforeseen circumstances or force majeure.

2. The Lessee shall replace damaged glass panes including display windows and mirrors at its own expense if it is at fault. The Lessee must take out glass breakage insurance for all window, display window, and door windowpanes of the rental premises in a sufficient amount at its own expense and prove to the Lessor that it has insurance. This shall not apply if and to the extent that the Lessor has concluded glass breakage insurance himself and allocates it to the Lessee as operating costs.
3. Before the Lessee sets up heavy items, machines or installations and brings equipment into the rental premises, it must make sure that the permissible load of the floor ceiling is not exceeded. It must have a static calculation required in each case drawn up at its own expense and provide this to the Lessor upon request. The Lessee shall be liable for all damage caused to the Lessor or third parties as a result of culpably failing to adhere to this provision. Adverse effects of the equipment on the building, such as vibrations and cracks, or on other tenants and neighbours, as well as unreasonable further annoyances, shall entitle the Lessor to revoke the consent granted and to prohibit the exercise, even if the effects are unavoidably associated with the operations.
4. The Lessee shall be liable towards the Lessor for damage to buildings, installations, facilities and to the other property culpably caused by its vehicles or the vehicles it operates. The Lessee's vehicles may only be parked on the property with the Lessor's consent in the assigned spaces, and third-party vehicles only during the time required for loading and unloading.
5. The Lessee undertakes to take out sufficient insurance (e.g. fire, water, inventory insurance, liability insurance, for the installations/facilities introduced by it as well as business liability insurance. At the Lessor's request, it must prove the conclusion and continuation of the insurance.
6. The Lessee must immediately inform the Lessor of all damage to the rental property, as soon as it notices said damage. The same shall apply for damage to other property and building sections. If it culpably fails to fulfil this obligation in a timely manner, it shall be liable for paying compensation for further damage.

Section 20 Advertising Activities and Protection against Competition

1. The Lessee shall only be entitled to affix a company nameplate whose size, design and position correspond to the surroundings and the style of the building and property respectively.

The Lessee shall be responsible for proper affixing and maintenance in accordance with legal and regulatory requirements. This shall apply mutatis mutandis for other equipment for sales and advertising purposes, which is permitted only after obtaining the Lessor's written agreement. Collective sign systems provided or kept ready by the Lessor shall be shared by the Lessee with proportional cost transfer. The Lessee shall be liable for all damage for which it is at fault, attributable to the objects in question and their affixing. Upon release of the rental property, it must return it to its former condition at its expense.

2. The Lessee shall not be granted protection against competition.

Section 21 Lessor's Lien

1. The Lessee declares that the items brought into the rental premises when it moves in are its own property and are neither pledged, attached, nor assigned as collateral.
2. The Lessee must immediately inform the Lessor of any seizure of the items brought in when moving in or subsequently.
3. The Lessor shall be entitled to terminate the tenancy without notice if the Lessee purposely provides incorrect declarations or does not inform him of subsequent restrictions.

Section 22 Access to the Rental Premises by the Lessor

1. The Lessor and his representative may access the rental premises during business hours with prior notification in order to verify its condition. If the Lessor wishes to sell the property, or if the tenancy is terminated or rescinded, then the Lessor or his representative may access the rental premises during business hours along with the potential purchasers or lessees.
2. The Lessee must ensure that the rental premises may also be accessed during a long absence (e.g. company holidays) in order to exercise the above lessor rights. For this purpose, it shall leave the keys in an easily accessible place and notify the Lessor thereof. If the keys are not available to the Lessor, in the event of imminent danger he shall be entitled to have the rental premises opened at the Lessee's expense.

Section 23 Termination of the Tenancy

1. At the end of the rental period, the Lessee must return the rental property to the Lessor in proper condition, cleared out and with the whole property freshly cleaned (including the glass surfaces/windows) along with all keys, including those which the Lessee acquired itself. A joint inspection report on the condition of the rental property shall be drawn up when it is handed over to the Lessor.
2. The Lessor may request that the Lessee remove the facilities, installations and structural changes introduced by it and return the property to its earlier condition and its own expense, taking into consideration any cosmetic repairs due. Furthermore, the Lessor may request that the Lessee leave behind or transfer to him any installations and facilities brought in at its own expense, insofar as he provides suitable compensation for this. If an agreement on the amount of compensation is not reached, then an expert to be determined by the competent Chamber of Industry and Commerce will establish this at the request of one of the parties with binding effect. The costs for the expert shall be borne proportionally by the parties in accordance with the expert's decision.
3. The late return of the rental property shall mean that the Lessee must pay compensation for the duration of the withholding at the Lessor's option in the amount of the agreed rent or rent which can customarily be obtained for comparable premises. If the rental property is returned in an untimely

manner, the compensation shall in any case be paid for the full month. The Lessor shall be entitled to assert further damage. This shall apply, in particular, if cosmetic repairs which the Lessee has refused to perform, or other repair works for which it is responsible are to be carried out.

4. If the Lessee is responsible for the early termination of the tenancy, then it shall be liable for the loss of rent, utilities and other payments and for all further damage caused to the Lessor for the rental property remaining empty during the contractual rental period or if the Lessor suffers a financial loss in the event of immediate re-letting, in particular through obtaining a lower rent.
5. If the Lessee leaves items behind when it moves out, then the Lessor shall only be liable for damage and loss if he or his vicarious agent has acted with intent or in a grossly negligent way.

Section 24 Assignment and Transfer

The Lessee shall not be entitled to transfer its rights under this lease, assign them, or contribute them to a company without the Lessor's prior written consent. The Lessee does not have a claim to this consent.

Section 25 Other Agreements

1. The Lessee shall acquire the rental property with the renovation of the 3rd floor (top floor) carried out and extensively inspected by it, in line with the contract.

Before the start of the tenancy, the Lessor must have the following works carried out:

Front building upper floor (top floor): painting of all walls, ceilings, doors, heaters and heating pipes, carpet laying, renovation of the washrooms.

2. A joint handover report concerning the handover shall be drawn up by the parties, which must be signed by both contracting partners.

Section 26 Amendments and Additions

Subsequent amendments and additions to the lease must be defined in a written agreement. This shall also apply for partial waiver of the written form requirement.

Section 27 Effectiveness of Contractual Provisions

Any invalidity of a provision, part of a provision or several provisions of this lease shall not affect the validity of the remaining provisions. This contract is issued in two identical copies, read by the parties themselves, approved in all places and signed personally. Both contracting parties have received a copy.

Signature and stamp of the Lessor

[signature]

Mainz, 17.8.2011

Signature and stamp of the Lessee,

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INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i)
NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE
COMPANY IF PUBLICLY DISCLOSED**

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**Addendum no. 1
of lease agreement for commercial premises from 17.08.2011**

between

As landlord:

Wolfram Richter
Kupferbergterrasse 15, 17-19
55116 Mainz
Tel.: [***]; fax: [***]
Tax number of the landlord: [***]

As tenant:

BioNTech AG
Represented by the director [***] (with German business degree)
Hölderlinstraße 8
D-55131 Mainz
registered in the commercial register of County Court Mainz, register number: HRB 41865

concerning the office areas on 3rd floor (attic floor) of front building, approx. 244 m².

The late completion of the expansion means that the above-mentioned office facilities could not be taken over on 01.10.2011 according to the agreement in section 5 of the lease agreement from 17.08.2011 for commercial premises. This area was not ready for the tenant to move in until 01.11.2011.

The parties therefore complete the following agreement to apply retrospectively from 01.10.2011:

The lease agreement concerning the office areas on the 3rd floor (attic floor), approx. 244 m² starts on 01.11.2011. The end of the lease agreement for this office area remains unchanged as 31.08.2013.

All other provisions of the lease agreement from 17.08.2011 continue to apply unchanged.

The rent paid by the tenant in excess for the month of October 2011 for the office area on the 3rd floor of € [***] gross will be offset against the rent for the month of November 2011.

Signature and stamp of the landlord

Mainz, on [pp. signature]

Signature and stamp of the tenant,
Michael Kring, director of BioNTech AG

Mainz, on 17.02.12 [signature]

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**Amendment no. 2 to the BioNTech
Parking Space Lease
to the lease of 17.08.11 and Amendment no. 1 of 17.02.2012**

between	<p>Wolfram Richter Kupferbergterrasse 15, 17-19 55116 Mainz Tel.: [***]; Fax: [***] Lessor tax registration number: [***]</p>	as the Lessor
and	<p>BioNTech AG represented by the Chair of the Board of Directors Mr [***] Hölderlinstrasse 8 D-55131 Mainz registered in the Commercial Register held by Mainz District Court, registration number: HRB 41865</p>	as the Lessee

the following Lease is entered into:

I.

At the property: **Kupferbergterrasse 15, 17-19, on the courtyard, in front of the brick building** _____ garage(s) 5 parking spaces _____ twin spaces _____ storage space are leased, for parking: **CARS**

II.

The lease shall begin on **01.02.2013** and continues for an unlimited term unless terminated with three months' notice from the end of a month.

III.

The monthly rent shall be	5 x EUR [***]	EUR [***]
	VAT @ EUR [***]	EUR [***]
	Total	EUR [***]

in words: -[***]- Euros

and must be paid to the Lessor, or to the person or establishment authorised by him to accept payments, no later than the third working day of the month.

Name of the bank:	[***]
Sort code:	[***]
Account number:	[***]

IV.

Vehicles shall be parked at the Lessee's own risk. In particular, the Lessor shall not be liable for fire, theft or damage to vehicles.

V.

The Lessee undertakes

- to drive in and out of the garage at walking pace only and to take the utmost care,
- not to wash vehicles in either the garage or on the Lessor's property, or carry out any repairs outside the garage on the property,
- to use electricity only for lighting purposes and not to make any changes to the electrical system in the garages,
- to comply with the applicable police guidelines, and more specifically never enter the garage with fire or naked flames, store fuel or flammable substances in the garage, or leave the engine running when the garage door is closed.

The Lessee shall be liable for all damage caused during the use of the garage or as a result of a failure to comply with the existing guidelines, either by itself, its employees or representatives or by any other persons whom it has authorised to use its vehicle.

VI.

The Lessee may not set off the rent with a counterclaim. No right of retention may be exercised with respect to the rent.

VII.

The Lessee may use the garage only for the contractual purposes. If it wishes to use it for other purposes, it must obtain written permission from the Lessor.

The garage must not be sublet to third parties and third parties shall not be authorised to use it free of charge.

VIII.

At the end of the lease, the Lessee must return the garage to the Lessor in a clean state and with all associated keys.

IX.

There are no oral ancillary agreements in relation to this lease. Amendments or supplements must be agreed in writing.

X.

The place of performance and jurisdiction is Mainz.

XI.

Special agreements:

Place/date: Mainz,

[Stamp: BioNTech AG

Hölderlinstrasse 8

55131 Mainz

Tel.: +49 (0) 6131 / 57 62 70 0 – Fax: +49 (0) [illegible]]

pp. [signature]
Lessor

[signature]
Lessee

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Amendment no. 3 - Agreement regarding an extension to the lease agreement

to the lease agreement of 17.08.2011 for commercial premises and Amendment no. 1 of 17.02.2012, as well as Amendment no. 2 of 01.02.2013

between:

As the Lessor:

Wolfram Richter
Kupferbergterrasse 15, 17-19
55116 Mainz
Tel.: [***]; Fax: [***]
Lessor tax registration number: [***]

As the Lessee:

BioNTech AG
Represented by the Chair of the Board of Directors [***], (with German business degree)
Hölderlinstraße 8
D-55131 Mainz
registered in the Commercial Register held at Mainz District Court, registration number: HRB 41865

for the office space on the property Kupferbergterrasse 15, 17-19; 55116 Mainz, on the second floor of the front building, the third floor of the front building (loft), the second floor of the original building and the ancillary areas.

With immediate effect, by way of deviation from sections 3 (1) and (2) of the lease of 17.08.2011 and from the agreement in Amendment no. 1 of 17.02.2012, the Parties agree as follows:

The leasehold is extended to 31.03.2014. Within an appropriate timeframe and before the end of the leasehold, the parties shall come to an agreement on the possibility of further extending the lease and on the duration of any such extension.

All other provisions laid down in the lease of 17.08.2011 and Amendments nos. 1 and 2 shall remain in place and continue to apply without amendments.

Signature and stamp of the Lessor:

Mainz, on 11.04.2013 pp. [signature]

Signature and stamp of the Lessee;
[***], Chair of the Board of Directors of BioNTech AG

Mainz, on 06.03.2013 [signature]

[Stamp: **BioNTech AG**
Hölderlinstraße 8
55131 Mainz
Tel.: +49 (0) 6131 / 57 62 70 0 –
Fax: +49 (0) 6131 / [illegible]

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Amendment 4 BioNTech – Agreement regarding an extension to the lease agreement

to the lease agreement of 17.08.2011 for commercial premises and the Amendment of 17.02.2012, as well as Amendment no. 2 of 01.02.2013 and Amendment no. 3 of 06.03.2013

Agreement no.: _____ of: 19.11.2013

The lease is entered into by and between the following contractual parties:

As the Lessor:

Wolfram Richter
Kupferbergterrasse 15, 17-19
55116 Mainz
Tel.: [***]; Fax: [***]
Lessor tax registration number: [***]
If the Lessor exercises the value added tax option, the Lessor's tax registration number is: [***]

As the Lessee:

BioNTech AG
Represented by the Chair of the Board of Directors [***] (with German business degree)
Hölderlinstraße 8
D-55131 Mainz
registered in the Commercial Register held at Mainz District Court, registration number: HRB 41865

for the office space on the property Kupferbergterrasse 15, 17-19; 55116 Mainz, on the second floor of the front building, the third floor of the front building (loft), the second floor of the original building and the ancillary areas.

The Parties agree to extend the contractual term by a further two years until 31.03.2016, after expiry of the leasehold as agreed in Amendment no. 3 of 06.03.2013.

All other provisions laid down in the lease of 17.08.2011 and Amendments nos. 1, 2 and 3 shall remain in place and continue to apply without changes.

Mainz, on 10.12.2013

Signature and stamp of the Lessor:

[Stamp: WOLFRAM RICHTER
PROPERTY MANAGER
KUPFERBERGTERRASSE 15-19 – 55116 MAINZ
E-MAIL: [***]

Mainz, on 03.12.13

[signature]

Signature and stamp of the Lessee:

[signature]

THE SYMBOL “[*]” DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED**

This document is an English translation of a document prepared in German. In preparing this document, an attempt has been made to translate as literally as possible without jeopardizing the overall continuity of the text. Inevitably, however, differences may occur in translation and if they do, the German text will govern by law.

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Amendment 5 BioNTech – Agreement regarding an extension to the lease agreement

to the lease agreement of 17.08.2011 for commercial premises and the lease of 01.10.2012 for the main area, in addition to the Amendment of 17.02.2012, as well as Amendment no. 2 of 01.02.2013, Amendment no. 3 of 06.03.2013, Amendment no. 4 of 19.11.2013 and the lease of 30.03.2012 are joined together in this Amendment and consolidated into a combined lease term.

Agreement no.: _____ of: 10.03.2016

The lease is entered into by and between the following contractual parties:

As the Lessor:

Wolfram Richter
Kupferbergterrasse 15, 17-19; 55116 Mainz
Tel.: [***]; Fax: [***]
Lessor’s tax registration number: [***]
If the Lessor exercises the value added tax option, the Lessor’s tax registration number is: [***]

As the Lessee:

BioNTech AG
Represented by [***]
An der Goldgrube 12; 55131 Mainz
registered in the Commercial Register held at Mainz District Court, registration number: HRB 41865

for the office space on the property Kupferbergterrasse 15, 17-19; 55116 Mainz, on the second floor of the front building, the third floor of the front building (loft), the second floor of the original building, - second floor of the main building, main area and ancillary areas.

The Parties agree to extend the contractual term by a further three years until 31.03.2019 after expiry of the lease of 17.08.2011, as agreed in Amendment no. 4 of 19.11.2013, plus the option to extend by another three years; the lease of 30.03.2012 which would end on 30.06.2016 shall also be extended by a further three years to 31.03.2019, plus option.

The leasehold term is therefore extended for both leases consolidated in this Amendment, to 31.03.2019.

The leases shall be extended once by three years until 31.03.2022, if one party does not object to the extension by giving six months’ notice in writing.

All other provisions laid down in the leases of 17.08.2011, in addition to Amendments nos. 1, 2, 3 and 4 and the lease of 30.03.2012 shall remain in place and continue to apply without changes.

Mainz, on 29.3.2016

Signature and stamp of the Lessor: [signature]

[signature], on 16.3.2016

Signature and stamp of the Lessee:

THE SYMBOL “[*]” DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED**

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Amendment no. 6 BioNTech AG – Lease of an additional 10 parking spaces on the bastion property

to the lease agreement of 17.08.2011 for commercial premises and the lease of 01.10.2012 for the main area, Amendment of 17.02.2012, Amendment no. 2 of 01.02.2013, Amendment no. 3 of 06.03.2013, Amendment no. 4 of 19.11.2013, lease of 30.03.2012 and Amendment no. 5 of 10.03.2016

Agreement no.: _____ of: 21.07.2017

The lease is entered into by and between the following contractual parties:

As the Lessor:

Wolfram Richter
Kupferpergterrasse [sic] 15, 17-19
55116 Mainz
Tel.: [***]; Fax: [***]
Lessor's tax registration number: [***]
If the Lessor exercises the value added tax option, the Lessor's tax registration number is:
[***]

As the Lessee:

BioNTech AG
Represented by: [***]
An der Goldgrube 12
55131 Mainz
registered in the Commercial Register held at Mainz District Court, registration number: HRB 41865

for the lease of an additional 10 parking spaces on the bastion property

Lease no.: 104.01.01

Section 5: Rent from 01.06.2017 onwards and allocation thereof due to the lease of an additional 10 parking spaces on the bastion property

1.		
	Office space front building, second floor, approx. 256 m ² , €[***]/m ²	€[***]
	Office space original building, second floor, approx. 146 m ² , €[***]/m ²	€[***]
	for other space, approx. 71 m ² , €[***]/m ²	€[***]
	for the parking spaces 30 at €[***]each	€[***]
	Net rent excluding utilities:	€[***]
	Advance payments on the operating costs for approx. 473 m ³ at €[***]m ²	€[***]
	Net rent including advance payments on operating costs:	€[***]
	Value added tax, currently 19% VAT	€[***]
	Gross rent	€[***]

2.	Office space front building, second floor, main area, 299.00 m ² , €[***/m ²]	€[***/m ²]
	for other space, approx. 29.00 m ² , €[***/m ²]	€[***/m ²]
	Net rent excluding utilities:	€[***/m ²]
	Advance payments on the operating costs for 328.00 m ² at €[***/m ²]	€[***/m ²]
	Net rent including advance payments on operating costs:	€[***/m ²]
	Value added tax, currently 19%	€[***/m ²]
	Gross rent	€[***/m ²]
3.	Office space front building, third floor (loft), approx. 244.00 m ² , €[***/m ²]	€[***/m ²]
	for other space, approx. 24.00 m ² , €[***/m ²]	€[***/m ²]
	Net rent excluding utilities:	€[***/m ²]
	Advance payments on the operating costs for 248.00 m ² at €[***/m ²]	€[***/m ²]
	Net rent including advance payments on operating costs:	€[***/m ²]
	Value added tax, currently 19%	€[***/m ²]
	Gross rent	€[***/m ²]
	Total gross rent from 01.06.2017	€[***/m ²]

All other provisions in the lease of 17.08.2011 and Amendments nos. 1, 2, 3, 4 and 5, as well as the lease of 30.03.2012 shall remain in place and continue to apply without amendments.

Mainz, on 6.10.2017

Signature and stamp of the Lessor:
pp. [signature]

Mainz, on 04 October 2017

Signature and stamp of the Lessee:
[signature]

[Stamp: **BioNTech AG**
An der Goldgrube 12
55131 Mainz
Tel.: +49 (0)6131 / 90 840 – Fax: +49 (0)6131/9084390]

THE SYMBOL “[*]” DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED**

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L e a s e

between WISTA-MANAGEMENT GMBH
Rudower Chaussee 17
12489 Berlin

VAT id. no.: [***]

represented by the Managing Director
[***]

- hereinafter referred to as the “Lessor” -

and JPT Peptide Technologies GmbH
Invalidenstraße 130
10115 Berlin
represented by the Managing Directors
[***]
and [***]

- hereinafter referred to as the “Lessee” -

the following lease is entered into:

**Section 1
Leased Property**

The Lessor shall lease to the Lessee the rooms and areas described in **Annex 1**, in the Centre for Environmental Technology, Biotechnology and Energy Technology at Berlin Adlershof Science and Technology Park, Volmerstraße 5, 12489 Berlin, with a total rental area of **855.46 m²**.

This total area encompasses: 343.53 m² of office space,
 69.70 m² of storage space,
 372.02 m² of laboratory space and
 70.21 m² of ancillary space (proportionate).

The technical features of the leased property are set out in **Annex 2**.

**Section 2
Usage**

- (1) The Lessee shall use the leased property for the purposes described below and shall only deviate from this intended use if prior written permission has been obtained from the Lessor: **peptide synthesis**.
- (2) The Lessee is aware of the condition of the leased property, in particular the bearing capacity of the ceilings, the spatial extent of the leased rooms, the entrances and capacities of the individual utilities. The Lessee is also aware that the areas of the Berlin Adlershof Science and Technology Park that are located north of Rudower Chaussee belong to Drinking Water Protection Area III. The Lessor does not guarantee the suitability of the leased property for the agreed usage purposes or those envisaged by the Lessee.
- (3) The Lessee alone shall bear the expenses and responsibility with respect to necessary permits; the same applies to official or other requirements or restrictions. If permits required by the Lessee for the use can only be applied for by the Lessor as the owner, the contractual parties shall support each other to the best of their abilities with respect to the application process. If the intended use is not approved or approved only subject to conditions which cannot be fulfilled or removed by measures taken in accordance with the recognised state of the art, the Lessee shall be entitled to terminate the Lease without notice. Termination is only possible until 31.07.2005. In the event of termination, the Lessee must reimburse the Lessor for 50% of the costs incurred up to the date of termination for the additional technical installations pursuant to Annex 2a. The additional technical installations pursuant to Annex 2a do not constitute additions and alterations or fittings of the Lessee within the meaning of Section 22.

- (4) The Lessee may use the leased property only in a manner corresponding to its condition and only in accordance with the applicable provisions of law. The Lessee alone is responsible for observing and complying with the legal regulations concerning the Lessee's trade, occupational safety and fire protection, and industrial waste disposal.
- (5) Devices, machinery and systems operated on the premises must be installed in compliance with safety and environmental regulations, as well as in a manner that reduces noise and vibrations, in order to avoid causing unreasonable disturbance to the Lessor and other lessees.
- (6) Water-polluting substances may only be stored and handled in the dedicated facilities, in accordance with the legal regulations. When storing and handling water-polluting substances, the Lessor must be given the records concerning the type and quantity of water-polluting substances introduced, and after their usage, proper evidence of their disposal on a quarterly basis, on the 25th of the last month of each quarter. The laws and official requirements applicable to the storage, use, handling and disposal of such materials must be complied with by the Lessee. The Lessee must inform the Lessor upon request in the event that other polluting materials are stored and/or handled. The laws and official requirements applicable to the use, handling and disposal of hazardous goods must be complied with by the Lessee. The Lessor must be provided with evidence in this regard where requested.

Section 3 Handover

- (1) The Parties shall draw up a handover report at the time of the handover of the leased property to the Lessee. By signing the handover report, the Lessee acknowledges that the leased property is as agreed in the lease, if no damage or defects are recorded in the report. The Lessor undertakes to rectify the defects recorded and acknowledged as such within an appropriate timeframe. The Lessee cannot derive any rights against the Lessor from the existence of defects not recorded in the report. Sentences 2 and 4 do not apply to latent defects.
- (2) Defects that are minor and do not adversely affect the Lessee's normal business operations, uncompleted work, or a delay in providing the inventory made available to the Lessee on the basis of special contractual agreements shall not entitle the Lessee to refuse acceptance. This also applies to uncompleted work on the outdoor facilities which do not have any substantial adverse effect on the Lessee's business operations. With regard to works still to be completed by the Lessor after the handover, complaints about defects may only be raised with the Lessor within six weeks after their completion. A precise description of the defect must be given when the complaint is made.

Section 4 Term of the Lease

- (1) The lease shall begin once the necessary installations have been completed and the functioning premises handed over to the Lessee, however no earlier than 01.08.2005, and shall end on 31.07.2010 without any need to issue a termination notice. The Lessee shall be entitled to extend the term of the lease by an additional five years by making a written unilateral declaration to the Lessor before 31.07.2009. Irrespective of this, the term of the lease shall always be extended by a year if neither of the Parties object to the extension at least 12 months before expiry of the term of the lease.
- (2) After expiry of the lease due to an objection within the meaning of paragraph (1), no automatic renewal of the leasehold through continued use of the leased property shall take place; section 545 of the German Civil Code shall not apply.

Section 5 Rent, Utilities, Payment Dates

- (1) The rent is based on an estimate of €[***]m² for office and laboratory space.

The monthly rent shall be

€[***]

For the additional technical installations pursuant to Annex 2a, the Lessee shall pay the Lessor an additional monthly amount of €[***] (€ [***]/m²).

If the Lessor's expenses for the technical installations exceed or fall short of the costs specified in Annex 2a by more than 10%, a new calculation of the additional payment amount shall take place.

For the purposes of verifying the total expenditure for the technical installations and fittings, the Lessor shall provide the Lessee upon request with the documents on the invoiced construction costs.

The monthly rent shall be increased on 01.08 of each year of the lease by 2% each time, with respect to the rent applicable up to that point. The first increase shall take place on 01.08.2010.

If modernisations are carried out after the lease is entered into, the Lessor shall be entitled to increase the rent taking into account section 559 of the German Civil Code.

The following advance payments must be made by the Lessee for utilities and operating costs, in the form of monthly instalments:

Heating	€[***]
Electricity	€[***]
Water supply and wastewater disposal	€[***]
Rainwater drainage	€[***]
Gas supply	€[***]
Cooling	€[***]
Provision of special-purpose media	€[***]
Cleaning	€[***]
Maintenance	€[***]
Other	€[***]
Infrastructure services	€[***]
Technical management	€[***]
Property tax	€[***]
Subtotal:	€[***]
Rent:	€[***]
Additional amount:	€[***]
Rent, additional amount and utilities:	€[***]
plus applicable value added tax (currently 16%):	€[***]
Total amount	€[***]

An itemised list of the operating costs and utilities with identification of usage is provided in **Annex 3**.

If other public charges or obligations in direct relation to the leased property are introduced after entering into the lease, for example concerning the technical safety of the building and installations, the Lessor shall be entitled to charge these starting from the date on which the additional expenditure first occurred, provided that the Lessor claimed these from the Lessee in writing no more than six months after it first became aware of them, or otherwise from the date on which they were claimed in writing onwards.

- (2) The Lessee expressly warrants that in the leased property provided it shall exclusively generate taxable turnover which does not exclude input tax deduction within the meaning of the German Value Added Tax Act.

Upon the Lessor's request, the Lessee must provide evidence of its entitlement to deduct input tax. If the Lessee does not fulfil this obligation within an appropriate timeframe, it must compensate the Lessor for all resulting damage suffered.

- (3) The prepayment for the rent and utilities must be made in advance on the third working day of each month. The Lessee undertakes to grant the Lessor the direct debit authorisation provided in **Annex 4**. The Lessee is responsible for ensuring that there are sufficient funds in the account to which the direct debit authorisation relates. Costs incurred by the Lessor as a result of an unsuccessful direct debit must be reimbursed by the Lessee.
- (4) If a payment is not received on time, the Lessor shall be entitled to charge reminder fees amounting to €5.00 per reminder, as well as default interest of 8% above the base interest rate applicable as at 01.01. of the relevant year, pursuant to Section 247 of the German Civil Code. The right to make additional compensation claims shall remain unaffected.

Section 6

Utilities and Calculation Thereof

- (1) The utilities and operating costs described in Section 5 (1) are billed, where possible, depending on consumption. The portion of the utilities/operating costs not able to be directly attributed shall be billed according to the proportion of the area of the leased property described in Section 1 compared with the leasable area of the building.

To the extent that the Lessee is provided with cooling, gas and other special-purpose media beyond the ordinary requirements for business and office premises and this does not extend to the whole building, the following shall apply:

For the distribution of the utilities and operating costs charged in this regard, the contractual parties agree that the basis for the billing shall be the proportion of leased area used by the Lessee and supplied with the special-purpose media compared with the leasable area of the building supplied with special-purpose media in which the special-purpose media are used.
- (2) The infrastructure utilities/infrastructure operating costs for Berlin Adlershof Science and Technology Park shall be invoiced in accordance with the following allocation system:

Firstly, the portion allocated to the building in which the leased property is located shall be calculated using the proportion of the net floor space of the building compared with the total net floor space of all leasable buildings belonging to Berlin Adlershof Science and Technology Park; this portion allocated to the building shall then be distributed among the resident lessees of that building, based on paragraph (1).
- (3) By 30.06 of the following year, the Lessor shall establish a breakdown of the utilities incurred up to 31.12 of the previous calendar year. The invoicing documentation may be viewed by the Lessee at the Lessor's offices within four weeks after receipt of the invoice. The invoice shall be deemed accepted if the Lessee has not made any objection thereto in writing on reasonable grounds within six weeks of receipt of the bill, and the Lessor expressly informed it, at the beginning of this six week-period, of the intended significance of any failure to object following receipt of the invoice. Any differences between the invoice and the sum of the advance payments shall be subsequently paid by the Lessee within eight weeks following receipt of the invoice, or refunded by the Lessor. Section 5(4) shall apply accordingly.
- (4) In subsequent years, the advance payment for utilities shall be adjusted in accordance with the actual expenditure for the relevant previous calendar year. During the invoice period, the Lessor shall also be entitled to re-determine the advance payments for utilities if it is expected that they will not be sufficient to cover the operating costs for the invoice period.
- (5) Even if the lease or usage relationship ends during the invoice period, the utilities shall be invoiced in accordance with the foregoing provisions. If the Lessee requests interim invoicing, it shall be responsible for paying the associated costs.

Section 7 Security Deposit

- (1) By 01.09.2005, the Lessee shall transfer a security deposit to the Adlershof Facility Management GmbH management account

[***]

Account no.: [***]

Sort code: [***]

Purpose: Security deposit.

The amount of the security deposit shall be equal to two net monthly rent payments, i.e. €[***].

- (2) The obligation set out in paragraph (1) may be fulfilled by providing a corresponding, directly enforceable, unconditional and indefinite bank guarantee from a bank authorised as a domestic customs and tax guarantor with a branch office in Germany, or by pledging a lessee security deposit in accordance with standard banking practice. In the event of cash payments, the Lessor shall invest the rental security deposit separately from its other assets, at an interest rate that is customary for savings deposits with a three-month notice period. The interest earned shall increase the amount of the security.
- (3) The security deposit shall be refunded at the end of the lease, upon proper return of the leased property and billing of the utilities, as long as the Lessor has no additional claims under this lease.

Section 8 Structural Amendments

- (1) The Lessor may make structural amendments to the leased property which are necessary or advisable in order to increase the value of or preserve the leased property, or to rectify damage, even without the Lessee's permission. The Lessee is entitled to object to such measures if the usage of the leased property for the purpose provided for in the lease is seriously adversely affected by the construction measures. This does not apply to construction measures taken in order to prevent imminent danger or damage. The Lessee must keep the affected areas accessible. The Lessor must notify the Lessee at least two weeks before commencing the aforementioned construction measures, unless they are being undertaken in order to prevent imminent danger.
- (2) Structural amendments by the Lessee, more specifically additions and alterations, installations, and even barring of windows, may only take place with the prior written permission of the Lessor. The equipment brought onto the premises by the Lessee during the term of the lease must be continually documented in a report to be signed by both Parties. The installation of external antennas requires the conclusion of an antenna agreement. The Lessor shall only refuse to give consent to such structural amendments if there are important grounds to do so. The Lessee shall be responsible for all costs and damage incurred in connection with the construction measures carried out by it. The Lessee must obtain all required official permits.
- (3) The Lessee shall be liable for all damage caused by the construction measures undertaken by it.
- (4) Any operating equipment and other equipment taken over from the previous lessee are not regarded as belonging to the leased property, but instead as being installed and provided by the Lessee.

Section 9 Advertising Structures, Signs

- (1) Company signs shall be put up by the Lessor on an information panel at the entrance. The Lessee shall incur the costs of creating and installing its company signs.
- (2) With the Lessor's permission, the Lessee may install additional company signs and other fixtures used for self-promotion, advertising or sales on the outside of the building, including on the windows, as well as in Berlin Adlershof Science and Technology Park as a whole.

The Lessee shall incur the costs of creating and installing these.

Section 10 Maintenance and Repairs, Duty of Care

- (1) The Lessee is responsible for carrying out the following minor repairs and fulfilling the following maintenance obligations for the leased property: Wallpapering and painting internal walls and ceilings (except for exposed concrete surfaces), painting radiators including radiator pipes, internal doors, as well as windows and external doors from the inside, and maintaining the floor coverings. Such works must be carried out to a professional standard.
- (2) The Lessee shall also incur the costs of repairing windows, glazing and locks, doors and locks, internal glazing, sanitary and laboratory fixtures, light fixtures, as well as internal blinds, including providing replacements in the event of damage on the leased property, if the total annual costs for this do not amount to more than five per cent of the net annual rent excluding utilities.
- (3) The Lessee must handle the leased property with care, including the fixed and movable technical installations and systems provided to it for use, and to protect these from damage and loss. The installations and equipment on the leased property must be protected from frost damage by the Lessee. In the event of inclement weather or absence of the Lessee, doors and windows must be kept closed. The leased property provided must be sufficiently heated and ventilated. The Lessee must incur the costs of removing pests from the leased property.
- (4) The Lessee shall be liable for damage culpably caused as a result of non-compliance with its duty of care. This shall also apply in particular if supply and discharge lines, toilets, heating appliances, etc. are improperly handled. The Lessee shall incur the costs of clearing pipe blockages caused by it up to the main pipe.
- (5) Damage on and in the leased property must be notified to the Lessor or one of its agents immediately. The Lessee shall be liable for additional damage caused as a result of a delayed notification. In the event of danger ahead, the Lessee itself must take the necessary measures in order to avoid damage.

Section 11 Supply of Utilities

- (1) The Lessee is obliged to receive heating, gas, electricity, telecommunications and other utilities for the leased property from the Lessor or from one of the suppliers or service companies appointed by the Lessor, provided that this is legally authorised and these services are provided under the normal market conditions.
- (2) If the services are obtained from the Lessor, the contractual conditions and other conditions applicable between the Lessor and its supplier and which applied at the time of entering into the contract shall also apply to the Lessee. The Lessee agrees with their validity.
- (3) Special-purpose media shall be supplied during the normal usage period (Monday to Friday between 08:00 and 16:30). The supply of special-purpose media outside the normal usage period requires a separate agreement between the contractual parties. The supply of basic utilities – electricity, water, heating, gas and telecommunications – is not restricted to the normal usage period.
- (4) Any irregularities in the supply of utilities shall not entitle the Lessee to claim a reduction of rent or damages from the Lessor unless they are based on the intent or gross negligence of the Lessor. This shall also apply to business interruptions of any kind caused by the Lessor in the event of imminent danger. If it is ruled out that the Lessor is liable due to gross negligence, the Lessor nevertheless undertakes to assign its claims against the supplier to the Lessee.
- (5) In the event of failures or damage to the supply lines, the Lessee must ensure immediate disconnection and notify the Lessor or one of its representatives immediately.

- (6) In the event of a foreseeable interruptions to utility supplies, the Lessee must be informed immediately by the Lessor.
- (7) The Lessee is obliged to install consumption meters at its own expense for the utilities used by it, provided that these are not already available or do not function in a manner that suits the Lessee's requirements. They must be installed professionally. The Lessee may be released from this obligation by the Lessor if another amicable solution concerning the recording of the utilities consumption is agreed. The available utilities distribution networks may only be used by the Lessee in accordance with the recognised rules of technology. The Lessor must be informed of any increased requirement, and this may be covered by the Lessee via an extension of the supply line at its own expense and after prior permission has been given by the Lessor.

Section 12 Lift Facilities

The Lessee is not entitled to the uninterrupted opportunity to use the lift facilities if there are operational failures. The Lessor undertakes to have the operational failure rectified as soon as possible and to comply with the lift regulations in all respects. No lift operators are present in the lifts. The Lessor or its representative must be informed immediately of any operational failures.

Section 13 Operational Safety Obligation

For the construction measures undertaken by it on the leased property and for its company employees, the Lessee only assumes responsibility for compliance with the operational safety obligation and the other legal requirements and official regulations, in particular the accident prevention regulations.

Section 14 Liability, Compensation for Damage

- (1) The Lessee is liable for all damage caused by it, its employees, staff, sub-lessees, sub-contractors, visitors or the persons associated with its business at its request, or caused by the business activity itself on the leased property or other property of the Lessor or of the building owner. The Lessee is also liable for the environmental damage caused by it or by the abovementioned persons.
- (2) The Lessee must immediately rectify damage for which it is liable. If it does not fulfil this obligation within a suitable timeframe, even after a written reminder, the Lessor may have the necessary works undertaken at the Lessee's expense. In the event of danger ahead or unknown residence of the Lessee, no written reminder or deadline setting is required.
- (3) At its own expense, the Lessee is obliged to hold the Lessor harmless from all claims for damages made against the Lessor by third parties directly or indirectly resulting from the use or non-use of the leased property or from the operation of its business, or caused by items introduced by it, in particular hazardous substances or inventories.

Section 15 Insurance

- (1) It is the Lessee's responsibility to obtain insurance to cover all damage to the equipment and other items brought onto the site. The Lessor shall assume no liability for such damage even if the liability of its agents is considered, except in the case of intent or gross negligence. The Lessee shall hold the Lessor harmless from any "break-in damage" to the extent that a break-in is directed at items introduced by the Lessee.

- (2) The Lessee shall take out and maintain the following insurance policies during the term of the lease:
- a) business liability insurance for personal injuries and damage to property, and environmental liability basic coverage with a coverage amount of at least €1.5 million, including at least €50,000 for damage to rented property,
 - b) if the Lessee deals with water-polluting or hazardous substances on the property in accordance with Section 2 (6) of this lease, it must take out separate insurance for the water pollution risk (groundwater).
- Upon request, the Lessee shall provide the Lessor with evidence that the aforementioned insurance policies have been taken out.
- (3) Buildings and building components made available by the Lessor are insured by the Lessor against fire damage. The insurance premiums to be paid in this regard shall be incurred by the Lessee on a pro rata basis in accordance with the lease. Lessee installations are not insured, even if they are building components.
- (4) Damage in relation to insured risks must be notified to the Lessor by the Lessee immediately so that the Lessor can notify the insurance company of the damage within the requisite period. Any disadvantages occurring as a result of failure by the Lessee to notify the damage on time shall be incurred by the Lessee.

Section 16
Several Persons as the Lessee

- (1) In the event that the Lessee is constituted by more than one person, they shall all be jointly and severally liable under this lease.
- (2) For a declaration by the Lessor to be valid, it is sufficient for this to be given to one of the Lessees. Declarations of intent by one Lessee are also binding on the other Lessees. The Lessees are deemed to have authorised each other to make and receive declarations.
- (3) Circumstances that cause an extension or reduction of the leasehold for one Lessee or give rise to a claim for damages or other claim against it shall have the same effect on the other Lessees. Termination by one Lessee shall result in termination of the entire lease.

Section 17
Subletting, Change of Legal Form

- (1) The Lessee is not entitled to sub-let the leased property.
- (2) If there is a change to the legal form of the Lessee's company or if there are other amendments which are significant to the lease, the Lessee must immediately inform the Lessor of these and provide the corresponding evidence when requested. In the event of sale of all or a significant part of the Lessee's company, any transfer of the leasehold to the buyer requires the Lessor's prior permission in writing. There shall be no entitlement to a transfer of this lease.

Section 18
Entry into the Leased Areas by the Lessor

- (1) After providing notice, the Lessor and/or an agent may enter the leased areas during business hours in order to inspect the condition of the leased areas or for other important reasons. In the event of danger, they must be allowed to enter at any time of the day or night.
- (2) The Lessee must ensure that the rooms can also be entered during its absence. In the event of an extended absence (e.g. company close-down for holidays), the Lessee must leave the keys in a quickly accessible place and inform the Lessor of this.

**Section 19
Competitors**

The Lessor is authorised to allow the Lessee's competitors onto the property and/or into the building.

**Section 20
Notice to Terminate**

- (1) The Lessor may terminate the lease with immediate effect or by observing a notice period if
 - a) the Lessee falls into default with two consecutive rent payments or with a significant portion of the rent, or, for a period extending over more than two payment due dates, is in default by an amount equal to or more than the rental payments for two months;
 - b) the Lessee has significantly failed to fulfil its contractual obligations; more specifically, it fails to use the leased property in accordance with the lease or its usage causes unreasonable disturbance to the Lessor's areas or areas occupied by other lessees, and these contractual breaches are not rectified within two weeks following a written warning from the Lessor; no warning is required in the event of imminent danger.
- (2) In the event of early termination of the leasehold due to an extraordinary termination pursuant to Section 21 (1), the Lessee shall be liable for rent losses, ancillary charges and other services. Additional claims for damages shall not be affected by this.
- (3) Termination declarations must be provided via registered letter.

**Section 21
Obligations upon Termination of the Lease**

- (1) Following expiry of the lease, the leased areas must be returned by the Lessee in a tidy, professionally renovated and clean state, and with a clean floor. When returning the leased areas, the Lessee must provide all keys to the Lessor, even those obtained by the Lessee itself. A report concerning the return of the leased property must be signed by both Parties.
- (2) Equipment installed by the Lessee in the leased areas may be taken away by it. The Lessor may prevent the Lessee from exercising its right to remove the equipment by making a compensatory payment amounting to the market value of the equipment, which shall be determined on the basis of a valuation by an expert, unless the Lessee has a justified interest in removing the equipment.
- (3) The Lessee's installations and fittings must be removed by it in order to return the leased property to its original condition, unless the Lessor agrees that they can stay in the leased property without compensation.
- (4) The Lessee is not entitled to compensation for expenditure incurred for structurally improving the leased property.

**Section 22
General Cooperation for the Development of
Berlin Adlershof Science and Technology Park**

- (1) The Lessee and Lessor fulfil their respective duties in the interest of a positive development of Berlin Adlershof Science and Technology Park with the necessary cooperation. With this in mind, the Lessee contributes to cooperation and creating synergies between business and science.
- (2) The Lessee is obliged to agree its communal facilities and services (e.g. canteens, kiosks, leisure facilities) with the Lessor and avoid competition with the Lessor.

Section 23
House Rules

The Lessee acknowledges that the House Rules appended as **Annex 5** are binding. A breach of the House Rules constitutes a use of the leased property in breach of the lease. Amendments and supplements to the House Rules may be made by the Lessor if there are objective reasons to do so.

Section 24
Final Provisions

- (1) Annexes 1 to 5 are components of this lease.
- (2) Amendments or supplements to the lease must be made in writing. No oral ancillary agreements have been made.
- (3) If one of the provisions of this lease is or becomes completely or partially ineffective, the validity of the other provisions shall not be affected by this. The Parties are obliged to replace the ineffective provisions with a rule that comes as close as possible to the economic purpose of the ineffective provisions. The same applies to amendments and supplements to the lease.
- (4) The place of jurisdiction is Berlin.

Berlin, 12 April 2005

Berlin, 11.04.05

WISTA-MANAGEMENT GMBH

JPT Peptide Technologies GmbH

[signature] _____ pp. [signature]

[signature]

(Lessor)

[signature]

(Lessee)

[Stamp: Berlin Adlershof

WISTA MANAGEMENT GMBH

Rudower Chaussee 17

12489 Berlin

Tel.: (030) 63 92 22 00

Fax: (030) 63 92 22 01]

List of Leased Areas

Lessee: Jerini Peptide Technologies GmbH

Floor	Room no.	Usage	Area (m2)
Ground floor	234	Laboratory	20.63
Ground floor	228	Office	24.83
Second floor	2120	Office	16.26
Second floor	2121	Storage room	18.20
Second floor	2122	Laboratory	17.85
Second floor	2123	Office	23.82
Second floor	2124	Office	17.98
Second floor	2126	Office	11.79
Second floor	2127	Office	17.91
Second floor	2128	Office	11.79
Second floor	2129	Storage room	25.75
Second floor	2130	Office	14.09
Second floor	2131	Office	17.91
Second floor	2132	Office	39.43
Second floor	2134	Office	20.74
Second floor	2135	Laboratory	21.17
Second floor	2137	Laboratory	39.72
Second floor	2138	Laboratory	22.09
Second floor	2139	Laboratory	29.00
Second floor	2140	Office	17.73
Second floor	2141	Laboratory	23.77
Second floor	2142	Laboratory	25.59
Second floor		Proportion of corridor	52.41
Third floor	3123	Office	17.78
Third floor	3124	Office	17.98
Third floor	3126	Office	11.79
Third floor	3127	Office	17.91
Third floor	3128	Office	11.79
Third floor	3129	Storage room	25.75
Third floor	3130	Office	14.09
Third floor	3131	Office	17.91
Third floor	3132	Laboratory	39.43
Third floor	3134	Laboratory	20.74
Third floor	3135	Laboratory	21.17
Third floor	3137	Laboratory	39.72
Third floor	3138	Laboratory	22.09
Third floor	3140	Laboratory	29.05
Third floor		Proportion of corridor	17.80
		Total	855.46

Annex 2: Building Specification

Centre for Environmental Technology, Biotechnology and Energy Technology

Building Specification 1**Building Construction**

The Centre for Environmental Technology, Biotechnology and Energy Technology [UTZ] is a four-storey building for office and laboratory use with flexible usage possibilities. The building was designed as a reinforced concrete frame construction in pre-fabricated parts with concrete cores. The ceiling construction is developed as a suspended ceiling for installations and night cooling. Its span width straddles Vierendeel trusses set 2.40 m apart, the bottom ceiling panels create suspended pre-fabricated panels with an exposed concrete surface, and the top ceiling is a slab concrete ceiling. This construction is F90-compliant. The outer layer of the suspended ceiling forms the required escape balcony in front of all office and laboratory rooms, in accordance with fire protection regulations.

The extension grid for partition wall systems and facades is 1.20 m. The storey height is 4.450 m and the clear storey height 3.000 m.

The façade was designed as a wooden window façade made from larch wood, with floor-to-ceiling glazing, thermally separated steel doors with windows and tilt&turn hardware, as an escape door leading to the protruding escape balconies. Top light on the doors made using a slat construction technique.

Building entrances

The entrances to the individual parts of the building are located at the eight stair cores. Clear passage width of around 950 mm. The entrance doors are flush panelled aluminium elements with wooden handles. Next to the doors are the company signs made out of punctiform acrylic panels to accommodate labelled transparent foil strips, as well as an intercom system with a keyboard for entering codes.

Stair cores

The stair cores were generally designed as exposed concrete constructions. The individual cores contain the necessary internal staircases, and cores 1, 4 and 6 contain lifts equipped for disabled people, toilets for ladies and gentlemen, and electrical sub-distribution boards. The floor is made of ashlar stone slabs. The doors to the stairwell are made of a steel frame construction with glazing.

Stairwell

Prefabricated flights of stairs in reinforced concrete with integrated slip protection, steel banisters with wooden handrail, span width approx. 1.10 m, 2 x 12 steps 18.5 x 27 cm.

Access to offices

Double-leaf steel frame doors and glazed side section filled with satinised glass, designed as a portal construction with closed side sections made of varnished fibre cement panels. Doormats flush with the floor. Company signs made out of punctiform acrylic panels to accommodate labelled transparent foil strips. Doorbell.

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Building Specification 02

Office and laboratory rooms

Completely open floorplan layout between the cores throughout the column-free construction between the facades and the installation within the suspended ceiling. Division into the classic two-room layout is also possible, as is the configuration of combination or open-plan offices. Office or laboratory partition walls can be added in the 1.20 m extension and façade grid.

- Walls

The partition walls were designed as a post and beam construction with plasterboard panelling and abrasion-resistant emulsion coating in accordance with the DIN 53778 standard. Base made of floor covering materials, synthetic rubber attached to the floor covering in a watertight manner. For the façade windows see the building structure.

- Floor covering

Synthetic rubber covering with impact noise reduction, light grey colour, characteristics in accordance with data sheet.

- Ceiling

Exposed concrete ceiling with standard outlets for laboratory ventilation, light installation and electrical wires in the partition walls. The non-used ventilation outlets are covered with concealed covers made of coated sheet metal.

- Doors

Steel wrap-around frames with shadow groove, painted white, office doors with top light, clear passage width of around 810 mm. Laboratory doors in T30 design with glass cut-out, clear passage width of around 940 mm, opening onto the corridor (1 escape route). Flush-fitted wooden doors, natural ash with clear lacquer.

- additional room setup

Floor ducts in the office rooms near to the outer doors, 3.60 m clearance.

Suspended lighting.

Room height tube radiators in the escape door area.

Escape balconies

Angular pre-fabricated reinforced concrete part with exposed concrete finish.

Steel railings with stainless steel handrail, railing infill with horizontal stainless-steel sides.

Sun shading

The south-western and south-eastern sides have a movable sun shading made of combined horizontal and vertical sun shading elements. The vertical, storey-height elements are composed of perforated aluminium panels which are mechanically operated and can be locked into a summer position and winter position. It can be horizontally positioned for the steep south-facing midday sun. Aluminium grates are positioned in front of the escape balconies.

Building Specification 03

Technical features

On the north-western side, Nernststrasse, in front of the meander, there are two large laboratories with a clear room height of 7.450 m. The front sides have floor-to-ceiling windows. The construction grid (span distance) is 7.200 x 13.450 m.

- Flooring

Composite screed with surface treatment, colour-treated.

- Entrance doors

Double-leaf steel doors, clear passage width (width x height) of around 1.820 x 2.790 m.

- 3-storey installation

Ground floor: washrooms and changing rooms, as well as men's and women's toilets.

First floor: Seven think tanks per technical centre with a view (glass wall) into the technical centre, access via mounted steel construction with single-run metal grid staircase.

Second floor: Ventilation system for the technical centre.

- additional setup

Service lift to the storage room in the basement, lift area approx. 1.400 x 2.400 m, clear door width approx. 1.300 m. Utilities connection possibilities for water, gas, compressed air, water vapour and wastewater. Possibility to connect digesters to the air extraction system. Crane track in the technical centre, 5-tonne carrying capacity.

Entrance hall

The entrance hall of the UTZ is accessed via Volmerstrasse. Several uses are envisaged for the ground floor.

Cafeteria for around 100 persons, WISTA administrative offices, meeting rooms for 199 persons with a cloakroom, exhibition area, free-standing lift and single flight of stairs to the air quality measuring station on the roof of the building, disabled toilets.

- Floor covering

Dourit natural stone in the hall area, oak parquet in the cafeteria, carpet in the meeting room.

Annex 2: Technical Features**Centre for Environmental Technology, Biotechnology and Energy Technology****Standard laboratory****Technical equipment / media**

	<u>Services provided by the Lessor</u>	<u>Services provided by the Lessee</u>
Cooling	Cold water t_v/t_r 13/18° C 150 W per m ² of laboratory space Cold water supply in the suspended ceiling in the form of connection elements	Supply, laying and connection of cold-water pipes inside the suspended ceiling up to the lessee consumers.
Natural gas	Natural gas supply in the suspended ceiling, in each case on the duct outlet in the form of a connection pipe	Supply, laying and connection of the gas supply from the connection elements inside the suspended ceiling up to the lessee consumers, including gas meters.
Water	Cold water supply inside the suspended ceiling in the form of a water pipe. No supply of: <ul style="list-style-type: none"> • hot water • distilled water • demineralised water • soft water 	Supply, laying and connection of the pipelines from the lessor's water supply in the suspended ceiling up to the lessee laboratory equipment, including water meters.
Laboratory water	Provision of wastewater pipe inside the suspended ceiling No floor drains.	Supply, laying and connection of the wastewater pipelines from the lessor's wastewater pipeline inside the suspended ceiling up to the lessee wastewater consumers. No discharge of water-polluting substances (e.g. contaminated or infectious materials) into laboratory water; these hazardous materials must be disposed of under the lessee's own responsibility (in some circumstances, hazardous waste). Monitoring and cleaning measures must be taken when handling hazardous materials.

Technical equipment / media

Electricity supply
Communications equipment

Services provided by the Lessor

Laboratory entrance doors.
Potential equalisation line in accordance with VDE standard 0100 Part 701.
Electricity supply for laboratory benches from the suspended ceiling (distribution box) with three-phase current 230/400 V, including electricity supply up to the bottom edge of the laboratory ceiling.
In 3.60 m increments, a floor power feeder pillar (round), wet room type design, with screed canal system.
Following connection possibilities for each floor power feeder pillar:

- 3 x shockproof plug socket (230 V mains power)
- 1 electronic data processing shockproof plug socket (230 V mains power)
- 1 telephone socket
- 1 data connection

Security lighting for corridors. No central emergency electricity supply.

For each room module, direct pendant lights on the ceiling.

For laboratory entrance doors, a switch point with surge relays (inside and outside area separate). In the event of several laboratory entrance doors, a switching point with current surge relay (inside and outside area separate).

Services provided by the Lessee

Laying of potential equalisation line on the laboratory benches.
Laboratory equipment and connection of same.
Where required, lessee's own UPS system.
1 x electric laboratory distributor in the laboratory composed of

- Connecting power of approx. 18-20 kW
- Protection for emergency shutdown
- Residual-current device
- Three-pole fuse switch disconnectors with all pins able to be disconnected
- One-pole circuit breaker

EMERGENCY SHUTDOWN switch for laboratories.

Lighting

Ventilation	Mechanical air inflow and outflow: 25 m ³ /hm ² in accordance with DIN 1946, part 7. Separate extracted air from fume hoods. For every 40 m ² of laboratory space, two fume hoods with max. 450 m ³ /h of extracted air each can be provided for. Corresponding vents for fume hood extracted air are provided under the ceiling according to requirements. The exhaust duct system up to the extracted air vents are made of stainless steel (material no. 1.4541 V2a).	Fume hoods including particulate air filter. Supply, laying and connection of exhaust ducts inside the laboratory space.
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Technical equipment / media

	Services provided by the Lessor	Services provided by the Lessee
Heating equipment	Tubular radiators with hot water t _v /t _r 75/55°C including thermostatic valves	
Sanitary equipment	Emergency showers and eye baths for chemical laboratories on the laboratory entrance doors.	Laboratory equipment, laboratory facilities and fire extinguishers, The lessee is responsible for laying and supplying connecting pipelines and for the connection to the double sinks, emergency showers, eye baths and valves for sinks.
Compressed air	Compressed air supply in the suspended ceiling, in each case on the duct outlet in the form of a connection pipe	Supply, laying and connection of the compressed air pipeline by the consumers using the service up to the connection pipes in the suspended ceiling.
Vacuum, special gases, media	Central storage area for gas cylinders outside the building, for large quantities of gas which may not be stored inside the building. Gas supply from the gas storage location to the duct outlet (component 02,04,6,08) in the suspended ceiling in the form of a connection pipe.	If small quantities of gas are required which can be provided in the technical centre within the leased area, the user shall be responsible for providing this. The gas cylinders must be positioned in accordance with requirements (e.g. safety cylinder cupboards). The gas type, gas cylinders, safety cylinder cupboard, gas pipelines (within a leased area, including suspended ceiling), connection work and maintenance work are the responsibility of the lessee.
General	Installation of smoke alarms. The offices are naturally ventilated through opening façade elements.	

Centre for Environmental Technology, Biotechnology and Energy Technology

Installation instructions for connections from the suspended ceiling in laboratories

1. Cooling equipment, connection from suspended ceiling above

1.1 Define connection points in the laboratory

Position, cooling capacity, pressure level

(supply cooling temperatures 13/18°C, pressure level PN 6)

1.2 Agreement with building operator

- is the required cooling capacity still available
- which line can be connected to (metering)

1.3 Punching out of the nearest blind connection, where necessary drill holes into the suspended ceiling.

1.4 Supply and laying of the cold-water pipes with black steel or copper piping in the suspended ceiling, including installation in the laboratory.

1.5 Fitting of the cold-water pipes in the laboratory from the ceiling lead-through to the consumer, including isolation valves and control valves where necessary (including measuring and control units). Pressure regulator where necessary.

1.6 Filling system with soft water.

1.7 Venting of section on the return flow ventilator in the suspended ceiling.

2. Natural gas, connection from suspended ceiling above

2.1 Define connection point in the laboratory

Position, pressure

2.2 Agreement with building operator

- is the required capacity available

2.3 Punching out of the nearest blind connection, where necessary drill holes into the suspended ceiling

2.4 Supply and laying of the gas pipeline in the laboratory from the ceiling lead-through to the consumer, including installation in the laboratory.

2.5 Fitting of the cold-water pipes in the laboratory from the ceiling lead-through to the consumer, including isolation valves and gas meter, pressure regulator where necessary.

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3. Compressed air, connection from suspended ceiling above

3.1 Define connection point in the laboratory

Position, pressure

3.2 Agreement with building operator

- is the required capacity available

3.3 Punching out of the nearest blind connection, where necessary drill holes into the suspended ceiling.

3.4 Supply and laying of the pressure pipes: galvanised threaded steel pipes in the suspended ceiling, including installation in the laboratory.

3.5 Fitting of the gas pipes in the laboratory from the ceiling lead-through to the consumer, including isolation valves and gas meter. Pressure regulator where necessary.

4. Sanitary system, connection from suspended ceiling above

4.1 Define connection points in the laboratory

Position, water type (drinking water or laboratory water)

4.2 Agreement with building operator

- which line can be connected to
- which meter must be installed
- which wastewater systems can be introduced

- 4.3 Core drilling, lay fire protection sleeve for wastewater and set with mortar
- 4.4 Supply and laying of the water and wastewater pipeline in the suspended ceiling
 - Galvanised steel water pipe with meter according to WISTA requirements
 - PPS plastic wastewater pipe including installation in the laboratory area
- 4.5 Sealing of the pipes in the area of the floor ducts
- 4.6 Create connections in the laboratory, including isolation valve for water

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5. Ventilation systems, digester connection from the suspended ceiling above

5.1 Define connection point in the laboratory

Air flow rate, position

5.2 Agreement with building operator

- is the air flow capacity available
- which pollutants can be removed
(stability of the duct)

5.3 Punching out of the nearest blind connection.

5.4 Supply and laying of the ventilation pipes: galvanised steel pipes including the “laboratory control system” in the suspended ceiling, including installation in the laboratory.

5.5 Connection of the laboratory control system to the control and regulation technology construction work.

Completion of data points in the building control system

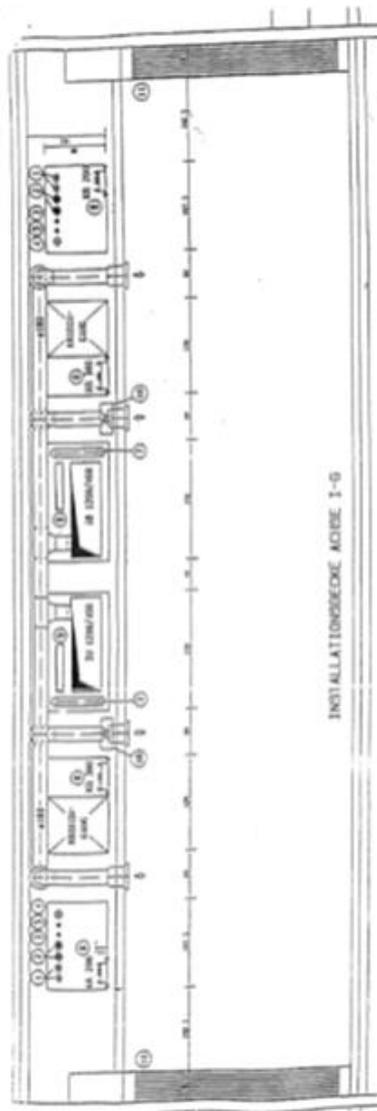
5.5. Fitting of the ventilation pipes in the laboratory and connection to the digester/outlet.

General:

The works mentioned above must be carried out by a professional company.

The works must be coordinated and monitored by WISTA.

We recommend arranging for the works to be carried out by the same company awarded the contract for maintaining the systems.



INSTALLATIONSDECKE ACHSE I-G = installation ceiling axis I-G

KEY

- | | |
|---|---|
| 1. HOT WATER VL AND [illegible], [illegible] 32 | 7. LABORATORY WATER ([illegible]) |
| 2. COLD WATER VL AND [illegible], [illegible] 50 | 8. CABLE [illegible] (KA) |
| 3. COLD PROCESS WATER [illegible] 32 [illegible] | 9. SPECIAL EXTRACTED AIR 600/100 |
| 4. COMPRESSED AIR – <i>not envisaged</i> | 10. TERMINAL BOARD (ONLY IN LABORATORY AREAS) |
| 5. COLD DRINKING WATER [illegible] 32 ([illegible]) | 11. RADIATOR |
| 6. CONNECTION WITH CONSUMPTION METER [illegible]
(REMOTE INDICATION) | |

KGR430

Supporting Document for Cost Calculation of 19.07.2004

Project name: **WISTA Berlin**
UTZ
Mieterausbau Jerini AG

Part of building/
building **BT 2/1, floor 2 and 3**
System(s) **Ventilation systems**
KG 430

Prices in euro (€)
Value added tax 16%

K-[text cut off]	Main weight	Description	Net basic price	Gross basic price	
430	RLT	Ventilation systems or cooling	[***]	[***]	
K- [text cut off]	Main weight	Description	Basic price	Basic price	
430	RLT	Ventilation systems or cooling	[***]	[***]	
Pos.	Quantity		Unit price	Basic price	Basic price
1	1	Unit Central unit special exhaust air, system 17, outdoor installation Air flow 20,300 m3/h, for process exhaust air	[***]	[***]	[***]
2	1	Flat fee Connection system 7 – supply air to system 5	[***]	[***]	[***]
3	1	Flat fee Galvanised sheet steel air duct	[***]	[***]	[***]
4	1	Flat fee Stainless steel air duct	[***]	[***]	[***]
5	1	Flat fee Air passages/displacement outlets	[***]	[***]	[***]
6	1	Flat fee Air flow control system 12 x room balance control, 17 x laboratory hood with air flow monitoring, 17 x automated fume hoods without air flow monitoring, 32 x source extraction, cupboard extraction	[***]	[***]	[***]
7	1	Flat fee Fire dampers	[***]	[***]	[***]
8	1	Flat fee Heating and cooling supply, central unit	[***]	[***]	[***]
9	1	Flat fee Thermal insulation	[***]	[***]	[***]
10	1	Flat fee Control system	[***]	[***]	[***]
11	1	Flat fee Activation	[***]	[***]	[***]
12	1	Flat fee Maintenance documents	[***]	[***]	[***]
13	1	Flat fee Disassembly	[***]	[***]	[***]

KGR435

Individual List of Operating and Utilities Costs with Usage Allocation

Lessee: Jerini Peptide Technologies GmbH

Heading	Subheading	Portion
Heating		yes
of which	Heating – ventilation technology	yes
of which	Maintenance of district heating supply	yes
of which	Heating settlement service	yes
Electricity		yes
Water supply and wastewater discharge		yes
Rainwater discharge		no
Gas		no
Cooling		yes
Special-purpose media supply		no
of which	Nitrogen	no
of which	Propane gas	no
of which	other media (e.g. deionised water, oxygen)	no
Cleaning		yes
of which	Cleaning of building	yes
of which	Window cleaning	yes
Maintenance		yes
of which	Electrical systems in building	yes
of which	Water/wastewater/sanitary fixtures	yes
of which	Heating system / water heater for building	yes
of which	Neutralisation systems	yes
of which	Deionised water systems	yes
of which	Ventilation systems	yes
of which	Special extracted air systems	yes
of which	Measurement and control technology systems	yes
of which	Cooling systems	yes
of which	Nitrogen supply systems	no
of which	Gas supply systems	yes
of which	Propane gas supply systems	no
of which	Compressed air systems	yes
of which	Lifts	yes
of which	Fire protection systems	yes
of which	Burglar alarm systems	yes
of which	Air washers	no
of which	Clean room	no
of which	Other systems (e.g. crane, vacuum systems)	no
of which	Door systems (e.g. automatic doors, revolving doors, intercom systems)	yes
of which	Examination of systems subject to a monitoring obligation	yes
Other		yes
of which	Telecommunications costs (e.g. emergency calls, fire and burglar alarms)	yes
of which	Fire insurance coverage	yes
of which	Chimney sweep	no
of which	Pest control	yes
Infrastructure		yes
of which	Street cleaning – Berliner Stadtreinigung [Berlin city cleaning company]	yes
of which	Waste collection – Berliner Stadtreinigung	yes
of which	Recycling (paper, glass, bulky waste)	yes
of which	Maintenance of private roads	yes
	Winter road clearance/cleaning/lighting/traffic safety	
of which	Maintenance of green spaces	yes
of which	Surveillance services	yes
of which	Maintenance of community facilities	yes
of which	Third party liability insurance	yes
of which	Public relations work	yes
Technical management		yes
of which	Company management – technical building services	yes
of which	On-call service / emergency service	yes
Property tax		yes

DIRECT DEBIT AUTHORISATION

I (we) hereby authorise Adlershof Facility Management GmbH, representing the owners, until revocation, to debit the payments for the leased property when due, via direct debit from my account specified below, from _____ [date].

Property: _____
Address: _____
Customer number: _____
Account holder: _____
Account number: _____
Sort code: _____
Banking institution: _____

If my (our) account does not contain the necessary funds, my bank is under no obligation to honour the payment.

Berlin, on

Signature of account holder

Annex to the Lease

between Jerini Peptide Technologies GmbH
and WISTA-MANAGEMENT GMBH

Acknowledgement of the House Rules

These House Rules constitute a component of the lease specified above. Where necessary, the Lessor reserves the right to amend and supplement these House Rules in the interest of the Lessee.

Such amendments and supplements shall also constitute a component of the lease once notified to the Lessee.

The Lessee acknowledges that it is bound by the House Rules. A breach of the House Rules constitutes usage of the leased property in breach of the lease.

In serious cases or in the event of a repeated breach, the Lessor may terminate the leasehold without giving notice. The Lessee is liable to compensate for all damage caused to the Lessor as a result of a breach or non-compliance with the House Rules, and in particular non-compliance with the reporting obligations.

General Provisions on Orderliness

The Lessee must use the leased areas only in accordance with the lease, clean them properly and ensure suitable ventilation. The noise and environmental control regulations must be carefully complied with. The other lessees must not be inconvenienced by gas, odours, smoke, soot, etc. The Lessee shall be liable for any violations.

The floors in the leased areas and the stairwell must be maintained in such a way as to ensure that no damage is caused. Indentations must be avoided by providing appropriate underlay.

No objects whatsoever may be placed or stored outside the leased areas, i.e. in and/or on the communal rooms and areas.

If the Lessor grants a special authorisation in this regard, the Lessee shall be liable for all resulting damage. Outside of the leased areas, i.e. also in the courtyard, no works may be undertaken by the Lessee. Vehicles belonging to the Lessee and its employees may only be parked with the Lessor's permission and in the designated spaces. Vehicles belonging to other persons may only park on the property for the time necessary for loading and unloading. In the event of non-compliance with these rules, the Lessor may claim an appropriate fee from the Lessee, without prejudice to its additional rights.

Cycling is not permitted in the courtyards and entrances.

Animals may only be kept with the Lessor's permission, which may be withdrawn at any time.

- The entrances shall remain closed from 18:00 to 06:00. During this time, the Lessor does not have to provide lighting in the stairwells and corridors. The building is *neither open nor lit* on Sundays and public holidays.

If the Lessee completely or temporarily moves out before expiry of the lease, it shall be obliged to provide the keys to the Lessor or its agent. This shall apply even if it has left items in the rooms, but it is clear from the quantity or condition of the left items that the Lessee intends to leave the premises permanently. In this case, the Lessor shall be entitled to take possession of the leased areas before they have been permanently vacated.

Lessee's Duty of Care

The Lessee has the following obligations, among others:

- Comply with its traffic safety obligation and ensure that no damage is caused to third parties through the use of communal areas (entrances, stairwells, lifts, courtyards, entrances, parking spaces and gates),
- Keep floors dry and ensure they are treated appropriately,
- Avoid damage to gas, water supply and water discharge systems, electrical systems and other equipment in the building, and blockages in the gas and water discharge systems,
- Notify any malfunctions in these systems immediately,
- Ensure that doors and windows are kept properly locked in the event of inclement weather, during the night and during absence,
- Avoid wasting light in communally used areas of the building and avoid wasting water,
- Clean cellar light wells and windows if these are located within the leased cellar. In the same case, ensure proper ventilation of cellars and lofts to the same extent required for the whole building cellar or loft, and also ensure that windows are closed at night and when it is cold and wet,
- refrain from making any amendments to the leased property unless the Lessor has given its written permission, and in particular refrain from making amendments to installations including electrical power lines and inserting nails (screws), hooks, etc. into wooden cladding of any kind,
- Ensure strict compliance with the rules – to be requested from the Lessor – concerning the operation of lifts, hot water preparation, positioning of furnaces, etc.

- Ensure proper care and handling of all keys and accessory parts,
- Ensure sufficient heating, ventilation and accessibility of the leased premises and ensure that taps are turned off, especially during temporary water stoppages and also during long absences of the Lessee,
- In the event of heavy frost, the water pipes must be properly emptied. The Lessee must also ensure that toilet bowls, toilet cisterns and other systems are emptied,
- Any absence shall not release the Lessee from its obligation to take the necessary measures against frost.

cannot be guaranteed if there is a restriction of the fuel supply, or if disturbances are caused by natural phenomena or an interruption of the peace in general within the Lessee's own company or within other companies.

Any existing hot water systems shall be operated in the proper manner, and more specifically in such a way that the temperature of the tap water does not fall below

- +19 degrees Celsius. The previous paragraph shall also apply accordingly.

Fire protection regulations

All general technical and official regulations, particularly those laid down by the building supervisory authority and fire service, must be complied with.

Naked flames and smoke are not permitted on the floor or in the cellar. Cellars and lofts must not be used to store highly flammable materials such as paper, packing materials, petrol, fuel etc. Combustible materials must be properly stored: combustible materials may not be stored in loft rooms. All official regulations, especially those regarding storage of flammable materials, must be observed and complied with by the Lessee.

All gas pipelines and installations must be continually checked for leak-tightness. In the event of suspected gas odours, the main shut-off valve must be closed immediately and the plumber or gas plant emergency line notified, as well as the Lessor or its representative! - In the event of prolonged absence of the Lessee, the isolation valve on the gas meter must be turned off.

Central heating and hot water supply

Any existing central heating systems shall be operated appropriately if required by the outside temperature.

As a guideline, the primarily used rooms shall be heated to

- + 20°C. For rooms which have been amended at the request of the Lessee or by the Lessee through installations and additions, this heating cannot be demanded. While the heating is on, the Lessee must keep doors and windows properly closed, even in non-heated rooms. Necessary ventilation must not result in the rooms becoming cold. To avoid any freezing, valves must not be set to "cold" in the event of frost. Between 1 May and 30 September there is no entitlement to heating. A certain temperature

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Lease No.: 19-0351-1-014

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20th Amendment to the Lease of 11./12.04.2005

between **WISTA Management GmbH**
Rudower Chaussee 17
12489 Berlin
VAT ID No.: [*]**

and **JPT Peptide Technologies GmbH**
Volmerstraße 5
12489 Berlin

The Lease is amended from 01.01.2019 as follows:

Reduction

Building: 03.51, Volmerstraße 5-9
 Premises: partial corridor areas (92.63m²)
 Rent office:

Period:	until 31.12.2018	from 01.01.2019 reduced by	from 01.01.2019 total
Rental space	1,597,68m ²	92.63m ²	1,505.05m ²
Rent	€ [***]	€ [***]	€ [***]
Rent increase in accordance with provisions of the 19 th lease amendment of 06./07.09.2018 (€[***]/m ² /month net)			€ [***]
Total rent			€ [***]
monthly advances for:			
<u>Building utilities/building operating costs</u>			
- Heat supply	€ [***]	€ [***]	€ [***]
- Electricity supply general	€ [***]	€ [***]	€ [***]
- Water supply/sewage disposal	€ [***]	€ [***]	€ [***]
- Rainwater removal	€ [***]	€ [***]	€ [***]
- Refrigeration supply	€ [***]	€ [***]	€ [***]
- Gas supply	€ [***]	€ [***]	€ [***]
- Special media supply	€ [***]	€ [***]	€ [***]
- Cleaning	€ [***]	€ [***]	€ [***]
- Maintenance	€ [***]	€ [***]	€ [***]
- Other	€ [***]	€ [***]	€ [***]
- Infrastructure levy	€ [***]	€ [***]	€ [***]
- Technical building management	€ [***]	€ [***]	€ [***]
- Property tax	€ [***]	€ [***]	€ [***]
Subtotal advances utilities/operating costs:	€ [***]	€ [***]	€ [***]
Subtotal rent and advances utilities/OC:	€ [***]	€ [***]	€ [***]
plus the relevant value-added tax in force (currently 19%)	€ [***]	€ [***]	€ [***]
Total amount	€ [***]	€ [***]	€ [***]

Berlin,
p.p. [signature]
WISTA Management GmbH

p.p. [signature]

[stamp: [image] Berlin Adlershof
WISTA-MANAGEMENT GMBH
Rudower Chaussee 17
D-12489 Berlin
Telephone: +49 30 6392 2200
Fax: +49 30 6392 2201
www.adlershof.de
Adlershof. Science at Work]

Berlin, 27.12.2018
[signature]
JPT Peptide Technologies GmbH

List of Rental Spaces

Appendix 1

Lessee: **JPT Peptide Technologies GmbH, Volmerstraße 5**

<u>Floor</u>	<u>Room No</u>	<u>Use</u>	<u>Floor area (m²)</u>
1st	1137	Office	20.14
1st	1138	Office	23.97
1st	1220	Office	17.91
1st	1222	Office	17.78
1st	1223	Office	17.98
1st	1224	Office	17.78
1st	1242	Laboratory	28.84
1st	1239	Laboratory	29.11
1st	1241	Laboratory	21.45
1st	1243	Office	15.05
1st	1320	Office	23.87
1st	1322	Office	17.91
1st	1325	Office	17.82
1st	1326	Office	17.98
1st	1328	Office	17.98
2nd	2120	Office	16.26
2nd	2121	Storage	18.20
2nd	2122	Storage	17.85
2nd	2123	Office	23.85
2nd	2124	Office	17.98
2nd	2126	Office	11.79
2nd	2127	Office	17.91
2nd	2128	Office	11.79
2nd	2129	Storage	28.75
2nd	2130	Office	17.09

2nd	2131	Office	17.91
2nd	3132	Office	39.43
2nd	2134	Office	20.74
2nd	2135	Laboratory	21.17
2nd	2137	Laboratory	39.72
2nd	2138	Laboratory	22.09
2nd	2139	Laboratory	29.00
2nd	2140	Office	17.73
2nd	2141	Laboratory	23.77
2nd	2142	Laboratory	25.59
2nd	2434	Laboratory	29.11
3rd	3120	Office	17.85
3rd	3121	Storage	29.34
3rd	3122	Office	17.91
3rd	3123	Office	17.78
3rd	3124	Office	17.98
3rd	3126	Office	11.79
3rd	3127	Office	17.91
3rd	3128	Office	11.79
3rd	3129	Storage	25.75
3rd	3130	Office	14.09
3rd	3131	Office	17.91
3rd	3132	Laboratory	39.43
3rd	3134	Laboratory	20.74
3rd	3135	Laboratory	21.17
3rd	3137	Laboratory	39.72
3rd	3138	Laboratory	22.09
3rd	3140	Laboratory	29.05
3rd	3141	Laboratory	29.25
3rd	3142	Laboratory	28.85
3rd	3143	Office-like	13.38
3rd	3320	Laboratory	17.91
3rd	3321	Laboratory	17.82
3rd	3323	Office	30.06
3rd	3325	Office	24.10
3rd	3326	Office	17.75
3rd	3327	Office	17.85
3rd	3328	Laboratory	23.81

3rd	3329	Office	11.73
3rd	3330	Laboratory	23.81
3rd	3332	Office	17.69
3rd	3333	Office	17.91
3rd	3335	Office	15.12
3rd	3422	Office	36.14
3rd	3424	Office	22.30
		Total	<u>1505.05</u>

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**Loan agreement
dated 21.11.2017
for a repayment loan of
EUR 10,000,000.00
from the
KfW energy efficiency program – Energy-efficient construction and renovation (276)**

between

**BioNTech Innovative Manufacturing
Services GmbH**
Vollmersbachstraße 66
55743 Idar-Oberstein

(“Borrower”)

and

**Deutsche Bank AG
Business in Germany**
Ludwigsstraße 8 - 10
55116 Mainz

(“Bank”)

the following agreement (“**Loan Agreement**”) has been concluded for the granting of a repayment loan (“**Loan**“):

[Copy for the Bank / ~~Copy for the client~~]

§ 1 LOAN

(1) Loan amount

The Bank is granting the Borrower a repayment loan (“**Loan**”) in the sum of **EUR 10,000,000.00** (in words ten million Euro) (“**loan amount**”).

(2) Term

This Loan has a term until 30.12.2027 (“**final due date**”).

(3) Purpose

The Loan serves to finance a new-build and extension of a laboratory building under the loan application of 23.05.2017.

Investment project in the area: KfW Efficiency House 70

Investment site: Vollmersbachstraße 66 in Idar-Oberstein, Stadt, Birkenfeld District

Investment plan in EUR:

Commercial building costs
Machinery, equipment,
fittings, vehicles
Total

Finance plan in EUR:

[***]	KfW energy efficiency program	[***]
[***]	Capital	[***]
[***]	Total	[***]

(4) Account

The Loan will be credited to the account Nr. [***] of the Borrower.

(5) Refinance

The Loan is being refinanced by KfW in order make possible the interest conditions agreed in this Loan Agreement.

(6) Definitions

“**Banking day**” is any day (with the exception of Saturday and Sunday) on which commercial banks are open to the public for business in Frankfurt/Main.

“**Financial liabilities**” are all liabilities from (i) borrowings (ii) issued letters of credit and accepted or issued bills (iii) the issue of bonds, “commercial papers” or other debentures, (iv) lease contracts that under the applicable edicts of the Federal Ministry of Finance or the respective tax or balance sheet provisions of the Jurisdictions regulating the lease contract, are to be treated as finance [operating] leases, (v) the sale of receivables where recourse against a member of the company group of the Borrower cannot be ruled out (recourse factoring), (vi) trade accounts payable when a payment schedule is granted that lies outside the common industry practices, (vii) derivatives, whereby when calculating the value of a derivative transaction only the “mark-to-market value” is taken into consideration, (viii) recourse liability in respect of third party sureties, guarantees, bonds, letters of credit or other financial instruments, where such are not included

twice in the balance sheet concerned since the respective principle debt is already accounted for, (ix) other transactions when these have the economic effect of a borrowings as defined in paras. (i) to (viii), (x) a guarantee, surety or other co-liability for one of the liabilities cited in paras. (i) to (ix) liabilities, and (xi) pension provisions.

§ 2 - LOAN DRAW-DOWN

(1) Drawings

The Borrower may draw down the Loan from the effectiveness of this Loan Agreement up to and including 21.11.2018 (“**draw-down deadline**”) provided the draw-down requirements under § 3 are satisfied (any such event hereinafter a “**drawing**”). Any part of the loan amount not drawn down within the draw-down deadline lapses.

(2) Notice of draw-down

The draw-down of the Loan takes place in one/several drawings on the basis of an irrevocable notice or notices of draw-down by the Borrower.

The notice of draw-down must be received by the Bank at the latest at 10.00 on the fifth banking day before payment and shall specify the date of payment, the amount and the account in which the draw-down is to be made available.

§ 3 – DRAW-DOWN REQUIREMENTS

The Borrower may draw-down the Loan as soon as all the following agreed requirements are satisfied and one or more have not subsequently lapsed and provided and as long as no important reason exists entitling the Bank to extraordinary termination of this Loan Agreement or that would provide such right of termination after an additional deadline and/ or warning.

(1) The Bank has all the following documents and evidence in satisfactory form and the corresponding evidence has not subsequently proved to be incorrect:

- (a) All the details required under the Federal Money Laundering Act (GwG) regarding the financial beneficiaries (§ 1 para. 6 GwG);
- (b) Declaration by the Borrower on the use of the funds within the framework of this agreement;
- (c) All the documents required to open and manage the account, signed with legal effect by the management of the Borrower;
- (d) All the agreed securities have been validly constituted.

(2) The Borrower is not in default towards the Bank in the satisfaction of a due claim.

The Bank may make payment without all payment requirements having to be satisfied. The obligation of the Borrower to satisfy the payment requirements remains thereby unaffected unless the Bank has waived satisfaction of specific payment requirements in writing.

§ 4 – AMORTISATION / REPAYMENT BONUS

The Loan is repayable in 32 equal consecutive instalments of EUR 312,500.00. The instalments are payable quarterly in arrears on 31.03., 30.06., 30.09. and 31.12; the first instalment is due on 31.03.2020, the last instalment is due on 30.12.2027.

If the Borrower has not, by the time of expiry of the draw-down deadline, drawn down the entire loan amount the respective last loan instalment is reduced by the difference and the loan term where applicable is reduced accordingly.

§ 5 – INTEREST / COMMISSIONS / PAYMENTS

(1) Debit authorisation

The Borrower herewith instructs the Bank to debit any due repayment amounts, interest, costs, payments, expenses and commissions against the Borrower's account [***].

(2) Commitment fee

From 21.11.2018 (exclusive) up until expiry of the drawn-down deadline the Bank shall charge, on the outstanding loan amount a commitment fee of 0.25% per month; this shall be paid quarterly in arrears.

(3) Interest

The interest rate is fixed for the entire term and amounts to **2.15% p.a.** The interest provisions of Clause 14 para. 4 AB-KfW are expressly referred to. By way of deviation from the 3-month deadline in the 4th bullet point, a period of 6 months is agreed.

The interest is charged on the basis of 30/360 days. It becomes due at the end of each Quarter.

6 – SECURITIES

The creation of the following additional securities has been agreed:

- First-priority land charges for of EUR 10,000,000.00 on Betriebsimmobil (“*commercial property*”) in 55743 Idar-Oberstein, Idar-Oberstein Land Register Page 14961
- Indefinite directly enforceable guarantee by BioNTech AG in the amount of EUR 10,000,000,00,
- Loan maintenance and subordination agreement in respect of an existing shareholder loan of EUR 8,000,000.00 and the new loan of the shareholder or sister companies serving the co-financing of the investment.

Individual details, in particular concerning the security purpose, are regulated in the security agreements.

§ 7 – GENERAL OBLIGATIONS

The Borrower, under the Federal Money Laundering Act (GwG) is obliged to give the Bank, where this has not already taken place, all the details required under this Law regarding the financial beneficiaries (§ 1 para. 6 GwG) and immediately and without being so requested to report any changes arising over the term of this Loan Agreement (§ 4 para. 6 and § 6 para. 2 Nr. 1 GwG). On request by the Bank the Borrower shall give the Bank the documentation and information required to ascertain and check such details.

The Borrower, until complete satisfaction of all the claims of the Bank from draw-down under this Loan Agreement, further assumes the following obligations:

(1) Information

The Borrower shall continually update the Bank regarding its financial situation and, where applicable, the financial situation of its group of companies.

In this regard it shall provide the Bank in particular with its latest annual accounts plus notes and management report and a consolidated annual account (consolidated balance sheet, consolidated P&L account and consolidated notes) together with a consolidated management report on the Group including the respective auditor's reports immediately on completion, at the latest however within 9 months of conclusion of the respective financial year, in the original and at least having the scope legally required. Where the annual accounts do not have to be certified, the Bank shall be given copies bearing the legally-binding signatures of all directors or all liable partners.

Moreover the Borrower shall provide the Bank with quarterly business evaluations, liquidity figures, balance sheet status and target-performance analyses.

Moreover the Borrower shall provide the Bank with its annual budget by 31st January of each calendar year.

Further documents providing an up-to-date view of the financial situation and information on the latest income and asset situation of the guarantors shall be submitted by the Borrower on request.

Where documentation is submitted by the Group parent company of the Borrower or its tax advisers or auditors, the Borrower herewith declares that these are authorised to confirm that the submitted documents are true and faithful copies of the originals in its name and to recognise the submitted documentation as binding on it.

The Borrower shall immediately notify the Bank should any information or documentation provided (also planning and forecasts) show significant negative changes or deviations or should it transpire that there are indications that the information or documentation supplied was incomplete or incorrect.

(2) Use of credit funds

The Borrower shall immediately demonstrate to the Bank through suitable documentation that it has used the drawn-down funds within six months of payment for the agreed purpose and that the agreed usage continues to exist.

The Borrower shall prove the scheduled and punctual use of the funds to the Bank within nine months of complete payment of the Loan and submit the "Confirmation after execution of the investment measure KfW-energy efficiency program – energy-efficient construction and renovation (276, 277, 278)" according to the attached KfW-Form (Number 600 000 3413) via the Bank to KfW, signed by it and the expert.

The Bank is not contractually-obligated to the Borrower to monitor compliance with the Loan purpose.

(3) Change in shareholder structure

The Parties are agreed that the current shareholder structure constitutes an important basis for the willingness of the Bank to grant this loan and the authorisation of all draw-downs under the same. In the event of any change in the shareholder structure the Parties shall reach a mutually-satisfactory agreement on the continuation of this Loan Agreement, where applicable subject to amended conditions, for example regarding interest, securities or other agreements before such a situation arises.

(4) Credit agreements with other credit institutions

The Borrower shall inform the Bank of any new loan agreements that exceed the amount of EUR 500,000.00 or if there are significant changes to its current loan agreements with other credit institutions (for example increase, termination or collateral requirements), where these are the subject of negotiations, where possible in advance, otherwise immediately thereafter.

§ 8 – EXTRAORDINARY RIGHT OF TERMINATION

An important reason entitling the Bank to extraordinary termination of this Loan Agreement under Nr. 19 para. 3 AGB in particular exists when:

- (1) A circumstance as cited in Nr. 11 para. 1 der AB-KfW is satisfied, or
- (2) The Borrower fails to satisfy the general obligations or other essential obligations agreed under this Loan Agreement or fails to comply with the security agreements concluded in connection with this Loan Agreement or
- (3) A change takes place to the shareholder structure and the Parties do not promptly agree to the continuation of any changed conditions, for example regarding interest accrual, securities or other agreements or
- (4) The Borrower fails to or cannot satisfy its financial liabilities towards third party credit institutions on becoming due or third party credit institutions prematurely call in or could call in such financial liabilities on the basis of a reason for termination where the financial liabilities concerned exceed a sum of EUR 100,000.00 (or the counter-value in other currencies).

§ 9 – MISCELLANEOUS

(1) General Business Terms and Conditions

The following General Business Terms and Conditions constitute part of this Loan Agreement:

- (a)** General Business Terms and Conditions of the Bank (“**AGB**”);
- (b)** General Terms and Conditions for Investment Loans of KfW – Contractual relationship between Bank—End Borrower—(“**AB-KfW**”) in the Version of 10/2015, whereby the AB-KfW in Clauses 14 para. 1 sub-para. 3 and 14, para. 4 sub-para. 1, 4th bullet point are amended such that the respective drawn-down amount are to be fully apportioned to the specified purpose within 6 months.
- (c)** Information Sheet “Energy efficiency in the company – Commercial buildings – KfW energy efficiency program – Energy-efficient construction and renovation (276/277/278)” in the Version of 08/2016 (“**Information Sheet**”) including the Annex “Technical Minimum Requirements” for the Information Sheet.

(2) Forward transactions

Where the Bank and Borrower, to secure the interest or currency risk under this Loan Agreement, conclude or have already concluded forward transactions – which the Bank is not obliged to do – the continued existence of these forward transactions is not affected by any termination of this Loan Agreement.

(3) Information disclosure

Where the Bank, for refinancing, risk hedging or capital relief, makes use of its right to transfer the credit risk or claims under this Loan Agreement or otherwise dispose of the same, the Bank is entitled to pass on borrower-related information to authorised recipients that by force of Law, contract or occupational or professional regulation are obliged to maintain confidentiality. Authorised information recipients are members of the European Central Bank system, credit institutions, development banks, financial service providers, finance companies, insurance companies, pension funds, capital management companies, special purpose vehicles founded for assuming credit risks and persons that for technical or legal reasons are to be involved in the transfer (for example auditors and rating agencies).

(4) Subsidy

According to KfW in its refinancing approval of 17.11.2017 the Loan receives no subsidy.

(5) Other KfW provisions

KfW continually receives all information on this Loan Agreement and its execution, moreover all information on the Borrower of relevance for the Loan and the Bank’s internal rating of the Borrower. This data is processed by KfW and used to monitor the proper use of the funds and for statistical purposes.

The Borrower expressly agrees to this data being forwarded by the Bank to KfW.

(6) Choice of Law and court of jurisdiction

This Loan Agreement and all rights and obligations under the same are governed by German Law. The court of jurisdiction is Mainz. Moreover legal action can also be taken against each Party at their registered office.

(7) Written form

Changes to this Loan Agreement must be made in writing.

(8) Offer deadline / Validity of agreement

- (a) The Bank considers itself bound by the offer submitted with this Loan Agreement until 20.12.2017 (“**offer deadline**”).
- (b) This Loan Agreement takes effect on receipt of the agreement signed by all the parties within the aforesaid offer deadline.

(9) Severability clause

Should individual provisions of this Loan Agreement be or become wholly or partly – for whatever reasons – void or invalid or unworkable, this shall not affect the other provisions of this Loan Agreement.

Declaration pursuant to the Federal Money Laundering Act:

The Borrower guarantees the Bank by crossing or initialling that it is solely drawing down the funds granted under this Loan Agreement for its own account.

x BioNTech Innovative Manufacturing Services GmbH

This Loan Agreement is cited under the date given in the heading.

Deutsche Bank AG
Branch Office Germany

Mainz, 21.11.2017
Place, date

[Signature]
[***]

[Signature]
[***]

BioNTech Innovative Manufacturing Services GmbH

Idar-Oberstein, 12th December 2017
Place, date

[***]
Legally-binding signature(s)

[***]

General Terms and Conditions for Investment Loans

- Contractual relationship Principal Bank—End Borrower -

For KfW investment loans the following General Terms and Conditions for Investment Loans in the Version for the contractual relationship between Principal Bank—End Borrower (AB-EKN) up to and including Clause 13 applies. For ERP loans and loans refinanced or subsidised from public budgetary funds, the special provisions of Clause 14 apply in addition. For loans where the Principal Bank is granted liability exemption on the basis of a national or state guarantee, the special provisions of Clause 15 additionally apply.

1. Use of funds

- (1) The Loan may only be used to finance the project for which the Loan was approved. The credit institution closing the Loan Agreement with the End Borrower (hereinafter the “Principal Bank”) must be informed immediately if the investment project or its financing change.
- (2) The End Borrower shall immediately and without being requested provide the Principal Bank on conclusion of the investments with evidence regarding the use of the loan funds and the satisfaction of any conditions.

2. Draw-down of funds

- 1) The draw-down of the Loan – where applicable in partial amounts – from the Principal Bank may only take place when this latter, within an appropriate deadline, can be apportioned for the specified purpose. Should it transpire after payment that correct use of the funds is not possible, the corresponding sums are to be immediately repaid to the Principal Bank for forwarding to KfW. Renewed draw-down is possible when the aforesaid requirements are satisfied. Sub-paras. 2 and 3 of this paragraph do not apply if the Loan does not exceed the sum of 25,000 Euro. Sub-paras. 2 and 3 of this paragraph also do not apply for the last payment instalment of a loan when this does not exceed the sum of 25,000 Euro. The Principal Bank is entitled to set appropriate minimum draw-downs.
- 2) Loan amounts may only be drawn down by natural persons as commercial or freelance end borrowers when these have demonstrated their power to manage and represent the company or law firm, the practice or comparable to the Principal Bank.
- 3) Should grounds exist providing entitlement to terminate the Loan Agreement, the Principal Bank may refuse payment of the loan funds.

3. Interest schedules

The Loan shall accrue interest at the agreed rate. Interest calculation takes place applying the German business interest method (30/360 Method). Interest payments are due quarterly in arrears on 31st March, 30th June, 30th September and 30th December of each year, unless the Loan Agreement specifies otherwise.

4. Costs and expenses

The costs and expenses of the directly-refinanced credit institution and the Principal Bank are settled with the interest rate and the program-dependent processing charges paid by KfW. Regardless of the provisions of sub-para. 1 any possible claim of the directly-refinanced credit institution or Principal Bank to reimbursement of expenses is regulated by the provisions of the Law. Compensation for non-acceptance or early repayment may only be charged when KfW has concluded a corresponding regulation. Where a charge is possible, this shall be made by the Principal Bank.

5. Repayment

- 1) The repayment instalments or annuities are due on the dates given in the Loan Agreement. Where with payment a deduction is made from the nominal amount of the Loan, the deduction amount is a fee demanded by KfW independent of term, which is not reimbursed in the event of premature redemption of the Loan.
- 2) Loans with a 100% payment can only be repaid early to the Principal Bank against payment of an early prepayment penalty to the Principal Bank unless expressly agreed otherwise. Loans with a payment of less than 100% may be repaid early partly or wholly at any time during the first fixed-interest period by giving 10 banking days’ notice to the Principal Bank. Legal rights of termination remain unaffected by the above provisions. Any levied prepayment penalty may be charged by the Principal Bank within the legally-permitted framework.
- 3) Unscheduled partial repayments are fundamentally set-off against the last repayments or annuities due under the redemption plan unless otherwise agreed with the End Borrower.

6. Default

Should the End Borrower be in default on its payment obligations, the Principal Bank is entitled to claim default interest in accordance with the provisions of the Law.

7. Securities

- 1) The Principal Bank assigns the claims deriving from the granting of the Loan against the End Borrower on their coming into existence to KfW. The Principal Bank is entitled to collect the claims assigned to KfW until KfW declares the cancellation of this collection authorisation. The Principal Bank is moreover entitled to assign the securities created for the Loan to KfW. After the security assignment to KfW the claims concerned are regulated by the security purpose agreed between the Principal Bank and End Borrower. Securities provided or created in future by the Principal Bank for a KfW-refinanced Loan of the End Borrower serve – where a further purpose has been or will be legally agreed – to secure all credit claims of the Principal Bank assigned or to be assigned in future to KfW against the End Borrower. This also applies when the security is provided by a third party.

- 2) The securities agreed for this Loan may not be used as a priority to secure other Principal Bank loans. Other securities given or to be given in future to the Principal Bank by the End Borrower or to a third party for loans to the End Borrower not refinanced by KfW serve – where a further purpose has been or will be legally agreed – subordinately to secure all credit claims of the Principal Bank against the End Borrower assigned or to be assigned to KfW.

8. Right of audit

The KfW is entitled to inspect business records and books of account at the End Borrower, inform itself of the latter's asset situation and monitor the use of the loan funds under Clause 1 para. 1 on site. KfW may have these audits executed by a third party acting on its behalf. The costs of these audits shall be borne by the End Borrower, provided there is no agreement otherwise. KfW shall ensure that any third party it engages shall also maintain confidentiality regarding such information.

9. Information obligations

The End Borrower is obliged to notify the Principal Bank of any significant events that may influence the purpose of the Loan or adversely affect service of the same. The Principal Bank is entitled to forward the information to KfW.

10. Submission of annual accounts

Where not otherwise agreed, the End Borrower is obliged to submit its annual accounts with the necessary explanations only on request of the Principal Bank or KfW. In the event of delay in the preparation of the annual accounts, the End Borrower shall initially submit the provisional figures.

11. Termination for important reason

- (1) The Principal Bank is entitled to terminate the Loan for immediate repayment at any time for an important reason completely or for a partial amount, in particular when
- a) The Loan has been illegally acquired, is not used for the specified purpose or the End Borrower regardless of an additional deadline set by the Principal Bank has not enabled an audit of the use of the funds complying with the specified purpose,
 - b) The requirements for it being granted have changed or are subsequently no longer satisfied (for example sale of the co-financed business or parts thereof, change in ownership or stake holding),
 - c) The End Borrower has provided incorrect details regarding its financial situation,
 - d) The End Borrower is in breach of an obligation assumed under the Loan Agreement,
 - e) There is a significant worsening in the financial situation of the End Borrower or the valuation of a provided security or such is threatened and as a result the repayment of the Loan, even realising the securities, is placed at risk,
 - f) The scale of the overall outgoings estimated in the investment plan and scale of eligible costs is reduced or the percentage of public finance increases.

Should the important reason consist of the breach of a contractual obligation, termination may only take place after unsuccessful expiry of an additional deadline or warning, unless one of the grounds cited in § 323 para. 2 BGB does not exist.

- (2) In the event of partial termination (reduction) the repaid amount is fundamentally set-off against the outstanding repayment instalments or annuities (proportional to the residual term of the Loan), unless otherwise agreed with the End Borrower.

12. Provision of information

The Principal Bank is entitled to give KfW or a third party authorised by KfW unrestricted information, allow them to inspect documentation and, for documentation purposes, provide the documentation. The provisions of this paragraph also apply for electronic archiving.

13. Limitation of applicability

If the General Business Terms and Conditions of the Principal Bank are incompatible with these General Terms and Conditions, the latter shall take precedence.

14. Special terms and conditions for ERP loans and loans refinanced or subsidised from public budgetary funds

For ERP loans and loans refinanced or subsidised from public budgetary funds, the following additional special provisions shall apply, unless the Loan Agreement specifies otherwise:

- 1) The Loan may only be drawn down pro rata with the other funds provided for in the finance plan. Only where the latter is not available can the loan, by way of exception, also be used earlier. The draw-down of the Loan – where applicable in partial amounts – may only take place when the requested sums can be apportioned to the specified purpose within 3 months. Should it transpire after payment that punctual use of the funds is not possible, the corresponding sums must be immediately repaid to the Principal Bank for forwarding to KfW. Renewed draw-down is possible when the above requirements are satisfied. Sub-paras. 1, 4 and 5 of this paragraph do not apply when the Loan does not exceed 25,000 Euro. Sub-paras. 1, 4 and 5 of this paragraph also do not apply for the last payment instalment of a Loan when this does not exceed the sum of 25,000 Euro.

- 2) Should the costs of individual items of the investment plan be reduced by 20% or more, the saved funds may only with the prior permission of the Principal Bank be used to cover the increased costs of other eligible items.
- 3) The Supreme Court, under § 91 BHO is entitled to carry out audits. Moreover the competent Federal Ministries or their agents are entitled to carry out the relevant audits.
- 4) Interest premium
The agreed interest rate increases from the date following payment, to 5 percentage points above the respective base rate under § 247 BGB if the Loan is illegally obtained, is not used according to the specified purpose, the End Borrower, regardless of any additional deadline set by the Principal Bank fails to enable an audit of the correct specified use or the End Borrower does not use the funds within 3 months for the specified purpose and also does not repay the funds immediately to the Principal Bank.

If the prerequisites for the granting of the Loan have subsequently changed or are not satisfied, the interest rate increases to 5 percentage points above the respective base rate under § 247 BGB from the time of change or failure to satisfy.

Where the interest rate cited in the Loan Agreement is higher than the base rate plus 5 percentage points, the interest rate cited in the Loan Agreement shall continue to apply.

15. Special terms and conditions for Loans where the Principal Bank is granted liability exemption on the basis of a national or state guarantee

In the case of Loans where the Principal Bank is granted liability exemption on the basis of a national or state guarantee, the Federal Supreme Court under § 91 BHO or the respective State Court of Audit is entitled under state regulations to carry out audits. Additionally the competent Federal or State Ministries or their agents are entitled to carry out the corresponding audits.

KfW energy-efficiency programme – Energy-efficient construction and renovation

276/277/278

Loan

On behalf of
Federal Ministry of
Economic Affairs
And Energy

Partner of
Deutschland macht's
Effizient

Financing construction, the initial purchase and renovation of commercial buildings including the implementation of individual measures for improving energy efficiency within the framework of the "CO₂ Building Refurbishment Programme" of the Federal Government.

Subsidy aim

The funding programme serves the low-interest long-term financing of measures for significant energy saving and reduction of CO₂ emissions in existing commercial buildings in Germany. Additionally the construction of KfW Efficiency Houses with low energy requirements and CO₂ emissions is funded. The interest rate is reduced for the first 10 years of the loan term from federal funding. For most purposes the projects are also assisted with government repayment subsidies.

Alongside the subsidising of new-builds and the renovation of buildings under the KfW energy efficiency programme measures are co-financed in the area of production facilities/processes. Detailed information on this can be found in the KfW Information Sheet "KfW-energy efficiency programme – Production facilities/processes" (Order Nr. 600 000 3416).

Who can make applications?

- The Programme is aimed at domestic and foreign commercial companies (production, tradesmen, commerce and other service sectors) which are predominantly under private ownership
- The self-employed, for example doctors, tax consultants, architects
- Companies buying existing commercial buildings (first- acquisition)
- Companies providing (energy) services for a third party for commercial non-residential buildings under a contracting agreement.

What is subsidised?

Subsidy
Content, requirements
combination options

Subsidies are provided for:

1. The energy renovation of commercial non-residential buildings that achieve the energy level of a KfW Efficiency House for existing buildings.
 - KfW Efficiency House
 - KfW Efficiency House 100
 - KfW Efficiency House Monument
2. The implementation of **individual measures** on the building shell and/or technical equipment to improve energy efficiency in existing commercial non-residential buildings.

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KfW energy-efficiency programme – Energy-efficient construction and renovation

The following individual measures are subsidised:

- a) Insulation of walls, roof surfaces, storey ceilings and floor surfaces
- b) Renewal and treatment of windows, curtain walls, outer doors and gates (incl. loading stations)
- c) Measures to improve summer heat insulation
- d) Installation, exchange or optimisation of ventilation and a/c systems incl. heat/cold recovery and waste heat use
- e) Renewal and/or optimisation of heat/cold generation, distribution and storage incl. power/heat or power/heat/cold coupling systems
- f) Exchange and/or optimisation of lighting
- g) Installation or optimisation of metering, control and regulation systems and building automation

For architectural monuments the Annex “Technical Minimum Requirements” to the Information Sheet (Order Nr. 600 000 3418) defines exceptional rules for the heat insulation of outer walls and roof surfaces and window renewal.

3. The **construction** of energy-efficient commercially-used buildings that achieve the energy level of a KfW Efficiency House for new builds.

The following levels are subsidised:

- KfW Efficiency House 55
 - KfW Efficiency House 70
4. Also eligible for subsidy are all **other measures** required for the preparation, realisation and start-up of the measures subsidised in the Programme. These also include:
 - Ancillary works, for example removal and disposal of old installations
 - Planning costs constituting a necessary element of the construction
 - Measures for regulating the subsidised system (metering measurement and adjustment of the control parameters including the hydraulic alignment of heat and cold distribution systems)
 - Costs for energy management systems

Only buildings or parts of buildings that after completion or implementation of all measures fall under the sphere of applicability of the Energy Savings Regulation (EnEV) are eligible for subsidy.

Subsidisation takes place in accordance with the requirements of the applicable EnEV and the Annex “Technical Minimum Requirements” to the Information Sheet (Order Nr. 600 000 3418).

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KfW energy-efficiency programme – Energy-efficient construction and renovation

Involvement of an expert

Expert

Compliance with the technical minimum requirements and the savings of energy and CO₂, on application, to be quantified and confirmed by an expert in the Form “Confirmation for loan application KfW energy efficiency programme – Energy-efficient construction and renovation” (Form Nr. 600 000 3415).

An expert for the purposes of this loan programme is a person authorised under § 21 EnEV for non-residential buildings.

We recommend the involvement of a quality-approved expert for non-residential buildings from the experts list for Government funding programmes in the Category “Energy-efficient construction and renovation – non-residential buildings KfW”) under www.energie-effizienz-experten.de.

Only the experts cited in the experts’ list for Government funding programmes under www.energie-effizienz-experten.de under the Category “KfW Efficiency House Monument and architectural monuments and other structures particularly worthy of preservation” are authorised for renovation to the KfW Efficiency House Monument and renovation of architectural monuments to other KfW Efficiency Houses or individual measures on architectural monuments.

Excluded from subsidisation are:

- Leasing or renting for residential, non-profit or urban use and for use in agricultural primary production.
- Trust constructions.
- So-called self-dealings, for example purchase from the spouse or partner, asset transfers/movements between companies in the same group or within the framework of company demergers or between corporate entities and their shareholders.

Is a combination with other funding programmes possible?

The combination of a loan from the KfW energy-efficiency programme – Energy-efficient construction and renovation with other subsidies (loans or grants/subsidies) is fundamentally possible within the framework of the respective relevant EU subsidy limits, provided the total of the loans, grants or subsidies does not exceed the total of the eligible costs. The legal cumulation provisions must be complied with (cf. “General Information Sheet on Subsidies”, Order Nr. 600 000 0065).

Heat generating systems for the use of renewable energies are subsidised:

- Under the programme “Subsidisation of measures for the use of renewable energies in the heat market” of the Federal Department for the Economy and Export Control (BAFA) (www.bafa.de) or
- In the KfW programme “Renewable energies—Premium” (www.kfw.de/271).

The simultaneous draw-down of a KfW loan and of a BAFA grant for the same measure is not possible.

The simultaneous draw-down of the KfW loan and a grant under the Renewable Energies Act for the same eligible costs is not possible.

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KfW energy-efficiency programme – Energy-efficient construction and renovation

Loan amount

Conditions
Loan amount, term
Interest rate, provision
Redemption

Up to 100% of the eligible costs are financed

The loan amount amounts to

- in general up to 25 million Euro per project.

This upper credit limit can be exceeded where the project is particularly worthy of subsidy.

Term

The following term variants are available with a minimum term of 2 years:

- Up to 5 years with max. 1 year grace period (5/1),
- Up to 10 years with max. 2-year grace period (10/2),
- Up to 20 years with max. 3-year grace period (20/3).

Interest rate

- The loan is granted with a customer-tailored interest rate within the framework of the maximum interest rate of the respective price class on the day of commitment.
- The interest rate is set taking into consideration the financial situation of the Borrower (creditworthiness) and the value of the securities provided for the loan by the credit institution.

Here classification takes place into KfW's creditworthiness and collateral classes. Through the combination of creditworthiness and collateral class the credit institution allocates the promotional loan to a price class given by KfW.

Each price class covers a band width with a fixed upper interest limit (maximum interest rate). The client's individual interest rate agreed between it and the credit institution may lie below the maximum interest rate of the respective price class. Information on determining the individual interest rate can be found in the KfW Information Sheet "Risk-adjusted Interest System", Order Nr. 600 000 0038.

- The interest rate is set for a maximum 10 year loan term.
- The price reduction from Federal funds applies for the first fixed-interest period, maximum 10 years.
- For loans with a term of over 10 years KfW will offer your credit institution, before the end of the fixed-interest period, an extension offer without price reduction from Federal funds.

The respective maximum interest rates (borrowing and effective interest rates under the Law) can be found in the overview of terms and conditions for KfW funding programmes on the Internet at www.kfw.de/konditionen or by fax under (069) 7431-4214.

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KfW energy-efficiency programme – Energy-efficient construction and renovation

Provision/Commission

- The payment of the loan takes place at 100% of the commitment.
- The loan can be drawn down in one amount or in instalments.
- The draw-down period amounts to 12 months after loan commitment. In justified instances this deadline may be extended up to a max. 36 months.
- It should be noted that the respective amounts requested must be completely allocated within 6 months to the specified purpose. Should this deadline be exceeded the Borrower must pay an interest surcharge.
- For the undrawn loan amount, commencing 12 months and 2 banking days after the commitment date, a commission of 0.25% per month is due.

Repayment

Repayment takes place after expiry of the grace period in equal quarterly instalments. During the grace years only the interest on the paid-out loan amounts must be paid.

Unscheduled repayments may only be made against payment of a prepayment penalty.

Repayment bonus

On providing evidence of the attained KfW Efficiency House level per the loan commitment or compliance with the technical minimum requirements in the case of individual measures you will receive a repayment bonus.

The amount of the repayment bonus derives from a percentage of the commitment and a maximum amount per m² net area (areas covered by the sphere of applicability of the EnEV, calculated under DIN 277):

Renovation:

- KfW Efficiency House 70 17.5% of the commitment; maximum 175 Euro/m²
- KfW Efficiency House 100 10.0% of the commitment; maximum 100 Euro/m²
- KfW Efficiency House Monument 7.5% of the commitment; maximum 75 Euro/m²
- Individual measures 5.0% of the commitment; maximum 50 Euro/m²

New-build:

- KfW Efficiency House 55 5.0% of the commitment; maximum 50 Euro/m²
- KfW Efficiency House 70 Only a subsidised loan is granted.

The crediting shall be made 3 months after the date of interest and/or redemption payments following the checking and recognition of the Form "Confirmation after execution" (Form number 600 000 3413) by KfW. The repayment bonus is calculated on the amount of the commitment at the time of acknowledgement of the "Confirmation after Execution" and set-off against the last due instalments under the redemption plan (shortening of the loan term).

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KfW energy-efficiency programme – Energy-efficient construction and renovation

Where at the time of crediting the loan is less than the amount of the credit amount, crediting of the repayment bonus only takes place to the amount of the actual loan amount. Cash payment or transfer of the repayment bonus is not possible.

How does one apply?

Application

Securities
Documents
Subsidy rules
Use of funds
Subsidy relevance

KfW grants the loans under this Programme exclusively through credit institutions (banks and savings banks), which fully assume liability for the loans. Please therefore submit your application to a credit institution of your choice before starting your project.

Prior to payment of the KfW refinance loan to the finance institution waiver of the loan is possible at any time. Should the Borrower waive a not-yet drawn-down loan, KfW can approve a new loan for the same project at the earliest after 6 months. An application is possible without a vesting period if the project is new or significantly altered.

Securities

Standard bank securities must be provided for your loan. The form and scope of the securities are agreed by you in the course of the credit negotiations with your credit institution.

What documentation is required?

Your credit institution presents us with the following documentation for your application:

- Your signed application form (Form number 600 000 0141). The credit institutions have the application forms. The Programme numbers to be given are:
 - **276** for new-builds
 - **277** for renovations and
 - **278** for individual measures
- Statistical Supplement “Investments in general” (Form Nr. 600 000 0139)
- Confirmation of loan application—KfW energy-efficiency programme—Energy-efficient construction and renovation (Form Nr. 600 000 3415)
- For applications within the framework of the subsidy de-minimis regulation (Component 1): Annex De-minimis declaration by the applicant (Form Nr. 600 000 0075) on already-received de-minimis-subsidisation
- When applying for “Investment subsidies for SME” under Article 17 of the General Group Exemption Regulation (AGVO) (Component 2): Self-declaration on compliance with the KM Definition (for associated companies Form Nr. 600 000 0196, for non-associated companies: Form Nr. 600 000 0095). The self-declaration remains in the possession of the credit institution.
- When applying for “Investment subsidies for energy efficiency measures” under Article 38 AGVO (Component 4): Annex “Subsidisable additional investment costs” (Form Nr. 600 000 0270).
- When exceeding the loan limit of 25 million Euro a supplementary project description of the energy efficiency effects.

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KfW energy-efficiency programme – Energy-efficient construction and renovation

KfW reserves the right to request supplementary documentation where this is required for processing.

State aid regulations

Under the “KfW energy efficiency programme – Energy-efficient construction and renovation” KfW grants subsidies under one of the following state aid regulations:

- De-minimis state subsidies under the De-minimis Regulation (Nr. 1407/2013/EU dated 18.12.2013, published in the Official Journal of the European Union L 352 on 24.12.2013) (Component 1).
- “Investment aid for SME” under Article 17 of the General Group Exemption Regulation (AGVO) (Commission Regulation (EU) Nr. 651/2014 dated 17th June 2014 on determining the compatibility of certain groups of subsidy with the internal market in application of Article 107 and 108 of the Treaty on the Functioning of the European Union, published in the Official Journal of the European Union L187/1 of 26.06.2014) (Component 2).
- “Investment aid for energy efficiency measures” under Article 38 AGVO (Component 4).

The various state aid regulations oblige KfW and applicants to comply with specific state aid regulations. Due to these regulations companies in specific branches and companies that have failed to comply with a state aid repayment decision of the EU Commission are not eligible for subsidy.

Where aid is requested under the AGVO, companies in difficulties as defined in the AGVO are excluded from eligibility.

KfW is obliged to publish loans with individual grants of over 500,000 Euro on a state aid subsidy website of the EU Commission under Art. 9 para. 1 lit. c) in conjunction with Annex III of Commission Regulation (EU) Nr. 651/2014 dated 17th June 2014 (Official Journal of the EU Nr. L 187 dated 26th June 2014) on determining the compatibility of certain groups of subsidy with the internal market in application of Article 107 and 108 of the Treaty on the Functioning of the European Union and under Clause 4.7 of the EU framework for state aid to promote research, development and innovation of the EU Commission dated 21st May 2014 (Official EU Journal Nr. C 198 dated 27th June 2014).

More detailed information on state aid regulations can be found in the KfW Information Sheet “General Information Sheet on Subsidies”, Order Nr. 600 000 0065.

Evidence of use of funding

After execution of the measures evidence of the proper use of the funds must be presented to the credit institution (Principal Bank) and within 9 months of complete payment of the loan presented to KfW in the Form “Confirmation after Execution” (Form Nr. 600 000 3413) as follows:

- The Borrower confirms the use of the funds in accordance with the application and programme.
- The expert checks the eligible measures and confirms the implementation of the subsidised project in accordance with the Annex “Technical Minimum Requirements” to the Information Sheet.

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KfW energy-efficiency programme – Energy-efficient construction and renovation

- The credit institution (Principal Bank) confirms the punctual use of the funds and submits the Form to KfW.

Invoices requiring safekeeping (cf. “Reportage and diligence duties of the Borrower”) must show the eligible measures, the work executed and the address of the investment property and be drafted in German.

Information and diligence duties of the Borrower

Within 10 days of loan approval you must preserve and submit to KfW on request:

- Evidence of the eligible investment costs
- Documents for documentation of the services provided by the expert (planning and project support)
- In the case of renovation or construction of a KfW Efficiency House:
The complete documentation of the calculations under § 4 EnEV and all relevant evidence for this under the Annex “Technical Minimum Requirements” to the Information Sheet (Order Nr. 600 000 3418)
- In the case of individual measures:
All the relevant evidence as per the Annex “Technical Minimum Requirements” to the Information Sheet (Order Nr. 600 000 3418)
- In the case of first acquisition:
For the KfW Efficiency House the aforesaid documentation, for the individual measures or in place of accounts evidence of the eligible investment measures and costs (at the least through confirmation by the vendor)
- In the case of renovation of architectural monuments:
The evidence of harmonisation required for the renovation works and approval by the Monument Protection Authority

An overview of the documentation to be preserved is enclosed as an Information Sheet with the Form “Confirmation after Execution” (Form Nr. 600 000 3413).

If you sell the subsidised building within 10 years, the buyer must be informed of the KfW subsidisation and the prohibition of deterioration of the energy quality of the building under § 11 para. 1 EnEV.

Fundamental instruction

KfW reserves the right at any time to check the calculation documents and evidence and to carry out an on-site control of the subsidised buildings/measures.

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KfW energy-efficiency programme – Energy-efficient construction and renovation

Information on subsidy relevance

The information on application entitlement, purpose and compliance with the state aid regulations of the EU-Commission have subsidy relevance as defined in § 264 of the Criminal Code in conjunction with § 2 of the Federal Subsidies Act.

Further information on this funding programme

Further information on this Programme (examples, FAQs etc.) can be found on the internet under www.kfw.de.

Annex

“Technical Minimum Requirements” (Order Nr. 600 000 3418)

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Technical Minimum Requirements

276/277
278
from 01.07.2015
217/218
220/219
From 01.10.2015
Sponsored by
Federal Ministry of
Economic Affairs and
Energy
on the basis of a
Bundestag Resolution

The pre-requisite for the subsidising of measures to improve energy efficiency in non-residential buildings is compliance with the following Technical Minimum Requirements and the supplementary information given in this Annex. Moreover the applicable legal requirements and technical Standards for the implementation of the measures must be observed.

Construction of KfW Efficiency Houses, renovation of KfW Efficiency House

The energy Standard of a KfW Efficiency House is achieved through construction and technical measures for the improvement of energy efficiency and the inclusion of renewable energies. The following minimum requirements must be complied with.

Requirements of a KfW Efficiency House

1. The annual primary energy requirement (Q_p) of a KfW Efficiency House may not, in respect of the primary energy requirement of the corresponding reference building ($Q_{p\text{ REF}}$) exceed the percentage maximum values for the subsidised Efficiency House Standard as shown in the Table below.

<u>KfW Efficiency House</u>	<u>EH 55</u>	<u>EH 70</u>	<u>EH 100</u>	<u>Monument</u>
Q_p in% of $Q_{p\text{ REF}}$	55%	70%	100%	160%

2. For areas heated with a room target temperature $T \geq 19^\circ$, the heat transition coefficient measured over these areas for the opaque outer building parts (U_{opak}), the transparent outer building parts ($U_{\text{transparent}}$) and curtain walls (U_{Vorhang}) and for glass roofs/strip lighting and light domes (U_{Licht}) may not exceed the following values:

<u>KfW Efficiency House ($T \geq 19^\circ\text{C}$)</u>	<u>EH 55</u>	<u>EH 70</u>	<u>EH 100</u>	<u>Monument</u>
	<u>[W (m² K)]</u>	<u>[W (m² K)]</u>	<u>[W (m² K)]</u>	<u>[W (m² K)]</u>
U_{opak}	0.22	0.26	0.34	0.60
$U_{\text{transparent, Vorhang}}$	1.2	1.4	1.8	—
U_{Licht}	2.0	2.4	3.0	—

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Technical Minimum Requirements

3. For areas heated to a target room temperature 19°, the heat transition coefficient measure over these areas for the heat transfer outer parts may not exceed the following values:

<u>KfW Efficiency House (T<math>19^{\circ}</math>)</u>	<u>EH 55</u>	<u>EH 70</u>	<u>EH 100</u>	<u>Monument</u>
	[W (m ² K)]			
Uopak	0.35	0.43	0.58	0.90
Utransparent, Vorhang	2.2	2.4	3.2	—
ULicht	2.2	2.6	3.6	—

- The annual primary energy requirement (Q_p) and the mean heat transition coefficients of the heat transfer enclosing areas of the building are to be calculated on the basis of the planned measures under the Energy Savings Regulation (EnEV) and DIN 18599 in force at the time of application. The project parameters for the primary energy requirement of the reference building (Q_{p REF}) is to be determined on the basis of the details in Annex 2, Table 1 (without application of Line 1.0) EnEV. The mean heat transition coefficients are to be calculated for the entire building under the rules of EnEV Annex 2. The interpretations of the “Construction Technology” Special Commission of the Construction Ministers Conference on the EnEV (www.bbsr-energieeinsparung.de) shall be taken into consideration for the KfW Efficiency House calculations.
- For KfW Efficiency Houses a ventilation concept is to be prepared in which the required fresh air flow rate and the solution for implementation are specified. For implementation of the ventilation concept particular attention is to be paid to the measures required to prevent condensation and humidity damage. Furthermore for all KfW Efficiency Houses attention is to be paid on the building shell to heat bridge-minimising design and execution of an airtightness concept. In the case of a hydraulically-driven water-fed heat supply system, hydraulic balancing of the distribution system must be carried out.
- In the case of the extension of a building by building parts for which there is an open connection with the existing building, Efficiency House evidence must be provided for the entire building. Here all the standard requirements must be satisfied for the renovation.

If, with the extension, there is no open spatial connection (i.e. there are separating parts such as walls and doors), for the extended building sections evidence of achieving a KfW Efficiency House Standard for New-builds must be provided. The evidence for the KfW Efficiency House may in this event be provided separately for the added building part and does not have to relate to the building as a whole.
- The application must demonstrate the saving in primary and end energy requirements and the CO₂ reduction in comparison to the original state (renovation) or the applicable minimum requirement level (new-build). The calculation of the saving derives from the difference between the energy requirement calculation under the EnEV for the condition prior to renovation or the requirements figure for a comparable new-build under the valid provisions of the EnEV and the calculated energy requirement figures for the planned project. The resulting CO₂ emission is to be determined applying the values cited in the Section “Emissions factors”.

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Technical Minimum Requirements

Required evidence and documents for a KfW Efficiency House

Complete documentation of the documentation per § 4 ErEV incl. detailed \dot{U} value calculations for the individual construction parts of the thermal building shell and the existing/planned technical systems

Documentation of the calculation for the reference building

All plans for the KfW Efficiency House (ground plans, views, sections, site plan) on the basis of which evidence for the primary energy requirement under the EnEV was prepared; the thermal building shell taken as a basis must be marked

Other planning documents where relevant for the calculation (for example thermal simulation of solar systems, evidence of the primary energy factor applied for remote heat, evidence of product-specific technical parameters, etc.)

Confirmation by a specialist firm of the execution of the hydraulic balancing (only for hydraulically-driven water-fed heat supply systems)

Ventilation concept

If for the primary energy factor when using local/remote heat the Table value under DIN V 18599-1: 2011 is not applied, the primary energy factor must be calculated either under DIN V 18599 and confirmed by an independent expert or determined under the AGFW Worksheet FW 309 and confirmed by a certified expert

If a heat bridge supplement $DU_{WB} < 0.10 \text{ W}/(\text{m}^2 \cdot \text{K})$ is applied, this is to be calculated or evidenced separately under the rules of technology. The preparation of evidence of equivalence under DIN 4108-Supplement 2 is always required in the event of the use of the lump heat bridge correction factors of $DU_{WB} = 0.05 \text{ W}/(\text{m}^2 \cdot \text{K})$ for renovation. When using a heat bridge correction factor $DU_{WB} < 0.05 \text{ W}/(\text{m}^2 \cdot \text{K})$ heat bridges must be calculated in detail.

For consideration of a ventilation system with heat recovery or reduced air renewal in the Efficiency House calculation airtightness measurements are required for the relevant area. The measurement results are to be recorded in a measurement protocol.

Requirements of individual measures for the renovation of existing buildings

Measures to improve energy efficiency in existing non-residential buildings satisfying the following minimum requirements are eligible for subsidy.

Calculation of energy saving and CO₂ reduction

For individual measures the anticipated saving in primary and end energy requirements and the associated CO₂ reduction must be determined. The calculation may be made using building balancing under DIN 18599 or a tailored calculation on the basis of system or specific building part parameters (efficiency, \dot{U} figure), the project dimensioning (for example power consumption of old system/new system, building areas) and the operating conditions (for example run times, usage conditions). To calculate the primary energy saving and CO₂ reduction the primary energy factors under EnEV and the CO₂ emissions factors in Annex 1 shall be applied.

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Technical Minimum Requirements

Monument Protection Authority regulations

For parts of buildings subject to Monument Protection Authority regulations as defined in § 24 para. 1 EnEV reduced requirements as per the following Tables are specified. The requirement for subsidisation with reduced requirements is confirmation by the expert that due to the Monument Protection Authority's regulations or also physical reasons only the respectively-attained requirement value is possible.

1) Insulation of walls, roof surfaces, storey ceilings and floor surfaces

Subsidies are provided for the insulation of walls, roofs, storey ceilings and the lower building envelope. The following requirements for heat transition coefficients (U value) must be complied with in the case of renovation of the respective building parts for subsidisation as an individual measure. The requirements only refer to the heat-transferring surrounding surfaces.

Nr.	Part group	Part	Max. \dot{U} in W/(m ² •K) T>=19°C	Max. \dot{U} in W/(m ² •K) T<19°C
1.1		Outer wall	0.20	0.25
1.2		Alternatively: core insulation with double-layer masonry	l </= 0.035 W/(m•K)	l </= 0.040 W/(m•K)
1.3	Walls	Outer walls of architectural monuments	0.45	0.45
1.4		Outer walls in the case of exposed works	0.65	0.65
1.5		Wall surfaces against soil / unheated spaces	0.25	0.25
2,1	Roof surfaces	Roofs (w/o glass roofs)	0.14	0.25
2.2		Alternatively: for architectural monuments Max. possible insulation thickness	l </= 0.035 W/(m•K)	l </= 0.035 W/(m•K)
3.1		Top floor ceiling	0.14	0.25
3.2		Ceilings of unheated rooms	0.25	0.25
3.3	Storey ceilings and floor surfaces			
		Storey ceilings against outside air	0.20	0.25
3.4		Floor surfaces against soil	0.25	0.25

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Technical Minimum Requirements

Note:

For all measures on the building shell, attention should be paid to heat bridge-minimising design and airtightness.

For renovation measures the required measures to avoid condensation and humidity damage under DIN 4108-3 must be taken and evidenced.

Required evidence to be safeguarded:

- Confirmation by the specialist firm of the fitting and type of insulation
- Manufacturer's evidence regarding properties, in particular the measured values for heat conductance of the fitted materials

2) Renewal and strengthening of windows and outer doors

Subsidies may be provided for the exchange, reinforcement or first installation of windows, outer doors and gates (including loading stations) in existing buildings. Also eligible are burglary-prevention measures, directly connected with the energy optimisation of windows, doors and gates.

Nr.	Group	Part	Max. \dot{U} in W/(m ² •K) T >/= 19°C	Max. \dot{U} in W/(m ² •K) T <19°C
1		Windows, French windows:		
		a) exchange	0.95	1.3
		b) reinforcement	1.3	1.6
1.2		Easy-access windows and French windows	1.1	1.4
1.3				
1	Transparent Parts (U _w)	Windows with special glazing	1.1	1.4
		Windows on monuments		
1.4		a) Exchange	1.4	1.7
		b) Reinforcement	1.6	1.9
1.5		Glass roofs	1.6	1.9
1.6		Strip lights and light domes	1.5	1.9
2	Curtain walls (UCW)	Curtain walls ²	1.3	1.6
3	Doors (U _p)	Outer doors	1.3	2.0
4	Gates	Outer doors	1.0	2.0

Air Permeability Class 3

1 *Special glazings are the glazings described in Annex 3 Number 2 EnEV for sound insulation, fire protection, bullet resistance, burglar prevention or explosive resistance.*

2 *Curtain walls whose construction is described in DIN EN 13947: 2007-07*

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Technical Minimum Requirements

When planning outer doors measures for user-independent control should be taken into consideration to ensure the shortest opening time within door opening cycles. In the event of use with frequent business-related opening cycles by way of alternative to the above requirements the fitting of fast-opening doors (closing speed 0,8 m/s) with suitable sensors for automatic opening or closing (radar, induction loop or similar) are eligible for subsidisation.

Also eligible for subsidy is the construction or conversion of lorry loading stations in hangars (dock levellers) when these are thermally separated from the building shell.

For the exchange of windows, the \dot{U} value of the outer wall and/ or the roof may be less than the \dot{U}_w value of the newly-fitted windows or measures must be taken to prevent condensation formation and humidity damage. When fitting new windows any resulting increased air humidity must be taken into consideration and measures taken to prevent condensation and humidity damage.

Required evidence to be safeguarded:

- Confirmation by the specialist firm of compliance with the requirements for the U values and the heat bridge-minimising installation; where necessary: information on the avoidance of humidity damage
- Manufacturer's evidence regarding the energy properties of the windows/doors/gates

3) Measures to improve summer heat insulation

Subsidies may be provided for the replacement of external solar protection systems through fitting the same with a daylight function or first installation of the same. The requirements of DIN 4108-2:2013-02 must be observed.

4) Installation, exchange or optimisation of ventilation and a/c systems incl. heat/cold recovery and waste heat use

Subsidies may be provided for the implementation of the following measures:

First installation/renovation of ventilation systems:

- Fitting of automatic air feed and removal systems with heat recovery regulated by sensor (CO₂, mixed gas, air humidity or VOC). The fitted ventilation systems must at least satisfy the requirements of Annex III Number 2 of Regulation (EU) Nr. 1253/2014 dated 7th July 2014. The system must be designed so that with a design flow the electrical fan output per fan relating to the delivery volume does not exceed the Category SFP 3 limit under DIN EN 13779 (validation load).

Exchange of components in existing ventilation systems:

- Installation of speed-controlled fans with an efficiency level as specified in Annex IV Table 1 of Regulation (EU) Nr. 327/2011
- Installation of air handling equipment that at least satisfies the requirements of Annex III Number 1 of Regulation (EU) Nr. 1253/2014 dated 7th July 2014

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Technical Minimum Requirements

- Installation of energy-efficient, speed-controlled motors Efficiency Class IE 2 or better as per Regulation (EC) Nr, 640/2009 or after-fitting of frequency converters for infinitely-variable regulation of existing motors
- Renewal and use of air lines to achieve at least Tightness Class B under DIN EN 15727:2010- 10
- Installation of heat recovery that at least attain H2 Classification under DIN EN 13053:2007-11
- Reduction of heat loss through added heat insulation of the external and exit air lines with interior installation or the air inlet and exhaust lines in the event of external installation ($d_{\min} \geq 6$ cm; $l = 0.035$ W/(mK) or equivalent)

Required evidence to be safeguarded:

- Manufacturer's evidence regarding the system-specific parameters
- In the case of first installation comprehensive renewal of the entire system or exchange of the fan: report on handover per the Annex under DIN EN 12599:2013-01 Section 9
- In the event of renewal of the air lines:
Protocol of the measurement of the leakage air flow per DIN EN 12599: 2013-01 Section D-8

5) Renewal and/or optimisation of heat/cold generation, distribution and storage incl. power-heat - or power-heat-cold coupling systems

Implementation of the following measures is eligible for subsidy:

Installation of new heat generators/optimisation of heat generation

- Condensing boilers, improved under DIN 18599-5: 2011-12
- Condensing hot air generators, multistage/modulating with adjustment of the combustion air volume
- Heat-fed systems for heat supply from power-heat coupling on the basis of fossil energy (cogeneration plant, fuel cells).
- Connections and heat transfer stations for the use of remote heat
- Infrared dark radiator with a radiation factor RF per DIN EN 416-2 > 0.69
- Infrared light radiator with a radiation factor RF per DIN EN 419-2 > 0.69
- Installation of waste gas systems with condensing waste gas heat exchanger for radiant heating per DIN 18599-5:2011-12
- Measures for the use of process heat for air conditioning

Installation of components for energy-efficient heat transfer

- Radiant ceiling panels with the Product feature *Design improved* (upper side min. 40 mm insulated, radiation >75% per DIN EN 14037)

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- Pl-regulated hot air feed in addition to the ventilation systems (centrally-fed air heaters)
- Surface heating systems operated with system flow temperature $\leq 35^{\circ}\text{C}$ and the required adaptation or renewal of pipelines
- Exchange of existing heaters with heaters with an overtemperature $\leq 30\text{ K}$ (for example designed for $55/45^{\circ}\text{C}$ with a room temperature of 20°C)

Optimisation of heat distribution

- Carrying out of hydraulic balance
- Hydraulic conversion of the distribution system for requirement-based adaptation of the water circulation volumes
- Installation of high-efficiency pumps (Efficiency Class A)
- Installation of pre-adjustable thermostat valves, regulator valves and differential pressure regulators
- Conversion from one- to two-line systems
- Expansion and renovation of local heat networks located 100% on the surfaces belonging to the building(s)
- Heat insulation of uninsulated or inadequately-insulated heat distribution lines

Optimisation of heat storage

- Installation of buffer storage with minimum heat insulation per DIN EN 12828

Installation of energy-efficient cold generation

- Heat-driven cold systems for the use of heat from the power-heat coupling or process waste heat
- Compression refrigeration system with electronic rpm regulation and a nominal cooling output EER of at least 4.0 in full-load operation

The measures cited for heat distribution and transfer apply analogously for cold distribution.

The pre-requisite for subsidisation of measures for heat/cold generation, distribution and storage for hydraulic systems to the carrying out of a hydraulic balancing of the connected distribution system.

Required evidence to be safeguarded:

- Evidence of the hydraulic balancing
- Manufacturer evidence for the system parameters

For systems for heat and cold generation from renewable energies special funds may be provided from the Market Incentive Program, which be applied for via KfW Programme 271/281 Renewable energies Premium or via the BAFA.

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Technical Minimum Requirements

6) Exchange and/or optimisation of lighting

Subsidies may be granted for the implementation of the following measures:

Conversion of the existing lighting systems to an energy-efficient lighting technology that satisfies all the following requirements:

- The system efficiency (light efficiency) of the installed lighting system must be at least 100 lm/W.
- The useful life of the lights used must achieve at least the following:
 - for LED lights $\geq 80\%$ (L80) with 50,000 operating hours
 - for all other light types $\geq 90\%$ with 16,000 operating hours
- The colour rendering (Ra) of the lighting systems must be at least 80%. For activities with higher colour rendering requirements the requirements of DIN EN 12464-1:2011-08 should be applied.
- Regulation of the lighting system must at least match the reference design under EnEV Annex 2 Table 1 for the corresponding area of use.
- Lighting planning per DIN EN 12464-1:2011-08 or for sports area per DIN EN 12193 must be carried out by qualified planners.

The complete exchange of lights including any other ancillary work and components are eligible for subsidy. Bulbs intended for subsequent installation or for installation in existing fittings (for example retrofits, replacement lights) are not eligible.

The use of lights with an ENEC-Plus-Performance symbol is recommended.

It is also recommended that for the lights or light sources used a colour distance of 3-step macadam ellipses is not exceeded.

Required evidence to be safeguarded:

- Lighting concept including the corresponding planning evidence
- Manufacturer's evidence regarding the product features Light output, Colour Rendering Index, rate lamp lifetime and light quality over the lifetime
- For LED: Data Sheet per IEC 62717 for each light type

7) Installation or optimisation of measurement, control and regulation systems and building automation

Installation and replacement of measurement, control and regulation systems serving the realisation of a buildings automation level of at least Class B under DIN 18599-5: 2011-12 (incl. the necessary field devices) for example:

- Requirement-based regulation of ventilation and a/c systems
- Daylight or presence-dependent control or regulation of lighting systems

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Technical Minimum Requirements

- Requirement-based regulation of heating systems, for example a usage-based room-by-room regulation of the room temperature
- Components for realisation of a technical energy management system with the aim of energy saving through efficient operation of the building (for example monitoring of system or area-based characteristics and energy consumption, incl. building control technology and the required automation and field elements)

Required evidence to be safeguarded:

- Measurement, control and regulation concept
- For technical energy management: metering concept

Emissions factors for calculating CO2 saving

<u>Energy source</u>	<u>Direct CO2 emissions factors</u>	
		<u>Kg/kWend</u>
	Heating oil EL	0.266
	Natural gas H (compound)	0.202
	Liquid gas	0.234
	Hard coal	0.353
Fuels	Lignite (briquette)	0.359
	Wood	0
	Bio-oil, self-generated+used	0
	Biogas, self-generated+used	0
Local/remote heat	Fossil fuel mix	0.260
N	Renewable fuel	0
Electricity	Electricity – domestic consumption	0.595
	Eco-electricity, self-generated+used	0

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THE SYMBOL “[*]” DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED**

This document is an English translation of a document prepared in German. In preparing this document, an attempt has been made to translate as literally as possible without jeopardizing the overall continuity of the text. Inevitably, however, differences may occur in translation and if they do, the German text will govern by law.

In this translation, German legal concepts are expressed in English terms and not in their original German terms. The concepts concerned may not be identical to concepts described by the English terms as such terms may be understood under the laws of other jurisdictions.



**Loan agreement
dated 18.07.2018
for a DM SME loan of
EUR 9,450,000.00**

Between

JPT Peptide Technologies GmbH
Volmerstraße 54
12489 Berlin

(“Borrower”)

and

Deutsche Bank AG
Business in Germany
Ludwigsstraße 8-10
55116 Mainz

(“Bank”)

the following agreement (**“Loan Agreement”**) has been concluded for the granting of a repayment loan (**“Loan”**) on the basis of the Bank’s General Business Terms and Conditions:

[Copy for the Bank / Copy for the client]

1. DEFINITIONS

The following terms have the following meanings in the contractual text:

“Payment date” is 15.12.2018 EUR 1,600,000.00; on 15.05.2019 EUR 3,000,000.00; on 15.10.2019 EUR 3,000,000.00 and on 15.01.2020 EUR 1,850,000.00.

“Banking day” is any day (with the exception of Saturday and Sunday) on which commercial banks are open to the public for business in Frankfurt/Main.

“Final due date” is 30.09.2028.

“Financial liabilities” are all liabilities from (i) borrowings (ii) issued letters of credit and accepted or issued bills (iii) the issue of bonds, “commercial papers” or other debentures, (iv) lease contracts that under the applicable edicts of the Federal Ministry of Finance or the respective tax or balance sheet provisions of the Jurisdictions regulating the lease contract, are to be treated as finance [operating] leases, (v) the sale of receivables where recourse against a member of the company group of the Borrower cannot be ruled out (recourse factoring), (vi) trade accounts payable when a payment schedule is granted that lies outside common industry practices, (vii) derivatives, whereby when calculating the value of a derivative transaction only the “mark-to-market value” is taken into consideration, (viii) recourse liability in respect of third party sureties, guarantees, bonds, letters of credit or other financial instruments, where such are not included twice in the balance sheet concerned since the respective principle debt is already accounted for, (ix) other transactions when these have the economic effect of borrowings as defined in paras. (i) to (viii), (x) a guarantee, surety or other co-liability for one of the liabilities cited in paras. (i) to (ix) liabilities, and (xi) pension provisions.

2. LOAN

a) Loan amount

The Bank is granting the Borrower a redeemable loan of **EUR 9,450,000.00** (in words: nine million four hundred and fifty thousand Euro) (“**loan amount**”).

b) Purpose

The loan serves the co-financing of the company property to be built in Berlin-Adlershof. The Bank is entitled but not obliged, in respect of the Borrower, to monitor compliance with the loan purpose.

3. PAYMENT

a) Payment date

The Bank shall pay the Borrower the loan amount on the payment dates at the payout ratio of 100% provided that at that time the payment requirements specified below in Clause 6 of this Loan Agreement have been satisfied.

b) Non-acceptance indemnity

If the payment cannot, or cannot fully, be paid out on the payment date for reasons attributable to the Borrower, the Borrower is obliged to compensate the Bank for any losses caused through non-acceptance or late acceptance.

4. REDEMPTION/REPAYMENT

a) Standard repayment

The loan is to be repayable in 32 equal consecutive instalments of EUR 286,364.00 and a final, differing instalment of EUR 286,352.00. The instalments are payable quarterly in arrears on 31.03., 30.06., 30.09. and 31.12. of each year; the first instalment is due on 09.2020, the final instalment is repayable on the final due date.

Any loan amounts outstanding on the final due date shall be paid on the final due date.

b) Adjustment of payment schedules

If one of the dates cited in the above paragraphs is not a banking day, repayment shall take place on the next banking day, unless as a result the repayment would only take place in a new calendar month or the following banking day lies after the final due date; in such an event repayment shall take place on the next earlier banking day.

5. INTEREST / COMMISSIONS

a) Debit authorisation

The Borrower herewith instructs the Bank to debit any due repayment amounts, interest, costs, payments, expenses and commissions against the Borrower's account [***] provided no different agreement has been reached in any individual instance.

b) Interest

The interest rate is fixed for the entire term and amounts to **2.08% p.a.** The interest is charged on the basis of 30/360 days. It becomes due at the end of each Quarter.

6. PAYMENT REQUIREMENTS

The Borrower can draw down the loan as soon as all the following, agreed payment requirements have been satisfied and one or more of the same do not subsequently lapse:

a) The Bank has all the following documents and evidence in satisfactory form and the corresponding evidence has not subsequently proved to be incorrect:

- All the details required under the Federal Money Laundering Act (GwG) regarding the financial beneficiaries and the agreement on the loan purpose within the framework of this agreement
- All the agreed securities have been validly constituted
- Submission of the signed annual accounts 31.12.2017

- b) The Borrower is not in default towards the Bank in the satisfaction of a due claim;
- c) No important reason exists that would entitle the Bank to extraordinary termination of this Loan Agreement or that may entitle it to such termination after an additional deadline and/ or warning.

The Bank may make payment without all payment requirements having to be satisfied. The obligation of the Borrower to satisfy the payment requirements remains thereby unaffected unless the Bank has waived satisfaction of specific payment requirements in writing.

7. SECURITIES

- a) The creation of the following securities has been agreed:
 - First-priority land charges of EUR 9,450,000.00 on Betriebsimmobil (“*commercial property*”) Berlin-Adlershof; Treptow Land Register, Page 31392N
 - Indefinite directly enforceable guarantee by BioNTech AG in the amount of EUR 9,450,000.00
 - Loan maintenance and subordination agreement in respect of a still-to-be provided shareholder group loan of EUR 9,450,000.00. Please send us the loan agreement when available.

Individual details, in particular concerning the security purpose, are or shall be regulated in the security agreements.

Where not agreed otherwise, the securities are to be created having first priority and free of third party rights of set-off, retention or other rights.

- b) On the basis of its lien under Nr. 14 AGB the Bank is in particular serviced by all current and future deposits in account Nr. [***] and time deposits deposited against this account with the Bank including interest as security for all existing, future and conditional claims against the Borrower from and in connection with this Loan Agreement. Disposal of these is only possible with the express permission of the Bank.

8. GENERAL OBLIGATIONS

The Borrower furthermore and until satisfaction of all claims of the Bank from draw-downs under this Loan Agreement assumes the following obligations:

a) Information obligations

Information on financial situation: The Borrower shall continually update the Bank regarding its financial situation and, where applicable, the financial situation of its group of companies.

In this regard it shall provide the Bank in particular with its latest annual accounts plus notes and management report and a consolidated annual account (consolidated balance sheet, consolidated P&L account and consolidated notes) together with a consolidated management report on the Group including the respective auditor’s reports immediately on completion, at the latest however within 9 months of conclusion of the respective financial year, in the original and at least having the scope legally required. Where the annual accounts do not have to be certified, the Bank shall be given copies bearing the legally-binding signatures of all directors or all liable partners.

Moreover the Borrower shall provide the Bank with quarterly business evaluations, liquidity figures, balance sheet status and target-performance analyses.

Moreover the Borrower shall provide the Bank with its annual planning per 31st January of each calendar year.

Further documents providing an up-to-date view of the financial situation shall be submitted by the Borrower on request.

Information under the Federal Money Laundering Act: The Borrower shall satisfy all its obligations under the Federal Money Laundering Act and in particular report any changes in the financial beneficiaries occurring over the term of this Loan Agreement immediately and without request and provide the Bank on request with documentation and information for ascertaining and checking its details.

Incorrect/incomplete information: The Borrower shall immediately notify the Bank should any information or documentation provided (also planning and forecasts) show significant negative changes or deviations or should it transpire that the information or documentation supplied was incomplete or incorrect.

b) Change in shareholder structure

The Parties are agreed that the current shareholder structure constitutes an important basis for the willingness of the Bank to grant this loan and the authorisation of all draw-downs under the same. In the event of any change in the shareholder structure the Parties shall reach a mutually-satisfactory agreement on the continuation of this Loan Agreement, where applicable subject to amended conditions, for example regarding interest, securities or other agreements before such a situation arises.

c) Credit agreements with other credit institutions

The Borrower shall inform the Bank of any new credit agreements that exceed the amount of EUR 500,000.00 or if there are significant changes to its current credit agreements with other credit institutions (for example increase, termination or collateral requirements), where these are the subject of negotiations, where possible in advance, otherwise immediately thereafter.

9. EXTRAORDINARY RIGHT OF TERMINATION

An important reason entitling the Bank to extraordinary termination of this Loan Agreement under Nr. 19 para. 3 AGB in particular exists when:

- a)** The Borrower fails to satisfy the general obligations or other essential obligations agreed under this Loan Agreement and fails to comply with the security agreements concluded in connection with this Loan Agreement or

- b) A change takes place to the shareholder structure and the Parties do not promptly agree to the continuation of any changed conditions, for example regarding interest accrual, securities or other agreements or
- c) The Borrower fails to or cannot satisfy its financial liabilities towards third party credit institutions on becoming due or third party credit institutions prematurely call in or could call in such financial liabilities on the basis of a reason for termination, where the financial liabilities concerned exceed a sum of EUR 100,000.00 (or the equivalent value in other currencies).

10. MISCELLANEOUS

a) Forward transactions

Where the Bank and Borrower, to secure the interest or currency risk under this Loan Agreement, conclude or have already concluded forward transactions – which the Bank is not obliged to do – the continued existence of these forward transactions is not affected by any termination of this Loan Agreement.

b) Information disclosure

Where the Bank, for refinancing, risk hedging or capital relief, makes use of its right to transfer the credit risk or claims under this Loan Agreement or otherwise dispose of the same, the Bank is entitled to pass on borrower-related information to authorised recipients that by force of Law, contract or occupational or professional regulation are obliged to maintain confidentiality. Authorised information recipients are members of the European Central Bank system, credit institutions, development banks, financial service providers, finance companies, insurance companies, pension funds, capital management companies, special purpose vehicles founded for assuming credit risks and persons that for technical or legal reasons are to be involved in the transfer (for example auditors and rating agencies).

c) Written form

Changes to this Loan Agreement must be made in writing.

d) Acceptance deadline/ Validity of agreement

The Bank considers itself bound by the offer submitted with this Loan Agreement until 17.08.2018.

This Loan Agreement takes effect on receipt of the agreement signed by all the parties within the aforesaid acceptance deadline.

e) Severability clause

Should individual provisions of this Loan Agreement be or become wholly or partly – for whatever reasons – void or invalid or unworkable, this shall not affect the other provisions of this Loan Agreement.

This Loan Agreement is cited under the date given in the heading.

Declaration pursuant to the Federal Money Laundering Act:

The Borrower guarantees the Bank by crossing or initialling that it is solely drawing down the funds granted under this Loan Agreement for its own account:

x JPT Peptide Technologies GmbH

Deutsche Bank AG
Business in Germany

Mainz, 19.07.2018
Place, date

[Signature]
[***]

Mainz, 19.07.2018
Place, date

[Signature]
[***]

JPT Peptide Technologies GmbH
Place, date

Legally-binding signature(s)