# 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)

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98-151-1032

(I.R.S. Employer Identification Number)

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.  $\Box$ 

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.  $\Box$ 

+ 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

mil (n. l.c). (		Proposed Maximum	Proposed Maximum	
Title of Each Class of Securities To Be Registered(1)	Amount to be Registered	Offering Price Per Share	Aggregate Offering Price(2)	Amount Of Registration Fee
Ordinary shares, no par value per share	5,750,000	\$81.41	\$468,107,500	\$60,761

- All ordinary shares will be represented by American Depositary Shares, or ADSs, with each ADS representing one ordinary share. ADSs issuable upon deposit of the ordinary shares registered hereby are registered pursuant to a separate Registration Statement on Form F-6 (File No. 333-233898).
- (2) The offering price has been estimated solely for the purpose of computing the amount of the registration fee in accordance with Rule 457(c) under the Securities Act of 1933, as amended, or the Securities Act. The maximum price per share and maximum aggregate offering price are based on the average of the high and low sale prices of the ADSs as reported on the Nasdaq Global Select Market on July 17, 2020, which date is within five business days prior to filing this Registration Statement.

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.

### EXPLANATORY NOTE

This registration statement contains a prospectus relating to a firm commitment underwritten offering of our ordinary shares to be represented by American Depositary Shares, or ADSs, which we refer to as the Underwritten Offering. The Underwritten Offering is part of a Global Offering that consists of (i) a rights offering to be extended to our ordinary shareholders and ADS holders, or the Rights Offering, and (ii) the Underwritten Offering. Under German law, where a company obtains binding, irrevocable agreements from certain existing shareholders not to transfer or exercise rights to be granted in a future rights offering, the company is permitted to attempt to sell the new shares represented by such rights either before or after the rights offering. Based on binding irrevocable agreements not to transfer or exercise rights that we have obtained from certain holders of our ordinary shares, representing 74.83% of our outstanding ordinary shares (including ordinary shares represented by ADSs), we intend to conduct the Underwritten Offering pursuant to this registration statement prior to the commencement of the Rights Offering.

The Rights Offering will be conducted pursuant to a separate registration statement and prospectus. The price to public that is set in the Underwritten Offering will be the subscription price for the Rights Offering. Shareholders and ADS holders as of the respective record dates for our ordinary shares and the ADSs representing our ordinary shares who have not agreed to forego exercising their rights will have the opportunity in the Rights Offering to subscribe for up to 1,681,849 new ordinary shares or new ADSs (representing approximately 0.72% of our outstanding ordinary shares) at the subscription price. ADSs PURCHASED IN THE UNDERWRITTEN OFFERING WILL NOT BE ENTITLED TO RECEIVE RIGHTS TO SUBSCRIBE FOR NEW ORDINARY SHARES OR NEW ADSs IN THE RIGHTS OFFERING. Accordingly, assuming no change in the assumed public offering price or the number of ADSs offered by us in the Underwritten Offering, as set forth on the cover page of this prospectus, a total of up to 6,681,849 ordinary shares (including new ordinary shares represented by new ADSs) may be sold in the Global Offering. We may also increase or decrease the number of ADSs we are offering in the Underwritten Offering, which would affect the number of our ordinary shares and ADSs representing our ordinary shares underlying rights granted in the Rights Offering. See "Dilution" for additional information.

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 JULY 21, 2020

# 5,000,000 American Depositary Shares



# Representing 5,000,000 Ordinary Shares

We are offering 5,000,000 American Depositary Shares, or the ADSs, with each ADS representing one ordinary share, or the Underwritten Offering. The Selling Shareholder identified in this prospectus is offering 750,000 ADSs if and to the extent that the underwriters exercise their option to purchase additional ADSs described below. We will not receive any of the proceeds from the sale of ADS by the Selling Shareholder. The public offering price is \$ per ADS. ADSs representing our ordinary shares are listed on the Nasdaq Global Select Market under the symbol "BNTX." On July 17, 2020, the last reported sale price of the ADSs on the Nasdaq Global Select Market was \$85.25 per ADS.

This offering is part of a Global Offering consisting of a rights offering and this Underwritten Offering, covering, in the aggregate, up to 6,681,850 ordinary shares (including ordinary shares represented by ADSs), as described further in this prospectus. The ADSs being offered by this prospectus are being so offered based upon irrevocable, binding agreements under German law from certain holders of our ordinary shares, representing 74.83% of our outstanding ordinary shares (including ordinary shares represented by ADSs), not to transfer or exercise rights to subscribe for our new ordinary shares that we intend to grant in a rights offering we will conduct following the time at which the price to public for the offering to which this prospectus relates has been set. This offering together with the rights offering constitute the Global Offering.

Certain new and existing investors, including Pfizer Inc., have indicated an interest in purchasing up to an aggregate of \$200 million in ADSs representing our ordinary shares in this offering at the public offering price of \$ and on the same terms and conditions as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, these investors may determine to purchase fewer ADSs than they indicate an interest in purchasing or not to purchase any ADSs in this offering. It is also possible that these investors could indicate an interest in purchasing more ADSs. In addition, the underwriters could determine to sell fewer ADSs to any of these investors than the investors indicate an interest in purchasing or not to sell any ADSs to these investors.

Investing in the ADSs representing our ordinary shares involves a high degree of risk. See "Risk Factors" beginning on page 23 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, are 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 us before expenses	\$	\$

<sup>(1)</sup> We have agreed to reimburse the underwriters for certain expenses incurred in the Underwritten Offering. See "Underwriting" for details.

The underwriters have the option for a period of 30 days from the date of this prospectus to purchase an additional 750,000 ADSs from the Selling Shareholder.

, 2020.

Delivery of the ADSs is expected to be made on or about

J.P. Morgan
UBS Investment Bank
COMMERZBANK

**BofA Securities** 

Wolfe Capital Markets and Advisory

Berenberg Canaccord Genuity Bryan, Garnier & Co.

Prospectus dated , 2020

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Neither we, the Selling Shareholder, nor any of the underwriters have 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. Neither we, the Selling Shareholder, nor any of the underwriters take responsibility for, or provide 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, the Selling Shareholder, 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 the ADSs representing our ordinary shares and the distribution of this prospectus outside of the United States.

The prospectus summary beginning on page 1 herein 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 the ADSs representing our ordinary shares, you should read this entire prospectus carefully, including the sections titled "Risk Factors" and "Business" in this prospectus and 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 in our Forms 20-F and 6-K incorporated by reference herein. You should also read the other documents incorporated by reference into the registration statement of which this prospectus forms a part. See "Where You Can Find More Information."

#### 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.

#### ABOUT THE GLOBAL OFFERING

This prospectus relates to a firm commitment underwritten offering of our ordinary shares to be represented by American Depositary Shares, or ADSs, which we refer to as the Underwritten Offering. The Underwritten Offering is part of a Global Offering that consists of (i) a rights offering to be extended to our ordinary shareholders and ADS holders, or the Rights Offering, and (ii) the Underwritten Offering. Under German law, where a company obtains binding, irrevocable agreements from certain existing shareholders not to transfer or exercise rights to be granted in a future rights offering, the company is permitted to attempt to sell the shares represented by such rights either before or after the rights offering. Based on binding irrevocable agreements not to transfer or exercise rights that we have obtained from certain holders of our ordinary shares, representing 74.83% of our outstanding ordinary shares (including ordinary shares represented by ADSs), we are conducting the Underwritten Offering pursuant to this prospectus prior to the commencement of the Rights Offering.

The Rights Offering will be conducted pursuant to a separate registration statement and prospectus. The price to public that is set in the Underwritten Offering will be the subscription price for the Rights Offering. Shareholders and ADS holders as of the respective record dates for our ordinary shares and the ADSs representing our ordinary shares who have not agreed to forego exercising their rights will have the opportunity in the Rights Offering to subscribe for up to 1,681,849 new ordinary shares or new ADSs (representing approximately 0.72% of our outstanding ordinary shares) at the subscription price. ADSs PURCHASED IN THE UNDERWRITTEN OFFERING WILL NOT BE ENTITLED TO RECEIVE RIGHTS TO SUBSCRIBE FOR NEW ORDINARY SHARES OR NEW ADSs IN THE RIGHTS OFFERING. Accordingly, assuming no change in the assumed public offering price or the number of ADSs offered by us in the Underwritten Offering, as set forth on the cover page of this prospectus, a total of up to 6,681,849 ordinary shares (including ordinary shares represented by ADSs) may be sold in the Global Offering. We may also increase or decrease the number of ADSs we are offering in the Underwritten Offering, which would affect the number of our ordinary shares and ADSs representing our ordinary shares underlying rights granted in the Rights Offering. See "Dilution" for additional information.

#### PRESENTATION OF FINANCIAL INFORMATION

This prospectus includes financial information derived from our audited consolidated financial statements as of December 31, 2019 and 2018 and for the years ended December 31, 2019, 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, and are incorporated by reference herein. It also includes financial information derived from our unaudited interim condensed consolidated financial statements as of March 31, 2020 and for the three months ended March 31, 2020 and 2019 that have been prepared on the same basis as the audited financial statements and are incorporated by reference herein.

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 \$1.1107, the noon buying rate of the Federal Reserve Bank of New York on May 29, 2020. 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 and all references in this prospectus to "\$" refer to thousands of U.S. dollars and thousands of Euros, respectively.

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®, RECON® and NEO-STIM™ 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 selected information contained elsewhere in this prospectus and in the documents we incorporate by reference herein. This summary does not contain all of the information you should consider before making an investment decision. You should read this entire prospectus carefully, especially the risks of investing in the ADSs representing our ordinary shares discussed under "Risk Factors" beginning on page 23 of this prospectus, along with our consolidated financial statements and notes to those consolidated financial statements and the other information incorporated by reference 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 immunotherapies for cancer and 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. The breadth of our immunotherapy technologies and expertise has also enabled us to develop therapies to address a range of rare and infectious diseases, and we have recently rapidly mobilized these with the aim of addressing the COVID-19 pandemic. 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 approach to therapeutic development in oncology is based on the key drivers of cancer heterogeneity. 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.

# THREE KEY FACTORS INFLUENCE THE PATIENT'S UNIQUE TUMOR PROFILE TENVIRONMENT A ENTROPHICAL STREET AND A STRE IMMUNE DIVERSITY SOMATIC MUTATIONS Tumor Environment Immunosuppression Specificity, quantity Recognition and editing d functio al state ne effect Tumor Heterogeneity Mutation and neoantigen profile, biology and evolution INTERINDIVIDUAL HETEROGENEITY AFFECTS EFFICACY

Leveraging our expertise in the field of immunology, we and our collaborators have advanced a development pipeline of over 20 product candidates, of which 12 have entered into 13 ongoing clinical trials. Our most advanced programs are focused on oncology, where we have treated over 500 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 codeveloping with Genentech, Inc., or Genentech. For both product candidates, we have also observed durable reduction in tumor volume, including objective responses, in both the monotherapy and checkpoint-combination settings.

INDIVIDUALIZED APPROACHES ARE NEEDED

We believe our technology and expertise is broadly applicable across a number of therapeutic areas, such as infectious diseases and rare diseases. In April 2020, we initiated a first-in-human clinical trial program for our BNT162 vaccine program to prevent COVID-19, which includes four vaccine candidate variants based on three distinct mRNA formats. We are co-developing BNT162 with Pfizer Inc., or Pfizer, worldwide (ex-China) and with

Shanghai Fosun Pharmaceutical (Group) Co., Ltd, or Fosun Pharma, in China. We initiated the BNT162 program in late January 2020 in response to the global COVID-19 pandemic, and initiated human testing following preclinical studies and within approximately three months of initiating the research program. Our ability to rapidly design and test multiple vaccine variants leveraged our deep experience with mRNA vaccines and our prior preclinical work in the infectious disease field.

Our immunotherapy product candidates span four distinct 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.
- **Cell Therapies.** We are developing a range of cell therapies, including CAR-T cells, neoantigen-based T cell therapies and TCR therapies, in which the patient's T cells are modified or primed 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.

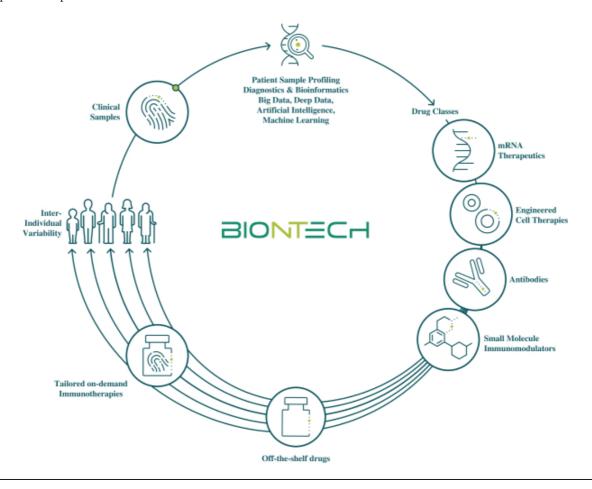
# **Our Approach**

In oncology, 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.

Similarly, in infectious disease, we are deploying our full suite of technologies and immunotherapeutic understanding to develop mRNA vaccines against emerging infectious diseases, such as COVID-19, in a manner that is designed to be faster and more easily scalable, and with more flexible constructs, than traditional vaccine development.

Our patient-centric approach starts with profiling and diagnostics by utilizing a target identification engine. This engine combines next generation sequencing, genomics, bioinformatics, machine learning and artificial intelligence to (a) identify gene targets of interest, (b) characterize the functional relevance of these targets (i.e., the ability to raise an immune response to or through a target) and (c) demonstrate their drugability. From our founding onwards, we have been developing the novel technologies needed to match the identified targets to the optimal individualized treatment approach. Our patient-centric model is 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)	Pre- clinical		Phase 2	Phase 3	Rights/ Collaborator	Milestones
	FixVae (fixed combination of shared cancer antigens)	BNT111	Advanced melanoma (Adjuvant & Metastatic)		-			Global	Report Phase 1 data: publication upcoming: Phase 2 with registrational potential start 2H 2020
		BNT112	Prostate cancer					Global	potential start 2H 2020
		BNT113	HPV16+ head and neck cancer <sup>1</sup>					Global	Phase 2 with registrational potential start 2H 2020
		BNT114	Triple negative breast cancer					Globel	Data update 2H 2020
		BNT115	Ovarion cancer <sup>1</sup>					Global	
		BNT116	NSCLC					Global	Phase 1 start 1H 2021
			IL melanoma with CPI <sup>3</sup>						Enrollment update 2H 2020 <sup>4</sup> ; interim
mRNA	iNeST (patient specific cancer	RO7198457 (BNT122 <sup>2</sup> )	Multiple solid tumors		_			Genentech (global 50:50	data update in 2H 2021
Ē	antigen therapy)	(BN1122)	NSCLC and colorectal cancer (Adjuvant)					profit/loss share)	Two Phase 2 trials planned 2H 2020
	Intratumoral Immunotherapy	SAR441000 (BNT131)	Solid tumors (IL-12sc, IL-15sashi, GM-CSF, IFNa)		-			Sanofi (global profit/ loss share)	Data update 2H 2020 <sup>a</sup>
	RiboMabs (mRNA- encoded antibodies)	BNT141	Multiple solid tumors					Global	Phase 1 start 1H 2021
		BNT142	Multiple solid tumors (CD3+CLDN6)					Global	Phase 1 start 1H 2021
	RiboCytokines (mRNA-encoded	BNT151	Multiple solid tumors (Optimized IL-2)					Global	Phase 1 start 1H 2021
	cytokines)	BNT152, BNT153	Multiple solid tumors (R-7, R-2)					Global	Phase 1 start 1H 2021
		BNT211	Multiple solid tumors (CLDN6)					Global	Phase 1/2 start 2H 2020
# B	CAR-T Cells	BNT212	Pancreatic, other cancers (CLDN/8.2)					Global	
Therapi	Neoantigen-based T cell therapy	BNT221 (NEO-PTC-01)						Global	Phase 1 start 2H 2020
	TCRs	To be selected	All tumors					Global	
	Next-Gen CP <sup>6</sup> Immunomodulators	GEN1046 (BNT311)	Multiple solid tumors (PD-L1×4-18B)					Genmab (global 50:50	Data update 2H 2020
		GEN1042 (BNT312)	Multiple solid tumors (CD40×4-1BB)					profit/loss share)	
Αm	Targeted Cancer Antibodies	BNT321 (MVT-5873)	Pancreatic cancer (sLe-)					Global	
SMIN	Toll-Like Receptor Binding	BNT411	Solid tumors (TLR7)		-			Global	

### Other

Drug Class	Platform	Product Candidate	Indication (Targets)	Pre- Pha- clinical 1	Phase 2	Phase 3	Rights/ Collaborator	Milestones
		BNT161	Influenza				Pfizer	Phase 1 start 2021
		BNT162	COVID-19				Fosun Pharma (China), Pfizer (Global, except China)	Phase 2/3 start late July 2020
Ý.	Infectious Disease Immunotherapies	To be selected	Up to 10 indications				Penn*	First Phase 1 trial to start 1H 2021
mRNA		To be selected	HIV and tuberculosis				Bill & Melinda Gates Foundation	
	Rare Disease PRT <sup>6</sup>	BNT171 To be selected	Not disclosed 4 more rare disease indications				Genevant (global 50:50 profit/loss share)	Phase 1 start 2H 2021

<sup>1</sup> BNT113 and BNT115 are currently being straded in investigator-initiated phase 1 trials
2 BNT114 as an optional treatment; BNT114 is investigated in arm 1 (Ne12) and arm 3 (Ne15) of the TNBC-MERIT trial, with BNT114 as an optional treatment; BNT114 is investigated in arm 1 (Ne12) and arm 3 (Ne15) of the TNBC-MERIT trial (total patients in study; Ne42)
3 Checkpoint Inhibitor

Checoporat Intertors
 Update on the orgoning study including patient enrollment mamber, efficacy and safety data for an interim update expected in the second half of 2021
 As the trial is sponsored and conducted by Sanofi, the timing of data updates is not under our control and is subject to change by Sanofi
 Checoporat
 To small Molecule Immunomodulators
 We are eligible to receive worldwide licenses
 Protein Ropkocement Therapy

We believe the breadth of our technology positions us to combine modes of action in a coordinated, potentially synergistic way to treat cancer in a more efficacious manner than current existing therapies. For example, we have capitalized on synergies in our portfolio by combining our CAR-T cell development with a CARVac primer based on our FixVac platform. We further believe that our patient-centric approach and our broad, potentially synergistic portfolio of drug platforms place us at the forefront of a paradigm shift toward individualized immunotherapies in oncology and allow us to potentially address a larger share of cancer patients, as illustrated below:

Cancer segment	Patient Population	Challenge	Our Therapeutic Strategy
High mutational burden/ adjuvant stage cancers	Significant portion of cancer patients	Poor risk-benefit profile of checkpoint inhibitors	• mRNA Neoantigen Immunotherapy (iNeST)
Low mutational burden cancers	>60% of cancers	Poor response to checkpoint inhibitors	Shared Antigens     (FixVac, CAR-T cells, Antibodies)
"Immune desert" cancers	>40% of high-mutational cancers	Poor infiltration and activation of T-cells in TME <sup>1</sup>	mRNA Immunotherapy     Immunostimulatory Compounds     (intratumoral, RiboCytokines)
Cancers with MHC / B2M loss	20-30% of CPI-experienced advanced cancers	Failure of immune system to recognize tumor cells	Antibodies     CAR-Ts
Refractory tumors	Patients with large tumors and multiple resistance mechanisms	Few treatment options	Engineered Cell Therapies     Combination Therapies

Tumor microemironment

We have established relationships with seven pharmaceutical collaborators, which comprise Genentech, Sanofi S.A., or Sanofi, Genmab A/S, or Genmab, Genevant Sciences GmbH, or Genevant, Bayer AG, or Bayer, Pfizer Inc., or Pfizer, and Shanghai Fosun Pharmaceutical (Group) Co., Ltd, or Fosun Pharma, in order to advance our science and development capabilities and provide capital, most of which has been non-dilutive. 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 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 pioneers 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.

#### **Recent Developments**

# June 30, 2020 Preliminary Financial Results

As of June 30, 2020, we maintained cash and cash equivalents of €573.1 million (\$636.5 million). Cash and cash equivalents as of June 30, 2020 is preliminary, unaudited and subject to completion and may differ from what will be reflected in our unaudited interim financial statements as of and for the three months ended June 30, 2020. Our unaudited interim condensed consolidated financial statements as of and for the three and six months ended June 30, 2020 will not be available to you prior to investing in the Underwritten Offering.

In addition to €573.1 million (\$636.5 million) in cash and cash equivalents at June 30, 2020, we expect to receive €223.9 million (\$251.0 million, translated using the exchange rate then in effect as published by the German Central Bank (*Deutsche Bundesbank*)) as proceeds from the June 2020 Private Placement described below, which is expected to settle in August 2020.

# Pfizer COVID-19 Collaboration

On April 9, 2020, we announced that we and Pfizer had entered into a collaboration agreement to co-develop our potential first-in-class COVID-19 mRNA vaccine program, BNT162, aimed at preventing COVID-19. Under the terms of the agreement, Pfizer agreed to pay us \$185 million in upfront payments, including an equity investment of €103.9 million (\$113 million, translated using the exchange rate then in effect as published by the German Central Bank (*Deutsche Bundesbank*)), which was received in late April 2020, and a cash payment of €6.5 million (\$72 million, translated using the exchange rate then in effect as published by the German Central Bank (*Deutsche Bundesbank*)), which was received in May 2020. The issuance of 2,377,446 ordinary shares with the nominal amount of €2,377,446 was registered within the commercial register (*Handelsregister*) as of May 5, 2020. We are eligible to receive future milestone payments of up to \$563 million for potential aggregate consideration of \$748 million. Pfizer and we will share development costs equally. Initially, Pfizer will fund 100% of the development costs, and we will repay Pfizer our 50% share of these costs if success-based milestones are reached, or with proceeds generated from the commercialization of the vaccine, if approved. If the vaccine program is not successful or does not generate sufficient proceeds, we will not be required to pay back our 50% share of the development costs incurred.

We and Pfizer are jointly conducting clinical trials for four COVID-19 vaccine candidate variants initially in the United States and Europe across multiple sites. In late April 2020, we and Pfizer announced that the German regulatory authority, the Paul-Ehrlich-Institut, approved the Phase 1/2 clinical trial and the first patients in the first cohort of our Phase 1/2 clinical trial were dosed shortly thereafter. In early May 2020, Pfizer and we initiated a clinical trial for BNT162 in the United States and the first participants were dosed shortly thereafter. On July 13, 2020, we and Pfizer announced that our BNT162b1 and BNT162b2 vaccine candidate variants were granted Fast Track designation by the FDA. During the clinical development stage, we and our partners will provide clinical supply of the vaccine from our GMP-certified mRNA manufacturing facilities in Europe. We and Pfizer are working together to scale-up manufacturing capacity at risk to provide worldwide supply in response to the pandemic. If the vaccine candidate is approved, we and Pfizer would also work jointly to commercialize the vaccine worldwide (excluding China which is covered by our collaboration with Fosun Pharma). If the vaccine candidate is approved, we and Pfizer expect to manufacture up to 100 million doses by the end of 2020 and potentially more than 1.3 billion doses by the end of 2021.

On July 20, 2020, we announced that we and Pfizer entered into a binding term sheet for a supply agreement with the United Kingdom. Pursuant to the term sheet, we and Pfizer expect to supply 30 million doses of BNT162, if approved, to the United Kingdom. Under the terms of the binding term sheet, we and Pfizer are eligible to receive a fully refundable advance payment per dose upon signing of a definitive supply agreement. The advance payment will be treated as a prepayment towards the total cost of the contracted number of doses of BNT162, with the remainder of the contracted price per dose to be paid upon delivery of the contracted doses.

We are also in late-stage discussions with several other governments and governmental bodies related to the establishment of supply agreements for BNT162, if approved. Based on the current status of discussions, we expect that we and Pfizer will enter into further binding and non-binding agreements to supply hundreds of millions of additional doses of BNT162 as early as 2020 and 2021. Certain of the agreements may also provide an option to purchase additional doses, under specified circumstances.

## July 2020 BNT162 Data Announcements

On July 1, 2020, we and Pfizer announced preliminary data from our ongoing U.S. Phase 1/2 trial of BNT162b1. The initial part of this randomized, placebo-controlled, observer-blinded study is evaluating the safety, tolerability and immunogenicity of escalating dose levels of BNT162b1, one of four vaccine candidate variants in development as part of our BNT162 program, in 45 healthy adults between 18 and 55 years of age.

The participants received two doses, 21 days apart, of placebo, 10µg or 30µg of BNT162b1, or received a single dose of 100µg of the vaccine candidate. Because of a strong vaccine booster effect, the highest neutralizing titers were observed seven days after the second dose of 10µg or 30µg on day 28 after vaccination. The neutralizing GMTs were 168 and 267 for the 10µg and 30µg dose levels, respectively, corresponding to 1.8-and 2.8-times the neutralizing GMT of 94 observed in a panel of 38 sera from subjects who had contracted SARS-CoV-2.

In all 24 subjects who received 2 vaccinations at 10µg and 30µg dose levels of BNT162b1, elevation of RBD-binding IgG concentrations was observed after the second injection with respective GMCs of 4,813 and 27,872 units/ml at day 28, seven days after immunization. These concentrations are 8- and 46.3-times the GMC of 602 units/ml in a panel of 38 sera from subjects who had contracted SARS-CoV-2.

At day 21 after a single injection, the 12 subjects who received 100µg of BNT162b1 had an RBD-binding IgG GMC of 1,778 units/ml and a SARS-CoV neutralizing GMT of 33, which are 3-times and 0.35-times, respectively, the GMC and GMT of the convalescent serum panel.

At the 10 $\mu$ g or 30 $\mu$ g dose levels, adverse reactions, including low grade fever, were more common after the second dose than the first dose. Following dose 2, 8.3% of participants who received 10 $\mu$ g and 75.0% of participants who received 30 $\mu$ g BNT162b1 reported fever <sup>3</sup> 38.0 °C. Local reactions and systemic events after injection with 10 $\mu$ g and 30 $\mu$ g of BNT162b1 were dose-dependent, generally mild to moderate, and transient. The most commonly reported local reaction was injection site pain, which was mild to moderate, except in one of 12 subjects who received a 100 $\mu$ g dose, which was severe. No serious adverse events were reported. Given higher numbers of subjects experiencing local reactions and systemic events after a single 100 $\mu$ g dose with no significant increases in immunogenicity compared to the 30 $\mu$ g dose level, the 12 participants in the 100 $\mu$ g group were not administered a second dose.

On July 20, 2020, we and Pfizer announced preliminary data from our ongoing German Phase 1/2 trial of BNT162b1. The initial part of this open-label, non-randomized, non-placebo-controlled study is evaluating the safety, tolerability and immunogenicity of escalating dose levels of BNT162b1, one of four vaccine candidate variants in development as part of our BNT162 program, in 60 healthy adults, between 18 and 55 years of age.

The preliminary data we reported was from 12 subjects each who received two doses of 1µg, 10µg, 30µg and 50µg (except for one individual each in the 10µg and 50µg who discontinued due to non-study drug related reasons) and 12 subjects who received a single dose of 60µg. The two doses received by the participants were given 21 days apart.

In 34 of the 36 subjects who received two vaccinations at 10µg, 30µg, or 50µg dose levels of BNT162b1, RBD-specific CD4+ T cell responses were observed. All subjects but the two exceptions at the lowest dose level had cytokine profiling of the RBD-specific CD4+ T cells that demonstrated a TH1-dominant profile for these cells. While the magnitude varied between individuals, participants with the strongest CD4+ T cell responses to RBD had more than 10-fold of the memory responses observed in the same participants when stimulated with cytomegalovirus (CMV), Epstein Barr virus (EBV), influenza virus and tetanus toxoid-derived immuno- dominant peptide panels. The strength of RBD-specific CD4+ T cell responses correlated positively with both RBD-binding IgG and with SARS-CoV-2 neutralizing antibody titers. Among vaccine-induced CD8+ T cell responses, which were observed in 29 of 36 participants, strong responses were mounted by the majority of participants and were comparable with memory responses against CMV, EBV, influenza virus and tetanus toxoid in the same participants. The strength of RBD-specific CD8+ T cell responses correlated positively with vaccine-induced CD4+ T cell responses, but did not significantly correlate with SARS-CoV-2 neutralizing antibody titers. Additionally, although at 1µg the immunogenicity rate was lower (6 of 8 responding participants), the magnitude of vaccine-induced CD4+ and CD8+ T cells in some participants was almost as high as with 50µg BNT162b1.

Elevation of SARS-CoV-2 RBD-binding IgG concentrations was observed, with respective GMCs ranging from 265 units/ml to 1,672 units/ml at day 21. At day 29, seven days after the second dose, RBD-binding IgG GMCs ranged from 2,015 units/ml to 25,006 units/ml. At day 43, RBD-binding IgG GMCs ranged from 3,920 units/ml to 18,289 units/ml. These concentrations are 6.5- to 30.4-times the GMC of 602 units/ml in a panel of sera from 38 subjects who had contracted SARS-CoV-2. At day 29, the SARS-CoV-2 neutralizing GMTs reached 36 (1µg dose), 158 (10µg dose), 308 (30µg dose) and 578 (50µg dose) compared to neutralizing GMT of 94 observed in the convalescent serum panel. At day 43, SARS-CoV-2 neutralizing GMTs reached .7-fold (1µg dose) to 3.2-fold (50µg dose) compared to those of a panel of SARS-CoV-2 infection convalescent human sera. Furthermore, sera of vaccinated subjects displayed broadly neutralizing activity in pseudovirus neutralization assays across a panel of sixteen SARS-CoV-2 RBD variants represented in publicly available SARS-CoV-2 sequences and against the newly dominant D614G strain. In summary, antibody responses elicited by BNT162b1 in our German clinical trial largely mirrored those observed in our U.S. clinical trial.

At the 10µg, 30µg and 50µg dose levels, certain adverse reactions, including low grade fever, were more common after the second dose than the first dose. Following the second dose, 25.0%, 25.0% and 33.3% of participants who received the 10µg, 30µg and 50µg doses, respectively reported fever of at least 38.0 degrees Celsius. Local reactions and systemic events after injection with 10µg, 30µg and 50µg of BNT162b1 were dose- dependent, generally mild to moderate and transient, with occasional severe events (grade 3) of flu-like symptoms and injection site reactions. The most commonly reported local reaction was injection site pain, which was mild to moderate, except in one of 12 subjects who received a 60µg dose, which was severe. No serious adverse events were reported, and there were no withdrawals due to adverse events related to the vaccine. Based on the adverse reactions reported after the 50µg boost dose, a second 60µg dose was not administered to participants who had received an initial 60µg dose.

For additional information on these preliminary results, please review our reports on Form 6-K filed with the SEC on July 1, 2020 and July 20, 2020 and incorporated by reference herein.

Based on preclinical and clinical data observed to-date, we and Pfizer have decided to progress our BNT162 development program into a Phase 2b/3 trial, which is anticipated to commence in late July 2020, subject to input and approval from the appropriate regulatory bodies. For the initial Phase 2b/3 trial, we intend to select either BNT162b1 or BNT162b2. Both the BNT162b1 and the BNT162b2 vaccine candidates have received Fast Track

status from the FDA. Since clinical evaluation of the BNT162b2 candidate started several weeks later than BNT162b1, only preliminary clinical data are currently available for the BNT162b2 candidate. A set of data obtained for a cohort of subjects 18-55 years of age immunized with 10µg of BNT162b2 indicates that BNT162b2 induces similar virus neutralizing antibody responses as observed for BNT162b1. The preliminary observations are subject to further data collection and analysis. Assessment of dose dependent immune response and safety profile as well as analysis of T cell responses is currently pending. On the basis of additional data expected to be collected and analyzed for BNT162b1 and BNT162b2 in the coming days, along with input from the FDA, we intend to select a lead candidate to take into a Phase 2b/3 trial. We and Pfizer currently expect to inform the FDA of our selection of the BNT162 candidate variant before the closing of this offering. Based on clinical data from our ongoing Phase 1/2 trials of BNT162b1 in the United States and Germany, BNT162b1 appears to be a viable variant to advance into a Phase 2b/3 trial. However, given that additional information relating to BNT162b2 is becoming available over the next few days, we and Pfizer plan to make the ultimate decision on the final candidate based on multiple factors, including the overall observed safety, tolerability and immunogenicity profiles for each vaccine candidate at different dose levels, a full immunogenicity data set and feedback from the FDA on the data collected for each candidate. If we ultimately move forward with the BNT162b2 variant, it will be due to the fact that based on our scientific judgment in light of the totality of preclinical data and clinical data available to us at the time of selection and the other factors described above, the BNT162b2 variant has better potential for clinical and commercial success. We do not plan to disclose which BNT162 variant has been selected until we receive FDA approval to commence the Phase 2b/3 clinical trial, and we likely will not publish any data with respect to the BNT162b2 variant before we make our selection.

### June 2020 iNeST Data Update

In June 2020, we presented data from a monotherapy dose-finding cohort of our RO7198457 (BNT122) Phase 1 trial in multiple solid tumors in which RO7198457 (BNT122) was observed to have a manageable safety profile and induced strong neoantigen-specific immune responses in patients with low and intermediate mutational load tumors types. This data related to 31 patients enrolled in cohorts with doses ranging from 25-100µg. The most common tumor types were HR+/HER2+ breast, prostate, and ovarian cancer with a median of 5 lines of prior therapies (range 1-17). Most patients enrolled had a low level of PD-L1 expression in the tumor as determined by immunohistochemistry (97% patients with <5% PD-L1 expression on tumor cells (TC) and 93% patients with <5% expression on immune cell (IC)). The majority of adverse events were Grade 1 or Grade 2 and those occurring in more than 20% of patients included infusion related reaction (IRR), fatigue, cytokine release syndrome (CRS), nausea, and diarrhea. IRR and CRS were transient and reversible and presented primarily as Grade 1 or Grade 2 chills and fever. A single dose limiting toxicity of Grade 3 CRS occurred at the 100µg dose level. None of the patients discontinued RO7198457 (BNT122) due to AEs. RO1798457 (BNT122) induced pulsatile release of pro-inflammatory cytokines with each dose, consistent with TLR agonist activity of RNA. *Ex vivo* T cell responses were detected in approximately 86% of patients treated with RO7198457 (BNT122) as a monotherapy. Analysis of MHC multimers showed the induction of up to 5.3% neo-epitope specific CD8 T-cells with effector memory phenotype in the peripheral blood. RO7198457 (BNT122) induced T cells against multiple neoantigens were detected in post-treatment tumor biopsies. Of 26 patients that underwent at least one tumor assessment, one patient with gastric cancer and metastatic liver lesions had a durable best response of confirmed complete response and remains on study after 1.5 years (3.8%) and 12 patients had stable disease (46.2%).

Also in June 2020, we presented data from 132 patients enrolled in cohorts with doses ranging from 15µg to 50µg of RO7198457 (BNT122) in combination with 1200mg atezolizumab. The most common tumor types enrolled were non-small cell lung cancer, or NSCLC, triple-negative breast cancer, or TNBC, melanoma and colon cancer with a median of three lines of prior therapies (range 1-11). Most patients enrolled had low levels of PD-L1 expression in the tumor as determined by immunohistochemistry (93% patients with <5% PD-L1 expression on tumor cells (TC0/1) and 79% patients with <5% PD-L1 expression on immune cell (IC0/1)). The

majority of adverse events were Grade 1 or Grade 2 and those occurring in more than 15% of patients included infusion related reaction (IRR), fatigue, nausea, cytokine release syndrome (CRS) and diarrhea. IRR and CRS were transient and reversible and presented primarily as Grade 1 or Grade 2 chills and fever. There were no dose

limiting toxicities. Eight patients (5.6%) discontinued due to AEs related to study drugs. RO1798457 (BNT122) induced a self-limiting increase of pro-inflammatory cytokines with each dose, consistent with the TLR agonist activity of RNA. *Ex vivo* T cell responses were observed in peripheral blood in 46 out of 63 (73%) patients. Induction of up to 5.7% MHC multimer-stained CD8+ T-cells with effector memory phenotype was observed in the peripheral blood. RO7198457 (BNT122) induced T cells against multiple neoantigens were detected in post-treatment tumor biopsies. Of 108 patients that underwent at least one tumor assessment, 1 patient had a complete response as their best response (0.9%), 8 patients had partial responses (7.4%), and 53 patients had stable disease (49.1%).

Based on data from our study of BNT121 as an adjunct to surgery in patients with metastatic melanoma, we believe that RO7198457 (BNT122) is potentially well suited to control metastatic relapses in patients with a lower tumor burden. Additionally, RO7198457 (BNT122) as a monotherapy and in combination with atezolizumab has been observed to have a manageable safety profile to date and to induce significant levels of neoantigen-specific immune responses, even in late-stage, heavily pre-treated patients. Accordingly, we and our collaborator, Genentech, intend to initiate two additional randomized Phase 2 trials in the second half of 2020 in early and adjuvant stage NSCLC and colorectal cancer, where we believe the mechanism of action of RO7198457 (BNT122) is best suited. We also continue to investigate RO7198457 (BNT122) in our ongoing Phase 2 trial in first line melanoma in combination with pembrolizumab.

#### June 2020 Private Placement

On June 29, 2020, we announced the signing of a private investment by a fund associated with Temasek Capital Management Pte. Ltd., or Temasek, and another accredited investor, which investment we refer to as the June 2020 Private Placement. The June 2020 Private Placement consisted of approximately €123.9 million (\$138.9 million, using the exchange rate then in effect as published by the German Central Bank (*Deutsche Bundesbank*)) in ordinary shares and a €100.0 million (\$112.1 million, using the exchange rate then in effect as published by the German Central Bank (*Deutsche Bundesbank*)) four-year mandatory convertible note. Upon the closing of the June 2020 Private Placement, which is expected to occur in August 2020, subject to customary closing conditions, the investors will receive an aggregate of 2,595,996 of our ordinary shares and will be subject to a 180-day lock-up period. The four-year mandatory convertible note will have a coupon of 4.5% per annum and a conversion premium of 20% above the reference price.

# Acquisition of Neon Therapeutics, Inc.

On May 6, 2020, we announced the closing of our acquisition of Neon Therapeutics, Inc., or Neon, a biotechnology company developing novel neoantigen-based T cell therapies, through a stock transaction and including de minimis cash consideration, or the Merger. The Merger was first announced on January 16, 2020. Neon, now BioNTech US Inc., or BioNTech US, is operated as our wholly owned subsidiary. The transaction combines two organizations with a common culture of pioneering translational science and a shared vision for the future of cancer immunotherapy. Through the acquisition, we leverage Neon's deep expertise in the development of neoantigen therapies, with both vaccine and T-cell capabilities. Our most advanced program acquired in the Merger is NEO-PTC-01, a personalized neoantigen-targeted T cell therapy candidate consisting of multiple T cell populations targeting the most therapeutically relevant neoantigens from each patient's tumor. We also acquired a precision T cell therapy program targeting shared neoantigens in genetically defined patient populations. The lead program from this approach, NEO-STC-01, is a T cell therapy candidate targeting shared RAS neoantigens. In addition, Neon had assembled libraries of high-quality TCRs against various shared neoantigens across common HLAs. This pipeline is underpinned by Neon's platform technologies including RECON®, its machine-learning bioinformatics platform, and NEO-STIM™, its proprietary process to directly prime, activate and expand neoantigen-targeting T cells ex vivo.

Based on the acquisition date share price, the implied aggregate value of the Merger consideration was approximately €89.9 million (\$97.1 million) financed by issuing new ordinary shares as a stock transaction and including a de minimis cash consideration which was paid to settle Neon's outstanding stock options. The new subsidiary is based in Cambridge, Massachusetts and serves as our U.S. headquarters.

# Impacts of COVID-19

On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 as a pandemic, which continues to spread throughout the United States, the European Union and around the world. As we advance our clinical programs, we are in close contact with our principal investigators and clinical sites, which are located in jurisdictions affected by the COVID-19 pandemic, and are assessing the impact of the COVID-19 pandemic on our clinical trials, expected timelines and costs on an ongoing basis. In light of recent developments relating to the COVID-19 pandemic, the primary focus of healthcare providers and hospitals is currently on fighting the novel coronavirus. In addition, in response to the spread of COVID-19, we have modified our business practices, including restricting employee travel, developing social distancing plans for our employees and cancelling physical participation in meetings, events and conferences. In addition, for certain of our earlier-stage programs, including BNT141 and BNT142 (RiboMabs), BNT151 and BNT152/153 (RiboCytokines), BNT161 (Influenza), BNT171 (Rare Disease) and BNT411 (TLR7), we have delayed commencement of trials, experienced slowed patient enrollment or experienced other delays as a result of the COVID-19 pandemic. This partial disruption, even temporary, may severely impact our operations and overall business by delaying the progress of our clinical trials and preclinical studies. All anticipated milestones set forth in this prospectus are subject to further future adjustment as a result of the COVID-19 pandemic. See "Risk Factors."

#### **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 and in the section titled "Risk Factors" in our Annual Report on Form 20-F for the year ended December 31, 2019, incorporated by reference herein. These risks include, but are not limited to, the following:

- Data from our COVID-19 vaccine development program is not predictive of the safety or efficacy of any vaccine candidate. Even if a COVID-19 vaccine is approved for use, we will need to devote significant resources to scale-up our manufacturing and distribution capabilities, which would divert resources away from our other clinical and preclinical programs. Even if a COVID-19 vaccine is approved for use, there can be no assurance that it would ever become profitable, due to, among other things, government interest, public perception regarding a vaccine and competing treatments being developed.
- 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 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.
- 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.
- No mRNA immunotherapy has been approved, and none may ever be approved. mRNA drug development has substantial clinical
  development and regulatory risks due to the novel and unprecedented nature of this new category of therapeutics.

- 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.
- 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.
- 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.
- We face risks related to health epidemics, such as the current COVID-19 outbreak, that could adversely affect our operations.
- 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.
- 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.
- 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.
- 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.
- 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.
- 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.
- 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 have entered into several arrangements with a related party for the performance of nonclinical research programs, and these
  arrangements present potential conflicts of interest.

- 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.
- 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 not fully realize the anticipated benefits of the Neon acquisition or realize such benefits within the timing anticipated.
- The price of the ADSs may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of the ADSs.

#### **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. We completed our initial public offering in October 2019. ADSs representing our ordinary shares are currently listed on the Nasdaq Global Select Market under the symbol "BNTX."

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 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 from the completion of our initial public offering 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 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. As of June 30, 2020, which was the last business day of our most recently completed second fiscal quarter, the market value of our common equity held by non-affiliates exceeded \$700 million. Consequently, we expect that we will cease to be an emerging growth company no later than December 31, 2020, and we expect to qualify as a large accelerated filer as of that date. As a result, we expect that, as of December 31, 2020, we will be required to adhere to, among other things, the auditor attestation requirement in the assessment of internal control over financial reporting and 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. For additional information, please see "Risk Factors" in our Annual Report on Form 20-F for the year ended December 31, 2019, incorporated by reference herein.

#### Foreign Private Issuer

We 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 are 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, as long as we remain a foreign private issuer, even after we no longer qualify as an emerging growth company, 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 UNDERWRITTEN OFFERING

Public offering price \$ per ADS.

ADSs offered by us 5,000,000 ADSs, each representing one ordinary share

The Selling Shareholder MIG Verwaltungs AG, through MIG GmbH & Co. Fonds 7 KG, MIG GmbH & Co. Fonds

8 KG and MIG GmbH & Co. Fonds 9 KG

Ordinary shares to be outstanding immediately after the 237,673,455 ordinary shares, including ordinary shares represented by ADSs

**Underwritten Offering** 

Option to purchase additional ADSs

The underwriters have an option, exercisable for a period of 30 days after the date of this

prospectus, to purchase an aggregate of up to 750,000 additional ADSs from the Selling

Shareholder.

American Depositary Shares The underwriters will deliver American Depositary Shares, or the ADSs. Each ADS

represents one of our ordinary shares, no par value per share.

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 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 incorporated by reference as an exhibit to the registration

statement of which this prospectus forms a part.

Depositary The Bank of New York Mellon

Risk factors See "Risk Factors" beginning on page 23 as well as the risk factors contained in our

Annual Report on Form 20-F for the year ended December 31, 2019 and the other information contained in this prospectus or incorporated by reference herein for a discussion of factors you should consider before deciding to invest in the ADSs.

Use of proceeds We estimate that the net proceeds to us from the Underwritten Offering will be

approximately \$400.7 million (€360.7 million), based on an assumed public offering price of \$85.25 per ADS, which was the closing sale price of the ADSs on the Nasdaq Global Select Market on July 17, 2020, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We will not receive any proceeds from the potential sale of ADSs in this Underwritten Offering by the Selling Shareholder, pursuant to the underwriters' option to purchase additional ADSs from the

Selling

Shareholder. We intend to use the net proceeds from the Underwritten Offering and the net proceeds, if any, from the Rights Offering, to:

- advance our iNeST program candidate RO7198457 (BNT122) into late-stage trials:
- advance our ongoing and currently planned clinical trials for our FixVac product candidates, BNT111, BNT112, BNT113, BNT114, BNT115 and our targeted cancer antibody, MVT-5873 (BNT321), as well as fund our portion of the research and development expenses for SAR441000 (BNT131), which is being developed in collaboration with Sanofi, GEN1046 (BNT311) and GEN1042 (BNT312), which are being developed in collaboration with Genmab and advance the development of BNT162, our COVID-19 vaccine candidate, which is being developed in collaboration with Pfizer;
- initiate clinical trials for additional product candidates, including product candidates from our CAR T, RiboMabs, RiboCytokines and TCR platforms in oncology;
- further accelerate and expand our infectious disease immunotherapy programs;
- advance our rare disease protein replacement therapy platforms outside of oncology;
- advance additional preclinical product candidates, develop additional product candidates leveraging our therapeutic platforms and fund the further development of our core technologies; and
- fund the further expansion of our manufacturing and laboratory capacity, the continued development of our infrastructure and investment in preparation for commercialization for launch of BNT162, if approved.

We expect to use the remainder of any net proceeds from the Global 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 commitments or obligations to do so.

See "Use of Proceeds" for a more complete description of the intended use of proceeds from the Global Offering.

Nasdaq Global Select Market symbol

ADSs representing our ordinary shares are listed on the Nasdaq Global Select Market under the symbol "BNTX."  $\,$ 

As required by German law, following the setting of the price to public for this underwritten offering, which we refer to as the Underwritten Offering, we intend to commence a rights offering, or the Rights Offering, to holders of our ordinary shares and ADSs representing our ordinary shares. The Underwritten Offering and the Rights Offering are part of a single, global offering which we refer to in this prospectus as the "Global Offering." We have obtained irrevocable, binding agreements from certain holders of our ordinary shares, representing

74.83% of our outstanding ordinary shares (including ordinary shares represented by ADSs), not to transfer or exercise their rights to subscribe for new ordinary shares in the Rights Offering. Under German law, the law of our jurisdiction of organization, we are permitted to offer new ordinary shares and ADSs, in an amount equal to the percentage of securities represented by the irrevocable agreements not to transfer or exercise rights, to new investors in advance of the Rights Offering. We intend to accomplish this through the Underwritten Offering described above. Following the Underwritten Offering, our shareholders and ADS holders as of the respective record dates who have not agreed to forego exercising rights will have the opportunity in the Rights Offering to subscribe for up to 1,681,849 new ordinary shares or new ADSs (representing approximately 0.72% of our outstanding ordinary shares) at a subscription price equal to the price to public in the Underwritten Offering. ADSs purchased in the Underwritten Offering will not be entitled to receive rights to subscribe for new ordinary shares or new ADSs in the Rights Offering. Accordingly, a total of up to 6,681,849 ordinary shares (including ordinary shares represented by ADSs) may be sold in the Global Offering. If all of the shares and ADSs in the Rights Offering are subscribed for (excluding those attributable to holders that have irrevocably agreed not to transfer or exercise rights), we will offer 6,681,849 ordinary shares (including ordinary shares represented by ADSs) in the Global Offering and will have 239,355,304 ordinary shares outstanding immediately after the Global Offering.

Unless otherwise indicated, the number of our ordinary shares to be outstanding after the Underwritten Offering is based on 226,779,744 ordinary shares outstanding as of March 31, 2020 and excludes:

- 16,338,305 ordinary shares available for issuance upon the exercise of options outstanding as of March 31, 2020;
- 254,065 ordinary shares available for issuance upon the exercise of options expected to be granted in 2021 and 2022 under our long-term incentive program as of March 31, 2020;
- 5,282,436 ordinary shares available for future issuance under our Employee Stock Ownership Plan or any future share option plan as of March 31, 2020 (after taking into account the issuance of options expected to be granted in 2021 and 2022);
- 1,580,777 ordinary shares issued to Fosun Pharma in connection with our collaboration with Fosun Pharma;
- 2,377,446 ordinary shares issued to Pfizer in connection with our collaboration with Pfizer;
- · 1,935,488 ADSs representing our ordinary shares issued to former stockholders of Neon in the Merger; and
- 5,524,506 ordinary shares held in treasury.

Unless otherwise indicated, all information contained in this prospectus:

- excludes the 2,595,996 ordinary shares to be issued in the June 2020 Private Placement, which is expected to close in August 2020;
- assumes no exercise of the outstanding options described above;
- assumes a public offering price of \$85.25 per ADS in the Underwritten Offering, which was the last reported sale price of the ADSs on the Nasdaq Global Select Market on July 17, 2020;
- assumes a subscription price of \$85.25 per ordinary share and ADS in the Rights Offering;
- assumes an exact ADS and ordinary share subscription ratio, based on our 232,673,455 ordinary shares (including those represented by ADSs) outstanding as of July 21, 2020 and an offering size of 5,000,000 ADSs in the Underwritten Offering; however, because we intend to round down the actual subscription ratio to the tenths column, the actual number of shares offered in the Global Offering will differ once the actual ADS and ordinary share subscription ratios are known.
- assumes no exercise of the option granted to the underwriters to purchase up to 750,000 additional ADSs from the Selling Shareholder in the Underwritten Offering; and
- excludes the effects of our acquisition of Neon; for more information, see "Unaudited Pro Forma Condensed Combined Financial Information."

Certain new and existing investors, including Pfizer Inc., have indicated an interest in purchasing up to an aggregate of \$200 million in ADSs representing our ordinary shares in this offering at the public offering price of \$ and on the same terms and conditions as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, these investors may determine to purchase fewer ADSs than they indicate an interest in purchasing or not to purchase any ADSs in this offering. It is also possible that these investors could indicate an interest in purchasing more ADSs. In addition, the underwriters could determine to sell fewer ADSs to any of these investors than the investors indicate an interest in purchasing or not to sell any ADSs to these investors.

## SUMMARY CONSOLIDATED FINANCIAL DATA

The following tables set forth a summary of our historical consolidated financial data for the years ended December 31, 2019, 2018 and 2017, as of March 31, 2020 and for the three months ended March 31, 2020 and 2019. We derived the summary of our results for the years ended December 31, 2019, 2018 and 2017 from our audited consolidated financial statements incorporated by reference herein. The summary consolidated financial data as of March 31, 2020 and for the three months ended March 31, 2020 and 2019 have been derived from our unaudited interim condensed consolidated financial statements incorporated by reference herein and have been prepared on the same basis as the audited financial statements. In the opinion of management, the unaudited interim data reflects all adjustments necessary for a fair presentation of the financial information in those statements. 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, and our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus, as well as the section of this prospectus titled "Selected Consolidated Financial Data" and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Forms 20-F and 6-K incorporated by reference herein. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period, and the results for the three months ended March 31, 2020 are not necessarily indicative of the results to be expected for the full year ended December 31, 2020.

	For the Three Months Ended March 31,		For the Years Ended December 31, 2019 2018		i
(in thousands except per share data)	2020	2020 2019 (unaudited)		2018	2017
Consolidated statements of operations:	(unau	aitea)			
Revenues from contracts with customers	€ 27,663	€ 26,154	€ 108,589	€ 127,575	€ 61,598
Cost of sales	(5,842)	(3,205)	(17,361)	(13,690)	(9,318)
Gross profit	€ 21,821	€ 22,949	€ 91,228	€ 113,885	€ 52,280
Research and development expenses	(65,122)	(57,241)	(226,466)	(143,040)	(85,496)
Sales and marketing expenses	(486)	(560)	(2,718)	(3,041)	(6,603)
General and administrative expenses	(15,815)	(9,276)	(45,547)	(26,334)	(23,520)
Other operating income	425	331	2,724	5,396	2,349
Other operating expenses	(100)	(38)	(739)	(720)	(288)
Operating loss	€(59,277)	€(43,835)	€(181,518)	€ (53,854)	€(61,277)
Finance income	6,417	3,578	4,122	8,046	2,133
Finance expenses	(103)	(74)	(326)	(48)	(26,007)
Interest expenses related to lease liability	(415)	(425)	(1,718)	(1,721)	(676)
Share of loss of equity method investees				(84)	(78)
Loss before tax	€(53,378)	€(40,756)	€(179,440)	€ (47,662)	€(85,905)
Income taxes	(8)	(6)	268	(600)	(45)
Loss for the period	<b>€</b> (53,386)	<b>€(40,762)</b>	<b>€(179,172</b> )	<b>€</b> (48,262)	<b>€(85,950</b> )
Loss attributable to equity holders of the parent	(53,386)	(40,646)	(179,056)	(48,019)	(85,653)
Loss attributable to non-controlling interests	_	(116)	(116)	(243)	(297)
Basic and diluted loss per share	€ (0.24)	€ (0.20)	€ (0.85)	€ (0.25)	€ (0.51)

The following table presents our summary consolidated statement of financial position as of March 31, 2020 (i) on an actual basis, (ii) on a pro forma basis to give effect to (a) the issuance of 1,935,488 ADSs representing our ordinary shares in our acquisition of Neon, (b) the issuance of 1,580,777 of our ordinary shares in a private placement to Fosun Pharma for proceeds of €45.6 million (\$50.0 million, translated using the exchange rate then in effect as published by the German Central Bank (*Deutsche Bundesbank*)) and (c) the issuance of 2,377,446 of our ordinary shares in a private placement to Pfizer for proceeds of €103.9 million (\$113.0 million, translated using the exchange rate then in effect as published by the German Central Bank (*Deutsche Bundesbank*)) and (iii) on a pro forma as adjusted basis to give further effect to the sale of up to 5,000,000 ADSs representing ordinary shares by us in the Underwritten Offering at the assumed public offering price of \$85.25 per ADS, which was the last reported sale price on the Nasdaq Global Select Market on July 17, 2020, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

		As of March 31, 2020	)
(in thousands)	Actual	Pro Forma(1) (unaudited)	Pro Forma As adjusted(1) (2)
Consolidated statements of financial position:			
Cash and cash equivalents	€ 451,597	€ 601,055	€ 961,770
Total assets	732,208	971,214	1,331,929
Total liabilities	284,078	284,078	284,078
Share capital	232,304	238,198	243,198
Capital reserve	686,714	919,826	1,275,541
Accumulated losses	(478,213)	(478,213)	(478,213)
Total equity	448,130	687,136	1,047,851

- (1) Does not reflect the issuance of 2,595,996 ordinary shares and a four-year mandatory convertible note for anticipated gross proceeds of €223.9 million (\$251.0 million, translated using the exchange rate then in effect as published by the German Central Bank (*Deutsche Bundesbank*)) in the June 2020 Private Placement, expected to close in August 2020.
- Each \$1.00 increase (decrease) in the assumed public offering price of \$85.25 per ADS, which was the last reported sale price of the ADSs on the Nasdaq Global Select Market on July 17, 2020, would increase (decrease) each of cash and cash equivalents, total assets and total equity by €4.3 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. If the Rights Offering is fully subscribed (excluding ordinary shares underlying rights offered to holders that have irrevocably agreed not to transfer or exercise their rights), our cash and cash equivalents, total assets and total equity would each increase by €122.6 million and our share capital would increase by €1.7 million. We may also increase or decrease the number of ADSs we are offering in the Underwritten Offering, which would affect the number of our ordinary shares and ADSs representing our ordinary shares underlying rights granted in the Rights Offering. An increase (decrease) of 1,000,000 in the number of ADSs offered by us would further increase (decrease) each of cash and cash equivalents, total assets, and total equity by approximately €91.3 million, assuming no change in the assumed public offering price, after deducting underwriting discounts and commissions and estimated offering expenses payable by us and after giving effect to a proportionate increase (decrease) in the number of ordinary shares and ADSs representing our ordinary shares underlying rights granted in the Rights Offering, assuming the Rights Offering is fully subscribed (excluding ordinary shares underlying rights offered to holders that have irrevocably agreed not to transfer or exercise their rights).

#### RISK FACTORS

Investing in the ADSs representing our ordinary shares involves a high degree of risk. You should carefully consider the following risks, together with all of the other information contained in this prospectus and in our filings with the Securities and Exchange Commission, or the SEC, that we have incorporated by reference in this prospectus. If any of the following risks actually occur, our business, prospects, operating results and financial condition could suffer materially. In such event, the trading price of the ADSs representing our ordinary shares could decline and you might lose all or part of your investment.

# Risks Related to Our COVID-19 Vaccine Development Program and Our Intellectual Property

We may experience significant volatility in the market price of the ADSs representing our ordinary shares following announcements and data releases regarding our ongoing development of BNT162 as a potential COVID-19 vaccine.

Biopharmaceutical companies that are developing potential therapeutics and vaccines to combat COVID-19 and SARS-CoV-2, including BioNTech SE, have experienced significant volatility in the price of their securities upon publication of preclinical and clinical data as well as news about their development programs. For example, following the announcement of our collaborations with Pfizer and Fosun Pharma relating to the development of BNT162, our vaccine candidate program for the prevention of COVID-19, the last reported sales price of the ADSs representing our ordinary shares on the Nasdaq Global Select Market increased from \$30.93 on March 13, 2020, the day before the announcement, to \$92.00 on March 18, 2020, before decreasing to \$46.50 on March 20, 2020. In addition to the preclinical and clinical data we and Pfizer have already disclosed in connection with our BNT162 development program, we and Pfizer intend over the coming months to make public several additional COVID-19 vaccine data readouts and clinical updates. We also expect to announce data, in due course, for the other three vaccine candidate variants that we are currently testing for the prevention of COVID-19 as part of our BNT162 program. On July 20, 2020, we announced that we and Pfizer have entered into a binding term sheet for a supply agreement with the United Kingdom. In addition, we are in late-stage discussions with several other governments and governmental bodies related to the establishment of supply agreements for BNT162, if approved. We cannot predict public reaction or the impact on the market price of the ADSs representing our ordinary shares once the terms of any or all of these supply arrangements are announced. We also cannot guarantee that the ultimate supply agreements we enter into, if any, will be for the number of doses we currently estimate and that aggregate consideration to be received under any such supply agreements will ultimately be what we currently expect. Given the attention being paid to the COVID-19 pandemic and the public scrutiny of COVID-19 development announcements and data releases to date, we expect that the public announcements we and Pfizer intend to make in the coming months regarding the ongoing development of BNT162 will attract significant attention and scrutiny and that, as a result, the price of the ADSs representing our ordinary shares may be particularly volatile during this time.

We are currently developing multiple candidate variants in our BNT162 program, which rely on different mechanisms of action, and the efficacy or safety of one variant is not indicative or predictive of the efficacy or safety of another variant.

We are currently developing four vaccine candidate variants for the prevention of COVID-19 as part of our BNT162 program. The first, which is the variant for which we and Pfizer announced Phase 1/2 data on July 1 and July 20, 2020, is BNT162b1, which utilizes nucleoside-modified mRNA (modRNA) and encodes the receptor binding domain antigen. Two of our four vaccine candidate variants, including BNT162b1, include a modRNA, one includes a uridine containing mRNA (uRNA), and the fourth variant utilizes self-amplifying mRNA (saRNA). Each mRNA format is combined with a lipid nanoparticle (LNP) formulation. The larger spike sequence is included in two of the vaccine candidate variants and the smaller optimized receptor binding domain from the spike protein is included in the other two candidate variants. Each variant has a distinct mechanism of action, and, as a result, clinical activity or safety results observed from one variant may not be indicative or

predictive of the efficacy or safety profile or results observed of another variant. For example, the data we recently announced for our BNT162b1 variant may differ in material respects from the safety or efficacy profile of the other vaccine candidate variants and should not be considered predictive of the safety or efficacy of our other vaccine candidate variants.

We cannot guarantee that the BNT162 variant we choose to advance into late stage clinical development will perform better than any of the variants we do not choose to advance. Further, even if we demonstrate a sufficient safety profile for BNT162 we may not be able to demonstrate sufficient efficacy in subsequent trials to obtain regulatory approval.

Based on preclinical and clinical data observed to-date, we and Pfizer have decided to progress our BNT162 development program into a Phase 2b/3 trial, which we plan to commence in late July 2020, subject to input and approval the from the appropriate regulatory bodies. For the initial Phase 2b/3 trial, we intend to select either the vaccine candidate variant for which we have already released data publicly, BNT162b1, or our modRNA vaccine candidate variant targeting the 2P-mutated full spike protein, BNT162b2. Both the BNT162b1 and the BNT162b2 vaccine candidates have received Fast Track status from the FDA. Since clinical evaluation of the BNT162b2 candidate started several weeks later than BNT162b1, only preliminary clinical data are currently available for the BNT162b2 candidate. A set of data obtained for a cohort of subjects aged to 18-55 years immunized with 10µg of BNT162b2 indicates that BNT162b2 may induce strong virus neutralizing antibody responses with titers in a similar range as observed for BNT162b1. The preliminary observations are subject to further data collection and analysis. Assessment of dose dependent immune response and safety profile as well as analysis of T cell responses is currently pending. On the basis of additional data expected to be collected and analyzed for BNT162b1 and BNT162b2 in the coming days, along with input from the FDA, we intend to select a lead candidate to take into a Phase 2b/3 trial. We and Pfizer currently expect to inform the FDA of our selection of the BNT162 candidate variant before the closing of this offering. Based on clinical data from our ongoing Phase 1/2 trials of BNT162b1 in the United States and Germany, BNT162b1 appears to be a suitable variant to advance into a Phase 2b/3 trial. If we and Pfizer ultimately determine to advance the BNT162b2 variant, we intend to base this decision on multiple factors, including the overall observed safety, tolerability and immunogenicity profiles for each vaccine candidate at different dose levels, as well as feedback from the FDA on the data collected for each candidate. If we ultimately move forward with the BNT162b2 variant, it will be due to the fact that based on our scientific judgment in light of the totality of preclinical data and clinical data available to us at the time of selection and the other factors described above, the BNT162b2 variant has better potential for clinical and commercial success. We do not plan to disclose which BNT162 variant has been selected until we receive FDA approval to commence the Phase 2b/3 clinical trial, and we do not plan to publish any data with respect to the BNT162b2 variant before we make our selection.

We cannot guarantee that the candidate variant that we select will ultimately prove to be the optimal variant. We and Pfizer intend to choose the variant to advance based on our scientific judgment in light of the preclinical and clinical data available to us at the time as to which variant has the best chance for success. It is possible that subsequent data regarding the variant we choose could prove to be less favorable or subsequent data from a variant that is not advanced could prove to be more favorable. In addition, it is possible that public perception of subsequently released data on the variant we choose to advance could be negative and could cause our stock price to decrease regardless of the progress of the Phase 2b/3 trial. It is also possible that the FDA may disagree with or have questions about our variant selection, which could delay the start of our Phase 2b/3 trial.

Regardless of the variant we select for Phase 2b/3, we cannot guarantee that the results from subsequent data analyses and announcements will be in line with the data that we have previously published. In addition, the total number of patients evaluated in Phase 1 is small relative to the number we intend to evaluate in Phase 2b/3 and may not be indicative of the safety or immunogenicity of BNT162 in a larger and more diverse patient population. Similarly, the samples of convalescent sera, or blood samples from people who have recovered from

COVID-19, used to benchmark the level of antibodies produced by subjects receiving BNT162 in clinical studies, have been taken from a small number of people and may not be representative of the antibody levels in a broader population of people who have recovered from COVID-19. Future results in clinical trials of BNT162 may not be as positive when compared to the antibody levels in other samples of convalescent sera.

Furthermore, because the assays being used to measure and analyze the effectiveness of COVID-19 vaccines have only recently been developed and are continuing to evolve, indications of immunogenicity and the duration of immunity observed in our Phase 1/2 trials may not be predictive of the achievement of clinically relevant endpoints.

In addition, by definition our Phase 1/2 clinical trials are designed to evaluate only safety and not efficacy. Positive results from these Phase 1/2 trials do not guarantee we will be able to demonstrate in our Phase 2b/3 trial that BNT162 is efficacious. More specifically, we do not yet know the levels of immunity required to prevent COVID-19 infection, and have not yet tested the ability of our vaccine candidates to prevent infection in humans. Failure to adequately demonstrate safety or to eventually demonstrate sufficient efficacy of BNT162 could delay or prevent us from receiving regulatory approval of BNT162 and there can be no assurance that BNT162 will be approved in a timely manner, if at all.

# The development of our BNT162 program may divert resources from the clinical development of our other product candidates and we may not recoup our investments in the program.

Although we believe that our BNT162 program could result in an effective COVID-19 vaccine, clinical trials involve a lengthy and expensive process with an uncertain outcome. Given the severity and urgency of the COVID-19 pandemic, we have committed significant capital and resources to fund and supply the development of BNT162. However, the development of BNT162 will require us to expend financial, personnel and other resources and may cause delays in or otherwise negatively impact our other development programs, despite uncertainties surrounding the longevity and extent of COVID-19 as a global health concern. Furthermore, our business could be negatively impacted by our allocation of significant resources to a global health threat that is unpredictable and could rapidly dissipate or against which our vaccine, if developed, may not be partially or fully effective.

# If we are successful in producing a vaccine against COVID-19, we may need to devote significant resources to its scale-up and development.

If any clinical trials for BNT162 are perceived to be successful, we may need to work toward the large scale technical development, manufacturing scale-up and larger scale deployment of this vaccine candidate through a variety of government mechanisms such as an Emergency Use Authorization program in the United States. We may also need to access facilities capable of rapidly manufacturing BNT162 in the volumes necessary to support large-scale clinical trials or commercial sales. If we are unable to conduct production and manufacturing activities or if our vaccine requires more doses to achieve sufficient efficacy than we expect, we may not complete our product development or commercialization efforts in a timely manner. In addition, during a global health crisis, such as the COVID-19 pandemic, where the spread of a disease needs to be controlled, closed or heavily regulated national borders will create challenges and potential delays in our development and production activities and may necessitate that we pursue strategies to develop and produce our vaccine candidate variants within self-contained national or international borders, at potentially much greater expense and with longer timeframes for public distribution.

# There can be no assurance that BNT162, even if approved, would ever become profitable, due to government interest and public perception regarding a vaccine.

As a result of the emergency situations in many countries, there is a heightened risk that a COVID-19 vaccine may be subject to adverse governmental actions in certain countries, including intellectual property expropriation, compulsory licenses, strict price controls or other actions. Additionally, we may need to, or we

may be required by governmental or non-governmental authorities to, set aside specific quantities of doses of BNT162 for designated purposes or geographic areas. We are likely to face challenges related to the allocation of supply of BNT162, particularly with respect to geographic distribution. Thus, even if BNT162 is approved, such governmental actions may limit our ability to recoup our current and future expenses.

Furthermore, public sentiment regarding commercialization of a COVID-19 vaccine may limit or negate our ability to generate revenues from sales of BNT162. Given that COVID-19 has been designated as a pandemic and represents an urgent public health crisis, we are likely to face significant public attention and scrutiny over any future business models and pricing decisions with respect to BNT162. If we are unable to successfully manage these risks, we could face significant reputational harm, which could negatively affect the price of the ADSs representing our ordinary shares.

# The regulatory pathway for BNT162 is highly dynamic and continues to evolve and may result in unexpected or unforeseen challenges.

To date, BNT162 has moved rapidly through the regulatory review process of the FDA and foreign regulatory authorities. The speed at which all parties are acting to create and test many therapeutics and vaccines for SARS-CoV-2 and COVID-19 is unusual, and evolving or changing plans or priorities within the FDA and foreign regulatory authorities, including changes based on new knowledge of COVID-19 and how the disease affects the human body, may significantly affect the regulatory timeline for BNT162. Results from clinical testing may raise new questions and require us to redesign proposed clinical trials, including revising proposed endpoints or adding new clinical trial sites or cohorts of subjects.

For example, the FDA on June 30, 2020 adopted guidance outlining the FDA's current recommendations regarding the data needed to facilitate clinical development and licensure of vaccines to prevent COVID-19. In particular, the June 30, 2020 guidance suggests that the primary efficacy endpoint estimate for a placebo-controlled efficacy trial should be at least 50%. The guidance also includes discussion of chemical, manufacturing and controls and safety concerns. Although we intend to design any future clinical trials for BNT162 in accordance with this guidance, we cannot be certain that, as the regulatory pathway continues to evolve, we will be able to complete a clinical trial in accordance with the FDA's guidance and regulations then in effect. A failure to complete a clinical trial in accordance with guidance and regulations then in effect could impair our ability to obtain approval for BNT162, which may adversely affect our operating results, reputation and ability to raise capital and enter into or maintain collaborations to advance our other product candidates.

Additionally, the FDA has the authority to grant an Emergency Use Authorization to allow unapproved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when there are no adequate, approved, and available alternatives. If we are granted an Emergency Use Authorization for BNT162, we would be able to commercialize BNT162 prior to FDA approval. However, the FDA may revoke an Emergency Use Authorization where it is determined that the underlying health emergency no longer exists or warrants such authorization, and we cannot predict how long, if ever, an Emergency Use Authorization would remain in place. Such revocation could adversely impact our business in a variety of ways, including if BNT162 is not yet approved by the FDA and if we and our manufacturing partners have invested in the supply chain to provide BNT162 under an Emergency Use Authorization.

Even if regulatory approval is received for a BNT162 vaccine candidate, the later discovery of previously unknown problems associated with BNT162 may result in restrictions, including withdrawal of the product from the market, and lead to significant liabilities and reputational damage.

Because the path to marketing approval of any vaccine against COVID-19 is unclear, we may have a widely used vaccine in circulation in the United States or another country prior to our receipt of marketing approval. Unexpected safety issues, including any that we have not yet observed in our Phase 1/2 clinical trials for BNT162, could lead to significant reputational damage for BioNTech and our technology platforms going

forward and other issues, including delays in our other programs, the need for re-design of our clinical trials and the need for significant additional financial resources.

We also may be restricted or prohibited from marketing or manufacturing a BNT162 vaccine, even after obtaining product approval, if previously unknown problems with the product or its manufacture are subsequently discovered. We cannot provide assurance that newly discovered or developed safety issues will not arise following regulatory approval. With the use of any vaccine by a wide patient population, serious adverse events may occur from time to time that did not arise in the clinical trials of the product or that initially appeared to be unrelated to the vaccine itself and only with the collection of subsequent information were found to be causally related to the product. Any such safety issues could cause us to suspend or cease marketing of our approved products, possibly subject us to substantial liabilities, and adversely affect our ability to generate revenue and our financial condition.

We may be unable to produce a successful COVID-19 vaccine and establish a competitive market share for our vaccine before a competitor or before the COVID-19 outbreak is effectively contained or the risk of coronavirus infection is significantly diminished.

A large number of vaccine manufacturers, academic institutions and other organizations currently have programs to develop COVID-19 vaccine candidates. While we are not aware of all of our competitors' efforts, we believe that the University of Oxford/AstraZeneca plc, CanSino Biologics Inc., Sanofi/GlaxoSmithKline plc Inovio Pharmaceuticals, Inc., China National Pharmaceutical Group (Sinopharm)/Beijing Institute of Biological Products and Wuhan Institute of Biological Products, Moderna, Inc., Johnson & Johnson, Novavax, Inc. and other companies are all in the early stages of developing vaccine candidates against COVID-19. Our competitors pursuing vaccine candidates may have greater financial, product candidate development, manufacturing and marketing resources than we do. Larger pharmaceutical and biotechnology companies have extensive experience in clinical testing and obtaining regulatory approval for their products, and may have the resources to heavily invest to accelerate discovery and development of their vaccine candidates.

Our efforts to develop BNT162 for regulatory approval and commercialization may fail if competitors develop and commercialize one or more COVID-19 vaccines before we are able to do so, or if they develop and commercialize one or more COVID-19 vaccines that are safer, more effective, produce longer immunity against COVID-19, require fewer administrations, have fewer or less severe side effects, have broader market acceptance, are more convenient or are less expensive than any vaccine candidate that we may develop.

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.

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. For example, various third parties have filed opposition papers challenging our issued EP patent 2714071 which relates to our iNeST product candidates, and whose claims recite steps relating to neoantigen selection.

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.

#### Risks Related to Ownership of the ADSs and the Underwritten Offering

A significant portion of our total outstanding ordinary shares after the Underwritten 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 July 21, 2020, we will have 237,673,455 ordinary shares outstanding after the Underwritten Offering. Additionally, if the Rights Offering is fully subscribed (excluding new ordinary shares underlying rights offered to holders that have irrevocably agreed not to transfer or exercise their rights), we will have 239,355,304 shares outstanding.

In connection with the Underwritten Offering, we, all of our directors and officers and certain significant shareholders have entered into lock-up agreements with the underwriters under which we and they agreed, subject to specific exceptions, not to sell any of our shares for at least 90 days following the date of this prospectus. The remaining ordinary shares will be available for sale after the Underwritten 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 the Underwritten 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 the Underwritten 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 the Underwritten Offering. Based on an assumed public offering price of \$85.25 per ADS, which was the last reported sale price of the ADSs on the Nasdaq Global Select Market on July 17, 2020, after giving effect to the Underwritten Offering, purchasers of ADSs in the Underwritten Offering will experience immediate dilution in net tangible book value of \$80.79 per ADS. In addition, after giving effect to the Underwritten Offering, investors purchasing ADSs in the Underwritten Offering will contribute 24.77% of the total amount invested by shareholders since inception but will only own 2.10% of the ordinary shares outstanding. See "Dilution" for a more detailed description of the dilution to new investors in the Underwritten Offering.

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. For example, purchasers who acquire ADSs in the Underwritten Offering will not receive rights to participate in the concurrent Rights Offering.

Under German law, the existing shareholders of a company generally have a preemptive right in proportion to the amount of shares they hold in connection with any issuance of ordinary shares, convertible bonds, bonds with warrants, profit participation rights and participating bonds. However, our shareholders in 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.

The deposit agreement provides that the depositary 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 future rights offerings and may experience dilution in their holdings. In addition, if the depositary 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. Purchasers who acquire ADSs in the Underwritten Offering will not receive rights to participate in the concurrent Rights Offering.

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 69.99% of our ordinary shares (including ordinary shares represented by ADSs) and, upon closing of the Underwritten Offering, that same group will beneficially own approximately % of our outstanding ordinary shares (including ordinary shares represented by ADSs), assuming no exercise of the underwriters' option to purchase additional ADSs from the Selling Shareholder. If the underwriters exercise in full their option to purchase additional ADSs from the Selling Shareholder, that same group will beneficially own approximately % of our outstanding ordinary shares (including ordinary shares represented by ADSs). Therefore, even after the Underwritten 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 the Underwritten 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 the Global 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 the Global Offering, in a manner that does not produce income or that loses value. See "Use of Proceeds" for more information.

### 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 and in our Annual Report on Form 20-F for the year ended December 31, 2019, incorporated by reference herein. 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 COVID-19 vaccine development program, including the timing thereof (including as it relates to the selection of a candidate variant
  and the FDA's acceptance of our candidate variant to advance into a Phase 2b/3 trial), the data therefrom, and our ability to successfully
  commercialize any approved vaccine;
- our ability to supply the quantities of BNT162 to support clinical development and, if approved, market demand, including our production estimates for 2020 and 2021;
- our expectations around the timing of entry, number of potential doses covered and amount of consideration under potential agreements for the supply of BNT162, our COVID-19 vaccine candidate, if approved;
- the impact of the evolving COVID-19 pandemic, and the global response thereto;
- 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;
- the ability to realize the anticipated benefits of transactions related to our acquisition of Neon and other acquisitions, restructuring activities, including in connection with our acquisition of Neon, or other initiatives in a timely manner or at all;
- the extent to which the Rights Offering is subscribed;
- our use of the proceeds from the Global Offering; and
- our expectations regarding the time during which we will be 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 the Underwritten Offering will be approximately \$400.7 million (€360.7 million), assuming a public offering price of \$85.25 per ADS, which was the last reported sale price of the ADSs on the Nasdaq Global Select Market on July 17, 2020, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We will not receive any proceeds from the potential sale of ADSs in this Underwritten Offering by the Selling Shareholder, pursuant to the underwriters' option to purchase additional ADSs from the Selling Shareholder.

Each \$1.00 increase (decrease) in the assumed public offering price of \$85.25 per ADS, which was the last reported sale price of the ADSs representing our ordinary shares on the Nasdaq Global Select Market on July 17, 2020, would increase (decrease) the net proceeds to us from the Underwritten Offering by approximately \$4.8 million (\$4.8 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.

If the Rights Offering to be commenced following the setting of the price to public for the Underwritten Offering, as part of the Global Offering, is fully subscribed (excluding ordinary shares underlying rights offered to holders that have irrevocably agreed not to transfer or exercise their rights), we estimate that the additional net proceeds to us in the Global Offering will be approximately \$136.2 million (€122.6 million), assuming a subscription price of \$85.25 per ordinary share or ADS, which was the last reported sale price of the ADSs on the Nasdaq Global Select Market on July 17, 2020, and after deducting fees and estimated offering expenses payable by us.

We may also increase or decrease the number of ADSs we are offering in the Underwritten Offering, which would affect the number of our ordinary shares and ADSs representing our ordinary shares underlying rights granted in the Rights Offering. An increase (decrease) of 1,000,000 in the number of ADSs offered by us would further increase (decrease) the net proceeds to us from the Global Offering by approximately €91.3 million, assuming no change in the assumed public offering price, after deducting underwriting discounts and commissions and estimated offering expenses payable by us and after giving effect to a proportionate increase (decrease) in the number of ordinary shares and ADSs representing our ordinary shares underlying rights granted in the Rights Offering, assuming the Rights Offering is fully subscribed (excluding ordinary shares underlying rights offered to holders that have irrevocably agreed not to transfer or exercise their rights).

We currently intend to use the net proceeds from the Global Offering to:

- advance our iNeST program candidate RO7198457 (BNT122) into late-stage trials;
- advance our ongoing and currently planned clinical trials for our FixVac product candidates, BNT111, BNT112, BNT113, BNT114, BNT115 and our targeted cancer antibody, MVT-5873 (BNT321), as well as fund our portion of the research and development expenses for SAR441000 (BNT131), which is being developed in collaboration with Sanofi, GEN1046 (BNT311) and GEN1042 (BNT312), which are being developed in collaboration with Genmab and advance the development of BNT162, our COVID-19 vaccine candidate, which is being developed in collaboration with Pfizer;
- initiate clinical trials for additional product candidates, including product candidates from our CAR-T, RiboMabs, RiboCytokines and TCR platforms in oncology;
- further accelerate and expand our infectious disease immunotherapy programs;
- advance our rare disease protein replacement therapy platforms outside of oncology;
- advance additional preclinical product candidates, develop additional product candidates leveraging our therapeutic platforms and fund the further development of our core technologies; and

• fund the further expansion of our manufacturing and laboratory capacity, the continued development of our infrastructure and investment in preparation for commercialization for launch of BNT162, if approved.

We expect to use the remainder of any net proceeds from the Global 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 the Global 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 closings of the Global 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 the Global Offering.

We expect that we will need to raise significant additional funds beyond the Global 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.

Based on our planned use of the net proceeds of the Global Offering and our existing cash and cash equivalents, 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 18 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 the Global 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. In addition, our ability to pay cash dividends is also limited in certain circumstances under the terms of an agreement we have entered into with the Bill & Melinda Gates Foundation. 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 March 31, 2020:

- on an actual basis;
- on a pro forma basis to give effect to (i) the issuance of 1,935,488 ADSs representing our ordinary shares in our acquisition of Neon, (ii) the issuance of 1,580,777 of our ordinary shares in a private placement to Fosun Pharma for proceeds of €45.6 million (\$50.0 million, translated using the exchange rate then in effect as published by the German Central Bank (*Deutsche Bundesbank*)) and (iii) the issuance of 2,377,446 of our ordinary shares in a private placement to Pfizer for proceeds of €103.9 million (\$113.0 million, translated using the exchange rate then in effect as published by the German Central Bank (*Deutsche Bundesbank*)); and
- on a pro forma as adjusted basis to give further effect to the sale of up to 5,000,000 ordinary shares (including ADSs representing ordinary shares) by us in the Underwritten Offering at the assumed public offering price of \$85.25 per ADS, which was the last reported sale price on the Nasdaq Global Select Market on July 17, 2020, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The table below does not reflect the effects of the issuance of the 2,595,996 ordinary shares and a mandatory convertible note to be issued in the June 2020 Private Placement, which is expected to close in August 2020, and our receipt of proceeds of €223.9 million (\$251.0 million, translated using the exchange rate then in effect as published by the German Central Bank (*Deutsche Bundesbank*)) therefrom.

Our capitalization following the Underwritten Offering will be adjusted based on the actual public offering price and other terms of the Underwritten 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 in this prospectus titled "Use of Proceeds" and "Selected Consolidated Financial Data" and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Forms 20-F and 6-K incorporated by reference herein.

	As of March 31, 2020		
	Actual	Pro Forma	Pro Forma As Adjusted(1)
(in thousands except share data)		(unaudited)	
Cash and cash equivalents	€ 451,597	€ 601,055	€ 961,770
Total debt	19,548	19,548	19,548
Equity			
Ordinary shares, no par value per share: 232,304,250 shares, actual; 238,197,961 shares, pro forma; 243,197,961 shares, pro forma as adjusted			
Share capital	232,304	238,198	243,198
Capital reserve	686,714	919,826	1,275,541
Treasury shares	(5,525)	(5,525)	(5,525)
Accumulated losses	(478,213)	(478,213)	(478,213)
Other reserves	12,850	12,850	12,850
Total equity	448,130	687,136	1,047,851
Total capitalization	€ 467,678	€ 706,684	€ 1,067,399

(1) Each \$1.00 increase (decrease) in the assumed public offering price of \$85.25 per ADS, which was the last reported sale price of the ADSs on the Nasdaq Global Select Market on July 17, 2020, would increase

(decrease) each of cash and cash equivalents, capital reserve, total equity and total capitalization by approximately €4.3 million (€4.3 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. If the Rights Offering is fully subscribed (excluding ordinary shares underlying rights offered to holders that have irrevocably agreed not to transfer or exercise their rights), our cash and cash equivalents and total equity would each increase by €122.6 million, our share capital would increase by €1.7 million and our capital reserve would increase by €120.9 million. We may also increase or decrease the number of ADSs we are offering in the Underwritten Offering, which would affect the number of our ordinary shares and ADSs representing our ordinary shares underlying rights granted in the Rights Offering. An increase (decrease) of 1,000,000 in the number of ADSs offered by us would increase (decrease) each of cash and cash equivalents, total equity, and total capitalization by approximately €91.3 million, assuming no change in the assumed public offering price, after deducting underwriting discounts and commissions and estimated offering expenses payable by us and after giving effect to a proportionate increase (decrease) in the number of ordinary shares and ADSs representing our ordinary shares underlying rights granted in the Rights Offering, assuming the Rights Offering is fully subscribed (excluding ordinary shares underlying rights offered to holders that have irrevocably agreed not to transfer or exercise their rights).

The number of our ordinary shares issued and outstanding actual is based on 232,304,250 ordinary shares outstanding (including 5,524,506 shares held in treasury) as of March 31, 2020 and excludes:

- 16,338,305 ordinary shares available for issuance upon the exercise of options outstanding as of March 31, 2020;
- 254,065 ordinary shares available for issuance upon the exercise of options expected to be granted in 2021 and 2022 under our long-term incentive program as of March 31, 2020; and
- 5,282,436 ordinary shares available for future issuance under our Employee Stock Ownership Plan or any future share option plan as of March 31, 2020 (after taking into account the issuance of options expected to be granted in 2021 and 2022).

#### DILUTION

If you invest in the ADSs in the Underwritten Offering, your interest will be diluted immediately to the extent of the difference between the public offering price per ADS and our as adjusted net tangible book value per ADS after completion of the Underwritten Offering. The discussion in this section does not reflect the effects of the issuance of the 2,595,996 ordinary shares and a mandatory convertible note to be issued in the June 2020 Private Placement, which is expected to close in August 2020, and our receipt of proceeds of €223.9 million (\$251.0 million, translated using the exchange rate then in effect as published by the German Central Bank (*Deutsche Bundesbank*)) therefrom.

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 March 31, 2020. As of March 31, 2020, we had a historical net tangible book value of €354.2 million (\$393.4 million), corresponding to a net tangible book value per ordinary share of €1.56 (\$1.73) (equivalent to \$1.73 per ADS). Our pro forma net tangible book value as of March 31, 2020 was €593.2 million (\$658.9 million), corresponding to a pro forma net tangible book value per ordinary share of €2.55 (\$2.83) (equivalent to \$2.83 per ADS), based on the total number of shares of our common stock outstanding as of March 31, 2020, and after giving effect to (i) the issuance of 1,935,488 ADSs representing our ordinary shares in connection with our acquisition of Neon, (ii) the issuance of 1,580,777 of our ordinary shares in a private placement to Fosun Pharma for proceeds of €45.6 million (\$50.0 million, using the exchange rate then in effect as published by the German Central Bank (*Deutsche Bundesbank*)) and (iii) the issuance of 2,377,446 of our ordinary shares in a private placement to Pfizer for proceeds of €103.9 million (\$113.0 million, using the exchange rate then in effect as published by the German Central Bank (*Deutsche Bundesbank*)).

After giving effect to the issuance and sale of 5,000,000 ADSs in the Underwritten Offering at an assumed public offering price of \$85.25 per ADS, which was the last reported sale price of the ADSs on the Nasdaq Global Select Market on July 17, 2020, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of March 31, 2020 would have been  $\$ 954.0 million (\$1,059.6 million), corresponding to a net tangible book value per ordinary share of  $\$ 4.02 (\$4.46) (equivalent to \$4.46 per ADS). This represents an immediate increase in net tangible book value of  $\$ 1.47 (\$1.63) per ordinary share (equivalent to \$1.63 per ADS) to existing shareholders and immediate dilution of \$80.79 per ADS to new investors purchasing ADSs in the Underwritten Offering. Dilution per ADS to new investors is determined by subtracting our pro forma as adjusted net tangible book value per ADS from the assumed public offering price per ADS paid by new investors.

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

Assumed public offering price per ADS		\$85.25
Historical net tangible book value per ADS as of March 31, 2020	\$1.73	
Pro forma net tangible book value per ADS as of March 31, 2020	\$2.83	
Increase in net tangible book value per ADS attributable to the Underwritten		
Offering	\$1.63	
Pro forma as adjusted net tangible book value per ADS after the Underwritten Offering		\$ 4.46
Dilution per ADS to new investors participating in the Underwritten Offering		\$80.79

Each \$1.00 increase (decrease) in the assumed public offering price of \$85.25 per ADS, which was the last reported sale price of the ADSs on the Nasdaq Global Select Market on July 17, 2020, would increase (decrease) our pro forma as adjusted net tangible book value as of March 31, 2020 by \$0.02 (\$0.02) per ADS, and would

increase (decrease) dilution to new investors in the Underwritten Offering by \$0.02 (\$0.02) 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. In addition, if the Rights Offering is fully subscribed (excluding ordinary shares underlying rights offered to holders that have irrevocably agreed not to transfer or exercise their rights), our pro forma as adjusted net tangible book value per ADS would be \$5.00, representing an immediate increase in pro forma as adjusted net tangible book value to existing shareholders of \$2.17 per ADS and immediate dilution of \$80.25 per ADS to new investors, after deducting underwriting discounts and commissions, fees and estimated offering expenses payable by us. We may also increase or decrease the number of ADSs we are offering in the Underwritten Offering, which would affect the number of our ordinary shares and ADSs representing our ordinary shares underlying rights granted in the Rights Offering. An increase (decrease) of 1,000,000 in the number of ADSs offered by us would further increase (decrease) our pro forma as adjusted net tangible book value as of March 31, 2020 by \$0.39 (\$0.40) per ADS, and would decrease (increase) dilution to new investors in the Underwritten Offering by \$0.39 (\$0.40) per ADS, assuming no change in the assumed public offering price, after deducting underwriting discounts and commissions and estimated offering expenses payable by us and after giving effect to a proportionate increase (decrease) in the number of ordinary shares and ADSs representing our ordinary shares underlying rights granted in the Rights Offering, assuming the Rights Offering is fully subscribed (excluding ordinary shares underlying rights offered to holders that have irrevocably agreed not to transfer or exercise their rights).

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

The following table sets forth, on a pro forma as adjusted basis as of March 31, 2020, after giving effect to (i) the issuance of 1,935,488 ADSs representing our ordinary shares in connection with our acquisition of Neon, (ii) the issuance of 1,580,777 of our ordinary shares in a private placement to Fosun Pharma for proceeds of €45.6 million (\$50.0 million, using the exchange rate then in effect as published by the German Central Bank (*Deutsche Bundesbank*)) and (iii) the issuance of 2,377,446 of our ordinary shares in a private placement to Pfizer for proceeds of €103.9 million (\$113.0 million, using the exchange rate then in effect as published by the German Central Bank (*Deutsche Bundesbank*)), the number of ordinary shares owned by existing shareholders and to be owned by new investors purchasing ADSs in the Underwritten Offering, the total consideration paid by existing shareholders and new investors purchasing ADSs in the Underwritten Offering. The calculation below is based on an assumed public offering price of \$85.25 per ADS, which was the last reported sale price on the Nasdaq Global Select Market on July 17, 2020, before deducting underwriting discounts and commissions and estimated offering expenses payable by us:

	Ordinary Shares			Average				
	Purchase Number	Percent	Total Consideration Amount Percent			rice Share	Average Price Per ADS	
Existing shareholders	232,673,455	97.90%	\$1,294,746,948	75.23%	\$	5.56	\$	5.56
Investors participating in the Underwritten Offering	5,000,000	2.10%	\$ 426,250,000	24.77%				
Total	237,673,455	100%	\$1,720,996,948	\$ 100%	\$	7.24	\$	7.24

Each \$1.00 increase (decrease) in the assumed public offering price of \$85.25 per ADS, which was the last reported sale price of the ADSs on the Nasdaq Global Select Market on July 17, 2020, would increase (decrease) the total consideration paid by new investors by \$5.0 million and increase (decrease) the percentage of total consideration paid by new investors by approximately 0.22% (0.22%), 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. We may also increase or decrease the number of ADSs we are offering in the Underwritten Offering, which would affect the number of our ordinary shares and ADSs representing our ordinary shares underlying rights granted in the Rights Offering.

An increase (decrease) of 1,000,000 in the number of ADSs offered by us would increase (decrease) the total consideration paid by investors participating in this offering by \$106.7 million (\$106.7 million), and increase (decrease) the percentage of total consideration paid by new investors by 4.39% (4.97%), assuming no change in the assumed public offering price and before deducting underwriting discounts and commissions and estimated offering expenses payable by us and after giving effect to a proportionate increase (decrease) in the number of ordinary shares and ADSs representing our ordinary shares underlying rights granted in the Rights Offering, assuming the Rights Offering is fully subscribed (excluding ordinary shares underlying rights offered to holders that have irrevocably agreed not to transfer or exercise their rights).

The number of our ordinary shares issued and outstanding actual, is based on 226,779,744 ordinary shares outstanding as of March 31, 2020 and excludes:

- 16,338,305 ordinary shares available for issuance upon the exercise of options outstanding as of March 31, 2020;
- 254,065 ordinary shares available for issuance upon the exercise of options expected to be granted in 2021 and 2022 under our long-term incentive program as of March 31, 2020;
- 5,282,436 ordinary shares available for future issuance under our Employee Stock Ownership Plan or any future share option plan as of March 31, 2020 (after taking into account the issuance of options expected to be granted in 2021 and 2022); and
- 5,524,506 ordinary shares held in treasury.

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 December 31, 2019, for the years ended December 31, 2019, 2018 and 2017, as of March 31, 2020 and for the three months ended March 31, 2020 and 2019. We derived the selected consolidated statements of operations for the years ended December 31, 2019, 2018 and 2017 and the selected consolidated statement of financial position data as of December 31, 2019 from our audited consolidated financial statements incorporated by reference herein. The selected consolidated statements of operations data for the three months ended March 31, 2020 and 2019 and the selected consolidated statement of financial position data as of March 31, 2020 have been derived from our unaudited interim condensed consolidated financial statements incorporated by reference herein and have been prepared on the same basis as the audited financial statements. In the opinion of management, the unaudited interim data reflects all adjustments necessary for a fair presentation of the financial information in those statements. 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, our unaudited interim condensed consolidated financial statements and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Forms 20-F and 6-K incorporated by reference herein, as well as the section of this prospectus titled "Capitalization." Our historical results for any prior period are not necessarily indicative of results to be expected in any future period, and the results for the three months ended March 31, 2020 are not necessarily indicative of the results to be expected for the full year ended December 31, 2020.

	For Three Mon Marc	ths Ended	Fo	i .	
(in thousands except per share data)	2020 (unau	2019	2019	2018	2017
Consolidated statements of operations:	(unau	uiteu)			
Revenues from contracts with customers	€ 27,663	€ 26,154	€ 108,589	€ 127,575	€ 61,598
Cost of sales	(5,842)	(3,205)	(17,361)	(13,690)	(9,318)
Gross profit	€ 21,821	€ 22,949	€ 91,228	€ 113,885	€ 52,280
Research and development expenses	(65,122)	(57,241)	(226,466)	(143,040)	(85,496)
Sales and marketing expenses	(486)	(560)	(2,718)	(3,041)	(6,603)
General and administrative expenses	(15,815)	(9,276)	(45,547)	(26,334)	(23,520)
Other operating income	425	331	2,724	5,396	2,349
Other operating expenses	(100)	(38)	(739)	(720)	(288)
Operating loss	€(59,277)	€(43,835)	€(181,518)	€ (53,854)	€(61,277)
Finance income	6,417	3,578	4,122	8,046	2,133
Finance expenses	(103)	(74)	(326)	(48)	(26,007)
Interest expenses related to lease liability	(415)	(425)	(1,718)	(1,721)	(676)
Share of loss of equity method investees		_		(84)	(78)
Loss before tax	€(53,378)	€(40,756)	€(179,440)	€ (47,662)	€(85,905)
Income taxes	(8)	(6)	268	(600)	(45)
Loss for the period	€(53,386)	<b>€(40,762)</b>	<b>€(179,172)</b>	€ (48,262)	€(85,950)
Loss attributable to equity holders of the parent	(53,386)	(40,646)	(179,056)	(48,019)	(85,653)
Loss attributable to non-controlling interests		(116)	(116)	(243)	(297)
Basic and diluted loss per share	€ (0.24)	€ (0.20)	€ (0.85)	€ (0.25)	€ (0.51)

	A	s of
	March 31, 2020	December 31, 2019
(in thousands)	(unaudited)	
Consolidated statement of financial position:		
Cash and cash equivalents	€ 451,597	€ 519,149
Total assets	732,208	797,647
Total liabilities	284,078	304,155
Share capital	232,304	232,304
Accumulated losses	(478,213)	(424,827)
Total equity	€ 448,130	€ 493,492

### UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

On May 6, 2020, BioNTech SE, or BioNTech, announced the closing of the Neon Therapeutics, Inc., or Neon, acquisition. The merger agreement was first announced on January 16, 2020. Based on the acquisition date share price, the implied aggregate value of the merger consideration was approximately \$97.1 million (€89.9 million using the exchange rate as of closing) financed by issuing new ordinary shares as a stock transaction and including de minimis cash consideration which was paid to settle Neon's outstanding stock options.

The following unaudited pro forma condensed combined financial information are based on BioNTech's historical consolidated financial statements prepared in accordance with International Financial Reporting Standards as issued by the IASB, or IFRS, and Neon's historical consolidated financial statements as adjusted to give effect to our acquisition of Neon. As Neon prepared its financial statements in accordance with U.S. generally accepted accounting principles, or U.S. GAAP, and applied U.S. dollars as its reporting currency, adjustments have been made to convert Neon's financial statements to IFRS and its reporting currency to Euros. Please see Notes 2 and 3 to the unaudited pro forma condensed combined financial information for a discussion of the adjustments made to convert Neon's financial information from U.S. GAAP to IFRS.

The unaudited pro forma condensed combined statement of operations for the year ended December 31, 2019 and the three months ended March 31, 2020 gives effect to this transaction as if it had occurred on January 1, 2019. The unaudited pro forma condensed combined statement of financial position as of March 31, 2020 gives effect to this transaction as if it had occurred on March 31, 2020.

The unaudited pro forma condensed combined financial information includes the latest estimates of the fair value of Neon's assets to be acquired and liabilities to be assumed and the related allocations of the purchase price using the factual circumstances as of the time of closing. These figures are applied to the unaudited condensed combined statement of financial position as of March 31, 2020. As the detailed valuation studies are still ongoing, these estimates and assumptions are subject to change.

As indicated in Note 5 to the unaudited pro forma condensed combined financial information, BioNTech has made certain adjustments to adjust the historical book values of the assets and liabilities of Neon to reflect preliminary estimates of the fair values necessary to prepare the unaudited pro forma condensed combined financial information, with the excess of the estimated purchase price over the net assets of Neon, as adjusted to reflect estimated fair values, recorded as goodwill.

Additionally, as indicated in Note 2 to the unaudited pro forma condensed combined financial information, estimated effects related to the application of IFRS have been based on preliminary assessments and as indicated in Note 3 to the unaudited pro forma condensed combined financial information, the reporting currency has been applied based on a simplified method. Actual results are expected to differ from this unaudited pro forma condensed combined financial information once BioNTech has completed the valuation studies necessary to finalize the required purchase price allocation and finalized conforming accounting changes for Neon. Such differences may be material.

The assumptions and estimates underlying the unaudited adjustments to the pro forma condensed combined financial information are described in the accompanying notes, which should be read together with the pro forma condensed combined financial information. The unaudited pro forma condensed combined financial information should be read together with:

• BioNTech's audited consolidated financial statements and related notes incorporated by reference in this registration statement as of December 31, 2019 and 2018 and for the years ended December 31, 2019, 2018 and 2017;

- BioNTech's unaudited interim condensed consolidated financial statements and related notes incorporated by reference in this registration statement as of and for the three months ended March 31, 2020 and for the three months ended March 31, 2019;
- Neon's audited consolidated financial statements and related notes as of December 31, 2019 and 2018 and for the years then ended incorporated by reference in this registration statement; and
- Neon's unaudited interim condensed consolidated financial statements and related notes as of March 31, 2020 and for the three months ended March 31, 2020 and 2019 incorporated by reference in this registration statement.

The unaudited pro forma condensed combined financial information does not include the realization of any future cost savings or restructuring or integration charges that are expected to result from the Merger.

The unaudited pro forma condensed combined financial information is not intended to represent or be indicative of the consolidated results of operations and financial condition of the consolidated company that would have been reported had the acquisition been completed as of the dates presented, and should not be taken as being representative of the future consolidated results of operations or financial condition of the consolidated company.

# **Unaudited Pro Forma Condensed Combined Statement of Financial Position**

as of March 31, 2020 (in thousands)

	BioNTech SE Historical IFRS EUR	Neon Therapeutics, Inc. Historical US GAAP USD	Neon Therapeutics, Inc. Historical US GAAP EUR1	Neon Therapeutics, Inc. IFRS Adjustments EUR1	Pro Forma Adjustments EUR1	Notes	Pro Forma Combined EUR1
Intangible assets	93,932	_			83,618	5 a), 5 e)	177,550
Property, plant and equipment	96,290	6,694	6,110	_	(482)	5 e)	101,918
Right-of-use assets	49,131	7,228	6,597	290	_	2 a)	56,018
Other non-current assets	_	471	430	_	_		430
Total non-current assets	239,353	14,393	13,137	290	83,136		335,916
Inventories	9,629	_	_	_	_		9,629
Trade receivables	10,310	_	_	_	_		10,310
Deferred expenses and other current assets	21,319	1,962	1,791	_	_		23,110
Cash and cash equivalents	451,597	15,047	13,734	_	_		465,331
Total assets	732,208	31,402	28,662	290	83,136		844,296
Total shareholders' equity	448,130	14,431	13,172	290	74,868	2 a), 5 a), 5 d)	536,460
Contract liabilities	75,187	_	_	_	_		75,187
Deferred tax liabilities	_	_	_	_	7,931	5 b)	7,931
Other non-current liabilities	66,848	6,2042	5,663				72,511
Total non-current liabilities	142,035	6,204	5,663	_	7,931		155,629
Trade payables	19,417	3,043	2,777	_	_		22,194
Contract liabilities	94,824	_	_	_	_		94,824
Other current liabilities	27,802	7,7243	7,050		337	5 c)	35,189
Total liabilities	284,078	16,971	15,490		8,268		307,836
Total liabilities and equity	732,208	31,402	28,662	290	83,136		844,296

<sup>(1)</sup> Please see Note 3 to the unaudited pro forma condensed combined financial information.

<sup>(2)</sup> Consists of operating lease liabilities of \$6,200 and other liabilities of \$4.

<sup>(3)</sup> Consists of accrued expenses of \$6,437 and operating lease liabilities of \$1,287.

# **Unaudited Pro Forma Condensed Combined Statement of Operations**

For the year ended December 31, 2019 (in thousands, except for per share information)

	BioNTech SE	Neon Therapeutics, Inc.	Neon Therapeutics, Inc.	Neon Therapeutics, Inc.			
	Historical IFRS EUR	Historical US GAAP USD	Historical US GAAP EUR1	IFRS Adjustments EUR1	Pro Forma Adjustments EUR1	Notes	Pro Forma Combined EUR1
Revenue	108,589	_	_	_	_		108,589
Cost of sales	(17,361)	_	_	_	_		(17,361)
Research and development expenses	(226,466)	(59,718)	(53,768)	(226)	(1,117)	2 a), 2 b)	(281,577)
Sales and marketing expenses	(2,718)	_	_	_	_		(2,718)
General and administrative expense	(45,547)	(21,420)	(19,286)	(715)	_	2 a), 2 b)	(65,548)
Other operating income	2,724	_	_	_	_		2,724
Other operating expenses	(739)						(739)
Operating loss	(181,518)	(81,138)	(73,054)	(941)	(1,117)		(256,630)
Finance income, net	2,078	1,401	1,261	(660)	_	2 a)	2,679
Other expenses		(39)	(35)				(35)
Loss before tax	(179,440)	(79,776)	(71,828)	(1,601)	(1,117)		(253,986)
Income taxes	268	_	_	_	_		268
Loss for the period	(179,172)	(79,776)	(71,828)	(1,601)	(1,117)		(253,718)
Loss for the period attributable to							
non-controlling interests	(116)	_	_	_	_		(116)
Net loss attributable to common stockholders	(179,056)	(79,776)	(71,828)	(1,601)	(1,117)		(253,602)
Basic and diluted loss per share	(0.85)						(1.19)
Weighted-average shares	211,499				1,935		213,434

<sup>(1)</sup> Please see Note 3 to the unaudited pro forma condensed combined financial information.

### **Unaudited Pro Forma Condensed Combined Statement of Operations**

For the three months ended March 31, 2020 (in thousands, except for per share information)

	BioNTech SE Historical IFRS	Neon Therapeutics, Inc. Historical US GAAP	Neon Therapeutics, Inc. Historical US GAAP	Neon Therapeutics, Inc. IFRS Adjustments	Pro Forma Adjustments	N.	Pro Forma Combined
Revenue	EUR 27,663	USD	EUR1	EUR1	EUR1	Notes	EUR1 27,663
Cost of sales	(5,842)	_	_	_	_		(5,842)
Research and development expenses	(65,122)	(9,446)	(8,566)	407	(279)	2 a), 2 b)	(73,560)
Sales and marketing expenses	(486)		_	_		,, ,	(486)
General and administrative expense	(15,815)	(7,220)	(6,548)	518	_	2 a), 2 b)	(21,845)
Other operating income	425	_	_	_	_		425
Other operating expenses	(100)	_	_	_	_		(100)
Operating (loss) income	(59,277)	(16,666)	(15,114)	925	(279)		(73,745)
Finance income, net	5,899	68	62	(167)	_	2 a)	5,794
Other expenses	_	_	_	_	_		_
(Loss) income before tax	(53,378)	(16,598)	(15,052)	758	(279)		(67,951)
Income taxes	(8)	_	_	_	_		(8)
Net (loss) income attributable to common							
stockholders	(53,386)	(16,598)	(15,052)	758	(279)		(67,959)
Basic and diluted loss per share	(0.24)						(0.30)
Weighted-average shares	226,779				1,935		228,714

<sup>(1)</sup> Please see Note 3 to the unaudited pro forma condensed combined financial information.

### **Notes to Unaudited Pro Forma Condensed Combined Financial Information**

### 1 Basis of preparation

The historical consolidated financial statements of BioNTech and Neon have been adjusted in the unaudited pro forma condensed combined financial information to give effect to pro forma events that are (1) directly attributable to the business combination, (2) factually supportable and (3) with respect to the unaudited pro forma condensed combined statements of operations, expected to have a continuing impact on the combined results following the business combination. The business combination was accounted for under the acquisition method of accounting in accordance with IFRS 3, Business Combinations. As the acquirer for accounting purposes, BioNTech has performed preliminary estimates of the fair value of Neon's assets acquired and liabilities assumed and performed a preliminary conversion to conform the U.S. GAAP accounting policies of Neon to its own accounting policies under IFRS.

## 2 Accounting policy conformity changes

The historical financial information of Neon was prepared in accordance with U.S. GAAP. The following preliminary adjustments convert Neon's financial information from U.S. GAAP to IFRS and align Neon's accounting policies to those applied by BioNTech.

- a) Neon adopted ASC 842 as of January 1, 2019 for lease accounting. For the year ended December 31, 2019 and the three months ended March 31, 2020, BioNTech applied IFRS 16 for lease accounting. The following adjustments reflect as if Neon had adopted IFRS 16 as of January 1, 2019:
  - Decrease in research and development expenses of k€349 and decrease of general and administrative expenses of k€78 and increase of finance expense of k€660 the year ended December 31, 2019, respectively, due to increased depreciation and reclassification of operating lease interest expense into finance expense.
  - Decrease in research and development expenses of k€99 and decrease of general and administrative expenses of k€22 and increase
    of finance expense of k€167 the three months ended March 31, 2020, respectively, due to increased depreciation and reclassification
    of operating lease interest expense into finance expense.
  - Increase in right-of-use assets and total shareholder's equity of k€290 as of March 31, 2020.
- b) The following adjustments reflect the change from straight-line method to the accelerated method of recognizing stock compensation expense per IFRS 2 and the reversal of mark-to-market expense for stock options granted to non-employees:
  - Increase in research and development expenses of k€575 and increase in general and administrative expenses of k€793 for the year ended December 31, 2019.
  - Decrease in research and development expenses of k€308 and decrease in general and administrative expenses of k€496 for the three
    months ended March 31, 2020.

# 3 Foreign currency adjustments

The historical consolidated financial statements of Neon were presented in U.S. dollars. The historical financial information was translated from U.S. dollars to Euro using the following historical exchange rates:

	\$/€
Average exchange rate for the year ended December 31, 2019	1.11
Average exchange rate for the three months ended March 31, 2020	1.10
Period end exchange rate as of March 31, 2020	1.10
Exchange rate as of closing	1.08

### 4 Business combination

Financing transaction

BioNTech completed the acquisition of Neon for 0.063 new ADSs representing new ordinary shares of BioNTech in exchange for each outstanding share of Neon common stock and settled Neon's outstanding stock options in cash.

# Preliminary purchase price allocation

BioNTech has performed a preliminary valuation analysis of the fair market value of Neon's assets and liabilities. The following table summarizes the preliminary purchase price allocation as of March 31, 2020 including the consideration based on factual circumstances as of closing date (in thousands). The total consideration was calculated based on the new shares issued as of closing, and included the acquisition date share price as well as a cash consideration which will be made to settle Neon's outstanding stock options. The USD consideration is translated into Euro as of March 31, 2020 using the period end exchange rate as of March 31, 2020.

Total consideration	€88,667
Intangible assets	€ 482
Property, plant and equipment	€ 5,628
Right-of-use assets	€ 6,887
In-process research and development	€29,032
Prepaid expenses and other assets	€ 2,221
Cash and cash equivalents	€13,734
Long-term liabilities	€ (5,663)
Accounts payable	€ (2,777)
Other liabilities	€ (7,050)
Deferred tax liabilities, net	€ (7,931)
Goodwill	€54,104

This preliminary purchase price allocation has been used to prepare pro forma adjustments in the unaudited pro forma condensed combined statement of financial position and statement of operations. The final purchase price allocation will be determined when BioNTech has completed the detailed valuations and necessary calculations. The final allocation could differ materially from the preliminary allocation used in the pro forma adjustments. The final allocation may include material changes in allocations to intangible assets such as licenses, technology and customer relationships as well as goodwill and other changes to assets and liabilities.

### 5 Pro forma adjustments

The pro forma adjustments are based on BioNTech's preliminary estimates and assumptions that are subject to change. The following adjustments have been reflected in the unaudited pro forma condensed combined financial information:

- a) Reflects the adjustment of intangible assets acquired by BioNTech to their estimated fair values. As part of the preliminary valuation analysis, BioNTech identified intangible assets in form of in-process research and development projects. The fair value of identifiable intangible assets is determined primarily using the income method approach. Since all information required to perform a detailed valuation analysis of Neon's intangible assets could not be obtained as of the date of this filing, for purposes of these unaudited pro forma condensed combined financial information, BioNTech used certain assumptions based on publicly available data for the industry. Amortization for the in-process research and development in the amounts of k€1,117 for the year ended December 31, 2019 and k€279 for the three months ended March 31, 2020 has been reflected in the unaudited pro forma condensed combined statements of operations. These preliminary estimates of fair value will likely differ from final amounts BioNTech will calculate after completing a detailed valuation analysis, and the difference could have a material impact on the accompanying unaudited pro forma condensed combined financial information. A change in the valuation of intangible assets would correspond to an increase or decrease in the balance of goodwill.
- b) Adjusts the deferred tax liabilities resulting from the acquisition. The estimated increase in deferred tax liabilities to k€7,931 stems primarily from the fair value adjustments for non-deductible intangible assets based on an estimated tax rate of 27.32%. This estimate of deferred income tax balances is preliminary and subject to change based on management's final determination of the fair value of assets acquired and liabilities assumed by jurisdiction.
- c) Represents the cash consideration which will be made to settle Neon's outstanding stock options.

d) Represents the elimination of the historical equity of Neon and the issuance of ordinary shares to finance the acquisition, as follows (in thousands):

Net equity proceeds from issuance of 0.063 American Depositary Shares of the	
Company per share of Neon and cash settlement of Neon's outstanding stock	
options	€ 88,330
Less: historical Neon shareholders' equity converted into Euro and IFRS adjusted as	
of March 31, 2020	<b>€</b> (13,462)
Pro forma adjustment to shareholders' equity	€ 74,868

e) The adjustment reclassifies software assets of k€482 from property, plant and equipment to intangibles to conform the presentation of the balance of BioNTech's presentation.

#### 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 suite of patient profiling and bioinformatic tools to develop immunotherapies for cancer and 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. The breadth of our immunotherapy technologies and expertise has also enabled us to develop therapies to address a range of rare and infectious diseases, and we have recently rapidly mobilized these with the aim of addressing the COVID-19 pandemic. 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 12 have entered into 13 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 500 patients across 17 tumor types to date. Our immunotherapy drug classes consist of messenger ribonucleic acid, or mRNA, therapeutics, 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 1,400 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 GmbH, or Genevant, Bayer AG, or Bayer, Pfizer Inc., or Pfizer, and Shanghai Fosun Pharmaceutical (Group) Co., Ltd., or Fosun Pharma. We have built out comprehensive, highly automated, on-demand in-house manufacturing capabilities that complement the development of our individualized immunotherapies.

Our immunotherapy product candidates span the following four distinct 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, the University of Pennsylvania, Genevant and Fosun Pharma we are also leveraging our mRNA technology beyond oncology to address COVID-19, influenza, other infectious diseases and rare diseases.
- **Cell Therapies.** We are developing a range of cell therapies, including chimeric antigen receptor, or CAR, T cells, neoantigen-based T cell therapies and T cell receptor, or TCR, therapies, in which the patient's T cells are modified or primed to target cancer-specific antigens We are also combining our mRNA FixVac platform with our first CAR-T product candidates, using "CARVac" immune boosters 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.

We have leveraged these four drug classes to build a robust pipeline of product candidates. Our pipeline includes 12 product candidates in 13 ongoing clinical trials. Our most advanced programs are focused on oncology, where we have to-date treated over 500 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 are targeting the advancement of up to three product candidates into the clinic in 2020, with clinical data updates for up to four additional 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 believe our technology and expertise is broadly applicable across a number of therapeutic areas, such as infectious diseases and rare diseases. In April 2020, we initiated a first-in-human clinical trial program for our BNT162 vaccine program to prevent COVID-19, which includes four vaccine candidate variants based on three distinct mRNA formats. We are co-developing BNT162 with Pfizer worldwide (ex-China) and with Fosun Pharma in China. We initiated the BNT162 program in late January 2020 in response to the global COVID-19 pandemic, and initiated human testing following preclinical studies and within approximately three months of initiating the research program. On July 1 and July 20, 2020, we and Pfizer announced preliminary data from our Phase 1/2 clinical trials of BNT162. Our ability to rapidly design and test multiple vaccine variants leveraged our deep experience with mRNA vaccines and our prior preclinical work in the infectious disease field.

We have established multiple collaborations to advance our science and development capabilities and provide capital, most of which has been non-dilutive. 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, Bayer, Pfizer and Fosun Pharma. 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 and with Pfizer and Fosun Pharma to develop a COVID-19 vaccine, each utilizing our mRNA-based immunotherapy technology. We also have a collaboration with Genevant to develop protein replacement therapies in up to five rare disease indications. Furthermore, we are collaborating with the University of Pennsylvania, or Penn, to develop mRNA-based vaccines in up to 10 additional infectious disease indications. 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 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 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.

#### **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. 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, CorImmun, 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 office 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. Ryan Richardson, our Chief Strategy Officer, joined BioNTech from J.P. Morgan Securities LLC, where he served as Executive Director, Healthcare Investment Banking. 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.

# **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)	Pre- clinical		Phase 2	Phase 3	Rights/ Collaborator	Milestones
		BNT111	Advanced melanoma (Adjuvant & Metastatic)					Global	Report Phase 1 data: publication upcoming: Phase 2 with registrational
	FivVac	BNT112	Prostate cancer					Global	potential start 2H 2020
	(fixed combination	BNT113	HPV16+ head and neck cancer!					Global	Phase 2 with registrational potential start 2H 2020
	of shared cancer antigens)	BNT114	Triple negative breast cancer					Global	Data update 2H 2020
		BNT115	Ovarion cancer <sup>1</sup>					Global	
		BNT116	NSCLC					Global	Phase 1 start 1H 2021
mRNA	INeST (patient specific cancer artigen therapy)	RO7198457 (BNT122 <sup>2</sup> )	IL melanoma with CPF Multiple solid tumors NSCLC and colorectal cancer (Adjuvant)					Generatech (global 50:50 profit/loss share)	Encollment update 2H 2020 <sup>4</sup> ; interim data update in 2H 2021 Two Phase 2 trials planned 2H 2020
	Intratumoral Immunotherapy	SAR441000 (BNT131)	Solid tumors (IL-12rc, IL-15saski, GM-CSF, IFNa)		-			Sanofi (global profit/ loss share)	Data update 2H 2020*
	RiboMabs (mRNA-	BNT141	Multiple solid tumors					Global	Phase 1 start 1H 2021
	encoded antibodies)	BNT142	Multiple solid tumors (CD3+CLDN6)					Global	Phase 1 start 1H 2021
	RiboCytokines (mRNA-encoded	BNT151	Multiple solid tumors (Optimized IL-2)					Global	Phase I start IH 2021
	cytokines)	BNT152, BNT153	Multiple solid tumors (IL-7, IL-2)					Global	Phase 1 start 1H 2021
		BNT211	Multiple solid tumors (CLDN6)					Global	Phase I/2 start 2H 2020
. š.	CAR-T Cells	BNT212	Pancreatic, other cancers (CLDN/8.2)					Global	
Cell	Neoantigen-based T cell therapy	BNT221 (NEO-PTC-01)						Global	Phase 1 start 2H 2020
	TCRs	To be selected	All tumors					Global	
	Next-Gen CP <sup>4</sup>	GEN1046 (BNT311)	Multiple solid tumors (PD-L1×4-1BB)					Genmab (global 50:50	Data update 2H 2020
Antibodies	Immunomodulators	GEN1042 (BNT312)	Multiple solid tumors (CD40×4-1BB)					profit/loss share)	
Αn	Targeted Cancer Antibodies	BNT321 (MVT-5873)	Pancreatic cancer (sLe-)		-			Global	
MINS	Toll-Like Receptor Binding	BNT411	Solid tumors (TLR7)					Global	

### Other

Drug Class	Platform	Product Candidate	Indication (Targets)	Pre- clinical	Phase 1	Phase 2	Phase 3	Rights/ Collaborator	Milestones
		BNT161	Influenza					Pfizer	Phase 1 start 2021
mRNA		BNT162	COVID-19		-			Fosun Pharma (China), Pfizer (Global, except China)	Phase 2/3 start late July 2020
	Infectious Disease Immunotherapies	To be selected	Up to 10 indications					Penn*	First Phase 1 trial to start 1H 2021
		To be selected	HIV and tuberculosis					Bill & Melinda Gates Foundation	
	Rare Disease PRT <sup>6</sup>	BNT171 To be selected	Not disclosed 4 more rare disease indications					Genevant (global 50:50 profit/loss share)	Phase 1 start 2H 2021

- BNT113 and BNT115 are currently being studend in invostigated phase 1 trials

  2 BNT122 (NeST) is invostigated in arm 2 (Ne15) of the 3 arm TNBC-MERIT trial, with BNT114 as an optional treatment, BNT114 is investigated in arm 1 (Ne12) and arm 3 (Ne15) of the TNBC-MERIT trial (test) patients in study; Ne42)

  3 Checkpoint Inhibits

  4 Update on the orgoning study including patient enrollment number, efficacy and safety data for an interins update espected in the second half of 2021

  5 As the trial is sponsored and conducted by Sanoff, the timing of data updates is not under our control and is subject to change by Sanoff

  6 Checkpoint

  7 Small Molecule Immunomodulators

  8 We are eligible to receive worldwide licenses

  9 Protein Replacement Therapy

#### 1. Oncology

FixVac. Our FixVac product candidates contain selected combinations of pharmacologically optimized uridine mRNA encoding known cancerspecific 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 and investigators are currently evaluating five FixVac product candidates in clinical trials, including BNT111 in a Phase 1 trial in advanced melanoma, BNT112 in a Phase 1/2 trial in prostate cancer, BNT113 in a Phase 1 trial in HPV+ head and neck cancers, BNT114 in a Phase 1 trial in triple negative breast cancer and BNT115 in a Phase 1 trial in ovarian cancer.

As of the July 2019 interim cut-off, 95 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. Three of the 25 patients who received BNT111 as a monotherapy demonstrated a partial response, one patient had a metabolic complete response as measured by FGD-PET imaging 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 intend to publish a peer-reviewed article with additional data from our ongoing trial of BNT111 in melanoma in 2020.

We expect to initiate a Phase 2 trial with registrational potential for BNT111 in metastatic melanoma in the second half of 2020. We enrolled the first patient in a Phase 1/2 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 trial with registrational potential for BNT113 in HPV+ head and neck cancers by the end 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, multiple clinical trials of our iNeST product candidate, RO7198457 (BNT122). The iNeST Phase 1a (monotherapy)/1b (in combination with atezolizumab) trial is a non-registrational, signal seeking study recruiting mostly patients with late stage advanced cancers, including patients that failed multiple lines of prior treatment. We believe that iNeST is particularly well suited for patients with a lower tumor burden. This positioning is supported by clinical activity shown in our previously reported Phase 1 trial, in which BNT121 was administered intranodally in 13 patients with metastatic melanoma. In this trial, as of October 2019 we have observed stable, progression-free survival in nine patients for up to 60 months following surgery and treatment with BNT121. In addition, three out of five patients had an objective response, two patients received iNeST alone and the third patient also received checkpoint immunotherapy. We also observed a significant decrease in the cumulative recurrence rate post-treatment as compared to pre-treatment. Based on these findings, we, in collaboration with Genentech, initiated a randomized iNeST Phase 2 trial in first-line metastatic melanoma in combination with pembrolizumab. In June 2020, we reported data from a monotherapy dose-finding cohort of our RO7198457 (BNT122) Phase 1 trial in multiple solid tumors, which showed that *ex vivo* T cell responses were detected in approximately 86% of patients treated with RO7198457 (BNT122) as a monotherapy and later in June 2020 we provided a data update for an additional cohort in combination with atezolizumab. We and Genentech expect to provide an enrollment update from our RO7198457 (BNT122) Phase 2 trial in first-line melanoma in the second half of 2020. We expect this enrollment update to include an update on the ongoing study, including patient enrollment numbers, with efficacy and safety data expected in an interim update in the second half of 2021. We and Genentech plan to initiate two additional clinical trials for RO7198457 (BNT122) in 2020 in adjuvant NSCLC and adjuvant colorectal cancer.

mRNA intratumoral immunotherapy. In collaboration with Sanofi, we are conducting a Phase 1 trial of SAR441000 (BNT131), our first mRNA-based intratumoral immunotherapy, as a monotherapy and in combination with cemiplimab in patients with solid tumors. SAR441000 (BNT131) consists of a modified mRNA that encodes

the IL-12sc, IL-15sushi, GM-CSF and IFN-a cytokines. SAR441000 (BNT131) is 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).

*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 CARVac "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 patients with advanced CLDN6 + solid tumors in the second half of 2020.

Neoantigen-based T cell therapies. We recently acquired a neoantigen-based T cell platform. Our lead product candidate under this platform, NEO-PTC-01 (BNT221), is a personalized neoantigen-targeted adoptive T cell therapy candidate consisting of multiple T cell populations targeting the most therapeutically relevant neoantigens from each patient's tumor. We expect to initiate a Phase 1 clinical trial in NEO-PTC-01 (BNT221) in metastatic melanoma in the second 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 GEN1042 (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 Phase 1/2a trials of GEN1046 (BNT311) and GEN1042 (BNT312) in solid tumors. We expect to report interim data on GEN1046 (BNT311) in 2H 2020.

Targeted Cancer Antibodies. In May 2019, we acquired an antibody with a novel mode of action, MVT-5873 (BNT321). BNT321 is a fully human IgG1 monoclonal antibody targeting sialyl Lewis A (sLea), 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 resumed in December 2019 upon the enrollment of the first patient. 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 Phase 1 clinical trials for our first two RiboMab product candidates, BNT141 and BNT142, in the first half of 2021.
- *RiboCytokines*: novel classes of mRNA-based therapeutics that are designed to encode cytokines directly in the patient's body. We expect to initiate Phase 1 clinical trials for our first RiboCytokine product candidates, BNT151 and BNT152/BNT153 (combination), in the first half of 2021.
- *TCR therapy*: T cells with engineered TCRs that are designed to specifically target cancer cells.
- *Precision T cell therapy:* Autologous, non-engineered T cells targeting shared RAS neoantigens prevalent across many solid tumors.
- *Small molecule immunomodulators:* novel intratumoral agents that trigger inflammation and improvement of antigen presentation by antigen-presenting cells. We filed an IND for our first small molecule immunomodulator product candidate, BNT411, in the fourth quarter of 2019 and dosed the first patient in our Phase 1 clinical trial for BNT411 in solid tumors in July 2020.

#### 2. Infectious Disease Immunotherapies

We have collaborated with third parties to exploit the immunotherapeutic properties of our mRNA drug class for the treatment and prevention of infectious diseases. Notably, we have recently started development of four vaccine candidate variants for the prevention of COVID-19. We expect to advance our flu vaccine into the clinic by the end of 2021, and our first programs under our Penn collaboration into the clinic by the first half of 2021.

- COVID-19 vaccine: In response to the COVID-19 pandemic, we are developing a vaccine candidate based on mRNA technology to induce immunity and prevent COVID-19 in response to the growing global health threat posed by the disease. Building on our existing collaboration with Pfizer, in April 2020, we announced that we and Pfizer had entered into a collaboration agreement to co-develop our potential first-in-class COVID-19 mRNA vaccine program, BNT162, aimed at preventing COVID-19. We and Pfizer are jointly conducting clinical trials for four COVID-19 vaccine candidate variants initially in the United States and Europe across multiple sites. If a vaccine candidate is approved, we and Pfizer will also work jointly to commercialize the vaccine worldwide (excluding China which is covered by a collaboration with Fosun Pharma). If the vaccine candidate is approved, we and Pfizer expect to manufacture up to 100 million doses by the end of 2020 and potentially more than 1.3 billion doses by the end of 2021. In March 2020, we entered into a strategic alliance with Fosun Pharma to co-develop a COVID-19 vaccine in China. Upon regulatory approval, Fosun Pharma will commercialize the vaccine in China, while we retained the full rights to develop and commercialize the vaccine in the rest of the world (jointly with Pfizer). On July 1 and July 20, 2020, we and Pfizer announced preliminary data from our Phase 1/2 clinical trials of BNT162.
- *Flu vaccine:* In August 2018, we entered into a collaboration with Pfizer to develop mRNA-based immunotherapies for the prevention of influenza, product candidate BNT161.
- 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. In August 2019, we entered into a letter agreement and investment agreement with the Bill & Melinda Gates Foundation to advance the development of immunotherapies for the prevention and/or treatment of HIV and tuberculosis and up to three additional infectious diseases.

# 3. Rare Disease Protein Replacement Therapies

We are collaborating with Genevant in order to capitalize on opportunities for our mRNA technology in rare disease indications potentially featuring expedited paths to market. We are combining 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 in the second half of 2021.

### 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.

- Our team has consistently been first-movers and has 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 \$1.6 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 1,400 employees including over 600 in research and development, 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, cell therapies, antibodies and small molecule immunomodulators, which can be used alone or in combination to enhance therapeutic effect and produce potentially synergistic effects, as demonstrated in our combination of our BNT211 CAR-T product candidate with a CARVac immune primer.
- Our oncology pipeline includes 11 product candidates in 12 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. We further enhanced these
  capabilities with our acquisition of Neon.
- 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 500 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 500 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. In June 2020, we reported data from a monotherapy dose-finding cohort of our RO7198457 (BNT122) Phase 1 trial in multiple solid tumors, which showed that *ex vivo* T cell responses were detected in approximately 86% of patients treated with RO7198457 (BNT122) as a monotherapy and later in June 2020 we provided a data update for an additional cohort in combination with atezolizumab. 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.
- The combination of these platforms, formats and delivery formulations is designed to address a wide range of disease targets, and tailor drug products 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 four oncology programs and one in infectious disease 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; and
  - advancement of up to three product candidates into the clinic in 2020.
- Our preclinical oncology pipeline is progressing rapidly. We initiated clinical trials for both of our lead checkpoint immunomodulator antibody product candidates in 2019, and enrolled the first patients in clinical trials of BNT112 and BNT321 (MVT-5873). We initiated clinical trials for BNT162 for COVID-19 in the first half of 2020 and for our small molecule product candidate, BNT411, in July 2020. We expect to initiate clinical trials for our lead CAR-T product candidate, BNT211, and our recently acquired adoptive T cell therapy product candidate, NEO-PTC-01 (BNT221) in the second half of 2020. We also expect to initiate clinical trials for our RiboMab and RiboCytokine product candidates in the first half of 2021.
- We initiated clinical trials for BNT162 for COVID-19 in the first half of 2020. 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 capital, most of which has been non-dilutive.
- We are currently collaborating with three pharmaceutical companies with expertise in oncology, Genentech, Sanofi and Genmab, 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. We have
  collaborations with Pfizer focused on influenza and COVID-19, and Fosun Pharma for COVID-19. 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 over 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 over 50 countries around the world.
- We have participated in nearly 300 scientific publications, of which over 100 are in leading peer-reviewed journals.

### 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 and investigators are conducting five Phase 1 clinical trials with our wholly owned off-the-shelf FixVac mRNA immunotherapy. 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 with registrational potential in the second 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, and have two additional clinical trials planned for 2020. 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 Phase 1/2a clinical trials for our product candidates GEN1046 (BNT311) and GEN1042 (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.
- We have also initiated a Phase 1 clinical trial for our small molecule product candidate, BNT411, in solid tumors and plan to initiate a Phase 1/2 clinical trial for our wholly owned CAR-T product candidate, BNT211, in multiple solid tumors, targeting a novel solid-tumor specific antigen, CLDN6, and a Phase 1 clinical trial for our recently acquired adoptive T cell therapy product candidate, NEO-PTC-01 (BNT221) in the second half of 2020.

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 COVID-19, Fosun Pharma in COVID-19 and with Genevant in rare diseases underscore
  the potential of our approach. We intend to continue to seek value-adding 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 manufacturing 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 and infectious disease 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 have expanded our footprint in the United States, and continued to do so with the acquisition of Neon, creating a U.S. research and development hub.

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 Neon, 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, Keytruda and Tecentriq, 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.

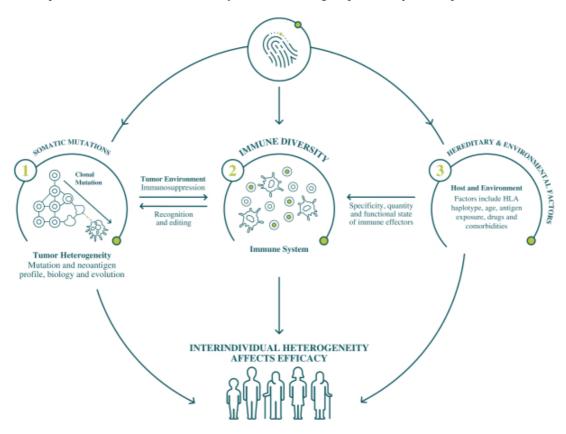
# V. Challenges and Opportunities of Cancer Therapies

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 escapes. 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 microenvironments 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 three key factors influencing the patient unique tumor profile:



**Interindividual heterogeneity of patients.** 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

In oncology, 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 is 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 achieve 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 (CARVac) 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.

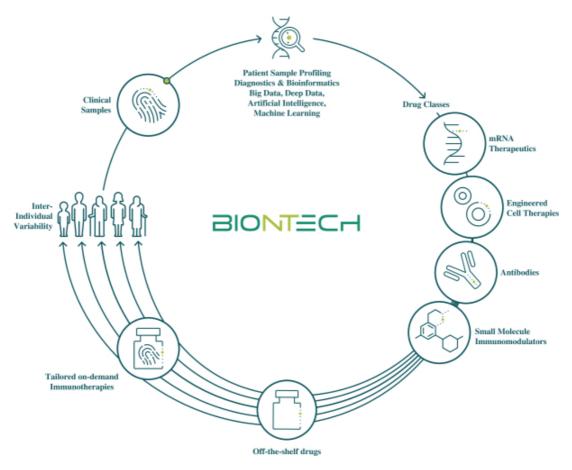
Similarly, in infectious disease, we are deploying our full suite of technologies and immunotherapeutic understanding to develop mRNA vaccines against emerging infectious diseases, such as COVID-19, in a manner that is designed to be faster and more easily scalable, and with more flexible constructs, than traditional vaccine development.

# Patient-Centric Approach

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 approach starts with profiling and diagnostics by utilizing a target identification engine. This engine combines next generation sequencing, genomics, bioinformatics, machine learning and artificial intelligence to (a) identify gene targets of interest, (b) characterize the functional relevance of these targets (i.e. the ability to raise an immune response to or through a target) and (c) demonstrate their drugability. From our very beginning onwards, we have been developing the novel technologies needed to match the identified targets to the optimal individualized treatment approach.

Our patient-centric approach is illustrated and described below:



Our patient-centric approach. Utilizing patient profiling, diagnostics and bioinformatics, we select from our suite of drug classes to provide optimal individualized treatment. Our treatments include off-the-shelf drugs as well as highly tailored immunotherapies that are produced on-demand for the individual patient.

# Utilizing this approach:

- 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 immuno-oncology 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.
- 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 immuno-oncology targets and are developing a diverse spectrum of immunotherapeutic approaches, as shown in the chart below.

	mRNA	Engineered Cell Therapies	Antibodies	Small Molecule Immunomodulators
>	FixVac	CAR-T Cells	Novel Generation CP* Immunomodulators	RNA-LPX
Oncology	iNeST	Neoantigen-targeted T cells	Targeted Cancer Antibodies	
	Intratumoral Immunotherapy	TCRs		Human studies initiated
	RiboMabs			* Checkpoint
	RiboCytokines			onesaponic

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, neoantigen-targeted T cell 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 breadth of our technology 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.

Cancer segment	Patient Population	Challenge	Our Therapeutic Strategy
High mutational burden/ adjuvant stage cancers	Significant portion of cancer patients	Poor risk-benefit profile of checkpoint inhibitors	mRNA Neoantigen Immunotherapy (iNeST)
Low mutational burden cancers	>60% of cancers	Poor response to checkpoint inhibitors	Shared Antigens     (FixVac, CAR-T cells, Antibodies)
"Immune desert" cancers	>40% of high-mutational cancers	Poor infiltration and activation of T-cells in TME <sup>1</sup>	mRNA Immunotherapy     Immunostimulatory Compounds (intratumoral, RiboCytokines)
Cancers with MHC / B2M loss	20-30% of CPI-experienced advanced cancers	Failure of immune system to recognize tumor cells	Antibodies     CAR-Ts
Refractory tumors	Patients with large tumors and multiple resistance mechanisms	Few treatment options	Engineered Cell Therapies     Combination Therapies

**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.

## 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 major histocompatibility complex, or 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

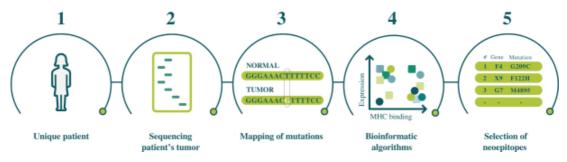
Immunostimulatory approaches are directed against receptors known to directly activate immune cells. Examples of these targets include co-stimulatory molecules such as CD40 and 4-1BB or cytokine receptors such as IL-2R, IL-7R and IL-12R. Immunostimulatory approaches provide a powerful opportunity to 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 GEN1042 (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 bioinformatic approaches to 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 manufacturing. 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 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. Neoepitope Selection

Only a portion of mutated peptides (neoepitopes) 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 neoepitope 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 neoepitope 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 neoepitopes.

Presentation of a neoepitope 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 neoepitopes tailored to patients' specific HLA types. With our acquisition of Neon, we further bolstered our neoepitope selection capabilities with the addition of Neon's RECON bioinformatics engine. RECON uses a number of inputs from each patient, including DNA sequences from samples of tumor and normal tissue, RNA sequences from tumor samples, and the patient's specific MHC allele profile. RECON processes data from these inputs using a proprietary combination of algorithms in order to produce a prioritized list of neoantigentargeting peptides that can be manufactured for use in our product candidates.

## 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 a cost-effective 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.

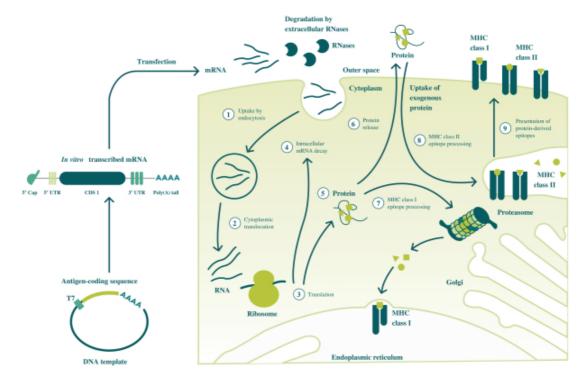
## A. General Principles of mRNA Pharmacology

As a drug, manufactured mRNA provides instructions 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;
- untranslated regions, or UTRs, which flank the ORF; and
- the cap and the poly(A) tail, which are the two terminal structures of the linear mRNA, and are responsible for increased stability and translational efficiency of mRNA.

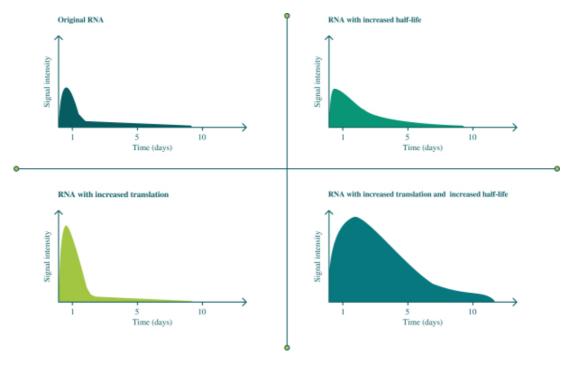
The mRNA drug needs to be appropriately formulated in order to protect it from breakdown by extracellular RNAses. The formulation is selected based on the intended application and route of delivery. After uptake into the target cell, the mRNA molecules are loaded into ribosomes, where translation into 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: mRNA is either delivered in a buffered solution as naked molecules or formulated as nano-particles to protect degradation by extracellular enzymes and is taken up by cells. Step 2: Subsequently, mRNA is released from endosomes into the cytoplasm. Step 3: mRNA is translated by the protein synthesis machinery of host cells. Step 4: Termination of translation

by degradation of mRNA. 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 systemic, body-wide mechanisms. Steps 7 and 8: For vaccine activity, mRNA encoded antigens are degraded into shorter fragments and loaded onto MHC class I and class II molecules. Step 9: Protein-derived epitopes can then be presented on the cell surface by both MHC class I and MHC class II molecules, enabling stimulation of CD8+ and CD4+ T cells.

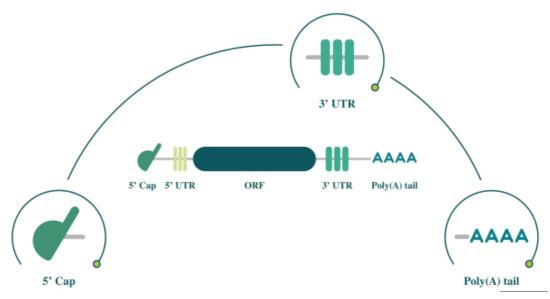
The structural elements of the mRNA have an impact on its performance. This includes potential immunogenicity, efficacy of translation and stability of the molecule. We leverage our extensive experience to design, synthesize, manufacture and formulate our therapeutic mRNA, and adapt its composition to suit the desired application.



Our strategy for optimizing mRNA potency. The pharmacological properties of mRNA can be improved by biochemical optimization of the molecule for either (i) increasing the half-life of the mRNA, i.e., the mRNA is translated for a longer period of time before it is degraded, which results in sustained protein production after mRNA delivery, or for (ii) increasing the mRNA translation efficiency, i.e., the peak protein production is increased. Our optimization approach relies on combining both strategies in order to maximize the mRNA therapeutic effect.

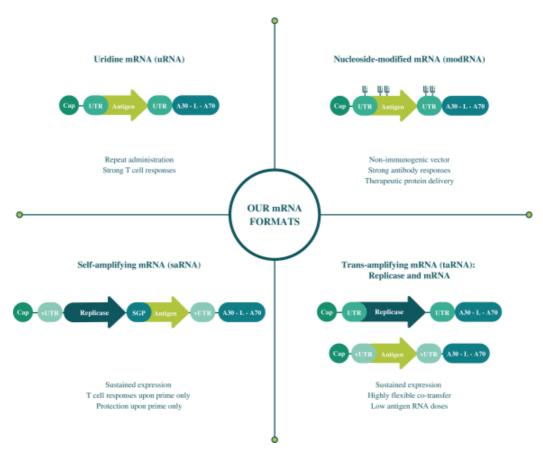
## B. Our mRNA Backbone Concepts and Technologies

Our mRNAs all contain basic structural elements, including the 5' cap, the untranslated regions and the poly(A) 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 5' and 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 UTRs that promote increased protein translation for long duration.
- We have performed extensive research on the structure of the poly(A) 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. Abbreviations: y, 1-methylpseudouridine; UTR, untranslated region.

Our mRNA formats include:

#### 1. Optimized Uridine 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 uridine mRNA makes it immunogenic by activating immune sensors. We have further optimized our uridine 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, and we are additionally using this mRNA format in one of our COVID-19 vaccine candidate variants.

## 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 antidrug 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. We are also testing this mRNA format in multiple COVID-19 vaccine candidate variants, including BNT162b1, the vaccine candidate variant for which we and Pfizer announced preliminary data from our Phase 1/2 clinical trials on July 1 and July 20, 2020, and BNT162b2.

## 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. Accordingly, we are testing this mRNA format in one of our COVID-19 vaccine candidate variants.

#### 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.

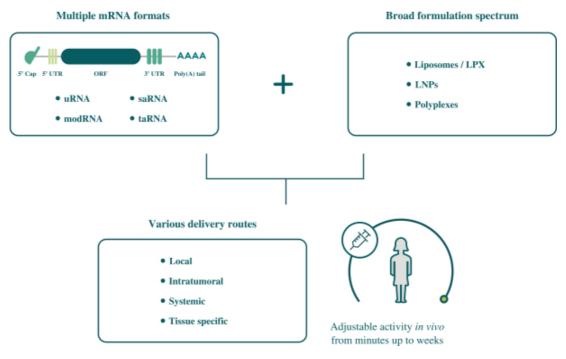


Our mRNA delivery formulation technologies. We utilize a range of mRNA delivery formulations for different therapeutic needs.

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.
- **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.

	mRNA Platform	Drug Targets	mRNA Formats	Delivery Formulations
	7 mRNA platforms	Broad range of biological targets	4 types of mRNA	Multiple optimized formulations
	FixVac	Shared Antigens	uRNA	RNA-LPX
	iNeST	Necepitopes	uRNA	RNA-LPX
Oncology	Intratumoral Immunotherapy	Immunomodulators	modRNA	Various formulations Intratumoral
Ŭ	RiboMabs	mAb targets	modRNA	LNPs Intravenous delivery
	RiboCytokines	Cytokines	modRNA	Various LNP formulations
Other	Infectious Disease Vaccines	Pathogens	saRNA, taRNA, modRNA	Various LNPs for i.m. & s.c. delivery
	Rare Disease Protein Replacement Therapy	Diverse Proteins	modRNA	Liver targeted LNPs

uRNA: uridine mRNA; modRNA: nucleoside-modified mRNA; saRNA: self-amplifying mRNA, taRNA: trans-amplifying mRNA;

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 potently expand tumor cell specific CD4+ and CD8+ T cells in cancer patients. Our cancer immunotherapy 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.

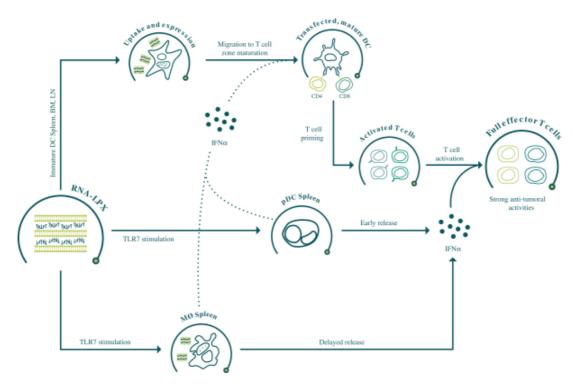
## RNA-LPX Technology

## At a glance: RNA-LPX Cancer Immunotherapy Technology

- $\bullet \quad \hbox{Potential first-in-class clinical intravenous nano-particulate mRNA immunotherapy, allowing systemic delivery.}$
- 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.

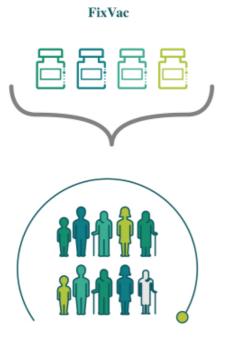
- Preclinical anti-tumoral activity demonstrated against multiple tumors.
- Unprecedented clinical immune responses against shared TAAs.
- Beneficial clinical activity demonstrated in advanced melanoma patients.

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.

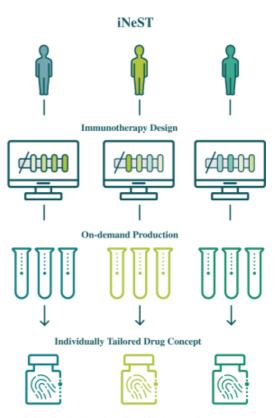


**Our RNA-LPX technology.** Our proprietary RNA-LPX formulation is designed to deliver vaccine mRNA precisely into DCs and macrophages in the spleen and other lymphoid compartments. The RNA-LPX has an inherent adjuvant function stimulating the release of cytokines such as IFN-a thereby promoting the activation of DCs and the induction of strong T cell responses. Abbreviations: BM, bone marrow; LN, lymph node; DC, dendritic cell; pDC, plasmacytoid dendritic cell; Mø, macrophage; IFN-a, 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. Our RNA-LPX technology is designed 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.



Fixed vaccine combination against shared tumor-associated antigens expressed in high percentages of target cancer.



Individualized Neoantigen Specific Immunotherapy (iNeST) concept. Truly individualized immunotherapies tailored for every different patient targeting individual patient's cancer mutation.

# 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 uridine 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:** Three partial responses, one complete response and seven stable diseases in 25 patients with metastatic lesions at enrollment, following BNT111 monotherapy.

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 six FixVac programs in development, with five in human trials, including 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. We expect to progress our advanced melanoma program into Phase 2 clinical trials with registrational potential in the second half of 2020. We enrolled the first patient in a Phase 1/2 trial in prostate cancer and the first patient was dosed in a Phase 1 ovarian cancer trial in the second half of 2019. In addition, we are planning to initiate a Phase 2 study with registrational potential for FixVac in HPV+ cancers by the end of 2020.

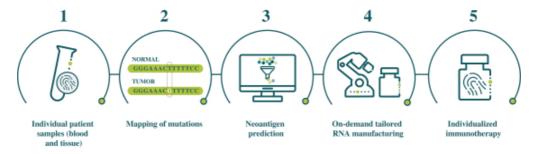
Candidate BNT111	Antigens Melanoma-specific antigens: NY-ESO-1, tyrosinase, MAGE-A3 and TPTE	Phase 1: Advanced melanoma	Next Potential Milestone Report Phase 1 data: publication upcoming; initiate Phase 2 trial with registrational potential in 2H 2020
BNT112	Five prostate cancer-specific antigens, including PAP and three internally identified antigens	Phase 1/2: Prostate cancer	_
BNT113	HPV E6 and E7 oncoproteins	Phase 1: HPV+ head and neck cancer (IST)	Initiate Phase 2 trial with registrational potential by end of 2020
BNT114	Selected breast cancer-specific antigens	Phase 1: TNBC	Report data update in 2H 2020
BNT115	Selected ovarian cancer-specific antigens	Phase 1	_
BNT116	Non-small cell lung cancer	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 uridine 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 60 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. In June 2020, we reported data from a monotherapy dose-finding cohort of our RO7198457 (BNT122) Phase 1 trial in multiple solid tumors, which showed that *ex vivo* T cell responses were detected in approximately 86% of patients treated with RO7198457 (BNT122) as a monotherapy and later in June 2020 we provided a data update for an additional cohort in combination with atezolizumab.

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 are investigating 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.
- 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 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. In June 2020, we presented data from a monotherapy dose-finding cohort of our RO7198457 (BNT122) Phase 1a/1b trial in multiple solid tumors, and later in June 2020 we provided a data update for an additional cohort in combination with atezolizumab. Further, we expect to provide an enrollment update from the first-line melanoma trial in the second half of 2020, and provide an interim data update in the second half of 2021. We and Genentech plan to initiate two additional clinical trials for RO7198457 (BNT122) in 2020 in NSCLC and colorectal cancer in the adjuvant setting.

<u>Candidate</u>	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	Enrollment update in 2H 2020; <sup>1</sup> Interim data update in 2H 2021
		Phase 1a/1b: multiple solid tumors	Phase 2 trials planned in NSCLC and colorectal cancer in the adjuvant setting in 2H 2020

1 We expect this enrollment update to include an update on the ongoing study, including patient enrollment numbers, with full efficacy and safety data for an interim update expected in the second half of 2021.

## c) Intratumoral mRNA Immunotherapy

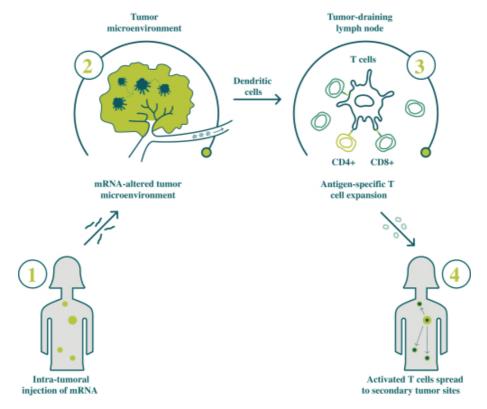
## At a glance: Our Intratumoral mRNA Platform

• 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.

In collaboration with Sanofi, 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 anti-tumor immune cells, known as an abscopal effect.

The first intratumoral immunotherapy product candidate arising from our collaboration, SAR441000 (BNT131), includes modified mRNA that encodes for the IL-15sushi, IL-12sc, GM-CSF and IFN- $\alpha$  cytokines. In preclinical studies, SAR441000 (BNT131) promoted increased levels of local cytokine expression within the tumor microenvironment and activated 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**

The lead intratumoral mRNA collaboration product candidate from our collaboration is being investigated in a Phase 1 clinical trial sponsored by Sanofi. This trial is expected to enroll approximately 264 patients with certain advanced solid tumors, as a monotherapy and in combination with cemiplimab. This trial is currently being run at four sites in Europe. A data update from this trial may be reported in the second half of 2020. As the trial is sponsored and conducted by Sanofi, the timing of data updates is not under our control, and is subject to change by Sanofi.

Candidate	Encoded Cytokines	Development Phase	Next Steps
SAR441000 (BNT131)	IL-15sushi, IL-12sc, GM-CSF and	Phase 1: Advanced solid tumors as a	Data update in 2H
	IFN-α	monotherapy and in combination with	2020*
		cemiplimab	

\* As the trial is sponsored and conducted by Sanofi, the timing of data updates is not under our control, and is subject to change by Sanofi.

#### 2. Infectious Disease Vaccines

#### At a glance: Our Infectious Disease Vaccine Platform

Concept: mRNA-based vaccines targeting infectious disease pathogens.

mRNA Format: Multiple.

mRNA Delivery Formulation: LNPs.

Development Approach: Collaborations with Pfizer and Fosun Pharma and exclusive option arrangement with Penn.

• Lead Candidates: COVID-19 vaccine candidate BNT162; Influenza vaccine candidate BNT161.

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 trans-replicating, 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.

#### COVID-19 Vaccine

In March 2020, we entered a strategic alliance with Fosun Pharma to advance a COVID-19 vaccine in China. In July 2020, we received notice of acceptance to begin our clinical trial for BNT162b1 in China. Upon regulatory approval, Fosun Pharma will commercialize the vaccine in China, while we retained the full rights to develop and commercialize the vaccine in the rest of the world. Also in March 2020, we and Pfizer began collaborating to co-develop our potential first-in-class COVID-19 mRNA vaccine program, BNT162 aimed at preventing COVID-19. We and Pfizer are jointly conducting clinical trials for the COVID-19 vaccine candidates initially in the United States and Europe across multiple sites. We are currently developing four potential candidates utilizing multiple different mRNA formats as part of this program. In late April 2020, we and Pfizer announced that the German regulatory authority, the Paul-Ehrlich-Institut, approved the Phase 1/2 clinical trial and the first cohort of our Phase 1/2 clinical trial were dosed shortly thereafter. In early May 2020, Pfizer and we initiated a clinical trial for BNT162 in the United States and the first participants were dosed shortly thereafter. We initiated the BNT162 program in late January 2020 in response to the global COVID-19 pandemic, and initiated human testing following preclinical studies and within approximately three months of initiating the research program.

During the clinical development stage, we and our partners will provide clinical supply of the vaccine from our GMP-certified mRNA manufacturing facilities in Europe. We and Pfizer are working together to scale-up manufacturing capacity at risk to provide worldwide supply in response to the pandemic. If the vaccine candidate is approved, we and Pfizer will also work jointly to commercialize the vaccine worldwide (excluding China which is covered by a collaboration with Fosun Pharma). If the vaccine candidate is approved, we and Pfizer expect to manufacture up to 100 million doses by the end of 2020 and potentially more than 1.3 billion doses by the end of 2021.

## July 2020 Data Announcements

On July 1, 2020, we and Pfizer announced preliminary data from our ongoing U.S. Phase 1/2 trial of BNT162b1. The initial part of this randomized, placebo-controlled, observer-blinded study is evaluating the safety, tolerability and immunogenicity of escalating dose levels of BNT162b1, one of four vaccine candidate variants in development as part of our BNT162 program, in 45 healthy adults between 18 and 55 years of age.

The participants received two doses, 21 days apart, of placebo, 10µg or 30µg of BNT162b1, or received a single dose of 100µg of the vaccine candidate. Because of a strong vaccine booster effect, the highest neutralizing titers were observed seven days after the second dose of 10µg or 30µg on day 28 after vaccination. The neutralizing GMTs were 168 and 267 for the 10µg and 30µg dose levels, respectively, corresponding to 1.8- and 2.8-times the neutralizing GMT of 94 observed in a panel of 38 sera from subjects who had contracted SARS-CoV-2.

In all 24 subjects who received 2 vaccinations at 10µg and 30µg dose levels of BNT162b1, elevation of RBD-binding IgG concentrations was observed after the second injection with respective GMCs of 4,813 and 27,872 units/ml at day 28, seven days after immunization. These concentrations are 8- and 46.3-times the GMC of 602 units/ml in a panel of 38 sera from subjects who had contracted SARS-CoV-2.

At day 21 after a single injection, the 12 subjects who received 100µg of BNT162b1 had an RBD-binding IgG GMC of 1,778 units/ml and a SARS-CoV neutralizing GMT of 33, which are 3-times and 0.35-times, respectively, the GMC and GMT of the convalescent serum panel.

At the 10µg or 30µg dose levels, adverse reactions, including low grade fever, were more common after the second dose than the first dose. Following dose 2, 8.3% of participants who received 10µg and 75.0% of participants who received 30µg BNT162b1 reported fever <sup>3</sup> 38.0 °C. Local reactions and systemic events after injection with 10µg and 30µg of BNT162b1 were dose-dependent, generally mild to moderate, and transient. The most commonly reported local reaction was injection site pain, which was mild to moderate, except in one of 12 subjects who received a 100µg dose, which was severe. No serious adverse events were reported. Given higher numbers of subjects experiencing local reactions and systemic events after a single 100µg dose with no significant increases in immunogenicity compared to the 30µg dose level, the 12 participants in the 100µg group were not administered a second dose.

On July 20, 2020, we and Pfizer announced preliminary data from our ongoing German Phase 1/2 trial of BNT162b1. The initial part of this open-label, non-randomized, non-placebo-controlled study is evaluating the safety, tolerability and immunogenicity of escalating dose levels of BNT162b1, one of four vaccine candidate variants in development as part of our BNT162 program, in 60 healthy adults, between 18 and 55 years of age. The preliminary data we reported was from 12 subjects each who received two doses of 1µg, 10µg, 30µg and 50µg (except for one individual each in the 10µg and 50µg who discontinued due to non-study drug related reasons) and 12 subjects who received a single dose of 60µg. The two doses received by the participants were given 21 days apart.

In 34 of the 36 subjects who received two vaccinations at 10µg, 30µg, or 50µg dose levels of BNT162b1, RBD-specific CD4+ T cell responses were observed. All subjects but the two exceptions at the lowest dose level

had cytokine profiling of the RBD-specific CD4+ T cells that demonstrated a TH1-dominant profile for these cells. While the magnitude varied between individuals, participants with the strongest CD4+ T cell responses to RBD had more than 10-fold of the memory responses observed in the same participants when stimulated with cytomegalovirus (CMV), Epstein Barr virus (EBV), influenza virus and tetanus toxoid-derived immuno- dominant peptide panels. The strength of RBD-specific CD4+ T cell responses correlated positively with both RBD-binding IgG and with SARS-CoV-2 neutralizing antibody titers. Among vaccine-induced CD8+ T cell responses, which were observed in 29 of 36 participants, strong responses were mounted by the majority of participants and were comparable with memory responses against CMV, EBV, influenza virus and tetanus toxoid in the same participants. The strength of RBD-specific CD8+ T cell responses correlated positively with vaccine- induced CD4+ T cell responses, but did not significantly correlate with SARS-CoV-2 neutralizing antibody titers. Additionally, although at 1µg the immunogenicity rate was lower (6 of 8 responding participants), the magnitude of vaccine-induced CD4+ and CD8+ T cells in some participants was almost as high as with 50µg BNT162b1.

Elevation of SARS-CoV-2 RBD-binding IgG concentrations was observed, with respective GMCs ranging from 265 units/ml to 1,672 units/ml at day 21. At day 29, seven days after the second dose, RBD-binding IgG GMCs ranged from 2,015 units/ml to 25,006 units/ml. At day 43, RBD-binding IgG GMCs ranged from 3,920 units/ml to 18,289 units/ml. These concentrations are 6.5- to 30.4-times the GMC of 602 units/ml in a panel of sera from 38 subjects who had contracted SARS-CoV-2. At day 29, the SARS-CoV-2 neutralizing GMTs reached 36 (1μg dose), 158 (10μg dose), 308 (30μg dose) and 578 (50μg dose) compared to neutralizing GMT of 94 observed in the convalescent serum panel. At day 43, SARS-CoV-2 neutralizing GMTs reached .7-fold (1μg dose) to 3.2-fold (50μg dose) compared to those of a panel of SARS-CoV-2 infection convalescent human sera. Furthermore, sera of vaccinated subjects displayed broadly neutralizing activity in pseudovirus neutralization assays across a panel of sixteen SARS-CoV-2 RBD variants represented in publicly available SARS-CoV-2 sequences and against the newly dominant D614G strain. In summary, antibody responses elicited by BNT162b1 in our German clinical trial largely mirrored those observed in our U.S. clinical trial.

At the 10µg, 30µg and 50µg dose levels, certain adverse reactions, including low grade fever, were more common after the second dose than the first dose. Following the second dose, 25.0%, 25.0% and 33.3% of participants who received the 10µg, 30µg and 50µg doses, respectively reported fever of at least 38.0 degrees Celsius. Local reactions and systemic events after injection with 10µg, 30µg and 50µg of BNT162b1 were dose-dependent, generally mild to moderate and transient, with occasional severe events (grade 3) of flu-like symptoms and injection site reactions. The most commonly reported local reaction was injection site pain, which was mild to moderate, except in one of 12 subjects who received a 60µg dose, which was severe. No serious adverse events were reported, and there were no withdrawals due to adverse events related to the vaccine. Based on the adverse reactions reported after the 50µg boost dose, a second 60µg dose was not administered to participants who had received an initial 60µg dose.

For additional information on these preliminary results, please review our reports on Form 6-K filed with the SEC on July 1, 2020 and July 20, 2020 and incorporated by reference herein.

Based on preclinical and clinical data observed to-date, we and Pfizer have decided to progress our BNT162 development program into a Phase 2b/3 trial, which is anticipated to commence in late July 2020, subject to input and approval from the appropriate regulatory bodies. For the initial Phase 2b/3 trial, we intend to select either BNT162b1 or BNT162b2. Both the BNT162b1 and the BNT162b2 vaccine candidates have received Fast Track status from the FDA. Since clinical evaluation of the BNT162b2 candidate started several weeks later than BNT162b1, only preliminary clinical data are currently available for the BNT162b2 candidate. A set of data obtained for a cohort of subjects 18-55 years of age immunized with 10µg of BNT162b2 indicates that BNT162b2 induces similar virus neutralizing antibody responses as observed for BNT162b1. The preliminary observations are subject to further data collection and analysis. Assessment of dose dependent immune response and safety profile as well as analysis of T cell responses is currently pending. On the basis of additional data expected to be collected and analyzed for BNT162b1 and BNT162b2 in the coming days, along with input from the FDA, we intend to select a lead candidate to take into a Phase 2b/3 trial. We and Pfizer currently expect to

inform the FDA of our selection of the BNT162 candidate variant before the closing of this offering. Based on clinical data from our ongoing Phase 1/2 trials of BNT162b1 in the United States and Germany, BNT162b1 appears to be a viable variant to advance into a Phase 2b/3 trial. However, given that additional information relating to BNT162b2 is becoming available over the next few days, we and Pfizer plan to make the ultimate decision on the final candidate based on multiple factors, including the overall observed safety, tolerability and immunogenicity profiles for each vaccine candidate at different dose levels, a full immunogenicity data set and feedback from the FDA on the data collected for each candidate. If we ultimately move forward with the BNT162b2 variant, it will be due to the fact that based on our scientific judgment in light of the totality of preclinical data and clinical data available to us at the time of selection and the other factors described above, the BNT162b2 variant has better potential for clinical and commercial success. We do not plan to disclose which BNT162 variant has been selected until we receive FDA approval to commence the Phase 2b/3 clinical trial, and we likely will not publish any data with respect to the BNT162b2 variant before we make our selection.

## 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.

We anticipate that our mRNA-based vaccines 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. In addition, the mRNA manufacturing process is designed to produce an HA vaccine antigen that matches the HA of circulating influenza strains, in contrast to egg- or cell-based processes which can introduce mutations in the HA amino acid sequence. The flexibility of the mRNA vaccine platform could allow for generation of vaccines against genetically drifted seasonal viruses or pandemic strains. We and Pfizer have moved the anticipated Phase 1 start for our mRNA flu vaccine program to 2021 due to the prioritization of our COVID-19 vaccine development efforts.

#### **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.

In August 2019, we entered into a letter agreement and investment agreement with the Bill & Melinda Gates Foundation to advance the development of immunotherapies for the prevention and/or treatment of HIV and tuberculosis and up to three additional infectious diseases.

## 3. mRNA-based Protein Replacement Platform for Rare Diseases

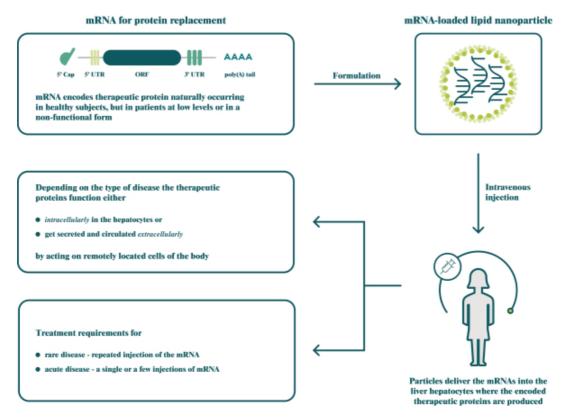
## At a glance: Our Protein Replacement Platform for Rare Diseases

- 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.

 $mRNA\mbox{-}based\ protein\ replacement\ technology\ has\ several\ advantages\ over\ recombinant\ proteins:$ 

- **No need to develop a 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 2021.

#### 4. RiboMabs

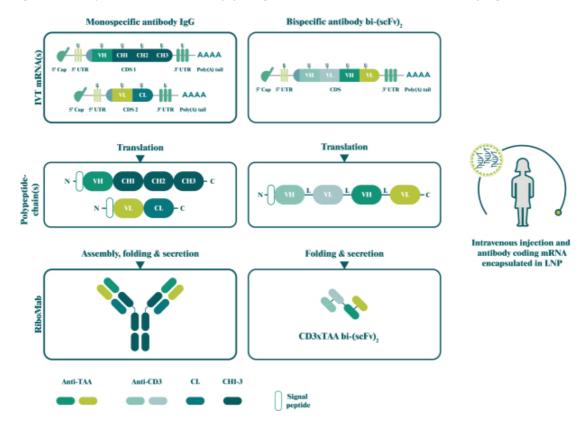
#### At a glance: Our RiboMab Platform

- 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.

Our RiboMab product candidates are designed to encode secreted antibodies for expression *in vivo* by the patient's cells. 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 provide an antibody's mRNA sequence, and the body does the production work itself. This simplicity is designed to allow 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 RiboMabs. 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 2021 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 first half of 2021.

Candidate	Target	Development Phase	Next Potential Milestone
BNT141 (monospecific)	Undisclosed	Preclinical	Initiate Phase 1 trial in 1H
			2021
BNT142 (bispecific)	CD3xCLDN6	Preclinical	Initiate Phase 1 trial in 1H 2021

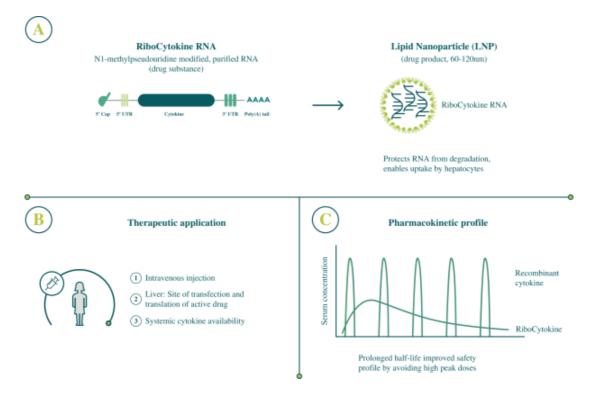
# 5. RiboCytokines

#### 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.

Our RiboCytokine product candidates utilize mRNA that encodes the desired cytokines for expression *in vivo* by the patient's cells. 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 RiboCytokines.
- Liver targeted expression. RiboCytokines are formulated using 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.
- 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/BNT153 (combination), to enter the clinic in the first half of 2021 in basket trials targeting multiple advanced malignancies.

Candidate	Cytokines	Development Phase	<b>Next Potential Milestone</b>
BNT151	Optimized IL-2	Preclinical	Initiate Phase 1 trial in 1H 2021
BNT152/BNT153	IL-7/IL-2	Preclinical	Initiate Phase 1/2 trial in 1H 2021

#### **IX. Our Cell Therapies Drug Class**

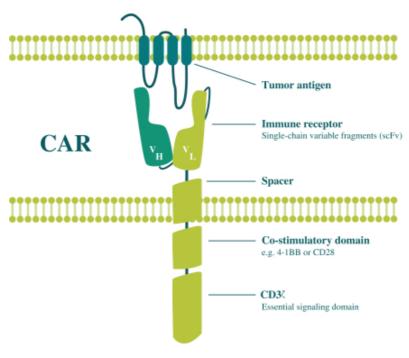
The tailored reprogramming of autologous T cells from cancer patients to recognize and attack their tumors has become a disruptive medical innovation. Retargeting of T cells can be achieved via introduction of tumor-specific receptors into patient-derived T cells. For that purpose, T cells are mostly 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. Additionally, with our Neon acquisition we recently acquired an adoptive T cell platform targeting patient-specific and shared neoantigens. This platform utilizes a proprietary *ex vivo* co-culture process, NEO-STIM, to prime, activate and expand autologous neoantigen-specific T cells specific either for a personal set of neoantigens for each patient or for a set of selected shared neoantigens.

## 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 an mRNA-based immune booster, which we refer to as CARVac, to enhance CAR-T cell expansion and persistence.
- Development Approach: Worldwide rights; wholly owned.
- Lead Candidate: BNT211 for multiple solid tumors.

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.



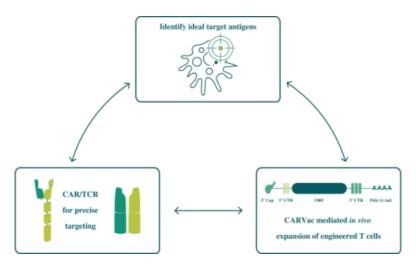
Second-generation CAR. The figure above illustrates the basic structure of a second-generation CAR, such as those included in our BNT211 and BNT212 product candidates.

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.

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 CARVac technology for controlled in vivo stimulation, activation and 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 vaccine immunotherapy to enhance T cell activation and expansion.

The powerful characteristics of CAR-T cells, including their potential to eradicate targeted tumor cells in combination with their potentially lifelong 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.

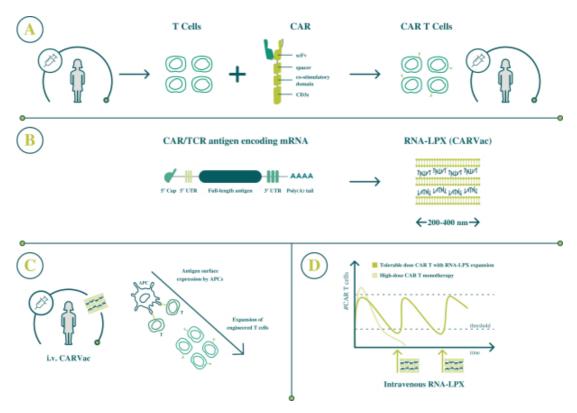
CLDN6 is an oncofetal cell surface antigen expressed in embryonic stem cells during fetal development. The gene encoding CLDN6 is strictly silenced and not expressed in healthy adult tissues but re-activated in different cancers with a high medical need including ovarian, endometrial, testicular and 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 CARVac-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 RNA-LPX lipoplexes (CARVac). (C) Intravenously administered CARVac 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) CARVac 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 CARVac product candidate in multiple solid tumors in the second half of 2020.

<u>Candidate</u>	Antigen Target	Development Phase	Next Potential Milestone
BNT211	CLDN6	Preclinical	Initiate Phase 1/2 trial in 2H
			2020
BNT212	CLDN18.2	Preclinical	_

## B. Neoantigen-targeting T Cells

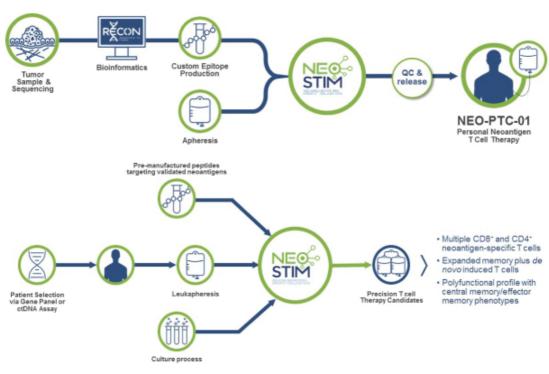
## At a glance: Our Neoantigen-targeting T Cell Platform

- **Concept:** Adoptive T cell therapies targeting personal or shared sets of cancer neoantigens.
- **Mechanism:** Autologous, neoantigen-specific T cells primed, activated and expanded utilizing a proprietary antigen-specific T cell induction protocol, NEO-STIM, to target either a personal set of neoantigens for each patient or a set of selected shared neoantigens.
- Development Approach: Worldwide rights.
- **Lead Candidate:** BNT221 for metastatic melanoma and other potential cancer indications.

Through our recent Neon acquisition, we obtained a neoantigen-targeting T cell platform. This platform can be utilized to develop product candidates across several neoantigen-targeting non-engineered and engineered T cell therapies using two distinct approaches:

- An individualized approach enabling neoantigen-targeted therapies that are tailored for the individual profile of each patient's tumor.
- A shared neoantigen approach enabling neoantigen therapies that target prevalent neoantigens that are shared across subsets of patients or tumor types.

Our RECON bioinformatics engine is designed to predict the most therapeutically-relevant neoantigen targets associated with each patient's tumor. Effective prediction is critical because, although many mutations within a patient's tumor will lead to the production of a mutated protein, not all mutated proteins lead to suitable therapeutic neoantigen targets. RECON uses a number of inputs from each patient, including DNA sequences from samples of tumor and normal tissue, RNA sequences from tumor samples, and the patient's specific MHC allele profile. RECON processes data from these inputs using a proprietary combination of algorithms in order to produce a prioritized list of neoantigen-targeting peptides that can be manufactured for use in product candidates. After selection of the target neoantigens, our proprietary method for *ex vivo* T cell stimulation, which we call NEO-STIM, allows us to directly prime, activate and expand antigen-specific T cells.



Our Neoantigen-targeting T Cell Processes. The illustrations above show our processes for neoantigen-targeting T cell development under our individualized and shared neoantigen approaches.

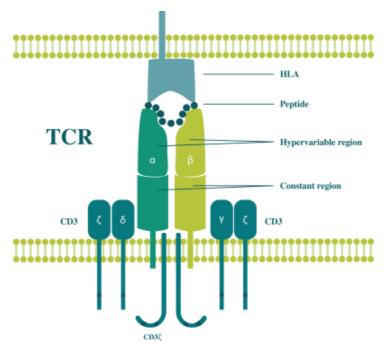
#### Our Neoantigen-targeting T Cell Development Plan

Our lead product candidate under this platform is our individualized neoantigen-targeting T cell therapy, NEO-PTC-01 (BNT221). We expect to initiate a Phase 1 dose escalation trial of NEO-PTC-01 (BNT221) in metastatic melanoma in the second half of 2020. The second planned indication for NEO-PTC-01 (BNT221) is metastatic ovarian cancer.

Candidate	Antigen Target	Development Phase	Next Potential Milestone
BNT221	Individualized	Preclinical	Initiate Phase 1 trial in 2H 2020

#### C. TCRs

The T cell receptor, or TCR, is part of a complex signaling machinery, which includes the TCR a and ß chains that are responsible for antigen recognition, the co-receptor 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. 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 antigenreactive 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 to target a specific antigen;
- a therapeutic TCR warehouse encompassing multiple TCRs to target 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.

#### 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

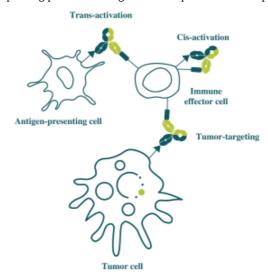
- **Concept:** Bispecific antibodies for dual immunomodulation, initially targeting 4-1BB, an immune checkpoint that is expressed on T cells and NK cells and can enhance immune cell proliferation and activation, in combination with simultaneous checkpoint inhibition.
- **Mechanism:** Conditional activation 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 approaches 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 tumor-targeted and dual immunomodulators, applying Genmab's proprietary DuoBody® technology in combination with our joint target identification and product concept 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. These 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 in collaboration with Genmab: GEN1046 (BNT311), our jointly owned PDL1x4-1BB bispecific antibody, and GEN1042 (BNT312), our jointly owned CD40x4-1BB bispecific antibody.

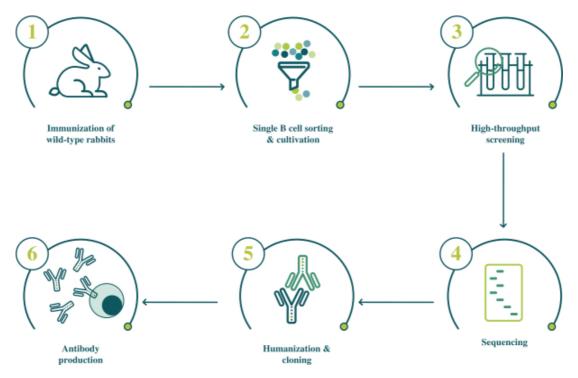
Candidate	Targets	Development Phase	Next Potential Milestone
GEN1046 (BNT311)	PD-L1x4-1BB	Phase 1/2a trial in multiple solid	Data update in 2H 2020
		tumors	
GEN1042 (BNT312)	CD-40x4-1BB	Phase 1/2a trial in multiple solid	_
		fumors	

# **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 Lewisa (sLea), 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.



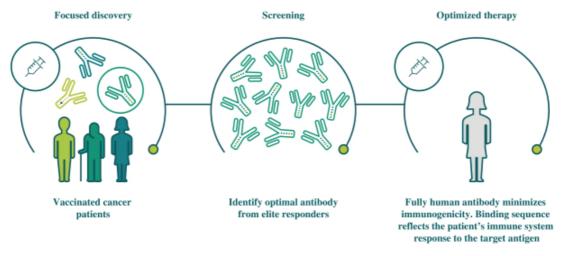
Our rabbit-based antibody discovery engine. The figure above depicts our semi-automated process for the discovery and production of high-affinity rabbit mAbs.

# 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>	Targets	Development Phase	Next Potential Milestone
MVT-5873 (BNT321)	sLea	Phase 1 basket trial in multiple	_
		solid tumors: first patient enrolled	

# 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 as a monotherapy or in combination with chemotherapy and/or checkpoint inhibitors.

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-a 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 are developing as a monotherapy or a combination therapy for small cell lung cancer and other solid tumors.

<u>Candidate</u>	Target	Development Phase	Next Potential Milestone
BNT411	TLR7	Phase 1/2a trial in extensive-stage	_
		small-cell lung carcinoma	

# 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 12 clinical trials.

# Oncology

Drug Class	Platform	Product Candidate	Indication ( Targets)	Pre- clinical	Phase 1	Phase 2	Phase 3	Rights/ Collaborator	Milestones
		BNT111	Advanced melanoma (Adjuvant & Metastatic)		-			Global	Report Phase 1 data: publication upcoming: Phase 2 with registrational
	FixVac	BNT112	Prostate cancer					Global	potential start 2H 2020
	(fixed combination	BNT113	HPV16+ head and neck cancer!					Global	Phase 2 with registrational potential start 2H 2020
	of shared cancer antigens)	BNT114	Triple negative breast cancer					Global	Data update 2H 2020
		BNT115	Ovarion cancer <sup>1</sup>					Global	
		BNT116	NSCLC					Global	Phase 1 start 1H 2021
			IL melanoma with CPI <sup>3</sup>						Enrollment update 2H 20201; interim
	iNeST (patient specific cancer	RO7198457	Multiple solid tumors		_			Genentech (global 50:50	data update in 2H 2021
	antigen therapy)	(BNT122°)	NSCLC and colorectal cancer (Adjuvant)					profit/loss share)	Two Phase 2 trials planned 2H 2020
	Intratumoral Immunotherapy	SAR441000 (BNT131)	Solid tumors (IL-12rc, IL-15sashi, GM-CSF, IFNa)		-			Sanofi (global profit/ loss share)	Data update 2H 2020 <sup>a</sup>
	KithoMabs (mKNA-	BNT141	Multiple solid tumors					Global	Phase 1 start 1H 2021
		BNT142	Multiple solid tumors (CD3+CLDN6)					Global	Phase 1 start 1H 2021
	RiboCytokines BNT151 (mRNA-encoded	BNT151	Multiple solid tumors (Optimized IL-2)					Global	Phase 1 start 1H 2021
	cytokines)	BNT152, BNT153	Multiple solid tumors (R-7, R-2)					Global	Phase 1 start 1H 2021
		BNT211	Multiple solid tumors (CLDN6)					Global	Phase 1/2 start 2H 2020
ě	CAR-T Cells	BNT212	Pancreatic, other cancers (CLDN/8.2)					Global	
Therapie	Neoantigen-based T cell therapy	BNT221 (NEO-PTC-01)						Global	Phase 1 start 2H 2020
	TCRs	To be selected	All tumors					Global	
Antibodies	Next-Gen CP <sup>4</sup> GEN1046 (BNT311) Immunomodulators GEN1042 (BNT312)	GEN1046 (BNT311)	Multiple solid tumors (PD-L1×4-18B)					Genmab (global 50:50	Data update 2H 2020
		Multiple solid tumors (CD40×4-1BB)					profit/loss share)		
	Targeted Cancer Antibodies	BNT321 (MVT-5873)	Pancreatic cancer (sLe-)		•			Global	
	Toll-Like Receptor Binding	BNT411	Solid tumors (TLR7)					Global	

# Other

Drug Class	Platform	Product Candidate	Indication (Targets)	Pre- Phase clinical 1	Phase 2	Phase 3	Rights/ Collaborator	Milestones
		BNT161	Influenza				Pfizer	Phase 1 start 2021
		BNT162	COVID-19				Fosun Pharma (China), Pfizer (Global, except China)	Phase 2/3 start late July 2020
ě	Infectious Disease Immunotherapies	To be selected	Up to 10 indications				Penn*	First Phase 1 trial to start 1H 2021
EX		To be selected	HIV and tuberculosis				Bill & Melinda Gates Foundation	
	Rare Disease PRT <sup>6</sup>	BNT171 To be selected	Not disclosed 4 more rare disease indications				Genevant (global 50:50 profit/loss share)	Phase 1 start 2H 2021

BNT113 and BNT115 are currently being studied in investigator-initiated phase I trials

BNT114 as an optional treatment; BNT114 is investigated in arm 1 (N=12) and arm 3 (N=15) of the TMBC-MERRT trial, with BNT114 as an optional treatment; BNT114 is investigated in arm 1 (N=12) and arm 3 (N=15) of the TMBC-MERRT trial (total patients in study; N=42)

Checkpoint Inhibitor

Update on the orgoning study including patient enrollment number, efficacy and safety data for an interim update expected in the second half of 2021

S as the trial is sponsored and conducted by Saxoff, the timing of data updates is not under our control and is subject to change by Saxofi

Checkpoint

S mall Molecule Immunomodulators

We are eligible to receive worldwide licenses

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. Our FixVac product candidates contain selected combinations of pharmacologically optimized uridine mRNA encoding known cancer-specific shared antigens. FixVac product candidates feature our proprietary immunogenic mRNA backbone and proprietary RNA-LPX delivery formulation, which are designed to enhance stability and translation as well as trigger both innate and adaptive immune responses.

# 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%.

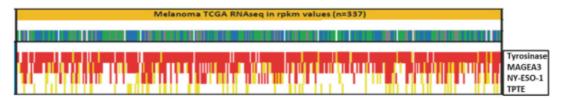
The current treatment regimen involves surgical removal for earlier stages, while a number of targeted therapies, such as BRAF and MEK inhibitors, and checkpoint inhibitors, or CPIs, are approved for advanced disease. CPIs include nivolumab (Opdivo) for advanced or metastatic melanoma after resection, 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 337 melanoma tumors and detected at least one of these four antigens in over 90% of such 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 7.2 ug up to the highest administered dose of 400 ug of total mRNA.

# July 2019 Interim Data

As of the July 2019 interim cut-off date, 95 patients with metastatic melanoma 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. So far, about half of the dosed patients have been analyzed for immune responses in this ongoing study. A first analysis in a subset of 18 patients evaluated vaccine antigen reactivity of CD4+ and CD8+ T cells by IFN-α 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 tumor antigens. Most patients exhibited either CD4+ or concurrently 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* IFN-α ELISpot, which due to its sensitivity level would capture only very strong T cell responses, and 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. Mostly, antigen-specific T cells counts showed a fast 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. Under monthly maintenance treatment, frequencies of individual antigen-specific T cells continued to slowly increase or remained stable up to over one year.

*Clinical activity.* As of the July 2019 cut-off date, 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. Twenty-five 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 checkpoint inhibitor, and 24 of the 25 patients had failed prior sequential or combination treatment with anti-PD-1 and anti-CTLA4 antibodies. Three of 25 patients (12%) showed a partial response, or PR, one patient had a metabolic complete response as measured by FGD-PET imaging 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 checkpoint inhibitor 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, 50µg and 100µg). Five of 10 (50%) patients who received the highest target dose of 100µg demonstrated a PR. By contrast, the expected ORR for anti-PD1 treatment in an anti-PD1 experienced patient population is in the range of 10%.

Safety. As of the July 2019 cut-off date, no dose-limiting toxicities to BNT111 have been reported. The highest explored dose level is 400μg total mRNA and doses up to 100μg total mRNA were tested further in expansion cohorts. The overall adverse event profile was dominated by mild-to-moderate, transient and manageable flu-like symptoms. This profile may have been driven by the mode of action of the RNA-LPX, which activates antigen presenting cells via signaling of TLRs, resulting in a temporary, self-limiting release of a distinct range of pro-inflammatory cytokines upon intravenous application. These symptoms were managed by pre-medication with non-steroidal antipyretics, such as ibuprofen and acetaminophen. Eight subjects dosed with BNT111 experienced related treatment-emergent serious adverse events, or TESAEs. The related TESAEs were comprised of two cases of Grade 2 pyrexia, and one case each of Grade 2 asthenia, Grade 2 dizziness, Grade 3 anaphylactic reaction, Grade 3 dizziness, Grade 3 syncope, Grade 3 exudative retinopathy, Grade 3 posterior reversible encephalopathy syndrome, Grade 3 epileptic seizure, and Grade 2 suspected pancreatitis. There were confounding factors, such as treatment with other therapies or underlying medical conditions, for the subjects with related TESAEs. We could not establish a clear causal relationship between BNT111 and the cases of anaphylactic reaction, retinopathy, encephalopathy syndrome, seizure and suspected pancreatitis. There have been no deaths in this study that were assessed by the investigators as related to BNT111.

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 with registrational potential for BNT111 in the second half of 2020.

# b) BNT112: Our FixVac Cancer Immunotherapy for the Treatment of Prostate Cancer

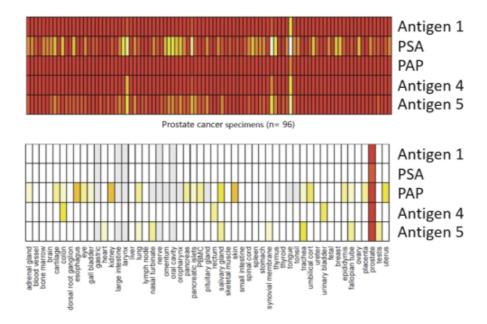
We are developing BNT112 for the treatment of prostate cancer.

# **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 becomes 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 additional tumor-associated antigens.



# **Our BNT112 Clinical Trials**

Phase 1/2 Clinical Trial

We enrolled the first patient in 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 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.

# 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 a 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 head and neck 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 with registrational potential of BNT113 in HPV+ cancers by the end 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 (TNBC)

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 second half of 2020 and assess the immunogenicity of the selected antigens.

# e) BNT115: Our FixVac Cancer Immunotherapy for the Treatment of Ovarian Cancer

We are developing BNT115 for the treatment of ovarian cancer. BNT115 is currently being studied in an ongoing investigator-sponsored Phase 1 study in ovarian cancer.

# **Our BNT115 Targets**

BNT115 is designed to elicit an immune response to selected antigens that are found in ovarian cancers.

### Our BNT115 Clinical Trial

Ongoing Phase 1 Trial (Investigator Sponsored)

BNT115 is being studied in a 10 patient investigator sponsored, first-in-human, open label, Phase 1 dose escalation study in ovarian cancer patients eligible for standard-of-care treatment with neo-adjuvant chemotherapy. Eight doses of BNT115 will be administered prior to and in combination with the neo-adjuvant chemotherapy to induce an anti-tumor immune response. Systemic immune responses will be determined using peripheral blood mononuclear cells collected before, during and after vaccinations. Intratumoral accumulation of T-cells recognizing vaccine-encoded tumor associated antigens will be determined before vaccination in a tumor biopsy and after 3 cycles of chemotherapy and the 5th vaccination using tumor tissue derived from interval surgery.

# f) Other FixVac Indications

We are also exploring FixVac development candidates in other cancer indications, including non-small cell lung 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 tumor. Our iNeST immunotherapies contain pharmacologically optimized uridine mRNA encoding up to 20 patient-specific neoantigens, as well as our proprietary RNA-LPX formulation. 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. We are currently conducting a randomized Phase 2 trial of RO7198457 (BNT122) in collaboration with Genentech in first-line melanoma in combination with pembrolizumab. In collaboration with Genentech, we are also studying RO7198457 (BNT122) as a monotherapy and in combination with atezolizumab in a Phase 1a/1b 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). The Phase 1a/1b trial is a non-registrational, signal-seeking study recruiting mostly patients with late-stage advanced cancers including patients who failed multiple lines of prior treatment.

# 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 primary endpoint is:

• progression-free survival, or PFS, of patients treated with RO7198457 (BNT122) compared with patients receiving pembrolizumab alone, according to RECIST v1.1.

# Secondary endpoints include:

- 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 partial response, or PR;
- 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 RO7198457 (BNT122) compared with patients receiving pembrolizumab only;
- mean change in health-related quality of life, scores of patients treated with RO7198457 (BNT122) compared with patients receiving pembrolizumab only;
- percentage of patients with CR or PR following cross-over from pembrolizumab monotherapy to combination therapy following cross-over, according to RECIST v1.1; and
- incidence and severity of adverse events.

# Ongoing Phase 1 Clinical Trial

The iNeST Phase 1a (monotherapy)/1b (in combination with atezolizumab) trial is a non-registrational, signal seeking study recruiting patients with locally advanced or metastatic solid tumors, including patients with melanoma, non-small cell lung cancer, bladder cancer, colorectal cancer, TNBC, renal cancer, head and neck cancer and sarcomas. The study is designed to enroll both patients with and without prior checkpoint inhibitor regimens.

The primary objective of the study was to assess safety (including dose-limiting toxicities), and additional objectives included evaluation of immunogenicity and preliminary assessment of anti-tumor activity. The trial included a Phase 1a (monotherapy) dose escalation, a Phase 1b (combination) dose escalation, and multiple Phase 1b expansion cohorts. Patients received nine doses of the vaccine administered I.V. in weekly and bi-weekly intervals during the induction phase and every eight cycles during the maintenance phase. In the Phase 1b portion of the trial, atezolizumab was administered on day one of each 21-day cycle.

BNT122 was manufactured on a per-patient basis including in-house determination of cancer mutation profiles, computational prediction of neoantigens, design, and manufacturing of the iNeST vaccine based on liposomally formulated RNA (RNA-LPX). Each vaccine contained up to 20 patient-specific neoepitopes. Importantly, the manufacturing of BNT122 for individual patients within clinical practice compatible turn-around times was shown to be feasible using clinical biopsies or routine clinical specimens across a range of tumor types including those with low or intermediate tumor mutational burden.

# June 2020 Data Updates

In June 2020, we presented data from a monotherapy dose-finding cohort of our RO7198457 (BNT122) Phase 1 trial in multiple solid tumors in which RO7198457 (BNT122) was observed to have a manageable safety profile and induced strong neoantigen-specific immune responses in patients with low and intermediate mutational load tumors types. This data related to 31 patients enrolled in cohorts with doses ranging from 25-100µg. Most patients enrolled had a low level of PD-L1 expression in the tumor as determined by immunohistochemistry. The majority of adverse events were Grade 1 or Grade 2 and those occurring in more

than 20% of patients included infusion related reaction (IRR), fatigue, cytokine release syndrome (CRS), nausea, and diarrhea. IRR and CRS were transient and reversible and presented primarily as Grade 1 or Grade 2 chills and fever. A single dose-limiting toxicity of Grade 3 CRS occurred at the 100µg dose level. None of the patients discontinued RO7198457 (BNT122) due to AEs. *Ex vivo* T cell responses were detected in approximately 86% of patients treated with RO7198457 (BNT122) as a monotherapy. RO7198457 (BNT122) induced T cells against multiple neoantigens were detected in post-treatment tumor biopsies. Of 26 patients that underwent at least one tumor assessment, one patient with gastric cancer and metastatic liver lesions had a durable best response of confirmed complete response and remains on study after 1.5 years (3.8%) and 12 patients had stable disease (46.2%).

Later in June 2020, we presented data from 132 patients enrolled in cohorts with doses ranging from 15µg to 50µg of RO7198457 (BNT122) in combination with 1200mg atezolizumab. The most common tumor types enrolled were NSCLC, TNBC, melanoma and colon cancer with a median of three lines of prior therapies (range 1-11). Most patients enrolled had low level of PD-L1 expression in the tumor as determined by immunohistochemistry (93% patients with <5% PD-L1 expression on tumor cells (TC0/1) and 79% patients with <5% PD-L1 expression on immune cell (IC0/1)). The majority of adverse events were Grade 1 or Grade 2 and those occurring in more than 15% of patients included infusion related reaction (IRR), fatigue, nausea, cytokine release syndrome (CRS) and diarrhea. IRR and CRS were transient and reversible and presented primarily as Grade 1 or Grade 2 chills and fever. There were no dose limiting toxicities. Eight patients (5.6%) discontinued due to AEs related to study drugs. RO1798457 (BNT122) induced a self-limiting increase of pro-inflammatory cytokines with each dose, consistent with the TLR agonist activity of RNA. *Ex vivo* T cell responses were observed in peripheral blood in 46 out of 63 (73%) patients. Induction of up to 5.7% MHC multimer-stained CD8+ T-cells with effector memory phenotype was observed in the peripheral blood. RO7198457 (BNT122) induced T cells against multiple neoantigens were detected in post-treatment tumor biopsies. Of 108 patients that underwent at least one tumor assessment, 1 patient had a complete response as their best response (0.9%), 8 patients had partial responses (7.4%), and 53 patients had stable disease (49.1%).

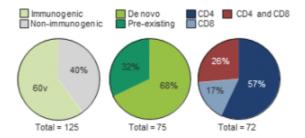
Based on data from our study of BNT121 as an adjunct to surgery in patients with metastatic melanoma, we believe that RO7198457 (BNT122) is potentially well suited to control metastatic relapses in patients with a lower tumor burden. Additionally, RO7198457 (BNT122) as a monotherapy and in combination with atezolizumab has been observed to have a manageable safety profile to date and to induce significant levels of neoantigen-specific immune responses, even in late-stage, heavily pre-treated patients. Accordingly, we and our collaborator, Genentech, intend to initiate two additional randomized Phase 2 trials in the second half of 2020 in early and adjuvant stage NSCLC and colorectal cancer, where we believe the mechanism of action of RO7198457 (BNT122) is best suited. We also continue to investigate RO7198457 (BNT122) in our ongoing Phase 2 trial in first line melanoma in combination with pembrolizumab.

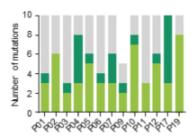
# Completed Phase 1 Clinical Trial (BNT121 First Generation iNeST)

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.

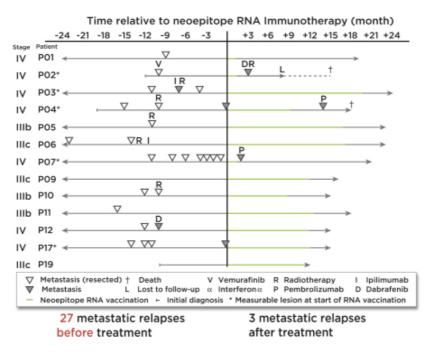
No severe adverse drug reactions were reported in the study. Common adverse events included flu-like symptoms.





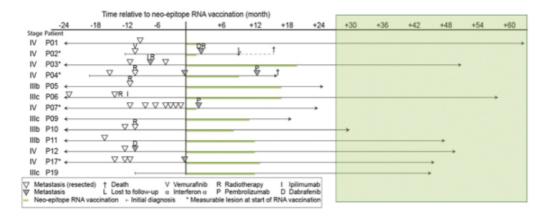
Immune responses documented in our prior BNT121 study. Patients showed immune responses, including both CD4+ and CD8+ responses, against multiple neoantigens. Source: Nature 547, 222-226 (13 July 2017).

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, three patients developed neoepitope treatment-related objective clinical responses. One of these patients exhibited a complete response and remained relapse-free for 26 months. The second patient had an immunotherapy-related partial response. This patient had a late relapse owing to outgrowth of \( \mathscr{B}2\)-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. Source: Nature 547, 222-226 (13 July 2017).

As of October 2019, nine out of 13 patients had remained recurrence-free through follow-up of up to 41 months post-vaccination.



# **Next Steps**

We expect to report an enrollment update from our RO7198457 (BNT122) first-line Phase 2 melanoma trial in the second half of 2020. We and Genentech plan to initiate two additional clinical trials for RO7198457 (BNT122) in 2020 in first-line solid cancers in the adjuvant setting, one in combination with atezolizumab and the other as a monotherapy.

# 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) consists of modified mRNA that is injected directly into the tumor, where it is thought to express cytokines to alter the tumor microenvironment. SAR441000 (BNT131) is being studied in a Sanofi-sponsored Phase 1 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 advanced solid tumors.

# Our SAR441000 (BNT131) Targets

SAR441000 (BNT131) comprises mRNA that encodes the cytokines IL-12sc, IL-15sushi, IFN- $\alpha$  and GM-CSF. By expressing 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

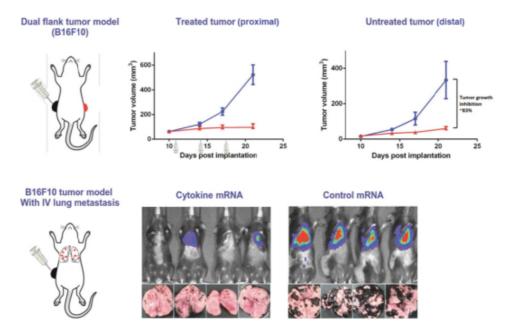
Sanofi, in collaboration with BioNTech, has commenced a first-in-human, multi-center, open-label, Phase 1, dose escalation and expansion trial to evaluate the safety, pharmacokinetics, pharmacodynamics and anti-tumor

activity of SAR441000 (BNT131) administered intratumorally as monotherapy and in combination with cemiplimab, with an estimated enrollment of 264 patients with certain advanced solid tumors.

# Our SAR441000 (BNT131) Preclinical Studies

In collaboration with Sanofi, we conducted a preclinical study of SAR441000 (BNT131) in mouse tumor models. In these *in vivo* models, the antitumor 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.

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). Source: Wagenaar et al., Local immunotherapy with a mixture of mRNAs encoding pro-inflammatory cytokines promotes potent anti-tumor immunity and tumor eradication across multiple preclinical tumor models; poster presented at SITC 2018.

Based on these preclinical results, we intend to investigate whether our synthetic mRNA technology can potentially deliver localized cytokine-based cancer immunotherapy with broad anti-tumor activity against treated and untreated lesions.

# **Next Steps**

A data update from this trial may be reported in the second half of 2020. As the trial is sponsored and conducted by Sanofi, the timing of data updates is not under our control, and is subject to change by Sanofi.

# 4. RiboMabs

Our RiboMab product candidates are designed to encode secreted antibodies for expression *in vivo* by the patient's cells. 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 LNPs for intravenous delivery. RiboMabs potentially address 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 published 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 2021.

# 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.

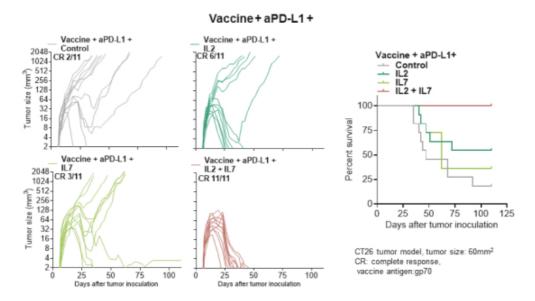
# **Next Steps**

We expect to initiate a Phase 1 basket trial of BNT142 for the treatment of numerous solid tumors in the first half of 2021.

# 5. RiboCytokines

Our RiboCytokine product candidates utilize mRNA that encodes the desired cytokines for expression *in vivo* by the patient's cells. 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.



In a preclinical mouse model, we observed RiboCytokines boost the activity of our RNA-LPX vaccination and a PD-L1 blockade in large tumors. Two out of 11 mice treated with our RNA-LPX vaccination and an anti PD-L1 alone achieved complete response. We observed three out of 11 mice achieve complete response with our RNA-LPX vaccination, an anti PD-L1 and IL7 RiboCytokine, six out of 11 mice with complete response after receiving our RNA-LPX vaccination, an anti PD-L1 and IL2 RiboCytokine and 11 out of 11 mice with complete response when given our RNA-LPX vaccination, an anti PD-L1 and both IL7 and IL2 RiboCytokines.

# 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 optimized 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 for the treatment of multiple solid tumors in the first half of 2021.

# 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 1/2 clinical trial of BNT152 in combination with BNT153 for the treatment of multiple solid tumors in the first half of 2021.

# 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.

# **Next Steps**

We expect to initiate a Phase 1/2 clinical trial of BNT153 in combination with BNT152 for the treatment of multiple solid tumors in the first half of 2021.

# **B. Our Oncology 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 2020 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 CARVac 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.

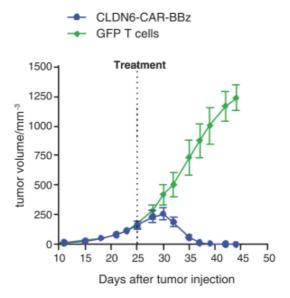
# **Our BNT211 Trials**

# 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 CARVac immunotherapy in the second 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.

In January 2020, we published results for a preclinical study in which BNT211 was evaluated both in vitro in tumor cell lines and in vivo in mice with human ovarian cancer transplants. In mice, BNT211 demonstrated complete tumor regression of transplanted large human tumors within two weeks after treatment initiation. Furthermore, the combination with CARVac achieved improved engraftment, proliferation and expansion of CAR-T cells in vivo, resulting in tumor regression even at sub-therapeutic CAR-T doses. CARVac was also successfully applied for CAR-T cells targeting the pan-cancer antigen CLDN18.2 and CD19, the target of approved CAR-T cell therapies. The combination of CAR-T cell therapy with CARVac underlines the value of cross-platform synergies to address key development challenges in the treatment of cancer.

# Next Steps

We are planning to initiate a Phase 1/2 clinical trial of the combination of BNT211 and a CLDN6-encoded CARVac in the second half of 2020 for the treatment of CLDN6+ solid tumors, including ovarian, testicular, uterine and lung cancer.

# 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 CARVac 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.

# 2. Neoantigen-Targeting T Cells.

We are advancing multiple neoantigen-targeting T cell product candidates, the most advanced of which, NEO-PTC-01 (BNT221), is targeting individualized sets of selected neoantigens, and which we expect to enter the clinic in the second half of 2020 for the treatment of metastatic melanoma. We are also developing NEO-STC-01 (BNT222), targeting shared RAS neoantigens prevalent across many solid tumor types.

# a) NEO-PTC-01 (BNT221): Our Individualized Neoantigen-targeting T Cell Therapy for the Treatment of Cancer

NEO-PTC-01 (BNT221) is our individualized neoantigen-targeting T cell therapy for the treatment of cancer. NEO-PTC-01 (BNT221) targets selected sets individualized neoantigens. The second planned indication for NEO-PTC-01 (BNT221) is metastatic ovarian cancer.

# Our NEO-PTC-01 (BNT221) Target

NEO-PTC-01 (BNT2211) targets sets of individualized neoantigens selected using our RECON bioinformatics engine.

# Our NEO-PTC-01 (BNT221) Trials

# Planned Phase 1 Clinical Trial

We are focusing the initial clinical development of NEO-PTC-01 (BNT221) in solid tumors where we believe we can generate *de novo* neoantigen T cell populations *ex vivo*. A CTA was filed with the Dutch Health Authority in December 2019 to evaluate NEO-PTC-01 (BNT221) in a first-in-human clinical trial in patients that are refractory to checkpoint inhibitors. We plan to initiate a Phase 1 dose escalation clinical trial in patients with metastatic melanoma who are refractory to checkpoint inhibitors in collaboration with the Netherlands Cancer Institute in the second half of 2020. The primary objectives of this trial will be to evaluate the safety and feasibility of administering NEO-PTC-01 (BNT221) to patients. Additional objectives will be to evaluate immunogenicity and clinical efficacy.

Based on the data from the first exploratory trial, we will decide how to best proceed with further clinical development of NEO-PTC-01 (BNT221), including expanding to other tumor types and potential development in the United States.

# Preclinical Studies

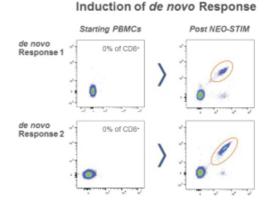
Preclinical data relating to NEO-PTC-01 (BNT221) was presented at the Society of Immunotherapy of Cancer 2019 meeting, highlighting the proof of feasibility of our NEO-STIM induction protocol. These data demonstrated reproducibly across multiple patient samples, the ability to generate multiple CD8+ and CD4+ T

cell populations in each patient sample from the memory and naïve compartment. These T cells were highly functional and were specific for mutant neoantigens. In addition, these data showed that these cells were capable of *in vitro* cell killing and NEO-PTC-01-induced T cell cultures directly recognize autologous tumor sample material. We can now reproducibly generate these cell populations from patient material at a therapeutic manufacturing scale.

Our NEO-STIM induction protocol generates a polyclonal population of T cells. Once generated, we deeply characterize this cell product to understand the specificity and functionality of the induced cells. Data analyzed from a melanoma patient shows that NEO-STIM can induce CD8+ T cell responses towards patient-specific neoantigens in autologous patient peripheral blood mononuclear cells, or PBMCs. Specifically, in this patient, as the charts below and to the left illustrate, a pre-existing memory response was expanded 16-fold, from 4.5% of CD8+ T cells to 72.1% of CD8+ T cells being specific for the selected neoantigen. Additionally, as the charts below and to the right illustrate, we induced two CD8+ T cell responses from the naïve compartment, generating 6.5% and 13.4% of CD8+ T cells, respectively. Finally, in this patient, we induced three neoantigen specific CD4+ T cell responses as well.

# Expansion of Memory Response Starting PBMCs Post NEO-STIM 72.1% of CD8\* PMHC Multimer B 16-fold increase

post NEO-STIM



# Next Steps

We are planning to initiate a Phase 1 dose escalation trial of NEO-PTC-01 (BNT221) in the second half of 2020 for the treatment of metastatic melanoma.

# C. Our Antibody Product Candidates in Oncology

# 1. Next-Generation Checkpoint Immunomodulators

In our 50:50 collaboration program with Genmab, we are currently studying two bispecific antibody checkpoint immunomodulators.

# a) GEN1046 (BNT311): Our Jointly Owned DuoBody® PD-L1x4-1BB Bispecific Antibody for the Treatment of Solid

GEN1046 (BNT311), our jointly owned PD-L1x4-1BB product candidate, is a potential first-in-class bispecific antibody combining PD-L1 checkpoint inhibition with 4-1BB checkpoint activation. The first patient in a Phase 1/2a trial of GEN1046 (BNT311) for the treatment of malignant solid tumors was dosed in May 2019.

# Our GEN1046 (BNT311) Targets

GEN1046 (BNT311) is a PD-L1x4-1BB bispecific antibody that induces conditional activation of T cells through 4-1BB stimulation which is dependent on simultaneous binding to PD-L1. In addition, the PD-L1-specific arm of DuoBody-PD-L1x4-1BB functions as a classical immune checkpoint inhibitor by blocking the PD-1/PD-L1 axis, also in the absence of 4-1BB binding. 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. DuoBody® is a registered trademark of Genmab.

# GEN1046 (BNT311) Trials

Ongoing Phase 1/2a Clinical Trial

The ongoing Phase 1/2a, open-label, single-arm GEN1046 (BNT311) trial with multiple expansion cohorts, conducted in collaboration with Genmab, is expected to enroll approximately 192 patients with malignant solid tumors. The trial consists of a dose escalation part and an expansion part. The dose escalation part 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 part will be initiated once the recommended Phase 2 dose has been established in Phase 1. In the expansion part, 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) induces conditional activation of T cells through 4-1BB stimulation which is dependent on simultaneous binding to PD-L1. In addition, the PD-L1-specific arm of DuoBody-PD-L1x4-1BB functions as a classical immune checkpoint inhibitor by blocking the PD-1/PD-L1 axis.

### Next Steps

We expect to report a data update for our ongoing Phase 1/2 trial in the second half of 2020.

# b) GEN1042 (BNT312): Our Jointly Owned DuoBody® CD40x4-1BB Bispecific Antibody for the Treatment of Solid Tumors

GEN1042 (BNT312), our jointly owned CD40x4-1BB 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. We and Genmab began recruitment and screening for a Phase 1/2a trial of GEN1042 (BNT312) for the treatment of malignant solid tumors in August 2019.

# GEN1042 (BNT312) Targets

GEN1042 (BNT312) is a bispecific antibody designed to enhance an anti-tumor immune response through conditional CD40-mediated stimulation of antigen presenting cells cross-linked with conditional stimulation of 4-1BB+ T cells. It has demonstrated increased tumor infiltrating lymphocyte expansion in human tumor tissue cultures *ex vivo* and has induced tumor regression of murine tumors superior to pure PD-L1 blockage associated with an increase in tumor-specific CD8 T-cells. The cell surface molecule CD40 is a member of the tumor necrosis factor receptor superfamily.

# GEN1042 (BNT312) Preclinical Studies

GEN1042 (BNT312) is designed to target CD40 and 4-1BB to enhance both dendritic cell and antigen-dependent T cell activation. In preclinical settings, GEN1042 (BNT312) activated antigen presenting cells and enhanced T cell activation. Preclinical studies also indicated the conditional activation and (clonal) expansion of previously activated CD8+ T cells and cytokine production resulting from GEN1042 (BNT312).

# 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

In 2019, the American Cancer Society estimated that approximately 56,770 people will be diagnosed with pancreatic cancer in the United States annually. 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 (sLea), 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+ 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+ 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.

We have resumed this trial and dosing has begun.

# D. Our Oncology Small Molecule Immunomodulator Product Candidates

# 1. BNT411: Our Small Molecule TLR7 Agonist for the Treatment of Solid Tumors, Including Small Cell Lung, Colorectal and Bladder Cancer

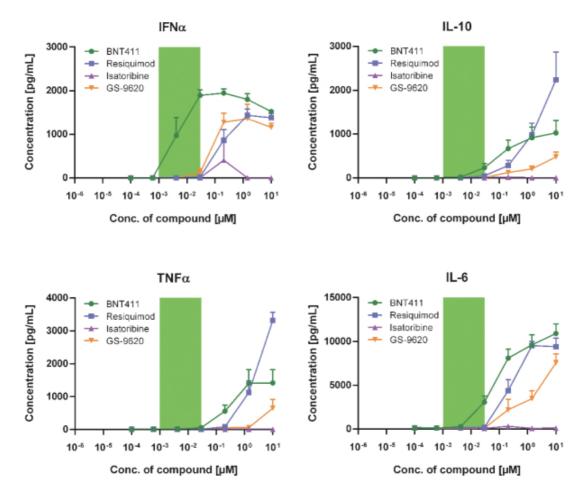
BNT411 is our novel small molecule TLR7 agonist product candidate. BNT411 is designed to activate both the adaptive and innate immune system through the TLR7 pathway. We are designing BNT411 to be used both as a monotherapy and in combination with chemotherapy and checkpoint inhibitors. We filed an IND for BNT411 in November 2019 and dosed the first patient in our Phase 1 trial in July 2020.

# 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- $\alpha$  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- $\alpha$  whereas other (pro-)inflammatory and CRS-related cytokines (IL-6, IL-10, TNF-a, IL-8) are only observed at higher concentrations.



# E. Our Infectious Disease mRNA Product Candidates

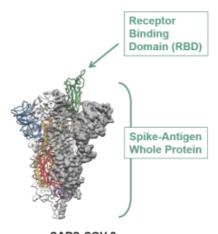
# 1. Prophylactic Vaccine for the Prevention of COVID-19

We are collaborating with Pfizer and Fosun Pharma for the development of a vaccine for the prevention of COVID-19 under our BNT162 program. We and Pfizer are jointly conducting clinical trials for the COVID-19 vaccine candidates initially in the United States and Europe across multiple sites.

We have begun development of four product candidate variants under our BNT162 program, including one prime-only and three prime-boost immunization strategies, utilizing different mRNA formats. In addition, we continue to develop additional product candidate variants and may bring additional candidates into the clinic if the preclinical data supports it.

# Our BNT162 Targets and mRNA Formats

We are developing multiple vaccine candidate variants, some of which target the entire 2P-mutated full Spike protein antigen and others which target the more specific receptor binding domain subunit of the antigen protein.



SARS-COV-2 Spike Protein 3D Structure

In addition, we are studying three different mRNA formats in our four vaccine candidate variants.

BNT 162 Candidate	Target	mRNA Format
162a1	RBD subunit	uRNA (prime/boost)
162b1	RBD subunit	modRNA (prime/boost)
162b2	2P-mutated full Spike protein	modRNA (prime/boost)
162c2	2P-mutated full Spike protein	saRNA (single injection)

The graphic below illustrates the potential benefits and rationale for each mRNA format used in our candidate variants.



Uridine mRNA (uRNA)

Prime / boost

Rationale

- Strong adjuvant effect
- Active at low doses
- Strong antibody response
- CD8 T-Cells > CD4 T-Cells

# Nucleoside-modified mRNA (modRNA)



# Rationale

- Prime / boost
- · Moderate adjuvant effect
- Very strong antibody response
- · CD8 T-Cells > CD4 T-Cells

# Self-amplifying mRNA (saRNA)



# Rationale

- · Prime (1x injection)
- Long-term activity
- Very strong antibody response
- Very strong T-Cell response (CD8 and CD4)
- Potent immune protection at low doses (approx. 60x lower dosage required to induce immunity vs. uRNA observed in preclinical models

### Our BNT162 Clinical Trial

We are conducting a multi-site, open label, Phase 1/2, two-part, dose-escalation trial investigating the safety and immunogenicity of our four BNT162 candidate variants using different dosing regimens in healthy adults. The trial is being conducted in multiple locations in Germany and the United States. The trial has two parts: a dose-finding part (Part A) with four dose cohorts (treatment groups) for each vaccine candidate variant and one pre-defined and one optional dose level for a de-escalation approach and a second part (Part B) dedicated to recruit expansion cohorts with dose levels which are selected from data generated in Part A. The vaccine candidate variants BNT162a1, BNT162b1, and BNT162b2 will be administered using a prime/boost regimen. The vaccine candidate variant BNT162c2 will be administered using a single-dose regimen.

# July 2020 Data Announcements

On July 1, 2020, we and Pfizer announced preliminary data from our ongoing U.S. Phase 1/2 trial of BNT162b1. The initial part of this randomized, placebo-controlled, observer-blinded study is evaluating the safety, tolerability and immunogenicity of escalating dose levels of BNT162b1, one of four vaccine candidate variants in development as part of our BNT162 program, in 45 healthy adults between 18 and 55 years of age.

The participants received two doses, 21 days apart, of placebo,  $10\mu g$  or  $30\mu g$  of BNT162b1, or received a single dose of  $100\mu g$  of the vaccine candidate. Because of a strong vaccine booster effect, the highest neutralizing titers were observed seven days after the second dose of  $10\mu g$  or  $30\mu g$  on day 28 after vaccination. The neutralizing GMTs were 168 and 267 for the  $10\mu g$  and  $30\mu g$  dose levels, respectively, corresponding to 1.8- and 2.8-times the neutralizing GMT of 94 observed in a panel of 38 sera from subjects who had contracted SARS-CoV-2.

In all 24 subjects who received 2 vaccinations at 10µg and 30µg dose levels of BNT162b1, elevation of RBD-binding IgG concentrations was observed after the second injection with respective GMCs of 4,813 and 27,872 units/ml at day 28, seven days after immunization. These concentrations are 8- and 46.3-times the GMC of 602 units/ml in a panel of 38 sera from subjects who had contracted SARS-CoV-2.

At day 21 after a single injection, the 12 subjects who received 100µg of BNT162b1 had an RBD-binding IgG GMC of 1,778 units/ml and a SARS-CoV neutralizing GMT of 33, which are 3-times and 0.35-times, respectively, the GMC and GMT of the convalescent serum panel.

At the 10µg or 30µg dose levels, adverse reactions, including low grade fever, were more common after the second dose than the first dose. Following dose 2, 8.3% of participants who received 10µg and 75.0% of participants who received 30µg BNT162b1 reported fever ³ 38.0 °C. Local reactions and systemic events after injection with 10µg and 30µg of BNT162b1 were dose-dependent, generally mild to moderate, and transient. The most commonly reported local reaction was injection site pain, which was mild to moderate, except in one of 12 subjects who received a 100µg dose, which was severe. No serious adverse events were reported. Given higher numbers of subjects experiencing local reactions and systemic events after a single 100µg dose with no significant increases in immunogenicity compared to the 30µg dose level, the 12 participants in the 100µg group were not administered a second dose.

On July 20, 2020, we and Pfizer announced preliminary data from our ongoing German Phase 1/2 trial of BNT162b1. The initial part of this open-label, non-randomized, non-placebo-controlled study is evaluating the safety, tolerability and immunogenicity of escalating dose levels of BNT162b1, one of four vaccine candidate variants in development as part of our BNT162 program, in 60 healthy adults, between 18 and 55 years of age. The preliminary data we reported was from 12 subjects each who received two doses of 1µg, 10µg, 30µg and 50µg (except for one individual each in the 10µg and 50µg who discontinued due to non-study drug related reasons) and 12 subjects who received a single dose of 60µg. The two doses received by the participants were given 21 days apart.

In 34 of the 36 subjects who received two vaccinations at 10µg, 30µg, or 50µg dose levels of BNT162b1, RBD-specific CD4+ T cell responses were observed. All subjects but the two exceptions at the lowest dose level had cytokine profiling of the RBD-specific CD4+ T cells that demonstrated a TH1-dominant profile for these cells. While the magnitude varied between individuals, participants with the strongest CD4+ T cell responses to RBD had more than 10-fold of the memory responses observed in the same participants when stimulated with cytomegalovirus (CMV), Epstein Barr virus (EBV), influenza virus and tetanus toxoid-derived immuno- dominant peptide panels. The strength of RBD-specific CD4+ T cell responses correlated positively with both RBD-binding IgG and with SARS-CoV-2 neutralizing antibody titers. Among vaccine-induced CD8+ T cell responses, which were observed in 29 of 36 participants, strong responses were mounted by the majority of participants and were comparable with memory responses against CMV, EBV, influenza virus and tetanus toxoid in the same participants. The strength of RBD-specific CD8+ T cell responses correlated positively with vaccine- induced CD4+ T cell responses, but did not significantly correlate with SARS-CoV-2 neutralizing antibody titers. Additionally, although at 1µg the immunogenicity rate was lower (6 of 8 responding participants), the magnitude of vaccine-induced CD4+ and CD8+ T cells in some participants was almost as high as with 50µg BNT162b1.

Elevation of SARS-CoV-2 RBD-binding IgG concentrations was observed, with respective GMCs ranging from 265 units/ml to 1,672 units/ml at day 21. At day 29, seven days after the second dose, RBD-binding IgG GMCs ranged from 2,015 units/ml to 25,006 units/ml. At day 43, RBD-binding IgG GMCs ranged from 3,920 units/ml to 18,289 units/ml. These concentrations are 6.5- to 30.4-times the GMC of 602 units/ml in a panel of sera from 38 subjects who had contracted SARS-CoV-2. At day 29, the SARS-CoV-2 neutralizing GMTs reached 36 (1µg dose), 158 (10µg dose), 308 (30µg dose) and 578 (50µg dose) compared to neutralizing GMT of 94 observed in the convalescent serum panel. At day 43, SARS-CoV-2 neutralizing GMTs reached .7-fold (1µg dose) to 3.2-fold (50µg dose) compared to those of a panel of SARS-CoV-2 infection convalescent human sera. Furthermore, sera of vaccinated subjects displayed broadly neutralizing activity in pseudovirus neutralization assays across a panel of sixteen SARS-CoV-2 RBD variants represented in publicly available SARS-CoV-2 sequences and against the newly dominant D614G strain. In summary, antibody responses elicited by BNT162b1 in our German clinical trial largely mirrored those observed in our U.S. clinical trial.

At the 10µg, 30µg and 50µg dose levels, certain adverse reactions, including low grade fever, were more common after the second dose than the first dose. Following the second dose, 25.0%, 25.0% and 33.3% of participants who received the 10µg, 30µg and 50µg doses, respectively reported fever of at least 38.0 degrees Celsius. Local reactions and systemic events after injection with 10µg, 30µg and 50µg of BNT162b1 were dose-dependent, generally mild to moderate and transient, with occasional severe events (grade 3) of flu-like symptoms and injection site reactions. The most commonly reported local reaction was injection site pain, which was mild to moderate, except in one of 12 subjects who received a 60µg dose, which was severe. No serious adverse events were reported, and there were no withdrawals due to adverse events related to the vaccine. Based on the adverse reactions reported after the 50µg boost dose, a second 60µg dose was not administered to participants who had received an initial 60µg dose.

For additional information on these preliminary results, please review our reports on Form 6-K filed with the SEC on July 1, 2020 and July 20, 2020 and incorporated by reference herein.

# Next Steps

Based on preclinical and clinical data observed to-date, we and Pfizer have decided to progress our BNT162 development program into a Phase 2b/3 trial, which is anticipated to commence in late July 2020, subject to input and approval from the appropriate regulatory bodies. For the initial Phase 2b/3 trial, we intend to select either BNT162b1 or BNT162b2. Both the BNT162b1 and the BNT162b2 vaccine candidates have received Fast Track status from the FDA. Since clinical evaluation of the BNT162b2 candidate started several weeks later than BNT162b1, only preliminary clinical data are currently available for the BNT162b2 candidate. A set of data obtained for a cohort of subjects 18-55 years of age immunized with 10µg of BNT162b2 indicates that BNT162b2 induces similar virus neutralizing antibody responses as observed for BNT162b1. The preliminary

observations are subject to further data collection and analysis. Assessment of dose dependent immune response and safety profile as well as analysis of T cell responses is currently pending. On the basis of additional data expected to be collected and analyzed for BNT162b1 and BNT162b2 in the coming days, along with input from the FDA, we intend to select a lead candidate to take into a Phase 2b/3 trial. We and Pfizer currently expect to inform the FDA of our selection of the BNT162 candidate variant before the closing of this offering. Based on clinical data from our ongoing Phase 1/2 trials of BNT162b1 in the United States and Germany, BNT162b1 appears to be a viable variant to advance into a Phase 2b/3 trial. However, given that additional information relating to BNT162b2 is becoming available over the next few days, we and Pfizer plan to make the ultimate decision on the final candidate based on multiple factors, including the overall observed safety, tolerability and immunogenicity profiles for each vaccine candidate at different dose levels, a full immunogenicity data set and feedback from the FDA on the data collected for each candidate. If we ultimately move forward with the BNT162b2 variant, it will be due to the fact that based on our scientific judgment in light of the totality of preclinical data and clinical data available to us at the time of selection and the other factors described above, the BNT162b2 variant has better potential for clinical and commercial success. We do not plan to disclose which BNT162 variant has been selected until we receive FDA approval to commence the Phase 2b/3 clinical trial, and we likely will not publish any data with respect to the BNT162b2 variant before we make our selection.

# 2. Prophylactic Vaccine for the Prevention of Influenza

We are collaborating with Pfizer to develop an influenza vaccine based on our mRNA drug classes. The product candidate, BNT161, will encode influenza virus antigens selected by the WHO in advance of the flu season. We and Pfizer have moved the anticipated Phase 1 start for our mRNA flu vaccine program to 2021 due to the prioritization of our COVID-19 vaccine development efforts.

# **Next Steps**

We anticipate beginning a first clinical trial for BNT161 in 2021.

# 3. 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. On September 20, 2019, Penn announced positive preclinical results of a vaccine product candidate using its mRNA technology. The preclinical study vaccinated mice and guinea pigs against Herpes simplex virus type 2. Penn reported that the immunization led to "mostly sterilizing immunity" from the virus.

# Next Steps

We expect to initiate our first Phase 1 clinical trial under Penn collaboration in the first half of 2021.

# F. Our Rare Disease Protein Replacement mRNA Product Candidates

We are collaborating with Genevant, in order to combine 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 in the second half of 2021. The first product candidate under the Genevant collaboration, BNT171, is currently being developed for an undisclosed indication. Our mRNA replacement product candidate is associated with a favorable tolerability profile and good protein expression (in mice) and demonstrated phenotype rescue in a mouse disease model.

### G. 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 MKI67 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. It 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 about 1000 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 a fully-automated, on-demand production of mRNA therapies.

# **Our Manufacturing Operations**

mRNA. We believe scaling up manufacturing for mRNA 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 batch production for our drug substances to match our development plans as they evolve. Our mRNA manufacturing is currently conducted at our in-house BioNTech IMFS facility and our BioNTech East Wing facility, the latter being dedicated to iNeST and bulk mRNA 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 milligrams for individualized applications (i.e., iNeST) to 10g for standard mRNA applications (i.e., FixVac, intratumoral immunotherapies and infectious diseases, e.g., COVID-19), with batch sizes of up to 250g planned for Q4 2020.

To date, we have produced about 1000 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 the capacity to supply needs of our product candidates 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 manufacturing and delivering individualized immunotherapies in under six weeks. This advancement represents significant progress toward our target commercial manufacturing turnaround time of less than 28 days. We believe this is achievable, and 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 neoepitope 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 and Bulk mRNA Clinical Manufacturing (East Wing). We dedicate our GMP-certified manufacturing facility at our headquarters in Mainz, Germany to the production of iNeST immunotherapies and bulk mRNA. 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. We plan to expand our manufacturing license for bulk mRNA in Q3 2020.

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 and has, since inception, manufactured and released more than 450 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.

# Manufacturing Financing

In June 2020, we signed a second financing arrangement with the EIB. The purpose of this financing is to partially support the development of BNT162 and fund expansion of our manufacturing capacity to provide worldwide supply of BNT162 in response to the pandemic, or the Second Investment. Under this arrangement, the EIB has agreed to provide us with a credit in an amount of up to  $\le$ 100 million to partially finance the Second Investment, provided that the amount of credit does not exceed 50% of the cost of the Second Investment. The credit consists of (i) a term loan in the amount of  $\le$ 50 million that may be drawn in a single tranche upon the achievement of certain milestone events, not all of which have been achieved (Credit A), and (ii) a term loan in the amount of  $\le$ 50 million that may be drawn in a single tranche (Credit B). Credit B may only be drawn after Credit A has been drawn down and upon the achievement of certain milestone events. Each tranche under Credit A and Credit B must be repaid within six years from the date on which the tranche is disbursed.

# 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 COVID-19 and influenza vaccine programs, which leverage technology from our infectious disease mRNA-based platform;

- Fosun Pharma for our COVID-19 vaccine program;
- · 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, as amended on June 1, 2018 and December 6, 2019, 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 agreed to perform joint research under a research plan to further improve our technology platform for the manufacturing of Genentech Collaboration Products. Under the terms of the Genentech Collaboration Agreement, Genentech paid us \$310 million in upfront and near-term milestone payments.

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 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 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 an 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 a 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. In connection with our entry into the Genmab Agreement, Genmab paid us an upfront fee of \$10 million.

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 19, 2022, 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 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 provides 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, 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-COVID-19 Collaboration

On April 9, 2020, effective as of March 17, 2020, we entered into a Collaboration Agreement with Pfizer for the research and development of immunogenic compositions comprising RNA encoding a SARS-CoV-2 polypeptide or fragment thereof for prophylaxis against SARS-CoV-2 in humans, which we refer to as the Pfizer Corona Field. We also entered into a binding term sheet for commercialization of the foregoing compositions, which we refer to, together with the Collaboration Agreement, as the Pfizer Corona Agreement. We plan to enter into a Commercialization Agreement based on such term sheet.

We and Pfizer agreed to collaborate on research and development in the Pfizer Corona Field worldwide excluding the Fosun Territory, which we refer to as the Pfizer Territory. The details of such activities are set forth in a research and development plan that is governed by a joint steering committee. Each party bears its own personnel and capital expenditures costs, but the parties will share the costs of all other agreed development activities (including the costs of manufacturing material for use in clinical trials) evenly. Each party will, in good faith, seek funding from government funds, non-governmental organizations and other third-party organizations to support their research and development activities. Under the Pfizer Corona Agreement, Pfizer will lead clinical development of and seek regulatory approval for any candidates or products in the USA and we will lead clinical development of and seek regulatory approval for any candidates or products in the EU, and we will agree on a strategy for all other countries.

If a vaccine candidate has been approved, we plan to hold the marketing authorizations for that vaccine throughout the Pfizer Territory and can solely commercialize the vaccine in Germany and Turkey, as well as

specified developing countries (collectively referred to as the BioNTech Territory) for so long as we or a third-party funding organization is conducting vaccine commercialization in such countries and subject to any future agreement with the third-party funding organization. We have the option to opt-out of commercializing the vaccine in Germany and/or Turkey, whereupon such countries will become part of the Pfizer Territory.

If a vaccine candidate is approved, Pfizer has the right to commercialize that vaccine and related products in the rest of the Pfizer Territory. On a country-by-country basis in relation to the United Arab Emirates and certain countries of southeast Asia, if we obtain funding from a third-party government, non-governmental organization or other organization that obligates us to commercialize an approved vaccine in such country, we are obligated to request from Pfizer in writing a decision as to whether Pfizer wishes to commercialize such vaccine in such country in accordance with the requirements agreed with the third-party funder. If Pfizer elects not to commercialize the vaccine in such country, then such country shall become a part of the BioNTech Territory.

If the Fosun Agreement expires or is otherwise terminated for any reason, as between us and any international pharmaceutical group headquartered outside of China, we granted Pfizer a right of first negotiation to expand the Pfizer Territory to include the Fosun Territory. See "—Fosun-COVID-19 Collaboration" below for more information on the Fosun Agreement.

We and Pfizer will share responsibilities for manufacturing and supplying a vaccine, if approved. If there is insufficient supply to satisfy the entire demand for a vaccine in the Pfizer Territory, we and Pfizer have agreed to determine by mutual consent the allocation of supplies on a fair and equitable basis, subject also to any applicable law, export controls, any government supply obligations, or supply obligations included in any agreement reached with a third-party funding organization.

Under the Pfizer Corona Agreement, we granted to Pfizer an exclusive, sublicensable license in the Pfizer Territory under certain of our intellectual property, including our patents and know-how, relating to uridine RNA, modified RNA and replicons in the Pfizer Corona 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 Corona Agreement. We undertake to maintain in full effect all intellectual property licenses held by us at the time we entered into the agreement and not to modify or amend any such license in a manner that would adversely affect any of the rights granted to Pfizer under the Pfizer Corona 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.

During the term of the Pfizer Corona Agreement and a certain period thereafter, we and Pfizer have committed not to research, develop, manufacture, commercialize or otherwise exploit immunogenic compositions comprising RNA in the Pfizer Corona Field, or exploit vaccine candidates or products developed under the agreement for any use, other than pursuant to the Pfizer Corona Agreement, provided, however, that Pfizer shall have the right to work as a contract manufacturer for a third party and Pfizer shall not be precluded from acquiring a third party, or being acquired by a third party, that at the time of acquisition is active in the development or commercialization of an immunogenic composition comprising mRNA in the Pfizer Corona Field.

On April 9, 2020, Pfizer also subscribed for \$113 million of our ordinary shares under a separate investment agreement. In addition, under the Pfizer Corona Agreement, Pfizer made an upfront payment of \$72 million and agreed to make potential payments of up to \$563 million upon the achievement of specified regulatory and commercial milestones. We and Pfizer agreed to share development costs equally. However, Pfizer will fund 100 percent of the development costs, and we will repay Pfizer its 50 percent share of these costs as a deduction from the milestones and other payments we would otherwise be due to receive under the Pfizer Corona Agreement, or as a lump sum in the case we are acquired by certain entities or if Pfizer terminates the agreement for cause. Subject to this repayment obligation, we and Pfizer will share the cost of and profits from commercializing a vaccine evenly.

The Pfizer Corona Agreement ends on the later of (i) the completion of all development and manufacturing obligation of the parties and (ii) termination or expiry of a separately executed Commercialization Agreement, or, if the parties do not enter into such agreement, Pfizer ceases to commercialize vaccine products pursuant to the binding term sheet. 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 (i) upon our insolvency or (ii) for convenience and with or without reason at any time after the six-month anniversary of the commencement date upon 180 days' prior written notice.

# 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.

We also granted Pfizer 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 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 compromising 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.

#### Fosun-COVID-19 Collaboration

On March 13, 2020, we entered into a Development and License Agreement with Shanghai Fosun Pharmaceutical Industrial Development, Co., Ltd, or Fosun Pharma, for the development and commercialization in People's Republic of China (including Hong Kong SAR, Macau SAR and Taiwan), or the Fosun Territory, of immunogenic compositions generated by BioNTech and comprising uridine RNA, modified RNA and/or replicon technology for prophylaxis against SARS-CoV-2 in humans. We refer to this agreement as the Fosun Agreement.

The details of the development activities to be undertaken by Fosun Pharma are to be set forth in a development plan that is overseen by a joint steering committee. Fosun Pharma's development activities are to be undertaken at its own cost and expense. Fosun Pharma is obligated to use commercially reasonable efforts to develop a vaccine candidate in accordance with the development plan with the goal to obtain regulatory approval for a vaccine candidate in the Fosun Territory in accordance with the timelines set forth in the development plan. Fosun Pharma has the sole responsibility to prepare, obtain and maintain regulatory approvals for the vaccine candidates in the Fosun Territory. We agreed to give Fosun Pharma reasonable assistance with the regulatory aspects of these activities.

Fosun Pharma has the sole responsibility, authority and control of the commercialization of a vaccine candidate in the Fosun Territory, but must use commercially reasonable efforts to do so in accordance with an agreed commercialization plan, including by launching a vaccine product in the Fosun Territory within three months after receiving marketing approval for it, provided sufficient quantities of the vaccine have been delivered.

We retain the sole right to manufacture (or have manufactured) and supply any vaccine candidates and products for development purposes and commercial sale in the Fosun Territory. We agreed to manufacture and supply all quantities of vaccine from a GMP-certified RNA manufacturing facility. As compensation for supply of the vaccine Fosun Pharma will reimburse us our manufacturing costs plus an administrative fee that is between 10 and 19 percent.

Under the Fosun Agreement, we granted to Fosun Pharma an exclusive license under certain of our owned or in-licensed intellectual property, including our patents relating to replicons, uridine RNA and modified RNA and other mRNA technology or a vaccine to use, develop, commercialize and otherwise exploit the vaccine candidates in the Fosun Territory. In the event of any failure of the development of a vaccine, we agreed to grant

Fosun Pharma a right of first negotiation on a separate competent vaccine for the prophylaxis of COVID-19 in the Fosun Territory.

In consideration of the rights granted to Fosun Pharma under the Fosun Agreement, Fosun Pharma subscribed for \$50 million of our ordinary shares under a separate investment agreement. In addition, under the Fosun Agreement, Fosun Pharma made an upfront payment of \$1 million and agreed to potential payments of up to \$14 million upon the achievement of specified development and regulatory milestones and up to \$70 million upon the achievement of specified sales milestones. Fosun Pharma further agreed to pay us a royalty rate that is between 30 and 39 percent of its profits on net sales of a vaccine product, if approved, for a period of 15 years from launch of that vaccine in the Fosun Territory.

The Fosun Agreement ends upon expiration of the royalty term. Fosun Pharma may elect to continue to pay royalties and extend the agreement and its rights thereunder. In addition to termination rights granted to each party in the case of the other party's uncured material breach or insolvency, Fosun Pharma may terminate the agreement, in whole, for convenience and with or without reason at any time upon 180 days' prior written notice. If the agreement is terminated by Fosun Pharma for cause, the licenses to Fosun Pharma survive, we will manufacture and deliver the vaccine candidate or product for one year and we will grant a non-exclusive license to a reasonably acceptable contract manufacturing organization for manufacturing of the vaccine candidate or product thereafter for development and commercialization by Fosun Pharma in the Fosun Territory.

During the term of the Fosun Agreement, we have committed not to, and not to license the licensed intellectual property to any third party to, develop or commercialize the same vaccine candidate or vaccine in the Fosun Territory.

#### Bill & Melinda Gates Foundation-HIV and Tuberculosis Collaboration

On August 30, 2019, we entered into a letter agreement and an investment agreement with the Bill & Melinda Gates Foundation, or BMGF, pursuant to which BMGF acquired 3,038,674 of our ordinary shares for \$55 million at the price of our Series B financing. The primary purpose of BMGF's investment is to further its charitable purposes, and the investment will be utilized to advance the development of products for the prevention and/or treatment of HIV and tuberculosis, or TB. About one-third of the investment will be used to help fund our infrastructure build-out; this expansion of the company's infectious disease capabilities is necessary to enable us to conduct BMGF projects.

In addition to the HIV and TB projects, BMGF has the right to initiate up to three additional projects focused on infectious diseases (from a list of mutually agreed upon diseases) within the first five years of the partnership. BMGF may also continue to fund certain projects beyond initial funding agreements. These additional activities may be funded through grants from BMGF of up to \$45 million. We must accept funding for the HIV and TB projects until the occurrence of defined event stamps and for the additional projects until the eighth anniversary of the closing of the investment. The event stamps involve the completion of Phase 1 safety and immunogenicity studies in healthy and/or infected individuals showing specific results.

If we elect not to proceed with any project following achievement of the event stamps, a new partner may further develop the project and manufacture any resulting products. Such partner will be identified through a series of defined steps and a technology transfer would take place. If a suitable manufacturing partner is not identified, we must manufacture the clinical and commercial supply of any product until a partner is identified. Such manufacturing may require us to increase our manufacturing capacities, which may be funded by BMGF. We retain the right to manufacture at any time

The primary objective of BMGF is to provide funding to accelerate the development of lifesaving, low-cost drugs to reduce the burden of diseases in developing countries. This objective is known as global access commitments, or GAC. The projects in this partnership are separate and distinct from our current proprietary and

partnered product candidates; all BMGF programs, however, will utilize our proprietary technology platforms. We retain rights for commercialization of products in the developed world. We can also independently develop any of the project results under new proprietary projects. The results which are funded under this partnership are always accessible by BMGF and are subject to GAC.

We have granted a non-exclusive, perpetual, royalty-free license (with limited rights to sub-license) to our platform technology that is specifically used in the defined projects for the purpose of benefiting people in developing countries. This license is known as the global health license and only becomes exercisable upon the occurrence of a charitability default (as detailed below) or if we become insolvent. BMGF has granted us a de-blocking license to ensure freedom to operate of our platform technology. We will negotiate in good faith to expand the geographic scope of the global health license to include developed countries if requested by the new partner.

The objective is to generate products that are affordable and accessible for the developing world. The final price, however, will not fall below our full costs of manufacturing the product.

We are required to publish, in accordance with certain "open access" terms and conditions, results and information developed under the projects.

BMGF has a right to withdraw from its investment in certain specified circumstances, including if we become insolvent or in the event of a charitability default, namely material breach of the GAC or breach of other specified requirements in the agreement. If we do not cure the charitability default within a specified period of time (if curable), we must repurchase all of the shares held by BMGF, to the extent consistent with applicable law, if we have sufficient free reserves and available liquidity, or we must locate a third-party purchaser of those shares. If we are not able to repurchase the shares or find a third-party purchaser, we must use our best efforts to effect BMGF's withdrawal right as soon as practicable, which may mean acquiring the shares in tranches over time. To the extent permitted by law, we must compensate BMGF for any shortfall if the price achieved on a sale to a third party is lower than its initial investment. During the period before a charitability default occurs, we can pay dividends on our shares, provided that our cash reserves exceed the price per share paid by BMGF times the number of shares BMGF holds (which is initially \$55 million), and to the extent permitted by law, we must contribute annual profits of that amount to the cash reserves. After a charitability default has occurred and until the withdrawal right has been satisfied in full, we may only pay dividends in excess of the aggregate minimum purchase price if BMGF has not exercised any option to require us to repurchase any remaining shares held by them. For any purchase resulting from a charitability default, the aggregate minimum purchase price of BMGF's shares will be valued at the greater of the original purchase price of the shares or the fair market value of such shares.

The term of the letter agreement continues in perpetuity.

#### 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 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
- 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 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 PHSA. 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.

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.

#### **Emergency Use Authorizations**

The Secretary of Health and Human Services has the authority to authorize unapproved medical products, including vaccines, to be marketed in the context of an actual or potential emergency that has been designated by government officials. The COVID-19 pandemic has been designated such a national emergency. After an emergency has been announced, the Secretary of Health and Human Services may authorize the issuance of, and the FDA Commissioner may issue, Emergency Use Authorizations, or EUAs, for the use of specific products based on criteria established by statute, including that the product at issue may be effective in diagnosing, treating, or preventing serious or life-threatening diseases when there are no adequate, approved, and available alternatives. An EUA is subject to additional conditions and restrictions and is product-specific. An EUA terminates when the emergency determination underlying the EUA terminates. An EUA is not a long-term alternative to obtaining FDA approval, licensure, or clearance for a product. FDA may revoke an EUA where it is determined that the underlying health emergency no longer exists or warrants such authorization, so it is not possible to predict how long an EUA may remain in place.

# 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 2020. 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 certain information from those results, with the exception of non-pediatric Phase 1 trials, will then 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 2020.

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.

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 a currently 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 and 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.
- 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" in our Annual Report on Form 20-F incorporated by reference herein for a more comprehensive description of risks related to our intellectual property.

As of January 15, 2020, 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. as well as intellectual property assets acquired through our acquisition of Lipocalyx GmbH and Neon Therapeutics, 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 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 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, certain 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, breast cancer (particularly triple negative breast cancer), prostate cancer, and ovarian 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 extending into the early- to mid-2030s, 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.*, certain 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 2030s, although none is a U.S. issued patent. Many of the Neoantigen Filings are solely owned by BioNTech RNA, or jointly owned by BioNTech RNA and TRON; our acquisition of Neon added various Neoantigen Filings, including both BioNTech US-owned and in-licensed filings. BioNTech RNA and TRON jointly own issued EP patent number 2714071, whose claims recite steps relating to neoantigen selection, that has recently been opposed by multiple third parties; claims in the related U.S. case have recently been allowed. If we are unsuccessful in these oppositions, the patent claims for our iNeST product candidates may be narrowed, or a patent may not issue at all. See "Risk Factors—Risks Related to our Intellectual Property" in our Annual Report on Form 20-F incorporated by reference herein for a more comprehensive description of these risks.

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, certain patent filings have arisen from our collaboration 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, Penn and Fosun Pharma, to develop infectious disease mRNA vaccines, including COVID-19 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 as well as certain patent filings under the MRT-CellScript Sublicenses, which include patent filings directed to nucleotide-modified mRNAs. Certain patent filings relating to certain features of self-amplifying RNAs may also be relevant, including filings jointly owned by BioNTech RNA and TRON; such filings are collectively referred herein as Self-Amplifying RNA Filings. Such Self-Amplifying RNA Filings, if issued, would have 20-year terms that extend into the late-2030s. These Self-Amplifying RNA Filings currently include at least a granted patent in Europe.

We have also licensed technologies relating to certain lipids and/or lipid nanoparticles and formulations that may be useful for certain infectious disease mRNA vaccines, including COVID-19 mRNA vaccines.

### 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 MRT-CellScript Sublicenses 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. Cell Therapy

### **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&GT, 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&GT, 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."

### Activated T Cells

Our acquisition of Neon included technologies for using peripheral blood mononuclear cells, or PBMCs, (*e.g.*, collected from apheresis material of patients) as a starting material to induce and/or expand *ex vivo* functional T cells specific for therapeutically-relevant neoantigens.

Neon's NEO-PTC-01 program (now referred herein as BNT221) is a personalized adoptive T cell therapy, which uses multiple T cell populations expanded from an individual patient's PBMCs that together target a set of neoantigens expressed by that patient's tumor.

Patent filings relevant to BNT221, referred to herein as the T Cell Induction/Expansion Filings, are generally solely owned by BioNTech US, or co-owned by BioNTech US and the Netherlands Cancer Institute (NKI). For example, the T Cell Induction/Expansion Filings include patent filings directed to therapeutic T cell compositions and methods of *ex vivo* induction and/or expansion of antigen-specific T cells, for example, using T cells of specific phenotypes for induction/expansion. The T Cell Induction/Expansion Filings, if issued, would have 20-year terms that would extend into the late-2030s to early-2040s. These filings do not currently include any issued patents. The terms of co-ownership of certain such patent filings with NKI are summarized below in "—C. In-Licensing."

Certain of the Neoantigens Filings may also be relevant to BNT221.

#### 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.

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 up to \$44.4 million for each Penn Product licensed under this agreement and royalties in a low-single digit percentage 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 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, 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. In 2019, we and our subsidiaries BioNTech RNA Pharmaceuticals GmbH, BioNTech Diagnostics GmbH, BioNTech Protein Therapeutics GmbH, BioNTech Cell & Gene Therapies GmbH, BioNTech Innovative Manufacturing Services GmbH and JPT Peptide Technologies GmbH, entered into a Framework Collaboration Agreement with TRON, or the TRON Collaboration 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 in certain shares to TRON, on the one hand, and BioNTech and/or Ganymed, on the other hand included therein is allocated. 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 and antibody fragments that bind to certain defined targets, 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 have an obligation to use reasonable efforts to develop and commercialize products in our field 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.

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.

## **TRON Collaboration Agreement**

Under the TRON Collaboration Agreement, TRON from time to time undertakes certain projects in collaboration with us under separate project specific agreements, comprising innovative non-clinical research and development projects. We and TRON meet regularly to review and update project plans, and no less than annually to agree the budget for the on-going projects for the coming calendar year. Individual project agreements set the specific binding terms of each project. TRON is obligated to perform its obligations in accordance with the scientific standards, all applicable technical laboratory and legal provisions and with the care customary in the non-clinical biotechnology research industry.

Except for the results of a particular research project which has been funded exclusively by TRON, or the RNT Project, all of the 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 Collaboration Agreement are jointly owned. The Results of the RNT Project are owned exclusively by TRON. Under the TRON Collaboration Agreement, TRON grants us an exclusive, worldwide, sublicensable license under its interest in the Results to research and have researched, develop and have developed, make and have made, use, and otherwise commercialize or have commercialized, and otherwise commercially exploit, products in a field that is specified in the corresponding project agreement. The field of use is either (a) the prophylaxis, diagnosis and treatment of all indications in humans and animals; (b) the prophylaxis, diagnosis and treatment of oncological diseases, infectious diseases and rare genetic diseases; or (c) in the case of the Results from the RNT Project only, the prophylaxis, diagnosis and treatment of rectal neuroendocrine tumors in humans. We are required to use our reasonable efforts to develop and commercialize products that exploit the Results.

Under the TRON Collaboration Agreement, TRON's activities are invoiced at cost. 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 Collaboration Agreement that is covered by a patent claiming any of the Results or, in certain circumstances, by a patentable invention forming part of the Results which we elect to maintain as a trade secret. If licenses under Results are granted to third parties, we are obligated to pay to TRON 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. In addition, we are obligated to pay a one-time only milestone of a low seven-figure amount to TRON the first time annual sales of a product developed under the TRON Collaboration Agreement reach a low nine-figure number.

The TRON Collaboration Agreement limits each party's liability to the other to cases of willful misconduct and gross negligence 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 Collaboration Agreement came into force with retroactive effect from January 2015 and has an indefinite term, but may be terminated by either party on nine months' notice. If one of our subsidiaries terminates its role in the TRON Collaboration Agreement, the agreement will survive and continue without that subsidiary.

#### 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.

### License Agreement with the Broad Institute

Through our acquisition of Neon Therapeutics, Inc., BioNTech US became a party to a license agreement with the Broad Institute, Inc., or Broad, entered into on November 13, 2015, and amended in January and November of 2018, as amended to date, the Broad Agreement. Under the Broad Agreement, BioNTech US has been granted an exclusive worldwide license to certain intellectual property rights owned or controlled by the Broad, Dana-Farber Cancer Institute, or DFCI and The General Hospital Corporation d/b/a Massachusetts General Hospital, or MGH, to develop and commercialize any diagnostic, prognostic, preventative or therapeutic product for humans, including any neoantigen vaccine product. In particular, BioNTech US has been granted both exclusive and non-exclusive licenses to a patent portfolio comprised of twelve patent families, including certain granted patents and pending patent applications in the U.S. and foreign jurisdictions.

Pursuant to the terms of the Broad Agreement, BioNTech US has also been granted (i) a non-exclusive license under each institution's respective interest in certain of its patent rights to exploit the licensed products in the field in the territory during the term of the license and (ii) a non-exclusive license under each institution's licensed know-how, to exploit any diagnostic, prognostic, preventative or therapeutic product in the field in the territory during the term of the license. BioNTech US is also entitled to sub-license the rights granted to it under the Broad Agreement. In connection with the Broad Agreement, BioNTech US has a non-exclusive software license with Broad under which it licenses certain object and source codes for several software programs. These licenses and rights are subject to certain limitations and retained rights, including field restrictions.

As consideration for the license, BioNTech US must pay Broad immaterial annual license maintenance fees. Under the Broad Agreement, BioNTech US agreed to reimburse Broad for future patent expenses related to the patents covered by the license agreement. BioNTech US could be obligated to make up to \$12.6 million of developmental milestone payments to Broad if certain development milestones are achieved over the term of the license agreement. Additionally, under the terms of the license agreement, BioNTech US could be obligated to make up to an aggregate of \$105 million of payments upon the achievement of specified sales milestones and to pay tiered royalties of low to mid single-digit percentages on net sales of products licensed under the agreement. BioNTech US is required to pay Broad a low double-digit percentage of any consideration received by BioNTech US from a sublicensee in consideration for a sublicense. No developmental or commercial milestones have been achieved to date. BioNTech US has the right to terminate the agreement for any reason, with or without cause.

#### The Netherlands Cancer Institute

### Collaboration and License Agreements

Through our acquisition of Neon, BioNTech US became a party to certain license and collaboration agreements with the Netherlands Cancer Institute, or NKI, that grant it certain license and/or assignment rights to intellectual property, including to intellectual property within the T Cell Induction/Expansion Filings.

# Manufacturing Agreement

Through our acquisition of Neon, BioNTech US also became a party to a manufacturing agreement, or the NKI Manufacturing Agreement with NKI, whereby NKI performs manufacturing, analytical testing and quality assurance services related to the manufacture of BioNTech US's autologous T cell therapy drug product NEO-PTC-01 (now BNT221) for use in preclinical and clinical activities. The NKI Manufacturing Agreement has a three-year term, which can be extended for an additional six months at BioNTech US's sole discretion, and can be terminated by BioNTech US for convenience with three-months' notice. All amounts incurred under the NKI Manufacturing Agreement are recognized as research and development expense as incurred.

#### 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®. Our acquisition of Neon included registrations for certain trademarks, including NEON THERAPEUTICS®, RECON®, NEO-STIM®, Precision NEO-STIM® and MAPTAC®, as well as certain other trademarks, including design versions of some of these trademarks.

### 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" in our Annual Report on Form 20-F incorporated by reference herein 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, 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.

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, 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.

Specifically, a large number of vaccine manufacturers, academic institutions and other organizations currently have programs to develop COVID-19 vaccine candidates. While we are not aware of all of our competitors' efforts, we believe that the University of Oxford/AstraZeneca plc, CanSino Biologics Inc., Sanofi/GlaxoSmithKline plc, Inovio Pharmaceuticals, Inc., China National Pharmaceutical Group (Sinopharm)/Beijing Institute of Biological Products and Wuhan Institute of Biological Products, Moderna, Inc., Johnson & Johnson, Novavax, Inc. and other companies are all in the early stages of developing vaccine candidates against COVID-19.

*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 May 31, 2020, we had 1,474 full-time equivalent employees working for BioNTech, of whom 400 hold a doctoral degree or higher. The following tables provide breakdowns of our full-time equivalent employees as of May 31, 2020 by function and by region (full-time equivalent numbers are presented rounded to the nearest whole number and accordingly may not add up to 1,474):

Function	Number
Clinical Research & Development	113
Scientific Research & Development	523
Operations	440
Quality	166
Supporting Functions	203
Commercial & Business Development	29
Region	Number
Region Mainz (Headquarters)	Number 1,037
Mainz (Headquarters)	1,037
Mainz (Headquarters) Munich (Neuried, Martinsried)	1,037 40
Munich (Neuried, Martinsried) Idar-Oberstein	1,037 40 222

Since December 2016, our workforce has grown by 300%. 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, but we maintain a company agreement (Betriebsvereinbarungen) with respect to certain topics at our Idar-Obarstein site. We have a workers' council at our Idar-Oberstein and Mainz sites. 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 31, 2027, but which we have the option to extend until October, 2042.
- 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 also own a plot of land of approximately 8,753 square meters (equivalent to 94,216 square feet) at Hechtsheimer Strasse, 55131 Mainz.

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. We also recently purchased a building of approximately 802 square meters (equivalent to 8,632 square feet) near our IMFS facility in Idar-Oberstein, which will be used as office space.

At our JPT facility in Berlin, Germany, we occupy approximately 1,794 square meters (equivalent to approximately 19,299 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 expiry date of June 20, 2020 and will continue for further six-month periods, unless terminated by either party on three months' prior written notice. Approximately 1,523 square meters (equivalent to approximately 16,199 square feet) are occupied under a lease for an indeterminate period of time but which may be terminated by either party on 12 months' prior written notice. The remaining approximately 20 square meters (equivalent to approximately 215 square feet) of storage space is occupied under a lease on a monthly basis and can be terminated by either party giving two weeks' written notice.

In Martinsried, Germany, outside Munich, 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, outside Munich, 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 period until terminated by either party on 12 months' prior written notice.

In Halle (Saale), Germany, we have since the beginning of 2020 occupied approximately 415 square meters (equivalent to approximately 4,467 square feet) of office and other space under a lease that expires on February 28, 2022. We further occupy 90 square meters (equivalent to approximately 968 square feet) of laboratory space under a lease that also expires on February 28, 2022. Each lease will renew automatically for an additional one-year period until terminated by either party on six months' prior written notice to expire at the end of the lease period (or any extension thereof).

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 the third quarter of 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 and 550 square meters (equivalent to approximately 5,900 square feet) of laboratory space, expanding our capacity for GMP cell therapy manufacturing and 650 square meters (equivalent to approximately 7,000 square feet) of office space.
- We anticipate completing the construction of a new complex of building for our JPT business in Berlin, Germany, possibly as early as 2023. Upon completion of the construction project we will occupy up to approximately 5,000 additional square meters (equivalent to approximately 53,820 square feet) of useable floor space split between laboratories, offices and storage.

We are committed to the continued development of world-class laboratory as well as manufacturing operations to support our research and development as well as 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 laboratory and 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;
- an expansion of our JPT facility, which is designed to more than double our capacity; and
- an expansion of our laboratory space for research and development on our Mainz campus.

## 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.

#### PRINCIPAL AND SELLING SHAREHOLDERS

The following table presents information, as of June 30, 2020, regarding the beneficial ownership of our ordinary shares (i) prior to the consummation of the Global Offering, (ii) as adjusted to reflect the sale of the ADSs in the Underwritten Offering and (iii) as further adjusted to reflect full subscription of the Rights 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;
- · all members of our Supervisory Board and Management Board as a group; and
- the Selling Shareholder for purposes of the underwriters' option to purchase additional ADSs.

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 30, 2020 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 the Global Offering is computed on the basis of 232,673,455 ordinary shares outstanding as of June 30, 2020. This amount excludes 5,524,506 shares held in treasury and does not reflect the issuance of 2,595,996 of our ordinary shares to be issued in the June 2020 Private Placement, which is expected to close in August 2020.

The percentage of shares beneficially owned on an adjusted basis after the Underwritten Offering is based on shares to be outstanding after the Underwritten Offering after giving effect to the completion of the Underwritten Offering. The percentage of shares beneficially owned on an adjusted basis after the Global Offering is based on 239,355,304 shares to be outstanding after the Global Offering after giving effect to the completion of the Underwritten Offering and assuming full subscription of the Rights Offering. Ordinary shares that a person has the right to acquire within 60 days of June 30, 2020 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.

<u>Shareholder</u>	Shares Beneficially Owned Before the Global Offering		Shares Beneficially Owned After the Underwritten Offering		Shares Beneficially Owned After the Global Offering, Assuming Full Subscription(1) in the Rights Offering	
5% Shareholders	Number	Percent	Number	Percent	Number	Percent
ATHOS KG(2)	114,141,520	49.06%		%		%
Medine GmbH(3)	41,690,970	17.92%		%		%
Members of the Supervisory Board and the Management Board	, , .					
Prof. Ugur Sahin, M.D.(4)	41,690,970	17.92%		%		%
Sean Marett(5)	1,091,502	*		%		%
Dr. Sierk Poetting <sup>(6)</sup>	711,828	*		%		%
Dr. Özlem Türeci	_	_		%		%
Ryan Richardson	_	_		%		%
Helmut Jeggle(7)	116,798,941	50.20%		%		%
Michael Motschmann	_	_		%		%
Prof. Christoph Huber, M.D.(8)	2,552,040	1.10%		%		%
Dr. Ulrich Wandschneider <sup>(9)</sup>	4,680	*		%		%
All members of our Supervisory Board and Management Board,						
as a group	162,849,961	69.99%		%		%
Selling Shareholder(10)	10,268,124	4.41%	9,518,124	4.00%	9,518,124	3.98%

<sup>\*</sup> Less than one percent

- Excluding rights attributable to holders that have irrevocably agreed not to transfer or exercise rights. Assumes no exercise of rights in the Rights
  Offering by any person listed in this section.
- (2) Consists of 114,141,520 ordinary shares held by AT Impf GmbH. The sole member of AT Impf GmbH is ATHOS KG, and, as a result, ATHOS KG is deemed to be the beneficial owner of the securities held by AT Impf GmbH. Helmut Jeggle and Thomas Maier are each general partners (*Komplementär*) of ATHOS KG and may be deemed to be beneficial owners of the securities held by AT Impf GmbH. Each of Messrs. Jeggle and Maier disclaim beneficial ownership of such shares except to the extent of their pecuniary interest therein.
- (3) The sole shareholder of Medine GmbH is Prof. Sahin, and, as a result, Prof. Sahin is deemed to be the beneficial owner of the securities held by Medine GmbH.
- (4) Consists of the shares described in note 3 above. Prof. Sahin is the sole shareholder of Medine GmbH.
- (5) Consists of 1,091,502 ordinary shares held by RLG GmbH. Mr. Marett is the sole shareholder of RLG GmbH.
- (6) Consists of 711,828 ordinary shares held by Tofino GmbH. Dr. Poetting is the sole shareholder of Tofino GmbH.
- (7) Consists of (a) the shares described in note 2 above, (b) 332,316 ordinary shares held directly by Mr. Jeggle, (c) 2,273,886 ordinary shares held by Salvia GmbH and (d) 51,219 ordinary shares held by Nils GmbH. Mr. Jeggle is the sole shareholder of Salvia GmbH and Mr. Jeggle and his wife are the sole shareholders of Nils GmbH. Mr. Jeggle 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.
- (8) Consists of 2,552,040 ordinary shares held by CHuber 2008 GmbH. Prof. Huber and his wife are the shareholders of CHuber 2008 GmbH.
- (9) Consists of 4,680 shares held by beebusy capital gmbh.
- (10) Consists of (a) 4,162,321 ordinary shares held by MIG GmbH & Co. Fonds 7 KG, Munich, (b) 1,348,268 ordinary shares held by MIG GmbH & Co. Fonds 8 KG, Munich and (c) 4,757,535 ordinary shares held by MIG GmbH & Co. Fonds 9 KG, Munich. The underwriters have an option to purchase 750,000 ADSs to be sold by funds associated with MIG Verwaltungs AG, Ismaninger Strasse 102. D-81675 Munich, Germany. If the underwriters exercise in full their option to purchase additional ADSs from funds associated with MIG

Verwaltungs AG, MIG Verwaltungs AG will hold 9,518,124 ordinary shares, or 4.09% beneficial ownership of our outstanding ordinary shares (including those held in the form of ADSs).

# Holdings by U.S. Shareholders

Prior to the completion of the Global Offering, we estimate that approximately 23.89% of our outstanding ordinary shares were held by three 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. We completed our initial public offering in October 2019. 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 (*Satzung*) 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**

We have share capital registered in the commercial register (Handelsregister) in the amount of €238,197,961.00, which is divided into 238,197,961 registered shares (Namensaktien). All shares are shares with no par value ( $Stückaktien\ ohne\ Nennbetrag$ ) with a notional amount attributable to each ordinary share of €1.00. 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. 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 or rights or certificates representing them 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**

Our share capital as registered with the commercial register (*Handelsregister*) amounts to 238,197,961. Since January 1, 2017, (up until and including the capital increase of August 16, 2019, without giving effect to the 18-to-1 stock split which became effective on September 18, 2019), our share capital has changed as follows:

- On September 14, 2017, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 9,083,000 shares:
- On February 1, 2018, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 1,254,884 shares:
- On September 12, 2018, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 32,373 shares;

- On October 18, 2018, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 186,715 shares:
- On January 29, 2019, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 282,678 shares;
- On April 24, 2019, our share capital as registered with the commercial register (*Handelsregister*) 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);
- On June 26, 2019, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 666,123 shares;
- On August 16, 2019, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 333,310 shares;
- On September 18, 2019, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 206,595,492 shares by way of a capital increase from our funds; thus, no contribution by investors was made;
- On September 26, 2019, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 3,038,674 shares;
- On October 14, 2019, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 10,000,000 shares;
- On November 6, 2019, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 517,408 shares:
- On April 23, 2020, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 1,580,777 shares;
- On May 5, 2020, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 2,377,446 shares; and
- On May 8, 2020, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 1,935,488 shares.

### **Anti-takeover Provisions of Our Charter Documents**

Our Articles of Association (*Satzung*) 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. Under

§ 4(5) 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 €99,924,291.00 by issuing, on one or more occasions, up to 99,924,291 new, registered shares with no par value (*Genehmigtes Kapital*), in each case with consent of the Supervisory Board. This authorization expires on August 18, 2024.

Any new shares issued from the authorized capital will participate in the profits starting with the fiscal year for which the annual financial statements have not yet been submitted to the general meeting at the time of registration of the implementation of the capital increase. Further details of a capital increase from the authorized capital may be specified by the Management Board.

# **Conditional Capital**

Pursuant to § 4(6) of our Articles of Association (*Satzung*), our share capital is conditionally increased by €21,874,806.00 through issuance of new, registered shares with no par value (*Bedingtes Kapital ESOP 2017/2019*). 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 serviced by our providing treasury shares or through cash payments. Any new shares issued under the conditional capital pursuant to the said § 4(6) of our Articles of Association (*Satzung*) shall be entitled to dividends from the beginning of the previous financial year in case they are created by the exercise of subscription rights until the start of the annual general meeting of the Company and otherwise from the beginning of the financial year in which they are created as a result of the exercise of the stock options.

Pursuant to § 4(7) of our Articles of Association (*Satzung*), our share capital is conditionally increased by €87,499,260.00 through issuance of new, registered shares with no par value (*Bedingtes Kapital WSV 2019*). The conditional capital may only be used to issue shares to the holders or creditors of option rights or conversion rights or those under an obligation to convert under warrant-linked or convertible bonds avail of their option rights or conversion rights or where they are under an obligation to convert, to the extent they satisfy their obligation to convert, or to the extent that we exercise a right to choose to grant our shares, in whole or in part instead of paying a monetary amount due, and to the extent cash compensation is not granted in each relevant case or treasury shares or shares of another stock-listed company are not utilized for servicing.

Any new shares issued under the said conditional capital pursuant to the said § 4(7) of our Articles of Association shall carry an entitlement to dividends from the beginning of the financial year in which they are created; however, as far as the law permits, the Management Board can confer dividend rights for new shares in derogation of the foregoing.

### Preemptive Rights

German law generally provides shareholders with preemptive rights when new shares convertible bonds, bonds with warrants, profit participation rights or participating bonds are issued. This requirement, however, may also be satisfied by way of a credit institution subscribing for the securities and then offering them to the shareholders for purchase (*mittelbares Bezuqsrecht*).

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 securities 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 securities; 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 (*Satzung*), 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 exclude fractional amounts from the subscription right;
- in the case of a capital increase against cash contributions, if the issue price of the new shares is not significantly lower than the market price of the company's shares already listed on the stock exchange at the time the issue price is finally determined. However, this authorization shall only apply subject to the provision that the shares issued excluding subscription rights in accordance with Section 186(3) Sentence 4 AktG may not exceed a total of 10% of the share capital either at the time this authorization takes effect or, if this amount is lower, at the time this authorization is exercised. This limit of 10% of the share capital includes shares which are issued or disposed of during the term of this authorization until the date of its exercise in direct or equivalent application of Section 186(3) Sentence 4 AktG. Shares which are used to service bonds with convertible or option rights or convertible obligations are to be offset against the 10% limit if these bonds were issued under exclusion of shareholder subscription rights in accordance with Section 186(3) Sentence 4 AktG during the entitlement period. Treasury shares are to be offset against the 10% limit, where they were disposed of by the company during the term of this authorization with the exclusion of subscription rights pursuant to or in analogous application of Section 186(3) Sentence 4 AktG;
- in the case of capital increases in exchange for contributions in kind, in particular in order to be able to offer the shares to third parties when purchasing companies, parts of companies or interests in companies as well as licenses or industrial property rights;
- in order to grant subscription rights to new shares to holders of conversion or option rights in respect of bonds issued by the company or its subordinated domestic or foreign Group companies, to the extent to which they would be entitled after exercising their conversion or option rights or after fulfilling an agreed conversion obligation;
- to implement an election dividend by which shareholders are given the option to contribute their dividend entitlements (either in whole or part) as a contribution in kind against issuance of our new shares;
- in case shares are to be issued to a member of our Management Board or to another person who is employed by us or one of our affiliates and a minimum holding period of at least one year and the obligation to transfer back the shares in the event that the beneficiary is not employed by us or one of our affiliated companies for the entire duration of the holding period or any other agreed period is agreed upon. Additional restrictions with regard to the shares issued may be agreed upon;
- after listing on Nasdaq, if excluding subscription rights, according to the written declaration of an internationally renowned investment bank, is expedient to the shares' successful placement in view of the requirements of eligible investors and if the discount by which the issue price of the shares may be below the current stock exchange price at the time the Management Board adopts the resolution on using authorized capital, according to such declaration, does not exceed the extent necessary for a successful placement; and
- in order to be able to satisfy an option to acquire additional ordinary shares or American Depositary Shares that has been agreed with the issuing banks in connection with a public offering of our shares in the form of American Depositary Shares.

The total number of new shares issued from the authorized capital and under exclusion of subscription rights pursuant to bullets one through three and seven above may not exceed 20% of the share capital, either at the time

this authorization becomes effective or, if lower, at the time it is utilized. To be counted against the aforementioned 20% limit are: (i) those shares issued or to be issued to service conversion or option rights or conversion or option obligations or tender rights of the issuer under bonds, if the bonds have been issued during the term of this authorization up to the time of its exercise, excluding the subscription rights of shareholders, as well as, to a certain extent (ii) treasury shares that have been disposed under exclusion of subscription rights during the term of this authorization (except in the case of certain exceptions of the resolution to item no. 8 of the general meeting of August 19, 2019).

With the registration with the commercial register (*Handelsregister*) of the change to our Articles of Association (*Satzung*) resolved upon by our shareholders on June 26, 2020, the list of authorizations to exclude subscription rights would be modified as follows:

- The second-to-last bullet of the list above would be deleted; and
- an authorization would be added to exclude subscription rights in capital increases, in each case if excluding subscription rights, according to the assessment by the Management Board, is expedient to the shares' successful placement in view of the requirements of eligible investors and if the discount by which the issue price of the shares may be below the current stock exchange price at the time the Management Board adopts the resolution on using authorized capital, according to the assessment by the Management Board, does not exceed the extent necessary for a successful placement and in any case does not exceed 10% of either the latest available closing price at the time when the issue price is fixed or the volume-weighted average price over a period of up to five trading days ending on the day on which the issue price is so fixed.

For the purposes of limiting the amount of shares to be issued under exclusion of subscription rights to 20% (as described above), this newly introduced authorization would, effective upon registration with the commercial register (*Handelsregister*), replace the one that will be deleted. Also, in order to calculate the actual maximum number of shares in this regard (as described above), the Articles of Association (*Satzung*) would no longer reference the share capital at the time the authorization originally came into effect, but the share capital at the time this amendment to the Articles of Association (*Satzung*), resolved upon by the general meeting of June 26, 2020, will come into effect by way of registration with the commercial register (*Handelsregister*).

### **Corporate Purpose of our Company**

Our business objective, as described in § 2 of our Articles of Association (*Satzung*), is to research and develop, as well as to manufacture and market immunological and RNA-based drugs and test methods for the diagnosis, prevention and treatment of cancer, infectious diseases and other serious diseases.

### Shareholders' Meetings and Voting Rights

Pursuant to our Articles of Association (*Satzung*), 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 €500,000.00 may request the addition of one or several items to the agenda of any shareholders' meeting. Shareholders' meetings may be summoned either via publication in the German Federal Gazette (*Bundesanzeiger*) or via mail or (after the pertinent amendment of our articles of association resolved upon by our annual general meeting of 2020 becoming effective) even via email, in each case generally 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 (*Satzung*), 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  $\[ \in \] 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.

### **Authorization to Purchase and Sell Our Own Shares**

We may not purchase our own shares unless authorized by the shareholders' meeting or in other very limited circumstances as set out in the German Stock Corporation Act. The Company's shareholders' meeting held on August 19, 2019 authorized the Management Board until August 18, 2024, provided it complies with the legal requirement of equal treatment, to acquire treasury shares up to a total of 10% of the Company's share capital at the time of the relevant resolution or at the time the authorization is exercised. These shares held by the Company (including shares attributable to it pursuant to the AktG) must never exceed 10% of the share capital. The shares may be purchased (i) through the stock exchange, (ii) by means of a public offer directed to all shareholders of the Company, (iii) by means of a public invitation to the shareholders to make a sales offer or (iv) from the Bill & Melinda Gates Foundation under very limited circumstances as specified in the authorization. Such shares may not be purchased for trading purposes. The Management Board is authorized to use the shares only as specified in the authorization.

### **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, e.g., 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.

**Board System** 

Appointment and Number of Directors

### **European Union/Federal Republic of Germany**

A European stock corporation may choose to have a two-tier 
Under Delaware law, a corporation has a unitary board board structure composed of the Management Board (Vorstand) and the Supervisory Board (Aufsichtsrat). We have chosen this structure.

The Management Board is responsible for running the company's affairs and representing the company in dealings with third parties.

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.

Under applicable European and German law, a European stock corporation governed by German law with a share capital of at least €3 million generally 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.

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 meet the quorum. The provisions of German law in relation to employees' co-determination do not apply to the Company.

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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.

Management is responsible for running the corporation and overseeing its day-to-day operations.

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.

Vacancies on the

**Board of Directors** 

Removal of Directors

**European Union/Federal Republic of Germany** 

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.

Under the law, vacant positions on the Management Board general rules of appointment, which provide that vacancies Board members present or represented by proxy at the vote position on the Management Board

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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.

are filled by the Supervisory Board in accordance with the are filled by the simple majority of votes of Supervisory (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

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) 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

Meetings

#### **European Union/Federal Republic of Germany** may be filled by an individual appointed by the court. remaining director elected by such class, will fill such vacancy. Vacant positions on the Supervisory Board are filled in accordance with the general rules of appointment. Annual General Meeting A European stock corporation which is governed by German Under Delaware law, the annual meeting of law must hold an annual shareholders' meeting within six stockholders shall be held at such place, on such date months of the end of its fiscal year. The annual shareholders' and at such time as may be designated from time to time meeting must be held at a location determined by the articles by the board of directors or as provided in the certificate of association. If the articles of association do not provide of incorporation or by the bylaws. 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. General Meeting Under the law, extraordinary shareholders' meetings, in Under Delaware law, special meetings of the addition to the annual shareholders' meetings, may be called stockholders may be called by the board of directors or by either the Management Board, or by the Supervisory by such person or persons as may be authorized by the Board. Shareholders holding at least 5% of the company's certificate of incorporation or by the bylaws. share capital are entitled to request that an extraordinary shareholders' meeting be convened. In the event that the meeting is not then so convened, a competent court may order that the meeting be convened or authorize the shareholders or their representative to convene the meeting themselves. Notice of General Under applicable European and German law, unless a longer Under Delaware law, unless otherwise provided in the period is otherwise provided for in the articles of association certificate of incorporation or bylaws, written notice of or applies because of registration requirements stipulated in any meeting of the stockholders must be given to each the articles of association, the shareholders must be given at stockholder entitled to vote at the meeting not less than least 30 days' advance notice of the shareholders' meeting. ten nor more than 60 days before the date of the Such notices must at least specify the name of the company, meeting and shall specify the place, date, hour, and the statutory seat of the company, and the location, date and purpose or purposes of the meeting. time 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.

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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.

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

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.

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.

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, 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.

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

### **European Union/Federal Republic of Germany**

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 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 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.

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

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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;
- any transaction from which the director derives an improper personal benefit.

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.

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

Voting Rights

Shareholder Vote on Certain Transactions

Standard of Conduct for

Directors

### **European Union/Federal Republic of Germany**

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*).

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.

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 as on certain important occasions;
- 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.

Statutory and fiduciary duties of members of the Supervisory Board to the company include, among others:

 to effectively supervise the Management Board's handling of the company's affairs;

#### Delaware

 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.

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.

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 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. In addition, under Delaware law, when the board of directors of a Delaware

### **European Union/Federal Republic of Germany**

- 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;
- to approve service contracts between individual members of the Supervisory Board and the company.

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.

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. 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.

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:

- state that the plaintiff was a stockholder at the time of the transaction of which the plaintiff complains or that the plaintiffs 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.

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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.

# **Stock Exchange Listing**

ADSs representing our ordinary shares are listed 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 one share (or a right to receive one share) deposited with The Bank of New York Mellon SA/NV as custodian for the depositary in Germany. 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 depositary for the purpose of exchanging your ADR for uncertificated ADSs. The depositary 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 depositary of a proper instruction from a registered holder of uncertificated ADSs requesting the exchange of uncertificated ADSs for certificated ADSs, the depositary 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 depositary how to vote the number of deposited shares their ADSs represent. If we request the depositary to solicit your voting instructions (and we are not required to do so), the depositary 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 depositary how to vote. For instructions to be valid, they must reach the depositary by a date set by the depositary. The depositary 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 depositary to solicit your voting instructions, you can still send voting instructions, and, in that case, the depositary may try to vote as you instruct, but it is not required to do so.

Except by instructing the depositary 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 depositary will not exercise any discretion in voting deposited securities and it will only vote or attempt to vote as instructed or as described in the following sentence. If (i) we asked the depositary to solicit your instructions at least 30 days before the meeting date, (ii) the depositary does not receive voting instructions from you by the specified date and (iii) we confirm to the depositary that:

- we wish the depositary to vote uninstructed shares;
- we reasonably do not know of any substantial shareholder opposition to a particular question; and
- the particular question is not materially adverse to the interests of shareholders,

the depositary will consider you to have authorized and directed it to vote the number of deposited securities represented by your ADSs in favor of any resolution that we proposed in the invitation to the shareholders' meeting.

We cannot assure you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote your shares. In addition, the depositary 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 depositary as to the exercise of voting rights relating to deposited securities, if we request the depositary to act, we agree to give the depositary notice of any such meeting and details concerning the matters to be voted upon at least 30 days in advance of the meeting date.

### Fees and Expenses

Persons depositing or withdrawing shares or ADS holders must pay:

\$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)

\$.05 (or less) per ADS

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

\$.05 (or less) per ADS per calendar year

Registration or transfer fees

Expenses of the depositary

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

Any charges incurred by the depositary or its agents for servicing the deposited

securities

For:

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

Any cash distribution to ADS holders

Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depositary to

ADS holders

Depositary services

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

Cable and facsimile transmissions (when expressly

provided in the deposit agreement)

Converting foreign currency to U.S. dollars

As necessary

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 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 or 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;
- 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 ability to prevent or counteract with reasonable care or effort 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;
- are not liable for the acts or omissions of any securities depository, clearing agency or settlement system; and
- the depositary 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 depositary agree to indemnify each other under certain circumstances.

## **Requirements for Depositary Actions**

Before the depositary will deliver or register a transfer of ADSs, make a distribution on ADSs, or permit withdrawal of shares, the depositary 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 depositary may refuse to deliver ADSs or register transfers of ADSs when the transfer books of the depositary or our transfer books are closed or at any time if the depositary 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 depositary 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 depositary 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 depositary 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 depositary will not determine whether the DTC participant 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 our initial public offering, there was no market for our ordinary shares or ADSs representing our ordinary shares. Future sales of substantial amounts of our ordinary shares or ADSs representing our ordinary shares in the public market, or the perception that such sales may occur, could adversely affect prevailing market prices of our ordinary shares or ADSs representing our ordinary shares.

Based on the 226,779,744 ordinary shares that were outstanding on March 31, 2020, upon the closing of the Underwritten Offering, 237,673,455 ordinary shares, including 63,296,755 ADSs representing 63,296,755 of those ordinary shares, will be outstanding, and also including (i) the issuance of 1,935,488 ADSs representing our ordinary shares in connection with our acquisition of Neon, (ii) the issuance of 1,580,777 of our ordinary shares in a private placement to Fosun Pharma for proceeds of €45.6 million (\$50.0 million, using the exchange rate then in effect as published by the German Central Bank (*Deutsche Bundesbank*)) and (iii) the issuance of 2,377,446 of our ordinary shares in a private placement to Pfizer for proceeds of €103.9 million (\$113.0 million, using the exchange rate then in effect as published by the German Central Bank (*Deutsche Bundesbank*)). The 5,000,000 ADSs sold in the Underwritten 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 216,262,336 ordinary shares we issued prior to our initial public offering may only be sold in the public market if registered or sold 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, 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 the Underwritten Offering without regard to whether current public information about us is available.

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 2,376,734 ordinary shares immediately after the Underwritten Offering; 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 the Underwritten 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 may be sold 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 agreements that we, members of our Supervisory Board and Management Board and certain significant shareholders have entered into in connection with the Underwritten Offering, see "Underwriting."

## **Options and Form S-8 Registration Statement**

As of March 31, 2020, options to purchase a total of 16,338,305 ordinary shares were issued and outstanding. Of the total number of issued and outstanding options, 2,101,842 have vested. Certain of our ordinary shares issuable under these options are subject to contractual lock-up agreements with us or the underwriters. For a description of the lock-up agreements that we, members of our Supervisory Board and Management Board and certain significant shareholders have entered into in connection with the Underwritten Offering, see "Underwriting."

We intend to file a registration statement on Form S-8 under the Securities Act to register ordinary shares, 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 90-day lock-up period in connection with the Underwritten Offering.

#### **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, e.g., 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 an increase 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 section.

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, as amended by the circular dated December 18, 2018 (reference number IV C 1 – S 2204/12/10003), 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 should 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 will 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, in light of the ADR Tax Circular, 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, e.g., 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 selected German tax consequences of acquiring, owning and disposing of the ADSs to a holder that is a U.S. treaty beneficiary. For purposes of this discussion, a "U.S. treaty

beneficiary" is a resident of the United States for purposes of the Convention 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 and Certain Other Taxes of 1989, as amended by the Protocol 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 eligible for relevant 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. tax resident corporation or individual;
- 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% (that amount consists of 25% on dividends distributed plus solidarity surcharge of 5.5% on the amount of the withholding tax). The basis for the withholding tax is the dividend approved for distribution by our general shareholder's meeting.

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 Depositary 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. 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 should 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, it should be noted that there is uncertainty as to how the German tax authorities will apply the refund process to dividends on the ADSs with respect to non-German resident holders. 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 qualifying Participation. A Qualifying Participation exists if a holder at any time during the five years preceding the disposition, directly or indirectly, owned at least 1% 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 disposal of a Qualifying 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 disposal of a Qualifying 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 disbursing agent to levy withholding tax on capital gains from the sale of ADSs or other securities held in a custodial account in Germany. With regard to the German taxation of capital gains, disbursing agent means a German credit institution, financial services institution, securities trading enterprise or securities trading bank (each as defined in the German Banking Act and, in each case including a German branch if a foreign enterprise, but excluding a foreign branch of a German enterprise) that holds the ADSs in custody or administers the ADSs for the investor or conducts sales or other dispositions and disburses or credits the income from the ADSs to the holder of the ADSs. 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, as most recently amended by circular dated September 16, 2019, reference number IV C 1-S2252/08/10004:027, 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 at least 1% of the share capital of a German corporation. 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 Qualifying 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. The restriction of the withholding tax credit does not apply if the holder has beneficially owned the ADSs for at least one uninterrupted year until receipt (*Zufluss*) of the dividends.

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 from the German tax authorities exists on the practical application of the procedure with respect to the ADSs and the respective limitations.

Recently, the German tax authorities have indicated that for ADR programs (which are considered comparable to ADS programs) a collective tax certificate may no longer be issued by the domestic depositary of the shares upon request of the foreign depositary agents. Moreover, the simplified refund procedure based on electronic data exchange (*Datenträgerverfahren*) for claims for reimbursement based on ADRs has been temporarily suspended by the tax authorities.

#### 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 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 seat (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 such 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 Qualifying 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 until receipt (*Zufluss*) 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.

In principle, dividends that a corporation receives from German or foreign corporations are subject to corporate tax (and solidarity surcharge thereon) at a rate of 15.825% and also subject to trade tax of between 7.0% and generally 19.0% depending on the multiplier applied by the relevant municipality. However, 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, or 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 generally should be 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 value-added tax on transactions that are otherwise tax-exempt. Net wealth tax (*Vermögensteuer*) is currently not imposed in Germany.

#### **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 the ADSs representing our ordinary shares 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 the ADSs representing our ordinary shares 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 more than 10% of our stock (by vote or by value), persons that hold the ADSs representing our ordinary 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 the ADSs representing our ordinary shares, 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 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 60 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 depositary 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% of our gross income is "passive income" or at least 50% 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 be required to 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 may be available to a U.S. Holder if we were a PFIC that might alleviate some of the adverse consequences of PFIC status and would result in an alternative treatment of the ADSs.

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 qualified electing fund election or a mark-to-market election with respect to the ADSs.

#### Net Investment Income 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 net investment income 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. and Berenberg Capital Markets LLC are acting as representatives of the underwriters. We and the Selling Shareholder 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:

Name	Number of ADSs
J.P. Morgan Securities LLC	
BofA Securities, Inc.	
Berenberg Capital Markets LLC	
UBS Securities LLC	
Canaccord Genuity LLC	
COMMERZBANK Aktiengesellschaft	
WR Securities, LLC	
Bryan, Garnier & Co. Limited	
Total	5,000,000

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 Underwritten Offering may be terminated.

The underwriters propose to offer the ADSs directly to the public at the 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 public offering price. After the initial offering of the ADSs to the public, if all of the ADSs are not sold at the 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 750,000 additional ADSs from the Selling Shareholder 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, Joh. Berenberg, Gossler & Co. KG will initially subscribe for all of the new ordinary shares represented by the new ADSs on behalf of and for the account of the underwriters, at an issue price of €1.00 per new ordinary share. This issue price will be credited against the amount due from the underwriters at closing.

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 for the ADSs offered by us and \$ per ADS for the ADSs offered by the Selling Shareholder. 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 the	With full exercise of
	option to purchase	option to purchase
	additional ADSs	_additional ADSs
Per ADS	\$	\$
Total	\$	\$

We estimate that the total expenses of the Global Offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding the underwriting discounts and commissions, will be approximately \$4,300,000. We have agreed to reimburse the underwriters up to \$40,000 for expenses relating to clearance of the Underwritten Offering with the Financial Industry Regulatory Authority.

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 Underwritten 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 representing our ordinary shares or securities convertible into or exchangeable or exercisable for any of our ordinary shares or ADSs representing our ordinary shares, 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 representing our ordinary shares, 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 representing our ordinary shares, 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 90 days after the date of this prospectus, other than (A) the ordinary shares and ADSs representing our ordinary shares to be sold in the Global Offering, (B) any of our ordinary shares or ADSs representing our ordinary shares issued upon the exercise of options granted under our existing share-based compensation plans, (C) the filing by us of any registration statement on Form S-8 or a successor form thereto relating to a company share plan and (D) any ADSs representing our ordinary shares or other securities issued in connection with a transaction with an unaffiliated third party that includes a bona fide commercial relationship (including joint ventures, marketing or distribution arrangements, collaboration agreements or licensing agreements) or any acquisition of assets of not less than a majority or controlling portion of the equity of another entity, provided that the aggregate number of the shares issued pursuant to this clause (D) shall not exceed more than five percent (5%) of the total number of outstanding ordinary shares immediately following the issuance and sale of the ADSs representing our ordinary shares hereunder.

Our directors and executive officers, and certain of our significant shareholders (including the Selling Shareholder), collectively representing approximately 74% of our outstanding ordinary shares (including ordinary shares represented by ADSs), have entered into lock-up agreements with the underwriters prior to the commencement of the Global Offering pursuant to which each of these persons or entities, with limited exceptions, for a period of 90 days (or 30 days in the case of the Selling Shareholder) 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 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 representing our ordinary shares or any securities convertible into or exercisable or exchangeable for our ordinary shares (including, without limitation, ordinary shares, ADSs representing our ordinary shares, 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 representing our ordinary shares, 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 representing our ordinary shares, 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 representing our ordinary shares or any security convertible into or exercisable or exchangeable for ADSs representing our ordinary shares 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 representing our ordinary shares acquired in the Global 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 representing our ordinary shares through a "cashless" exercise;
- transfers or dispositions of our ordinary shares or ADSs representing our ordinary shares 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 representing our ordinary shares 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 representing our ordinary shares was made solely to us in connection with a conversion;
- transfers or dispositions of our ordinary shares or ADSs representing our ordinary shares 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 representing our ordinary shares,
  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 representing our ordinary shares 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 representing our ordinary shares, provided that (i) such plan does not provide for the transfer of our ordinary shares and ADSs representing our ordinary shares representing our ordinary shares 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 representing our ordinary shares, merger, consolidation or other similar transaction approved by our Supervisory Board and made to all holders of our ordinary shares or ADSs representing our ordinary

shares 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 representing our ordinary shares in connection with such transaction, or vote any ordinary shares or ADSs representing our ordinary shares 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 representing our ordinary shares shall remain subject to the lock-up restrictions.

In addition, pursuant to the terms of our share options, holders of share options are restricted from exercising such share options for a period of at least one year following our initial public offering without our consent.

We and the Selling Shareholder have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act of 1933.

ADSs representing our ordinary shares are listed on the Nasdaq Global Select Market under the symbol "BNTX."

In connection with the Underwritten 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 the Underwritten Offering is in progress. These stabilizing transactions may include making short sales of the ADSs, which involves the sale by the underwritters of a greater number of ADSs than they are required to purchase in the Underwritten Offering, and purchasing ADSs on the open market to cover 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 the Underwritten 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 the Underwritten 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.

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 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. For instance, certain of the underwriters and their affiliates will serve as dealer-managers or subscription agents in the Rights Offering. 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.

COMMERZBANK Aktiengesellschaft as an underwriter is not a broker-dealer registered with the SEC. COMMERZBANK Aktiengesellschaft will only make sales of ADS in the United States, or to nationals or residents of the United States (including its territories and possessions), through one or more SEC registered broker-dealers in compliance with applicable securities laws and the rules of FINRA.

The address of the Selling Shareholder is Ismaninger Strasse 102. D-81675 Munich, Germany.

#### The Global Offering

The Underwritten Offering is part of a Global Offering consisting of a rights offering and the Underwritten Offering. Certain holders of our ordinary shares (representing 74.83% of our outstanding ordinary shares (including ordinary shares represented by ADSs)) have entered into irrevocable, binding agreements not to transfer or exercise their rights to subscribe for new ordinary shares in the Rights Offering. Under German law, the law of our jurisdiction of organization, we are permitted to offer new ordinary shares in an amount equal to the percentage of securities represented by the irrevocable agreements not to transfer or exercise rights to new investors in advance of the Rights Offering. We intend to accomplish this through the Underwritten Offering, Following the Underwritten Offering, our shareholders and ADS holders as of the respective record dates who have not agreed to forego exercising their rights will have the opportunity in the Rights Offering to subscribe for up to 1,681,849 new ordinary shares or new ADSs (representing approximately 0.72% of our outstanding ordinary shares (including ordinary shares by ADSs)) at a subscription price equal to the price to the public in the Underwritten Offering. ADSs PURCHASED IN THE UNDERWRITTEN OFFERING WILL NOT BE ENTITLED TO RECEIVE RIGHTS TO SUBSCRIBE FOR NEW ORDINARY SHARES OR NEW ADSs IN THE RIGHTS OFFERING. Accordingly, assuming no change in the assumed public offering price or the number of ADSs offered by us in the Underwritten Offering, as set forth on the cover page of this prospectus, a total of up to 6,681,849 ordinary shares (including ordinary shares represented by ADSs) may be sold in the Global Offering. We may also increase or decrease the number of ADSs we are offering in the Underwritten Offering, which would affect the number of our ordinary shares and ADSs representing our ordinary shares underlying rights granted in the Rights Offering. See "Dilution" for additional information.

## Notice to Prospective Investors in the European Economic Area and the United Kingdom

In relation to each Member State of the European Economic Area and the United Kingdom (each a "Relevant State"), no ADSs have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the ADSs which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that offers of ADSs may be made to the public in that Relevant State at any time under the following exemptions under the Prospectus Regulation:

(a) to any legal entity which is a qualified investor as defined under the Prospectus Regulation;

- (b) to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the representatives; or
- (c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of ADSs shall require us or any representative to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation and each person who initially acquires any ADSs or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with each of the representatives and the Company that it is a "qualified investor" within the meaning of 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 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 a Relevant State to qualified investors as so defined or in circumstances in which the prior consent of the representatives have been obtained to each such proposed offer or resale.

For the purposes of this provision, the expression an "offer to the public" in relation to ADSs in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any ADSs to be offered so as to enable an investor to decide to purchase or subscribe for any ADSs, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

#### 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 Prospectus Regulation) (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") or otherwise in circumstances which have not resulted and will not result in an offer to the public of the ADSs in the United Kingdom within the meaning of the Financial Services and Markets Act 2000.

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 a 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.

## 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 the Underwritten 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 does not constitute a prospectus within the meaning of, and 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 offering, may be publicly distributed or otherwise made publicly available in Switzerland. Neither this document nor any other offering or marketing material relating to the offering, the Company or the ADSs have 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 ("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 have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document other than (a) to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong) (the "SFO") of Hong Kong and any rules made thereunder; or (b) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32 of the Laws of Hong Kong) (the "CO") or which do not constitute an offer to the public within the meaning of the CO. No advertisement, invitation or document relating to the ADSs has been or may be issued or has been or may be in the possession of any person for the purposes of issue, 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 of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to ADSs which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the SFO and any rules made thereunder.

## **Notice to Prospective Investors in Japan**

The ADSs have not been and will not be registered pursuant to Article 4, Paragraph 1 of the Financial Instruments and Exchange Act. Accordingly, none of the ADSs nor any interest therein may be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any "resident" of Japan (which term, as used herein 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 or for the benefit of a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Act and any other applicable laws, regulations and ministerial guidelines of Japan in effect at the relevant time.

## **Notice to Prospective Investors in Singapore**

Each representative has acknowledged that this prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, each representative has represented and agreed that it has not offered or sold any ADSs or caused the ADSs to be made the subject of an invitation for subscription or purchase and will not offer or sell any ADSs or cause the ADSs to be made the subject of an invitation for subscription or

purchase and has not circulated or distributed, nor will it circulate or distribute, this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the ADSs, whether directly or indirectly, to any person in Singapore other than:

- to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time (the "SFA")) pursuant to Section 274 of the SFA;
- to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA; or
- 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 or securities-based derivatives contracts (each term as defined in Section 2(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, 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 37A of the Securities and Futures (Offers of Investments) (Securities and Securities-based Derivatives Contracts) Regulations 2018.

Singapore Securities and Futures Act Product Classification: Solely for the purposes of our obligations pursuant to sections 309B(1)(a) and 309B(1)(c) of the SFA, we have determined, and hereby notify all relevant persons (as defined in Section 309A of the SFA), that the ADSs are "prescribed capital markets products" (as defined in the Securities and Futures (Capital Markets Products) Regulations 2018) and Excluded Investment Products (as defined in MAS Notice SFA 04-N12: Notice on the Sale of Investment Products and MAS Notice FAA-N16: Notice on Recommendations on Investment Products).

## **Notice to Prospective Investors in the United Arab Emirates**

The ADSs have not been, and are not being, publicly offered, sold, promoted or advertised in the United Arab Emirates (including the Dubai International Financial Centre) other than in compliance with the laws of the United Arab Emirates (and the Dubai International Financial Centre) governing the issue, offering and sale of securities. Further, this prospectus does not constitute a public offer of securities in the United Arab Emirates (including the Dubai International Financial Centre) and is not intended to be a public offer. This prospectus has not been approved by or filed with the Central Bank of the United Arab Emirates, the Securities and Commodities Authority or the Dubai Financial Services Authority.

## **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 GLOBAL OFFERING

The following table sets forth the total costs and expenses, other than underwriting discounts and commissions and fees, that we expect to incur in connection with the offer and sale of the ordinary shares and ADSs in the Global Offering, constituting our costs and expenses in the Underwritten Offering and our costs and expenses in the Rights Offering. All of these amounts, except for the Securities and Exchange Commission registration fee and the FINRA filing fee, are estimates:

Expenses	Amount
Securities and Exchange Commission registration fee	\$ 131,368
FINRA filing fee	159,972
Printing and engraving expenses	450,000
Legal fees and expenses	1,900,000
Accounting fees and expenses	300,000
Depositary's fees	700,000
Miscellaneous costs	650,000
Total	\$ 4,291,340

#### LEGAL MATTERS

The validity of the ordinary shares 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 Underwritten 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. Members of Freshfields Bruckhaus Deringer LLP are the beneficial owners of less than 1% of our ordinary shares.

#### **EXPERTS**

The consolidated financial statements of BioNTech SE incorporated by reference from BioNTech SE's Annual Report on Form 20-F as of December 31, 2019 and 2018 and for each of the years in the three-year period ended December 31, 2019 have been audited by Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft, independent registered public accounting firm, as set forth in their report thereon included therein, and are incorporated herein by reference. Such consolidated financial statements are incorporated herein by reference 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.

The financial statements of Neon Therapeutics, Inc. incorporated in this Prospectus by reference to Neon Therapeutics, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2019 have been so incorporated in reliance on the report (which contains an explanatory paragraph relating to Neon Therapeutics, Inc.'s ability to continue as a going concern as described in Note 1 to the financial statements) of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

#### 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 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 the Underwritten Offering. 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 the ADSs representing our ordinary shares, we refer you to the registration statement and the exhibits and schedules included and incorporated by reference in the registration statement. Statements made in this prospectus concerning the contents of any contract, agreement or other document are summarizes of all material information about the documents summarized, but are not complete descriptions of all terms of these documents. If we file or incorporate by reference 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 or incorporated by reference as an exhibit is qualified in all respects by the filed exhibit.

We are subject to the information reporting requirements of the Exchange Act that are applicable to foreign private issuers. Accordingly, we are required to file reports and other information with the SEC, including annual reports on Form 20-F and reports on Form 6-K. The SEC maintains a website that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. These filings and 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 are not 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.

#### INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

We file annual and special reports and other information with the SEC (File Number 001-39081). These filings contain important information that does not appear in this prospectus. The SEC allows us to "incorporate by reference" information into this prospectus, which means that we can disclose important information to you by referring you to other documents which we have filed or will file with the SEC. We are incorporating by reference in this prospectus the documents listed below:

- Our Annual Report on Form 20-F for the fiscal year ended December 31, 2019, filed with the SEC on March 31, 2020;
- Our Form 6-K filed with the SEC on May 12, 2020, containing our unaudited interim condensed consolidated financial statements as of and for the three months ended March 31, 2020, our Form 6-K filed with the SEC on July 1, 2020 and our Forms 6-K filed with the SEC on July 20, 2020 and July 20, 2020;
- Neon Therapeutics, Inc.'s audited consolidated financial statements as of December 31, 2019 and 2018 and for the years then ended and the audit report of the independent registered public accounting firm, included on pages F-1 through F-28 of Neon Therapeutics, Inc.'s Form 10-K filed with the SEC on March 2, 2020;
- Neon Therapeutics, Inc.'s unaudited interim condensed consolidated financial statements as of March 31, 2020 and for the three-month
  periods ended March 31, 2020 and 2019 included in Item 1 of Neon Therapeutics, Inc.'s <u>Form 10-Q</u> filed with the SEC on May 1, 2020;
   and
- The description of the ADSs and ordinary shares contained in our <u>Form 8-A</u> filed with the SEC on October 7, 2019, including any
  amendment or report filed for the purpose of updating such description.

If you find inconsistencies between the documents and this prospectus, you should rely on the statements made in this prospectus. All information appearing in this prospectus is qualified in its entirety by the information and financial statements, including the notes thereto, contained in the documents incorporated by reference herein.

We will provide to each person, including any beneficial owner, to whom this prospectus is delivered, a copy of these filings, at no cost, upon written or oral request to us at the following address:

BioNTech SE An der Goldgrube 12 D-55131 Mainz Germany

Attention: James Ryan, Vice President, Legal and IP

Our SEC filings are also available (free of charge) from our web site at www.biontech.de. The information contained on, or that can be accessed from, our website does not form part of this prospectus.

You should rely only on the information contained or incorporated by reference in this prospectus. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus, or such earlier date, that is indicated in this prospectus. Our business, financial condition, results of operations and prospects may have changed since that date.

# 5,000,000 American Depositary Shares



# **Representing 5,000,000 Ordinary Shares**

PRELIMINARY PROSPECTUS

J.P. Morgan

UBS Investment Bank COMMERZBANK **BofA Securities** 

**Wolfe Capital Markets and Advisory** 

Berenberg

Canaccord Genuity Bryan, Garnier & Co.

#### PART II

#### INFORMATION NOT REQUIRED IN THE PROSPECTUSES

#### 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, 2017. 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 22,587,912 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 582,714 ordinary shares as part of our Stock Appreciation Rights program for aggregate consideration of €5.9 million (\$6.5 million).
- In October 2018 we issued 3,360,870 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 5,088,204 ordinary shares in private placements to Sanofi and an existing investor for aggregate proceeds received of \$92.1 million.

- In April 2019 we issued 2,374,794 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 August 2019 we issued an aggregate of 12,465,288 ordinary shares in private placements to a group of existing and new investors for aggregate proceeds received of \$225.6 million, which we refer to as our Series B financing.
  - We also issued 5,524,506 shares for anticipated proceeds of €89.3 million to a Hong Kong-based investor in connection with the Series B private placement. Under the terms of the Series B investment agreement, the investor agreed to fund the closing of such shares by August 23, 2019, but was unable to do so. The shares were transferred to us for no consideration and are held in treasury.
- In August 2019 we agreed to issue up to 3,038,674 ordinary shares in a private placement to the Bill & Melinda Gates Foundation for aggregate consideration of €49.9 million (\$55.0 million). Such issuance occurred upon registration of the shares in the commercial register (*Handelsregister*).
- In April 2020, upon the registration of the shares in the commercial register (*Handelsregister*), we issued 1,580,777 ordinary shares in a private placement to Fosun Pharma for aggregate consideration of €45.6 million (\$50.0 million, translated using the exchange rate then in effect as published by the German Central Bank (*Deutsche Bundesbank*))).
- In May 2020, upon the registration of the shares in the commercial register (*Handelsregister*), we issued 2,377,446 ordinary shares in a private placement to Pfizer for aggregate consideration of €103.9 million (\$113.0 million, translated using the exchange rate then in effect as published by the German Central Bank (*Deutsche Bundesbank*))).
- In June 2020, we agreed to issue 2,595,996 ordinary shares for anticipated proceeds of €123.9 million (\$138.9 million, using the exchange rate then in effect as published by the German Central Bank (*Deutsche Bundesbank*)) and a €100.0 million (\$112.1 million, using the exchange rate then in effect as published by the German Central Bank (*Deutsche Bundesbank*)) mandatory convertible note in a private placement to certain investors. Such issuance will occur upon the registration of the shares in the commercial register (*Handelsregister*), which is expected to occur in August 2020.

## Item 8. Exhibits

(a) The following documents are filed as part of this registration statement:

No.	Exhibit
1.1	Form of Underwriting Agreement
2.1	Agreement and Plan of Merger by and among the Registrant, Endor Lights, Inc. and Neon Therapeutics, Inc., dated January 15, 2020 (incorporated by reference to the Registrant's Registration Statement on Form F-4 (File No. 333-237515), filed with the SEC on March 31, 2020)
3.1	Articles of Association of the Registrant
4.1	Form of Specimen American Depositary Receipt (included in Exhibit 4.3)
4.2	Registrant's Specimen Certificate for Ordinary Shares (incorporated herein by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.3	Deposit Agreement among the Registrant, the depositary and holders and beneficial owners of the American Depositary Shares, dated October 9, 2019
5.1	Opinion of Freshfields Bruckhaus Deringer LLP regarding the validity of the Ordinary Shares being registered

Exhibit No.	Exhibit
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 (incorporated herein by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
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 (incorporated herein by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
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 (incorporated herein by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
10.4†	<u>License Agreement by and among the Registrant, TRON-Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz, Universitätsmedizin der Johannes Gutenberg-Universität Mainz, Universitätsmedizin der Johannes Gutenberg-Universität and Ganymed Pharmaceuticals AG, dated January 1, 2015 (incorporated herein by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)</u>
10.5†	Framework Collaboration Agreement 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, JPT Peptide Technologies GmbH and TRON-Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH, dated August 29, 2019 (incorporated herein by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
10.6†	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 (incorporated herein by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
10.7†	<u>License and Collaboration Agreement by and between the Registrant and Genmab A/S, dated May 19, 2015 (incorporated herein by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)</u>
10.8†	Amendment No. 1 to License and Collaboration Agreement by and between the Registrant and Genmab A/S, dated May 18, 2017 (incorporated herein by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)

Exhibit No.	Exhibit
10.9†	Amendment No. 2 to License and Collaboration Agreement by and between the Registrant and Genmab A/S, dated August 4, 2017 (incorporated herein by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
10.10†	Amendment No. 3 to License and Collaboration Agreement by and between the Registrant and Genmab A/S, dated May 18, 2018 (incorporated herein by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
10.11†	Amendment No. 4 to License and Collaboration Agreement by and between the Registrant and Genmab A/S, dated November 25, 2019
10.12†	Amendment No. 5 to License and Collaboration Agreement by and between the Registrant and Genmab A/S, dated May 8, 2020
10.13†	Collaboration and License Agreement by and between Sanofi S.A. and BioNTech RNA Pharmaceuticals GmbH, dated November 2, 2015 (incorporated herein by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
10.14†	Amendment to Collaboration and License Agreement by and between Sanofi S.A. and BioNTech RNA Pharmaceuticals GmbH, dated December 22, 2018 (incorporated herein by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
10.15†	<u>Development Agreement by and between Sanofi S.A. and BioNTech RNA Pharmaceuticals GmbH, dated March 29, 2018 (incorporated herein by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)</u>
10.16†	Collaboration Agreement by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH, Genentech, Inc. and F. Hoffman-La Roche Ltd, dated September 20, 2016 (incorporated herein by reference to Exhibit 10.14 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
10.17†	First Amendment to the Collaboration Agreement by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH, Genentech, Inc. and F. Hoffman-La Roche Ltd, dated June 1, 2018 (incorporated herein by reference to Exhibit 4.15 to the Registrant's Annual Report on Form 20-F, filed with the SEC on March 31, 2020)
10.18†	Second Amendment to the Collaboration Agreement by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH, Genentech, Inc. and F. Hoffman-La Roche Ltd, dated December 6, 2019 (incorporated herein by reference to Exhibit 4.16 to the Registrant's Annual Report on Form 20-F, filed with the SEC on March 31, 2020)
10.19†	Patent Sublicense Agreement by and between CellScript, LLC and BioNTech RNA Pharmaceuticals GmbH, dated July 19, 2017 (incorporated herein by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9,2019)
10.20†	Patent Sublicense Agreement by and between mRNA RiboTherapeutics, Inc. and BioNTech RNA Pharmaceuticals GmbH, dated July 19, 2017 (incorporated herein by reference to Exhibit 10.16 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)

Exhibit No.	Exhibit		
10.21†	License and Co-Development Agreement by and between Genevant Sciences GmbH and BioNTech RNA Pharmaceuticals GmbH, dated July 4, 2018 (incorporated herein by reference to Exhibit 10.17 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)		
10.22†	Research Collaboration and License Agreement by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH and Pfizer, Inc., dated July 20, 2018 (incorporated herein by reference to Exhibit 10.18 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)		
10.23†	Collaboration and License Agreement by and between the Trustees of the University of Pennsylvania and BioNTech RNA Pharmaceuticals GmbH, dated October 9, 2018 (incorporated herein by reference to Exhibit 10.19 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)		
10.24†	Sublease Agreement by and among the Registrant and Universitätsmedizin der Johannes Gutenberg-Universität Mainz, dated January 14, 2013 (incorporated herein by reference to Exhibit 10.21 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)		
10.25†	Amendment to Sublease Agreement by and among the Registrant and Universitätsmedizin der Johannes Gutenberg-Universität Mainz, dated July 5, 2014 (incorporated herein by reference to Exhibit 10.22 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)		
10.26†	Amendment to Sublease Agreement by and among the Registrant and Universitätsmedizin der Johannes Gutenberg-Universität Mainz, dated June 8, 2015 (incorporated herein by reference to Exhibit 10.23 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)		
10.27†	Amendment to Sublease Agreement by and among the Registrant and Universitätsmedizin der Johannes Gutenberg-Universität Mainz, dated January 18, 2017 (incorporated herein by reference to Exhibit 10.24 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)		
10.28†	Lease Agreement by and among the Registrant and Wolfram Richter, dated August 17, 2011 (incorporated herein by reference to Exhibit 10.25 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)		
10.29†	Amendment No. 1 to Lease Agreement by and among the Registrant and Wolfram Richter, dated February 17, 2012 (incorporated herein by reference to Exhibit 10.26 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)		
10.30†	Amendment No. 2 to Lease Agreement by and among the Registrant and Wolfram Richter, dated February 1, 2013 (incorporated herein by reference to Exhibit 10.27 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)		
10.31†	Amendment No. 3 to Lease Agreement by and among the Registrant and Wolfram Richter, dated March 6, 2013 (incorporated herein by reference to Exhibit 10.28 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)		
10.32†	Amendment No. 4 to Lease Agreement by and among the Registrant and Wolfram Richter, dated December 10, 2013 (incorporated herein by reference to Exhibit 10.29 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)		

Exhibit No.	Exhibit		
10.33†	Amendment No. 5 to Lease Agreement by and among the Registrant and Wolfram Richter, dated March 29, 2016 (incorporated herein by reference to Exhibit 10.30 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)		
10.34†	Amendment No. 6 to Lease Agreement by and among the Registrant and Wolfram Richter, dated October 6, 2017 (incorporated herein by reference to Exhibit 10.31 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)		
10.35†	<u>Lease Agreement by and among the Registrant and Wista-Management GmbH, dated April</u> 12, 2005 (incorporated herein by reference to Exhibit 10.32 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)		
10.36†	Amendment to Lease Agreement by and among the Registrant and Wista-Management GmbH, dated December 27, 2018 (incorporated herein by reference to Exhibit 10.33 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)		
10.37†	Amendment to Lease Agreement by and among the Registrant and Wista-Management GmbH, dated October 24, 2019 (incorporated herein by reference to Exhibit 4.35 to the Registrant's Annual Report on Form 20-F, filed with the SEC on March 31, 2020)		
10.38†	Amendment to Lease Agreement by and among the Registrant and Wista-Management GmbH, dated June 1, 2020		
10.39†	Loan Agreement by and between BioNTech Innovative Manufacturing Services GmbH and Deutsche Bank AG dated November 21, 2017 (incorporated herein by reference to Exhibit 10.34 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)		
10.40†	<u>Loan Agreement by and between JPT Peptides Technologies GmbH and Deutsche Bank AG dated July 18, 2018 (incorporated herein by reference to Exhibit 10.35 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)</u>		
10.41†	Investment Agreement by and between the Registrant and the Bill & Melinda Gates Foundation, dated August 30, 2019 (incorporated herein by reference to Exhibit 10.36 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)		
10.42†	<u>Letter Agreement by and between the Registrant and the Bill &amp; Melinda Gates Foundation, dated August 30, 2019 (incorporated herein by reference to Exhibit 10.37 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)</u>		
10.43†	<u>Finance Contract by and between the Registrant and the European Investment Bank, dated December 12, 2019 (incorporated herein by reference to Exhibit 4.41 to the Registrant's Annual Report on Form 20-F, filed with the SEC on March 31, 2020)</u>		
10.44†	<u>Finance Fee Letter by and between the Registrant and the European Investment Bank, dated December 12, 2019 (incorporated herein by reference to Exhibit 4.42 to the Registrant's Annual Report on Form 20-F, filed with the SEC on March 31, 2020)</u>		
10.45†	Collaboration Agreement by and between the Registrant and Pfizer Inc., dated March 17, 2020		
10.46†	Antiviral Vaccine RDI Finance Contract by and between the European Investment Bank and the Registrant, dated as of June 10, 2020		
10.47†	Finance Fee Letter by and between the Registrant and the European Investment Bank, dated June 10, 2020		
10.48†	License Agreement by and between the Broad Institute, Inc. and BioNTech US Inc. (as successor-by-merger to Neon Therapeutics, Inc.),		

Exhibit No.	- · · ·	
10.49†	First Amendment to the License Agreement by and between the Broad Institute, Inc. and BioNTech US Inc. (as successor-by-merger to Neon Therapeutics, Inc.), dated as of January 18, 2018	
10.50†	Second Amendment to the License Agreement by and between the Broad Institute, Inc. and BioNTech US Inc. (as successor-by-merger to Neon Therapeutics, Inc.), dated as of November 14, 2018	
21.1	List of Subsidiaries of the Registrant	
23.1	Consent of Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft, Independent Registered Public Accounting Firm	
23.2	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm	
23.3	Consent of Freshfields Bruckhaus Deringer LLP (included in Exhibit 5.1)	
24.1	Powers of Attorney (included on signature page)	

## 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.

<sup>†</sup> 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.

## **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 July 21, 2020.

## **BIONTECH SE**

By: /s/ Prof. Ugur Sahin, M.D.

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., Özlem Türeci, Sean Marett, Sierk Poetting and Ryan Richardson 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 hereto, including post-effective amendments and registration statements filed pursuant to Rule 462 under the Securities Act of 1933, as amended, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the U.S. 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, as amended, this registration statement has been signed by the following persons on July 21, 2020 in the capacities indicated:

Name	Title	Date
/s/ PROF. UGUR SAHIN, M.D. Prof. Ugur Sahin, M.D.	Chief Executive Officer (principal executive officer)	July 21, 2020
/s/ Dr. Sierk Poetting, Ph.D. Dr. Sierk Poetting, Ph.D.	Chief Financial Officer and Chief Operating Officer (principal accounting officer)	July 21, 2020
/s/ HELMUT JEGGLE Helmut Jeggle	Chair of the Supervisory Board	July 21, 2020
/s/ MICHAEL MOTSCHMANN Michael Motschmann	Director	July 21, 2020
/s/ PROF. CHRISTOPH HUBER, M.D. Prof. Christoph Huber, M.D.	Director	July 21, 2020
/s/ Dr. Ulrich WANDSCHNEIDER Dr. Ulrich Wandschneider	Director	July 21, 2020

# 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 July 21, 2020.

BIONTECH US INC.

/s/ BRIAN KICKHAM

Name: Brian Kickham Title: Secretary

#### BioNTech SE

# $[\bullet]$ ORDINARY REGISTERED SHARES, NO PAR VALUE, IN THE FORM OF $[\bullet]$ AMERICAN DEPOSITARY SHARES

Underwriting Agreement

[•], 2020

J.P. Morgan Securities LLC BofA Securities, Inc. Berenberg Capital Markets LLC

As Representatives of the several Underwriters listed in Schedule 1 hereto

c/o J.P. Morgan Securities LLC 383 Madison Avenue New York, New York 10179

c/o BofA Securities, Inc. One Bryant Park New York, New York 10036

c/o Berenberg Capital Markets LLC 1251 Avenue of the Americas New York, New York 10020

## Ladies and Gentlemen:

BioNTech SE, a European stock corporation (*Societas Europaea*) incorporated in Germany and governed by the laws of the European Union and the Federal Republic of Germany and registered with the commercial register (*Handelsregister*) of the local court (*Amtsgericht*) of Mainz, Federal Republic of Germany, under number HRB 48720 (the "Company"), proposes to issue and sell to the several underwriters listed in Schedule 1 hereto (the "Underwriters"), for whom you are acting as representatives (the "Representatives"), an aggregate of [●] new ordinary registered shares (*Namensaktien*) of the Company with no par value and a notional amount attributable to each share of €1.00 (any such share an "Ordinary Share") (the "Underwritten Shares") in the form of American Depositary Shares (the "Underwritten ADSs"). Certain shareholders of the Company named in Schedule 2 hereto (the "Selling Stockholders") propose to sell to the Underwritters, at the option of the Underwritters, up to an aggregate of [●] existing American Depositary Shares (the "Option ADSs"). The Underwritten Shares and the ordinary shares represented by the Option ADSs are herein referred to as the "Shares". The Underwritten ADSs and the Option ADSs (to the extent that the aforementioned option is exercised) are hereinafter collectively referred to as the "Offered ADSs". Any one ordinary registered share of the Company is referred to herein as a "Share", the Shares to be outstanding after giving effect to the sale of the Shares are referred to herein as the "Stock" and an American Depositary Share as an "ADS."

The Underwritten ADSs are to be issued, and the Option ADSs have been issued, pursuant to a deposit agreement (the "Deposit Agreement"), dated October 9, 2019, among the Company and The Bank of New York Mellon as depositary (the "Depositary"). Each Offered ADS will initially represent the right to receive one Ordinary Share deposited with the Depositary pursuant to the Deposit Agreement.

The Company and the Selling Stockholders hereby confirm their agreement with the several Underwriters concerning the purchase and sale of the Shares in the form of Offered ADSs, as follows:

1. Registration Statement. The Company has prepared and filed with the Securities and Exchange Commission (the "Commission") under the Securities Act of 1933, as amended, and the rules and regulations of the Commission thereunder (collectively, the "Securities Act"), a registration statement on Form F-1 (File No. 333-[●]), including a prospectus, relating to the Shares and the Offered ADSs. Such registration statement, as amended at the time it became effective, including the information, if any, deemed pursuant to Rule 430A, 430B or 430C under the Securities Act to be part of the registration statement at the time of its effectiveness ("Rule 430 Information"), is referred to herein as the "Registration Statement"; and as used herein, the term "Preliminary Prospectus" means each prospectus included in such registration statement (and any amendments thereto) before effectiveness, any prospectus filed with the Commission pursuant to Rule 424(a) under the Securities Act and the prospectus included in the Registration Statement at the time of its effectiveness that omits Rule 430 Information, and the term "Prospectus" means the prospectus included in the Registration Statement at the time of purchasers pursuant to Rule 430 Information, and the term "Prospectus" means the prospectus in the form first used (or made available upon request of purchasers pursuant to Rule 173 under the Securities Act in connection with a confirmation of sales of the Shares in the form of Offered ADSs. If the Company has filed an abbreviated registration statement pursuant to Rule 462(b) under the Securities Act (the "Rule 462 Registration Statement"), then any reference herein to the term "Registration Statement" shall be deemed to include such Rule 462 Registration Statement. Any reference in this underwriting agreement (this "Agreement") to the Registration Statement, any Preliminary Prospectus or the Prospectus or the Prospectus, as the case may be. Capitalized terms used but not defined herein shall have the meanings given to such t

At or prior to the Applicable Time (as defined below), the Company had prepared the following information (collectively with the pricing information set forth on Annex A hereto, the "Pricing Disclosure Package"): a Preliminary Prospectus dated [•], 2020 and each "free-writing prospectus" (as defined pursuant to Rule 405 under the Securities Act), if any, listed on Annex A hereto.

"Applicable Time" means [●] P.M., New York City time, on [●], 2020.

## 2. Purchase of the Underwritten ADS.

- (a) Each Underwriter, on the basis of the representations, warranties and agreements set forth herein and subject to the conditions set forth herein, agrees, severally and not jointly, to:
  - (i) purchase from the Company the respective number of Underwritten ADSs set forth opposite such Underwriter's name in Schedule 1 hereto,
  - (ii) cause BofA Securities, Inc. (the "Settlement Agent"), acting for the account of the several Underwriters, to make available to Joh. Berenberg, Gossler & Co. KG (the "German Subscription Agent"), on [●], 2020, an amount equal to an issue price of €1.00 (the "Issue Price") per Underwritten Share (i.e. the Issue Price multiplied by the number of the Underwritten Shares, with such product being the "Aggregate Issue Price"),
  - (iii) cause the German Subscription Agent, acting in its own name but for the account of the several Underwriters, (x) to subscribe, on [●], 2020, for the Underwritten Shares at the Aggregate Issue Price by way of executing and delivering to the Company a subscription certificate (*Zeichnungsschein*) (the "Subscription"

Certificate") for the Underwritten Shares in the form attached as Exhibit A hereto, duly signed in duplicate form pursuant to Section 185 of the German Stock Corporation Act (*Aktiengesetz* or "AktG"), such Subscription Certificate, in accordance with its terms, to expire at 11:30 a.m. Frankfurt am Main time on [●], 2020, (y) to pay the Aggregate Issue Price to the Company by crediting, with value date as of [●], 2020 the Aggregate Issue Price into a special account opened at the German Subscription Agent [(IBAN: DE76201200000067739003; BIC: BEGODEHHXXX)] and entitled "*Sonderkonto Kapitalerhöhung Juli 2020*" (the "Capital Increase Account"), such account to be noninterest bearing and free of charges (including negative interest), and (z) upon credit of the Aggregate Issue Price to the Capital Increase Account, to deliver to the Company a bank certificate (*Einzahlungsbestätigung*) in the form attached as Exhibit B hereto (the "Bank Certificate") confirming such credit (Sections 188(2), 36(2), 36a(1) and 37(1) AktG).

- (b) Promptly upon receipt of the Subscription Certificate and Bank Certificate pursuant to paragraph (a)(iii) above, the Company shall use its best efforts to effect the registration of the capital increase in the commercial register. Copies of all documents filed with the commercial register shall be delivered to the German Subscription Agent. Promptly upon the registration of the capital increase in the commercial register, but at the latest by 12:00 (noon) Frankfurt am Main time on [●], 2020, the Company shall, by telefax or pdf-document attached to an email, with two original certified copies to follow promptly by courier, furnish the German Subscription Agent with a certified copy of the registration notice of the commercial register, a certified chronological excerpt from the commercial register and a certified copy of the articles of association of the Company, each evidencing such capital increase. If the registration with the commercial register of the increase of the Company's registered share capital in an amount of €[•] has not been effected by 11:30 a.m. Frankfurt am Main time on [•], 2020, the Subscription Certificate for the Underwritten Shares shall expire and the Settlement Agent, on behalf of the several Underwriters, may obtain repayment of the Issue Price for the Underwritten Shares by way of instructing the German Subscription Agent to cancel the credit of the Aggregate Issue Price for the Underwritten Shares to the Capital Increase Account and to transfer the Aggregate Issue Price to the Settlement Agent for the account of the several Underwriters. In such event, the Representatives, on behalf of the several Underwriters, may cause the German Subscription Agent to submit to the Company a new Subscription Certificate for the Underwritten Shares (to expire in accordance with its terms on a date to be determined by the Representatives on behalf of the several Underwriters) and the Company shall use its best efforts to effect the registration of the capital increase in the commercial register. If the Representatives, on behalf of the several Underwriters, have not caused a submission of a new Subscription Certificate for the Underwritten Shares to the Company on or prior to [●], 2020, all obligations of the Underwriters to purchase, subscribe for and pay for the Underwritten Shares shall terminate. In this event, the reimbursement obligations of the Company pursuant to Section 15 and the provisions set out in Sections 11 and 13 of this Agreement shall remain in full force and effect.
- (c) Each Underwriter, agrees, severally and not jointly, to cause the German Subscription Agent, acting in its own name, but for the account of the several Underwriters, to transfer title to the Underwritten Shares to the Depositary on the Closing Date (as defined below), to enable the delivery by the Depositary of the Underwritten ADSs in respect of the Underwritten Shares to the Settlement Agent for the account of the several Underwriters, for subsequent delivery to the other several Underwriters or to investors, as the case may be, by way of book-entry.
- (d) On [•], 2020, the Company shall deliver to the German Subscription Agent one global share certificate in the form set forth as Exhibit C hereto representing the Underwritten Shares and each Underwriter, agrees, severally and not jointly, to cause the German Subscription Agent, acting in its own name, but for the account of the several Underwriters, to deliver such global share certificate to Clearstream Banking AG, Frankfurt am Main ("Clearstream"), and procure the Underwritten Shares to be credited to such securities account with a participant of Clearstream as the Depositary may designate (the "Custodian").

## 3. Option to Purchase Additional ADSs.

- (a) Each of the Selling Stockholders agrees, severally and not jointly, as and to the extent indicated in Schedule 2 hereto, to sell, the Option ADSs to the several Underwriters as provided in this Agreement, and the Underwriters, on the basis of the representations, warranties and agreements set forth herein and subject to the conditions set forth herein, shall have the option to purchase, severally and not jointly, from each Selling Stockholder the Option ADSs at \$[●] per Option ADS, less an amount per share equal to any dividends or distributions declared by the Company and payable on the Underwritten ADSs but not payable on the Option ADSs (the "Option ADS Purchase Price"). If the Underwriters exercise the option to purchase Option ADSs in part, the number of Option ADSs to be sold by each Selling Stockholder shall be the number of Option ADSs which bears the same ratio to the aggregate number of Option ADSs being purchased as the number of Option ADSs set forth opposite the name of such Selling Stockholder in Schedule 2 hereto bears to the aggregate number of Option ADSs that could be purchased from the Selling Stockholders by the several Underwriters upon exercise of the option to purchase Option ADSs in whole under this Agreement. In the event of fractional Option ADSs to be sold, each of the Selling Stockholders will round down to the nearest whole Option ADS and the largest Selling Stockholder will add the number of Option ADSs to its share necessary to ensure the total number of Option ADSs being purchased by the Underwriters is equal to the total number of Option ADSs being sold by the Selling Stockholders.
- (b) If any Option ADSs are to be purchased, the number of Option ADSs to be purchased by each Underwriter shall be the number of Option ADSs which bears the same ratio to the aggregate number of Option ADSs being purchased as the number of Underwritten ADSs set forth opposite the name of such Underwriter in Schedule 1 hereto (or such number increased as set forth in Section 14 hereof) bears to the aggregate number of Underwritten ADSs being purchased from the Company by the several Underwriters. In the event of fractional Option ADSs to be purchased, each of the Underwriters will round down to the nearest whole Option ADS and J.P. Morgan Securities LLC will add the number of Option ADSs to its share necessary to obtain the total aggregate number of Option ADSs being purchased by the Underwriters.
- (c) The Underwriters may exercise the option to purchase Option ADSs in whole or from time to time, in part, on or before the thirtieth day following the date of the Prospectus, by written notice (the "Option Exercise Notice") from the Representatives to the Attorneys-in-Fact (as defined below), with a copy to the Company. Such notice shall set forth the aggregate number of Option ADSs as to which the option is being exercised and the date and the time when the Option ADSs are to be delivered and paid for, which may be the same date and time as the Closing Date (as hereinafter defined) but shall not be earlier than the Closing Date nor later than the tenth full business day after the date of such notice (unless such time and date are postponed in accordance with the provisions of Section 14 hereof). Any such notice shall be given at least two full business days prior to the Additional Closing Date (as defined below).

## 4. Sale of ADSs to the Public; Delivery and Payment.

- (a) The Company and the Selling Stockholders understand that the several Underwriters intend to make a public offering of the Offered ADSs, and initially to offer the Offered ADSs on the terms set forth in the Pricing Disclosure Package. The Company and the Selling Stockholders acknowledge and agree that the several Underwriters may offer and sell Offered ADSs to or through any affiliate of an Underwriter.
- (b) Payment for the Underwritten ADSs shall be made, subject to the conditions set forth herein, by wire transfer in immediately available funds in U.S. dollar and with respect to the Aggregate Issue Price in euro to the accounts specified by the Company to the Representatives at the offices of Davis Polk & Wardwell LLP, New York, New York no later than 10:00 a.m. New York City time on [♠], 2020, or at such other time or place on the same or such other date, not later than the fifth business day thereafter. Payment for the Option ADSs shall be made, subject to the conditions set forth herein, by wire transfer in immediately available funds in U.S. dollar to the accounts specified by the Attorneys-in-Fact to the Representatives on the date and at the time and place specified by the Option Exercise Notice. The time and date of such payment for the Underwritten ADSs is referred to herein as the "Closing Date," and the time and date for such payment for the Option ADSs, if other than the Closing Date, is herein referred to as the "Additional Closing Date".
- (c) Payment for the ADSs to be purchased on the Closing Date or the Additional Closing Date, as the case may be, shall be made subject to the conditions set forth herein, against delivery of the ADSs to the Settlement Agent for the account of the several Underwriters of the Offered ADSs to be purchased on such date with any transfer taxes payable in connection with the sale of such ADSs (including any transfer taxes payable with respect to the underlying Ordinary Shares) duly paid by the Company. The Company shall procure (and in the form of the Deposit Agreement has made the necessary arrangements) that the Depository delivers the Underwritten ADSs through the facilities of The Depository Trust Company unless the Representatives shall otherwise instruct. The aggregate U.S. dollar amount to be paid by the several Underwriters to the Company on the Closing Date shall be \$[●] per ADS (the "Purchase Price") multiplied by the number of Underwritten ADSs delivered on such date, less the Aggregate Issue Price converted from euro into U.S. dollar (the "Excess Proceeds Amount"). Solely for the purpose of calculating the Excess Proceeds Amount, the Aggregate Issue Price shall convert from euro into U.S. dollars by applying the exchange rate, which the Settlement Agent can reasonably obtain at the time it converts U.S. dollars into a euro amount for purposes of making the payment of the Aggregate Issue Price to the German Subscription Agent. The Settlement Agent, on behalf of the several Underwriters, shall cause payment of the Excess Proceeds Amounts in U.S. dollars and shall instruct the German Subscription Agent via email to transfer the Aggregate Issue Price in euro to the accounts designated by the Company on the Closing Date. The Selling Stockholders shall deliver the Option ADSs through the facilities of The Depository Trust Company unless the Representatives shall otherwise instruct. The aggregate U.S. dollar amount to be paid by the several Underwriters to the respective Selling Stockholder on the applicable Additional Closing Date shall be the Option ADS Purchase Price multiplied by the number of Option ADSs delivered by the respective Selling Stockholder on such date.
- (d) Each of the Company and each Selling Stockholder acknowledge and agree that each of the Representatives and the other Underwriters are acting solely in the capacity of an arm's length contractual counterparty to the Company and the Selling Stockholders with respect to the offering of the Offered ADSs contemplated hereby (including in connection with determining the terms of the offering) and not as a financial advisor or a fiduciary to, or an agent of, the Company, the Selling Stockholders or any other person. Additionally, neither the Representatives nor any other Underwriter is advising the Company, the Selling Stockholders or

any other person as to any legal, tax, investment, accounting or regulatory matters in any jurisdiction. The Company and the Selling Stockholders shall consult with their own advisors concerning such matters and each shall be responsible for making its own independent investigation and appraisal of the transactions contemplated hereby, and neither the Representatives nor any other Underwriters shall have any responsibility or liability to the Company or the Selling Stockholders with respect thereto. Any review by the Representatives and the other Underwriters of the Company, the transactions contemplated hereby or other matters relating to such transactions will be performed solely for the benefit of the several Underwriters and shall not be on behalf of the Company or the Selling Stockholders. Moreover, each Selling Stockholder acknowledges and agrees that, although the Representatives may be required or choose to provide certain Selling Stockholders with certain Regulation Best Interest and Form CRS disclosures in connection with the offering, the Representatives and the other Underwriters are not making a recommendation to any Selling Stockholder to participate in the offering, enter into a "lock-up" agreement, or sell any Shares at the price determined in the offering, and nothing set forth in such disclosures is intended to suggest that the Representatives or any Underwriter is making such a recommendation.

- 5. Representations and Warranties of the Company. The Company represents and warrants to each Underwriter and the Selling Stockholders that:
- (a) *Preliminary Prospectus*. No order preventing or suspending the use of any Preliminary Prospectus has been issued by the Commission, and each Preliminary Prospectus included in the Pricing Disclosure Package, at the time of filing thereof, complied in all material respects with the Securities Act, and no Preliminary Prospectus, at the time of filing thereof, contained any untrue statement of a material fact or omitted to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; provided that the Company makes no representation or warranty with respect to any statements or omissions made in reliance upon and in conformity with information relating to any Underwriter furnished to the Company in writing by such Underwriter through the Representatives expressly for use in any Preliminary Prospectus, it being understood and agreed that the only such information furnished by any Underwriter consists of the information described as such in Section 11(c) hereof.
- (b) *Pricing Disclosure Package*. The Pricing Disclosure Package as of the Applicable Time did not, and as of the Closing Date and as of the Additional Closing Date, as the case may be, will not, contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; provided that the Company makes no representation or warranty with respect to any statements or omissions made in reliance upon and in conformity with information relating to any Underwriter furnished to the Company in writing by such Underwriter through the Representatives expressly for use in such Pricing Disclosure Package, it being understood and agreed that the only such information furnished by any Underwriter consists of the information described as such in Section 11(c) hereof. No statement of material fact included in the Prospectus has been omitted from the Pricing Disclosure Package and no statement of material fact included in the Pricing Disclosure Package that is required to be included in the Prospectus has been omitted therefrom.
- (c) *Issuer Free Writing Prospectus*. Other than the Registration Statement, the Preliminary Prospectus and the Prospectus, the Company (including its agents and representatives, other than the Underwriters in their capacity as such) has not prepared, made, used, authorized, approved or referred to and will not prepare, make, use, authorize, approve or

refer to any "written communication" (as defined in Rule 405 under the Securities Act) that constitutes an offer to sell or solicitation of an offer to buy the Shares or the Offered ADSs (each such communication by the Company or its agents and representatives (other than a communication referred to in clause (i) below) an "Issuer Free Writing Prospectus") other than (i) any document not constituting a prospectus pursuant to Section 2(a)(10)(a) of the Securities Act or Rule 134 under the Securities Act or (ii) the documents, if any, listed on Annex A hereto, each electronic road show and any other written communications approved in writing in advance by the Representatives. Each such Issuer Free Writing Prospectus complies in all material respects with the Securities Act, has been or will be (within the time period specified in Rule 433) filed in accordance with the Securities Act (to the extent required thereby) and does not conflict with the information contained in the Registration Statement or the Pricing Disclosure Package, and, when taken together with the Preliminary Prospectus accompanying, or delivered prior to delivery of, such Issuer Free Writing Prospectus, did not, and as of the Closing Date and as of the Additional Closing Date, as the case may be, will not, contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; provided that the Company makes no representation or warranty with respect to any statements or omissions made in each such Issuer Free Writing Prospectus or Preliminary Prospectus in reliance upon and in conformity with information relating to any Underwriter furnished to the Company in writing by such Underwriter through the Representatives expressly for use in such Issuer Free Writing Prospectus or Preliminary Prospectus, it being understood and agreed that the only such information furnished by any Underwriter consists of the informa

- (d) *Emerging Growth Company*. From the time of initial confidential submission of the Registration Statement to the Commission through the date hereof, the Company has been and is an "emerging growth company," as defined in Section 2(a) of the Securities Act (an "Emerging Growth Company").
- (e) *Testing-the-Waters Materials*. The Company has not alone engaged in any Testing-the-Waters Communications (as defined below) other than Testing-the-Waters Communications with the consent of the Representatives with entities that are qualified institutional buyers within the meaning of Rule 144A under the Securities Act or institutions that are accredited investors within the meaning of Rule 501 under the Securities Act. "Testing-the-Waters Communication" means any oral or written communication with potential investors undertaken in reliance on Section 5(d) of the Securities Act.
- (f) Registration Statement and Prospectus. The Registration Statement has been declared effective by the Commission. No order suspending the effectiveness of the Registration Statement has been issued by the Commission, and no proceeding for that purpose or pursuant to Section 8A of the Securities Act against the Company or related to the offering of the Shares or Offered ADSs has been initiated or, to the knowledge of the Company, threatened by the Commission; as of the applicable effective date of the Registration Statement and any post-effective amendment thereto, the Registration Statement and any such post-effective amendment complied and will comply in all material respects with the Securities Act, and did not and will not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein not misleading; and as of the date of the Prospectus and any amendment or supplement thereto and as of the Closing Date and as of the Additional Closing Date, as the case may be, the Prospectus will comply in all material respects with the Securities Act and will not contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; provided that the Company makes no

representation or warranty with respect to any statements or omissions made in reliance upon and in conformity with information relating to any Underwriter furnished to the Company in writing by such Underwriter through the Representatives expressly for use in the Registration Statement and the Prospectus and any amendment or supplement thereto, it being understood and agreed that the only such information furnished by any Underwriter consists of the information described as such in Section 11(c) hereof.

- (g) *Incorporated Documents*. The documents incorporated by reference in the Registration Statement, the Prospectus and the Pricing Disclosure Package, when they were filed with the Commission conformed in all material respects to the requirements of the Exchange Act, and none of such documents contained any untrue statement of a material fact or omitted to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.
- (h) *Registration Statement on Form F-6*. (i) A registration statement on Form F-6 (No. 333-233898) in respect of the ADSs has been filed with the Commission and such registration statement has become effective pursuant to the Rules and Regulations (such registration statement, including all exhibits thereto, at the time it became effective, being hereinafter referred to as the "ADS Registration Statement"), (ii) no order suspending the effectiveness of the ADS Registration Statement has been issued by the Commission, and no proceedings for that purpose or pursuant to Section 8A of the Securities Act has been initiated or, to the knowledge of the Company, threatened by the Commission, (iii) the ADS Registration Statement complies and, as amended or supplemented, will comply in all material respects with the Securities Act, and (iv) the ADS Registration Statement, when it became effective, did not contain and, as of the Closing Date and as of the Additional Closing Date, as the case may be, and as amended or supplemented, will not contain, any untrue statement of a material fact required to be stated therein or omit to state a material fact necessary to make the statements therein not misleading. All of the Offered ADSs have been duly registered under the Securities Act pursuant to the ADS Registration Statement.
- (i) Financial Statements. The financial statements (including the related notes thereto) of the Company and its consolidated subsidiaries and of Neon Therapeutics, Inc. ("Neon"), each of which are included or incorporated by reference in the Registration Statement, the Pricing Disclosure Package and the Prospectus, comply in all material respects with the applicable requirements of the Securities Act and the Exchange Act, as applicable, and present fairly in all material respects the financial position of the Company and its consolidated subsidiaries or of Neon (as applicable) as of the dates indicated and the results of their respective operations and the respective changes in their cash flows for the periods specified; the financial statements of the Company and its consolidated subsidiaries have been prepared in conformity with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board applied on a consistent basis throughout the periods covered thereby, except as may be expressly stated in the related notes thereto, and except in the case of unaudited financial statements, which are subject to normal year-end adjustments and do not contain certain footnotes as permitted by the applicable rules of the Commission, and any supporting schedules included or incorporated by reference in the Registration Statement present fairly in all material respects the information required to be stated therein; the financial statements of Neon have been prepared in conformity with generally accepted accounting principles in the United States ("GAAP") applied on a consistent basis throughout the periods covered thereby, and any supporting schedules included or incorporated by reference in the Registration Statement present fairly in all material respects the information required to be stated therein; and the other financial information included or incorporated by reference in the Registration Statement, the

Pricing Disclosure Package and the Prospectus has been derived from the accounting records of the Company and its consolidated subsidiaries or of Neon and presents fairly in all material respects the information shown thereby; all disclosures included or incorporated by reference in the Registration Statement, the Pricing Disclosure Package and the Prospectus regarding "non-GAAP financial measures" (as such term is defined by the rules and regulations of the Commission) comply in all material respects with Regulation G of the Exchange Act and Item 10 of Regulation S-K of the Securities Act, to the extent applicable.

The pro forma financial statements (including the related notes thereto) of the Company and its consolidated subsidiaries, after giving effect to the acquisition of Neon, included or incorporated by reference in the Registration Statement, the Pricing Disclosure Package and the Prospectus have been prepared in conformity with IFRS and the Commission's rules and guidelines with respect to pro forma financial statements and have been properly compiled on the bases described therein, and the assumptions used in the preparation thereof are reasonable and the adjustments used therein are appropriate to give effect to the transactions and circumstances referred to therein. The pro forma financial statements present fairly in all material respects the financial position of the Company and its consolidated subsidiaries as of the dates indicated and the results of their operations and the changes in their cash flows for the periods specified.

- (j) No Material Adverse Change. Since the date of the most recent financial statements of the Company included or incorporated by reference in the Registration Statement, the Pricing Disclosure Package and the Prospectus, (i) there has not been any material change in the capital stock (other than the issuance of Ordinary Shares upon exercise of stock options and warrants described as outstanding in, and the grant of options and awards under existing equity incentive plans described in, the Registration Statement, the Pricing Disclosure Package and the Prospectus), short-term debt or long-term debt of the Company or any of its subsidiaries, or any dividend or distribution of any kind declared, set aside for payment, paid or made by the Company on any class of capital stock, or any material adverse change, or any development involving a prospective material adverse change, in or affecting the business, properties, management, financial position, stockholders' equity, results of operations or prospects of the Company and its subsidiaries taken as a whole; (ii) neither the Company nor any of its subsidiaries has entered into any transaction or agreement (whether or not in the ordinary course of business) that is material to the Company and its subsidiaries taken as a whole or incurred any liability or obligation, direct or contingent, that is material to the Company and its subsidiaries taken as a whole; and (iii) neither the Company nor any of its subsidiaries has sustained any loss or interference with its business that is material to the Company and its subsidiaries taken as a whole and that is either from fire, explosion, flood or other calamity, whether or not covered by insurance, or from any labor disturbance or dispute or any action, order or decree of any court or arbitrator or governmental or regulatory authority, except in each case as otherwise disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus.
- (k) Organization and Good Standing. The Company and each of its subsidiaries have been duly organized (and in good standing, to the extent such concept is applicable) under the laws of their respective jurisdictions of organization, are validly existing and are duly qualified to do business (and are in good standing, to the extent such concept is applicable), in each jurisdiction in which their respective ownership or lease of property or the conduct of their respective businesses requires such qualification, and have all power and authority necessary to own or hold their respective properties and to conduct the businesses as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, except where the failure to be so qualified (or in good standing, to the extent such concept is applicable) or have

such power or authority would not, individually or in the aggregate, reasonably be expected to have a material adverse effect on the business, properties, management, financial position, stockholders' equity, results of operations or prospects of the Company and its subsidiaries taken as a whole or on the performance by the Company of its obligations under the Transaction Documents (as defined below) (a "Material Adverse Effect"). The Company does not own or control, directly or indirectly, any corporation, association or other entity other than the subsidiaries listed in Exhibit 21 to the Registration Statement.

- (l) Capitalization. The Company has a capitalization as set forth in the Registration Statement, the Pricing Disclosure Package and the Prospectus under the heading "Capitalization"; all the outstanding Ordinary Shares of the Company have been duly authorized and validly issued and are fully paid and non-assessable and are not subject to any pre-emptive or similar rights other than those described in the Registration statement, the Pricing Disclosure Package and the Prospectus; except as described in or expressly contemplated by the Registration Statement, the Pricing Disclosure Package and the Prospectus, there are no outstanding rights (including, without limitation, pre-emptive rights), warrants or options to acquire, or instruments convertible into or exchangeable for, any Ordinary Shares or other equity interest in the Company or any of its subsidiaries, or any contract, commitment, agreement, understanding or arrangement of any kind relating to the issuance of any Ordinary Shares or other equity interest of the Company or any such subsidiary, any such convertible or exchangeable securities or any such rights, warrants or options; the Ordinary Shares of the Company conform in all material respects to the descriptions thereof contained in the Registration Statement, the Pricing Disclosure Package and the Prospectus; and all the outstanding shares of capital stock or other equity interests of each subsidiary owned, directly or indirectly, by the Company have been duly authorized and validly issued, are fully paid and non-assessable and are owned directly or indirectly by the Company, free and clear of any lien, charge, encumbrance, security interest, restriction on voting or transfer or any other claim of any third party.
- (m) Share Options. With respect to the share options or performance shares (the "Share Options") granted pursuant to the share-based compensation plans of the Company and its subsidiaries (the "Company Share Plans"), (i) each grant of a Share Option was duly authorized no later than the date on which the grant of such Share Option was by its terms to be effective by all necessary corporate action, including, as applicable, approval by the management board and supervisory board of the Company (or a duly constituted and authorized committee thereof) and any required shareholder approval by the necessary number of votes or written consents, and the award agreement governing such grant (if any) was duly executed and delivered by each party thereto, (ii) each such grant was made in accordance with the terms of the applicable Company Share Plans, the Exchange Act and all other applicable laws and regulatory rules or requirements, including the rules of the Nasdaq Global Select Market, and (iii) each such grant was properly accounted for in accordance with IFRS in the financial statements (including the related notes) of the Company.
  - (n) Underwriting Agreement. This Agreement has been duly authorized, executed and delivered by the Company.
- (o) *Deposit Agreement*. The Deposit Agreement has been duly authorized, executed and delivered by the Company and, assuming due authorization, execution and delivery by the Depositary, constitutes a valid and legally binding agreement of the Company enforceable against the Company in accordance with its terms, except as the enforceability thereof may be limited by bankruptcy, insolvency, reorganization or similar laws relating to or affecting creditors' rights generally or by general equitable principles. Upon (i) due issuance by the Depositary of the

Offered ADSs against the deposit of Shares in respect thereof and/or (ii) due execution and delivery by the Depositary of American Depositary Receipts ("ADRs") evidencing Offered ADSs against the deposit of Shares in respect thereof, in accordance with the provisions of the Deposit Agreement, such Offered ADSs and/or ADRs will be duly and validly issued and the persons in whose names the Offered ADSs and/or the ADRs are registered will be entitled to the rights specified therein and in the Deposit Agreement; and the Deposit Agreement conforms, and the ADRs will conform, in all material respects to the descriptions thereof in the Registration Statement, the Pricing Disclosure Package and the Prospectus.

- (p) *The ADSs and the Shares*. The Underwritten Shares and the Underwritten ADSs have been duly authorized by the Company and, when issued and delivered and paid for as provided herein, will be validly issued, will be fully paid and non-assessable and will conform to the descriptions thereof in the Registration Statement, the Pricing Disclosure Package and the Prospectus; and the issuance of the Underwritten Shares and the Underwritten ADSs is not subject to any pre-emptive or similar rights the exercise and transfer of which have not been validly and irrevocably waived or otherwise validly and irrevocably declined; the Underwritten Shares may be freely deposited by the Company with the Custodian against issuance by the Depositary of ADRs evidencing Underwritten ADSs; the Underwritten ADSs, when issued and delivered against payment thereof, will be freely transferable to or for the account of the several Underwriters and to the initial purchasers thereof; and there are no restrictions on subsequent transfers of the Underwritten ADSs under the laws of the Federal Republic of Germany.
- (q) No Violation or Default. Neither the Company nor any of its subsidiaries is (i) in violation of its articles of association or similar organizational documents; (ii) in default, and no event has occurred that, with notice or lapse of time or both, would constitute such a default, in the due performance or observance of any term, covenant or condition contained in any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which the Company or any of its subsidiaries is a party or by which the Company or any of its subsidiaries is bound or to which any property or asset of the Company or any of its subsidiaries is subject; or (iii) in violation of any law or statute or any judgment, order, rule or regulation of any court or arbitrator or governmental or regulatory authority, except, in the case of clauses (ii) and (iii) above, for any such default or violation that would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.
- (r) No Conflicts. The execution, delivery and performance by the Company of each of this Agreement and the Deposit Agreement (collectively, the "Transaction Documents"), the issuance and sale of the Underwritten Shares and the Underwritten ADSs, the deposit of the Underwritten Shares with the Custodian against issuance by the Depositary of the Underwritten ADSs and/or the ADRs evidencing the Underwritten ADSs, and the consummation of the transactions contemplated by the Transaction Documents, the Pricing Disclosure Package and the Prospectus will not (i) conflict with or result in a breach or violation of any of the terms or provisions of, or constitute a default under, result in the termination, modification or acceleration of, or result in the creation or imposition of any lien, charge or encumbrance upon any property, right or asset of the Company or any of its subsidiaries pursuant to, any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which the Company or any of its subsidiaries is a party or by which the Company or any of its subsidiaries is bound or to which any property, right or asset of the Company or any of its subsidiaries is subject, (ii) result in any violation of the provisions of the articles of association or similar organizational documents of the Company or any of its subsidiaries or (iii) result in the violation of any law or statute or any judgment, order, rule or regulation of any court or arbitrator or governmental or regulatory authority, except, in the case of clauses (i) and (iii) above, for any such conflict, breach, violation, default, lien, charge or encumbrance that would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

- (s) No Consents Required. No consent, approval, authorization, order, registration or qualification of or with any court or arbitrator or governmental or regulatory authority is required for the execution, delivery and performance by the Company of each of the Transaction Documents, the issuance and sale of the Underwritten ADSs and the consummation of the transactions contemplated by the Transaction Documents, except for the registration of the capital increase(s) in relation to the Underwritten Shares with the commercial register and the registration of the Underwritten Shares and the Underwritten ADSs under the Securities Act and such consents, approvals, authorizations, orders and registrations or qualifications as may be required by the Nasdaq Market, the Financial Industry Regulatory Authority, Inc. ("FINRA") and under applicable state securities laws in connection with the purchase and distribution of the Underwritten Shares and the Underwritten ADSs by the Underwritters.
- (t) Legal Proceedings. Except as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, there are no legal, governmental or regulatory investigations, actions, demands, claims, suits, arbitrations, inquiries or proceedings ("Actions") pending to which the Company or any of its subsidiaries is a party or to which any property of the Company or any of its subsidiaries is subject that would, individually or in the aggregate, if determined adversely to the Company or any of its subsidiaries, reasonably be expected to have a Material Adverse Effect; to the knowledge of the Company, no such Actions are threatened or contemplated by any governmental or regulatory authority or threatened by others; and (i) there are no current or pending Actions that are required under the Securities Act to be described in the Registration Statement, the Pricing Disclosure Package or the Prospectus and (ii) there are no contracts or other documents that are required under the Securities Act to be filed as exhibits to the Registration Statement or described in the Registration Statement, the Pricing Disclosure Package or the Prospectus that are not so filed as exhibits to the Registration Statement or described in the Registration Statement, the Pricing Disclosure Package and the Prospectus.
- (u) *Independent Accountants for the Company*. Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft, who has certified certain financial statements of the Company and its subsidiaries, is an independent registered public accounting firm with respect to the Company and its subsidiaries within the applicable rules and regulations adopted by the Commission and the Public Company Accounting Oversight Board (United States) and as required by the Securities Act.
- (v) *Independent Accountants for Neon.* To the Company's knowledge, PricewaterhouseCoopers LLP, who has certified certain financial statements of Neon, was an independent registered public accounting firm with respect to Neon within the applicable rules and regulations adopted by the Commission and the Public Company Accounting Oversight Board (United States) and as required by the Securities Act at the time PricewaterhouseCoopers LLP audited the financial statements of Neon included or incorporated by reference in the Registration Statement, the Pricing Disclosure Package and the Prospectus.
- (w) *Title to Real and Personal Property*. The Company and its subsidiaries have good and marketable title in fee simple (in the case of real property) to, or have valid rights to lease or otherwise use, all items of real and personal property that are material to the respective businesses of the Company and its subsidiaries, in each case free and clear of all liens,

encumbrances, claims and defects and imperfections of title except those that (i) do not materially interfere with the use made and proposed to be made of such property by the Company and its subsidiaries or (ii) would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect.

(x) Intellectual Property. Except as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, (i) the Company and its subsidiaries own or have a valid and enforceable right to use all (1) patents, patent applications, trademarks, service marks, trade names, Internet domain name registrations (and all applications for, and all goodwill associated with, such trademarks, service marks, trade names and Internet domain name registrations), copyrights, copyright registrations, licenses and trade secret rights, in each case, in any jurisdiction throughout the world (collectively, "Intellectual Property Rights") and (2) inventions, know-how, software, databases, systems, procedures, and other intellectual property (including trade secrets and proprietary or confidential information) (collectively, "Intellectual Property Assets") used or held for use in any material respect, or otherwise necessary for, the conduct of their respective businesses as currently conducted and as proposed to be conducted as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus; (ii) the Company's and its subsidiaries' conduct of their respective businesses does not infringe, misappropriate or otherwise violate, and has not infringed, misappropriated or otherwise violated, any Intellectual Property Rights or Intellectual Property Assets of any third party in any material respect (it being understood that the foregoing representation in this clause (ii) is made to the Company's knowledge with respect to patents); (iii) the Company and its subsidiaries have not received notice of any pending or threatened action, suit, or proceeding by any third party that would reasonably be expected to have a Material Adverse Effect on the Company's or any of its subsidiaries' respective businesses as presently conducted and as proposed to be conducted as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, (A) challenging the Company's or any of its subsidiaries' rights in or to any of the Intellectual Property Rights or Intellectual Property Assets owned by or licensed to the Company or any of its subsidiaries, (B) challenging the validity, enforceability or scope of any of the Intellectual Property Rights owned by or licensed to the Company or any of its subsidiaries, or (C) alleging that the Company or any of its subsidiaries has infringed, misappropriated or otherwise violated any Intellectual Property Rights or Intellectual Property Assets of any third party; (iv) to the knowledge of the Company, neither the Intellectual Property Rights nor the Intellectual Property Assets of the Company and its subsidiaries are being materially infringed, misappropriated or otherwise violated by any third party; (v) other than as would not reasonably be expected to have a Material Adverse Effect, all Intellectual Property Rights and Intellectual Property Assets owned by the Company or any of its subsidiaries are solely and exclusively owned by the Company or such subsidiaries and all other Intellectual Property Rights and Intellectual Property Assets used or held for use by the Company or any of its subsidiaries are licensed to the Company or such subsidiaries, and the Company and its subsidiaries hold all of such ownership and license rights, in each case, free and clear of all liens, encumbrances, defects or other restrictions; (vi) other than as would not reasonably be expected to have a Material Adverse Effect, the Company and its subsidiaries are not aware of any facts that could result in a finding that any of the Intellectual Property Rights owned by or licensed to the Company is invalid or unenforceable; (vii) other than as would not reasonably be expected to have a Material Adverse Effect, the Company and its subsidiaries have taken reasonable steps in accordance with customary industry practice to maintain and protect any confidential information and trade secrets of the Company and its subsidiaries and to protect any confidential information provided to them by any third party; (viii) other than as would not reasonably be expected to have a Material Adverse Effect, the Company and its subsidiaries have taken commercially reasonable actions to maintain and to protect all patents and trademark and copyright and Internet domain name registrations (including all

applications therefor) owned by the Company or any of its subsidiaries, including payment of applicable maintenance fees, filing of applicable statements of use, timely response office actions, and disclosure of any required information; and (ix) other than as would not reasonably be expected to have a Material Adverse Effect, all personnel (including founders, current and former employees, consultants, contractors, representatives, and agents) involved in the development of Intellectual Property Rights or Intellectual Property Assets for or on behalf of the Company or any of its subsidiaries have signed written and enforceable confidentiality and invention assignment agreements with the Company or any of its subsidiaries pursuant to which the Company or any of its subsidiaries either (A) has obtained sole and exclusive ownership of such Intellectual Property Rights or Intellectual

(y) Regulatory Matters; Products and Product Candidates. Except as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company (collectively with its subsidiaries): (i) has operated and currently operates its business in compliance in all material respects with applicable provisions of the Health Care Laws (as defined below) of the Food and Drug Administration ("FDA"), the Department of Health and Human Services and any comparable foreign or other regulatory authority to which they are subject (collectively, the "Applicable Regulatory Authorities") applicable to the ownership, testing, development, manufacture, packaging, processing, use, distribution, storage, import, export or disposal of any of the Company's or its subsidiaries' product candidates or any product manufactured or distributed by the Company; (ii) has not received any FDA Form 483, written notice of adverse finding, warning letter, untitled letter or other correspondence or written notice from any court or arbitrator or governmental or regulatory authority alleging or asserting non-compliance with (A) any Health Care Laws or (B) any licenses, certificates, approvals, clearances, exemptions, authorizations, permits and supplements or amendments thereto required by any such Health Care Laws ("Regulatory Authorizations"); (iii) possesses all Regulatory Authorizations required to conduct its business as currently conducted, except where the failure to possess the same would not, individually or in the aggregate, have a Material Adverse Effect, and such Regulatory Authorizations are valid and in full force and effect and the Company is not in violation, in any material respect, of any term of any such Regulatory Authorizations; (iv) has not received written notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from the Applicable Regulatory Authorities or any other third party alleging that any product of the Company is in material violation of any Health Care Laws or Regulatory Authorizations and has no knowledge that the Applicable Regulatory Authorities or any other third party is considering any such claim, litigation, arbitration, action, suit, investigation or proceeding; (v) has not received written notice that any of the Applicable Regulatory Authorities has taken, is taking or intends to take action to limit, suspend, modify or revoke any material Regulatory Authorizations and has no knowledge that any of the Applicable Regulatory Authorities is considering such action; (vi) has filed, obtained, maintained or submitted all material reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Health Care Laws or Regulatory Authorizations and that all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were materially complete and correct on the date filed (or were materially corrected or supplemented by a subsequent submission); (vii) is not a party to and does not have any ongoing reporting obligations pursuant to any corporate integrity agreements, deferred prosecution agreements, monitoring agreements, consent decrees, settlement orders, plans of correction or similar agreements with or imposed by any Applicable Regulatory Authority; and (viii) along with its employees, officers and directors, has not been excluded,

suspended or debarred from participation in any government health care program or human clinical research and, to the knowledge of the Company, is not subject to a governmental inquiry, investigation, proceeding, or other similar action that could reasonably be expected to result in debarment, suspension, or exclusion.

The term "Health Care Laws" means Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395hhh (the Medicare statute); Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v (the Medicaid statute); the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b); the civil False Claims Act, 31 U.S.C. §§ 3729 et seq.; the criminal False Claims Act, 42 U.S.C. 1320a-7b(a); any criminal laws relating to health care fraud and abuse, including but not limited to 18 U.S.C. Sections 286 and 287 and the health care fraud criminal provisions under the Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. §§ 1320d et seq., ("HIPAA"); the Civil Monetary Penalties Law, 42 U.S.C. §§ 1320a-7a and 1320a-7b; the Physician Payments Sunshine Act, 42 U.S.C. §§ 1320a-7h; the Exclusion Statute, 42 U.S.C. §§ 1320a-7; HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, 42 U.S.C. §§ 17921 et seq.; the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq.; the Public Health Service Act, 42 U.S.C. §§ 201 et seq.; the regulations promulgated pursuant to such laws; and any similar federal, state and local laws and regulations.

(z) Preclinical Studies and Clinical Trials. (i) Except as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the pre-clinical studies and clinical trials conducted by or, to the knowledge of the Company, on behalf of or sponsored by the Company, or in which the Company has participated that are described in the Registration Statement, the Pricing Disclosure Package and the Prospectus or the results of which are referred to in the Registration Statement, the Pricing Disclosure Package and the Prospectus, as applicable, were, and if still pending are, being conducted in all material respects in accordance with standard medical and scientific research standards and procedures for products or product candidates comparable to those being developed by the Company and all applicable statutes and all applicable rules and regulations of the Regulatory Authorities and current Good Clinical Practices and Good Laboratory Practices; (ii) the descriptions in the Registration Statement, the Pricing Disclosure Package and the Prospectus of the results of such studies and trials are, to the knowledge of the Company, accurate and complete in all material respects and fairly present the data derived therefrom; (iii) the Company has no knowledge of any other studies or trials not described in the Registration Statement, the Pricing Disclosure Package and the Prospectus the results of which are inconsistent with or which the Company reasonably believes call into question the results described or referred to in the Registration Statement, the Pricing Disclosure Package and the Prospectus; and (iv) the Company has not received any written notices or correspondence from the Regulatory Authorities or any other governmental agency requiring or threatening the termination, modification or suspension of any pre-clinical studies or clinical trials that are described in the Registration Statement, the Pricing Disclosure Package and the Prospectus or the results of which are referred to in the Registration Statement, the Pricing Disclosure Package and the Prospectus other than ordinary course communications with respect to modifications in connection with the design and implementation of such studies or trials, and, to the Company's knowledge, there are no reasonable grounds for the same.

(aa) *No Undisclosed Relationships*. No relationship, direct or indirect, exists between or among the Company or any of its subsidiaries, on the one hand, and the directors, officers, shareholders, customers, suppliers or other affiliates of the Company or any of its subsidiaries, on the other, that is required by the Securities Act to be described in each of the Registration Statement and the Prospectus and that is not so described in such documents and in the Pricing Disclosure Package.

- (bb) *Investment Company Act*. The Company is not and, after giving effect to the offering and sale of the Underwritten ADSs and the Underwritten Shares and the application of the proceeds thereof as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, will not be required to register as an "investment company" or an entity "controlled" by an "investment company" within the meaning of the Investment Company Act of 1940, as amended, and the rules and regulations of the Commission thereunder (collectively, the "Investment Company Act").
- (cc) *Taxes*. The Company and its subsidiaries have paid all federal, state, local and foreign taxes and filed all tax returns required to be paid or filed through the date hereof, except as may be being contested in good faith and by appropriate proceedings, or where the failure to pay or file such taxes or tax returns would not reasonably be expected to have a Material Adverse Effect; and except as otherwise disclosed in each of the Registration Statement, the Pricing Disclosure Package and the Prospectus, there is no tax deficiency that has been, or could reasonably be expected to be, asserted against the Company or any of its subsidiaries or any of their respective properties or assets that has or would reasonably be expected to have a Material Adverse Effect, except for any tax deficiency being contested in good faith and for which appropriate reserves have been provided in accordance with IFRS.
- (dd) *Licenses and Permits*. The Company and its subsidiaries possess all licenses, sub-licenses, certificates, permits and other authorizations issued by, and have made all declarations and filings with, the appropriate federal, state, local or foreign governmental or regulatory authorities that are necessary for the ownership or lease of their respective properties or the conduct of their respective businesses as described in each of the Registration Statement, the Pricing Disclosure Package and the Prospectus, except where the failure to possess or make the same would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect; and except as described in each of the Registration Statement, the Pricing Disclosure Package and the Prospectus, neither the Company nor any of its subsidiaries has received written notice of any revocation or modification of any such license, sub-license, certificate, permit or authorization or has any reason to believe that any such license, sub-license, certificate, permit or authorization would not reasonably be expected to have a Material Adverse Effect.
- (ee) *No Labor Disputes*. No labor disturbance by or dispute with employees of the Company or any of its subsidiaries exists or, to the knowledge of the Company, is contemplated or threatened, and the Company is not aware of any existing or imminent labor disturbance by, or dispute with, the employees of any of its or its subsidiaries' principal suppliers, contractors or customers, except as would not reasonably be expected to have a Material Adverse Effect. Neither the Company nor any of its subsidiaries has received any written notice of cancellation or termination with respect to any collective bargaining agreement that is material to the Company to which it is a party.
- (ff) Certain Environmental Matters. (i) The Company and its subsidiaries (A) are in compliance with all applicable federal, state, local and foreign laws (including common law), rules, regulations, requirements, decisions, judgments, decrees, orders and other legally enforceable requirements relating to pollution or the protection of human health or safety, the environment, natural resources, hazardous or toxic substances or wastes, pollutants or contaminants (collectively, "Environmental Laws"); (B) have received and are in compliance with all permits, licenses, certificates or other authorizations or approvals required of them under any Environmental Laws to conduct their respective businesses; and (C) have not received written notice of any actual or potential liability or obligation under or relating to, or any actual or

potential violation of, any Environmental Laws, including for the investigation or remediation of any disposal or release of hazardous or toxic substances or wastes, pollutants or contaminants, and have no knowledge of any event or condition that would reasonably be expected to result in any such notice, and (ii) there are no costs or liabilities associated with Environmental Laws of or relating to the Company or its subsidiaries, except in the case of each of (i) and(ii) above, for any such matter as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect; and (iii) except as described in each of the Pricing Disclosure Package and the Prospectus, (x) there is no proceeding that is pending, or that is known to be contemplated, against the Company or any of its subsidiaries under any Environmental Laws in which a governmental entity is also a party, other than such proceeding regarding which it is reasonably believed no monetary sanctions of \$100,000 or more will be imposed, (y) the Company and its subsidiaries are not aware of any facts or issues regarding compliance with Environmental Laws, or liabilities or other obligations under Environmental Laws or concerning hazardous or toxic substances or wastes, pollutants or contaminants, that would reasonably be expected to have a Material Adverse Effect, and (C) none of the Company or its subsidiaries anticipates material capital expenditures relating to any Environmental Laws.

(gg) Compliance with ERISA. Neither the Company nor any of its ERISA Affiliates (as defined hereafter) has any liability (contingent or otherwise) under the Employee Retirement Income Security Act of 1974, as amended ("ERISA") with respect to any "employee benefit plan," as defined in Section 3(3) of ERISA. An "ERISA Affiliate" of any person or entity means any other person or entity which, together with that person or entity, could be treated as a single employer under Section 414(b), (c), (m) or (o) of the Code. Each "employee benefit plan," as defined in Section 3(3) of ERISA that is maintained for the benefit of the employees of the Company or its affiliates (each, an "Employee Plan") has been maintained in material compliance with its terms and the requirements of applicable law. The Registration Statement, Preliminary Prospectus and the Prospectus identify each employment, severance or other similar agreement, arrangement or policy and each material plan or arrangement required to be disclosed pursuant to the Rules and Regulations providing for insurance coverage (including any self-insured arrangements), workers' compensation, disability benefits, severance benefits, supplemental unemployment benefits, vacation benefits or retirement benefits, or deferred compensation, profit-sharing, bonuses, stock options, stock appreciation rights or other forms of incentive compensation, or post-retirement insurance, compensation or benefits that is entered into, maintained or contributed to, as the case may be, by the Company or any of its affiliates for the benefit of any officer or director or former officer or director of the Company or any of its affiliates. These agreements, arrangements, policies or plans are referred to collectively as "Benefit Arrangements." Each Benefit Arrangement has been maintained in material compliance with its terms and with the requirements of applicable law. There is no liability in respect of post-retirement health and medical benefits for retired employees of the Company or any of

(hh) *Disclosure Controls*. The Company maintains an effective system of "disclosure controls and procedures" (as defined in Rule 13a-15(e) of the Exchange Act) that complies in all material respects with the requirements of the Exchange Act and that has been designed to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Commission's rules and forms, including controls and procedures designed to ensure that such information is accumulated and communicated to the Company's management as appropriate to allow timely decisions regarding required disclosure. The Company has carried out an evaluation of its effectiveness of its disclosure controls and procedures to the extent required by Rule 13a-15 of the Exchange Act.

(ii) Accounting Controls. The Company and its subsidiaries maintain systems of "internal control over financial reporting" (as defined in Rule 13a-15(f) of the Exchange Act) that comply in all material respects with the requirements of the Exchange Act and have been designed by, or under the supervision of, their respective principal executive and principal financial officers, or persons performing similar functions, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with IFRS. The Company and its subsidiaries maintain internal accounting controls that are designed to be sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with IFRS and to maintain asset accountability; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. Except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus, there are no material weaknesses in the Company's internal controls. The Company's auditors and the Audit Committee of the supervisory board (Aufsichtsrat) of the Company have been advised of: (i) all significant deficiencies and material weaknesses in the design or operation of internal controls over financial reporting which have adversely affected or are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and (ii) any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal controls over financial reporting.

(jj) *Insurance*. The Company and its subsidiaries have insurance covering their respective properties, operations, personnel and businesses, including business interruption insurance, which insurance is in amounts and insures against such losses and risks as are generally maintained by similarly situated companies and which the Company believes are adequate to protect the Company and its subsidiaries and their respective businesses; and neither the Company nor any of its subsidiaries has (i) received written notice from any insurer or agent of such insurer that capital improvements or other expenditures are required or necessary to be made in order to continue such insurance or (ii) any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain comparable coverage from similar insurers as may be necessary to continue its business as now conducted at a cost that would not reasonably be expected to have a Material Adverse Effect.

(kk) Cybersecurity; Data Protection. Except as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the information technology assets and equipment, computers, systems, networks, hardware, software, websites, applications and databases owned by, or leased or licensed to, the Company or any of its subsidiaries (collectively, "IT Systems"), to the knowledge of the Company, are adequate for, and operate and perform in all material respects as required in connection with, the operation of the business of the Company and its subsidiaries as currently conducted, and to the Company's knowledge are free and clear of all material bugs, errors, defects, Trojan horses, time bombs, malware and other corruptants; the Company and its subsidiaries have implemented and maintained commercially reasonable controls, policies, procedures, and safeguards to maintain and protect their material confidential information and the integrity, continuous operation, redundancy and security of all IT Systems and data (including all personal, personally identifiable, sensitive, confidential or regulated data of their respective customers, employees, suppliers, vendors and any third party data maintained by or on behalf of them ("Personal Data")) used in connection with their businesses; to the knowledge of the Company, there have been no material breaches, violations, outages, unauthorized uses of, accesses to or other compromise of or relating to any of the Company's or

any of its subsidiaries' Personal Data or IT Systems, except for those that have been remedied without material cost or liability or the duty to notify any third party; there are no material incidents under internal review or investigations relating to any security breach or other compromise of the Company's or any of its subsidiaries' Personal Data or IT Systems and the Company and its subsidiaries have not been notified of, and have no knowledge of any event or condition that would reasonably be expected to result in, any security breach or other compromise to their IT Systems or Personal Data; the Company and its subsidiaries have implemented commercially reasonable backup and disaster recovery technology consistent with industry standards and practices; and the Company and its subsidiaries are presently in material compliance with all applicable laws or statutes and all judgments, orders, rules and regulations of any court or arbitrator or governmental or regulatory authority and internal policies, procedures and contractual obligations relating to the security of IT Systems and the privacy, collection, use, transfer, storage, protection, disposal or disclosure of Personal Data and to the protection of such IT Systems and Personal Data from unauthorized use, access, misappropriation or modification.

(ll) No Unlawful Payments. Neither the Company nor any of its subsidiaries nor any member of the Company's management board or supervisory board or subsidiaries nor, to the knowledge of the Company, any employee of, or any agent, affiliate or other person associated with or acting on behalf of, the Company or any of its subsidiaries has (i) used any corporate funds for any unlawful contribution, gift, entertainment or other unlawful expense relating to political activity; (ii) made or taken an act in furtherance of an offer, promise or authorization of any direct or indirect unlawful payment or benefit to any foreign or domestic government official or employee, including of any government-owned or controlled entity or of a public international organization, or any person acting in an official capacity for or on behalf of any of the foregoing, or any political party or party official or candidate for political office; (iii) violated or is in violation of any provision of the Foreign Corrupt Practices Act of 1977, as amended, or any applicable law or regulation implementing the OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions, or committed an offence under the Bribery Act 2010 of the United Kingdom or any other applicable anti-bribery or anti-corruption law; or (iv) made, offered, agreed, requested or taken an act in furtherance of any unlawful bribe or other unlawful benefit, including, without limitation, any rebate, payoff, influence payment, kickback or other unlawful or improper payment or benefit. The Company and its subsidiaries have each instituted, maintain and enforce, policies and procedures designed to promote and ensure compliance with all applicable anti-bribery and anti-corruption laws.

(mm) Compliance with Anti-Money Laundering Laws. The operations of the Company and its subsidiaries are and have been conducted at all times in compliance with applicable financial recordkeeping and reporting requirements, including those of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the applicable money laundering statutes of all jurisdictions where the Company or any of its subsidiaries conducts business, the rules and regulations thereunder and any related or similar rules, regulations or guidelines issued, administered or enforced by any governmental agency (collectively, the "Anti-Money Laundering Laws") and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its subsidiaries with respect to the Anti-Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

(nn) *No Conflicts with Sanctions Laws*. Neither the Company nor any of its subsidiaries nor any member of the Company's management board or supervisory board or subsidiaries nor to the knowledge of the Company, any employee of, or any agent, affiliate or other person associated with or acting on behalf of, the Company or any of its subsidiaries is currently the subject or the target of any sanctions administered or enforced by the U.S.

government (including, without limitation, the Office of Foreign Assets Control of the U.S. Department of the Treasury or the U.S. Department of State and including, without limitation, the designation as a "specially designated national" or "blocked person"), the United Nations Security Council, the European Union, Her Majesty's Treasury or other relevant sanctions authority (collectively, "Sanctions"), nor is the Company or any of its subsidiaries located, organized or resident in a country or territory that is the subject or target of Sanctions, including, without limitation, Crimea, Cuba, Iran, North Korea and Syria (each, a "Sanctioned Country"); and the Company will not directly or indirectly use the proceeds of the offering of the Offered ADSs and the Shares hereunder, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other person or entity (i) to fund or facilitate any activities of or business with any person that, at the time of such funding or facilitation, is the subject or target of Sanctions, (ii) to fund or facilitate any activities of or business in any Sanctioned Country or (iii) in any other manner that will result in a violation by any person (including any person participating in the transaction, whether as underwriter, advisor, investor or otherwise) of Sanctions, except in cases where compliance with extraterritorial provisions in any such sanctions would be unlawful for the Company. For the past five (5) years, the Company and its subsidiaries have not knowingly engaged in and are not now knowingly engaged in any dealings or transactions with any person that at the time of the dealing or transaction is or was the subject or the target of Sanctions or with any Sanctioned Country.

- (oo) *No Restrictions on Subsidiaries*. Subject to the requirements of applicable law and the availability of distributable reserves (in such jurisdictions where relevant restrictions apply), no subsidiary of the Company is currently prohibited, directly or indirectly, under any agreement or other instrument to which it is a party or is subject, from paying any dividends to the Company, from making any other distribution on such subsidiary's capital stock or similar ownership interest, from repaying to the Company any loans or advances to such subsidiary from the Company or from transferring any of such subsidiary's properties or assets to the Company or any other subsidiary of the Company.
- (pp) *No Broker's Fees*. Except for the pertinent arrangements with Blättchen Financial Advisors and J.P. Morgan Securities LLC or pursuant to this Agreement, neither the Company nor any of its subsidiaries is a party to any contract, agreement or understanding with any person (other than this Agreement) that would give rise to a valid claim against the Company or any of its subsidiaries or any Underwriter for a brokerage commission, finder's fee or like payment in connection with the offering and sale of the Shares and the Offered ADSs.
- (qq) *No Registration Rights*. No person has the right to require the Company or any of its subsidiaries to register any securities for sale under the Securities Act by reason of the filing of the Registration Statement with the Commission or the issuance and sale of the Underwritten Shares and the Underwritten ADSs, except for such rights as have been duly waived.
- (rr) *No Stabilization*. Neither the Company nor any of its subsidiaries nor, to the Company's knowledge, any of its affiliates has taken, directly or indirectly, without giving effect to activities of the Underwriters, any action designed to or that could reasonably be expected to cause or result in any stabilization or manipulation of the price of the Offered ADSs.
- (ss) *Margin Rules*. Neither the issuance, sale and delivery of the Shares or the Offered ADSs nor the application of the proceeds thereof by the Company as described in each of the Registration Statement, the Pricing Disclosure Package and the Prospectus will violate Regulation T, U or X of the Board of Governors of the Federal Reserve System or any other regulation of such Board of Governors.

- (tt) *Forward-Looking Statements*. No forward-looking statement (within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act) included or incorporated by reference in any of the Registration Statement, the Pricing Disclosure Package or the Prospectus has been made or reaffirmed without a reasonable basis or has been disclosed other than in good faith.
- (uu) *Statistical and Market Data*. Nothing has come to the attention of the Company that has caused the Company to believe that the statistical and market-related data included or incorporated by reference in each of the Registration Statement, the Pricing Disclosure Package and the Prospectus is not based on or derived from sources that are reliable and accurate in all material respects.
- (vv) *Sarbanes-Oxley Act*. There is and has been no failure on the part of the Company or any of the Company's directors or officers, in their capacities as such, to comply with any provision of the Sarbanes-Oxley Act of 2002, as amended, and the rules and regulations promulgated in connection therewith (the "Sarbanes-Oxley Act") applicable to the Company as of the date the Company became subject to such provisions, including Section 402 related to loans.
- (ww) Status under the Securities Act. At the time of filing the Registration Statement and any post-effective amendment thereto, at the earliest time thereafter that the Company or any offering participant made a bona fide offer (within the meaning of Rule 164(h)(2) under the Securities Act) of the Offered ADSs and at the date hereof, the Company was not and is not an "ineligible issuer," as defined in Rule 405 under the Securities Act.
- (xx) *No Ratings*. There are (and prior to the Closing Date and each applicable Additional Closing Date, will be) no debt securities, convertible securities or preferred stock issued or guaranteed by the Company or any of its subsidiaries that are rated by a "nationally recognized statistical rating organization", as such term is defined in Section 3(a)(62) under the Exchange Act.
- (yy) *Stamp Taxes*. No stamp duties or other issuance or transfer taxes (for the avoidance of doubt this does not include any value added tax or similar taxes) are payable by or on behalf of the Underwriters in the Federal Republic of Germany, the United States or any political subdivision or tax authority thereof solely in connection with (i) the execution, delivery and performance of the Transaction Documents, (ii) the issuance and delivery of the Shares and the Offered ADSs in the manner contemplated by this Agreement and the Prospectus or (iii) the sale and delivery by the Underwriters of the Shares and the Offered ADSs as contemplated herein and in the Prospectus.
- (zz) No Immunity. Except as provided by laws or statutes generally applicable to transactions of the type described in this Agreement, neither the Company nor any of its subsidiaries or their respective properties or assets has immunity under German, U.S. federal or New York state law from any legal action, suit or proceeding, from the giving of any relief in any such legal action, suit or proceeding, from set-off or counterclaim, from the jurisdiction of any German, U.S. federal or New York state court, from service of process, attachment upon or prior to judgment, or attachment in aid of execution of judgment, or from execution of a judgment, or other legal process or proceeding for the giving of any relief or for the enforcement of a judgment, in any such court with respect to their respective obligations, liabilities or any other matter under or arising out of or in connection herewith; and, to the extent that the Company or any of its subsidiaries or any of their respective properties, assets or revenues may have or may hereafter become entitled to any such right of immunity in any such court in which proceedings arising out of, or relating to the transactions contemplated by the Transaction Documents, may at any time be commenced, the Company has, pursuant to Section 20(e) of this Agreement, waived, and it will waive, or will cause its subsidiaries to waive, such right to the extent permitted by law.

(aaa) *Enforcement of Foreign Judgments*. Any final judgment for a fixed or determined sum of money rendered by any U.S. federal or New York state court located in the State of New York having jurisdiction under its own laws in respect of any suit, action or proceeding against the Company based upon any of the Transaction Documents would be declared enforceable against the Company by the courts of the Federal Republic of Germany, without reconsideration or reexamination of the merits.

(bbb) *Valid Choice of Law.* The choice of laws of the State of New York as the governing law of the Transaction Documents is a valid choice of law under the laws of the Federal Republic of Germany and will be honored by the courts of the Federal Republic of Germany, subject to the restrictions described under the caption "Service of Process and Enforcement of Liabilities" in the Registration Statement, the Pricing Disclosure Package and the Prospectus. The Company has the power to submit, and pursuant to Section 20(c) of this Agreement and Section 7.6 of the Deposit Agreement, has legally, validly, effectively and irrevocably submitted, to the personal jurisdiction of each New York state and United States federal court sitting in the City of New York and has validly and irrevocably waived any objection to the laying of venue of any suit, action or proceeding brought in such court.

(ccc) *Indemnification and Contribution*. The indemnification and contribution provisions set forth in Section 11 hereof do not contravene German law or public policy.

(ddd) *Passive Foreign Investment Company*. The Company was not a "passive foreign investment company" ("PFIC") as defined in Section 1297 of the Code for its most recently completed taxable year and the Company does not expect to be a PFIC for the current tax year.

(eee) *Dividends*. Except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus, no approvals are currently required in the Federal Republic of Germany in order for the Company to pay dividends or other distributions declared by the Company to the holders of Shares and for the Depositary to distribute such dividends or other distributions to holders of the Offered ADSs. Under current laws and regulations of the Federal Republic of Germany and any political subdivision thereof, any amount payable with respect to the Shares or the Offered ADSs upon liquidation of the Company or upon redemption thereof and dividends and other distributions declared and payable on the share capital of the Company may be paid by the Company and distributed by the Depositary in United States dollars or euros and freely transferred out of the Federal Republic of Germany, and without the necessity of obtaining any governmental authorization in the Federal Republic of Germany or any political subdivision or taxing authority thereof or therein.

(fff) *Legality*. The legality, validity, enforceability or admissibility into evidence of any of the Registration Statement, the Pricing Disclosure Package, the Prospectus, this Agreement, the Shares or the Offered ADSs in any jurisdiction in which the Company is organized or does business is not dependent upon such document being submitted into, filed or recorded with any court or other authority in any such jurisdiction on or before the date hereof or that any tax, imposition or charge be paid in any such jurisdiction on or in respect of any such document.

(ggg) *Legal Action*. A holder of the Shares, a holder of the Offered ADS, and each Underwriter is entitled to sue as plaintiff in the court of the jurisdiction of formation and domicile of the Company for the enforcement of its respective rights under this Agreement and such access

to such courts will not be subject to any conditions which are not applicable to residents of such jurisdiction or a company incorporated in such jurisdiction except that plaintiffs not residing in the Federal Republic of Germany may be required to guarantee payment of a possible order for payment of costs or damages at the request of the defendant.

- (hhh) Foreign Private Issuer. The Company is a "foreign private issuer" as defined in Rule 405 under the Securities Act.
- (iii) *Personal Liability of Shareholders and ADS holders*. No holder of any of the Offered ADSs after the consummation of the transactions contemplated by the Transaction Documents is or will be subject to any personal liability in respect of any liability of the Company by virtue only of its holding of any such Offered ADSs; and, except as set forth in the Registration Statement, the Pricing Disclosure Package, and the Prospectus, there are no limitations on the rights of holders of the Offered ADSs to hold, vote or transfer their ADSs.
- (jjj) *Rights Waivers*. The Company has entered into binding and irrevocable agreements with certain holders of the Company's ordinary shares representing [●]% of the Company's outstanding ordinary shares (including ordinary shares represented by ADSs) which agreed not to exercise and/or transfer any preemptive rights (*Bezugsrechte*) in the Rights Offering described in the Registration Statement, the Pricing Disclosure Package and the Prospectus (such offering, the "Rights Offering"). Such agreements constitute valid, legally binding and irrevocable agreements of such holders enforceable against such holders in accordance with their terms.
- 6. <u>Representations and Warranties of the Selling Stockholders</u>. Each of the Selling Stockholders severally represents and warrants to each Underwriter and the Company that:
  - (a) *Required Consents; Authority*. All consents, approvals, authorizations and orders necessary for the execution and delivery by such Selling Stockholder of this Agreement, the Power of Attorney (the "Power of Attorney") and the Custody Agreement (the "Custody Agreement"), and for the sale and delivery of the Option ADSs to be sold by such Selling Stockholder hereunder, have been obtained; and such Selling Stockholder has full right, power and authority to enter into this Agreement, the Power of Attorney and the Custody Agreement and to sell, assign, transfer and deliver the Option ADSs to be sold by such Selling Stockholder hereunder; this Agreement, the Power of Attorney and the Custody Agreement have each been duly authorized, executed and delivered by such Selling Stockholder.
  - (b) No Conflicts. The execution, delivery and performance by such Selling Stockholder of this Agreement, the Power of Attorney and the Custody Agreement, the sale of the Option ADSs to be sold by such Selling Stockholder and the consummation by such Selling Stockholder of the transactions contemplated herein or therein will not (i) conflict with or result in a breach or violation of any of the terms or provisions of, or constitute a default under, result in the termination, modification or acceleration of, or result in the creation or imposition of any lien, charge or encumbrance upon any property, right or asset of such Selling Stockholder pursuant to, any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which such Selling Stockholder is a party or by which such Selling Stockholder is bound or to which any of the property, right or asset of such Selling Stockholder is subject, (ii) result in any violation of the provisions of the articles of association or similar organizational documents of such Selling Stockholder or (iii) result in the violation of any law or statute or any existing judgment, order, rule or regulation of any court or arbitrator or governmental or regulatory authority, except, in the case of clauses (i) and (iii) above, for any such default or violation that

would not, individually or in the aggregate, reasonably be expected to have a material adverse effect on the business, properties, management, financial position, stockholders' equity, results of operations or prospects of the Selling Stockholder.

- (c) *Title to Option ADSs.* Such Selling Stockholder has good and valid title to the Ordinary Shares underlying the Option ADSs to be sold at the Additional Closing Date by such Selling Stockholder hereunder, free and clear of all liens, encumbrances, equities or adverse claims; such Selling Stockholder will have, immediately prior to the Additional Closing Date, good and valid title to the Option ADSs (or the Ordinary Shares underlying such Option ADS) to be sold at the Additional Closing Date, by such Selling Stockholder, free and clear of all liens, encumbrances, equities or adverse claims; and, upon delivery of such Option ADS and payment therefor pursuant hereto, good and valid title to such Option ADSs, free and clear of all liens, encumbrances, equities or adverse claims, will pass to the several Underwriters.
- (d) *No Stabilization*. Such Selling Stockholder has not taken and will not take, directly or indirectly, any action designed to or that could reasonably be expected to cause or result in any stabilization or manipulation of the price of the Offered ADSs.
- (e) *Pricing Disclosure Package*. The Pricing Disclosure Package as of the Applicable Time did not, and as of the Closing Date and as of the Additional Closing Date, as the case may be, will not, contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; <u>provided, however</u>, that such Selling Stockholder's representation under this Section 6(e) shall only apply to any untrue statement of a material fact or omission to state a material fact made in reliance upon and in conformity with any information relating to such Selling Stockholder furnished to the Company in writing by such Selling Stockholder expressly for use in the Pricing Disclosure Package, it being understood and agreed that the only such information furnished by any Selling Stockholder consists of the information described as such in Section 11(b) hereof.
- (f) Issuer Free Writing Prospectus and Written Testing-the-Waters Communication. Other than the Registration Statement, the Preliminary Prospectus and the Prospectus, such Selling Stockholder (including its agents and representatives, other than the Underwriters in their capacity as such) has not prepared, made, used, authorized, approved or referred to and will not prepare, make, use, authorize, approve or refer to any Issuer Free Writing Prospectus or Written Testing-the-Waters Communication, other than (i) any document not constituting a prospectus pursuant to Section 2(a)(10)(a) of the Securities Act or Rule 134 under the Securities Act or (ii) the documents, if any, listed on Annex A hereto, each electronic road show and any other written communications approved in writing in advance by the Company and the Representatives.
- (g) Registration Statement and Prospectus. As of the applicable effective date of the Registration Statement and any post-effective amendment thereto, the Registration Statement and any such post-effective amendment complied and will comply in all material respects with the Securities Act, and did not and will not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein not misleading; and as of the date of the Prospectus and any amendment or supplement thereto and as of the Closing Date and as of the Additional Closing Date, as the case may be, the Prospectus will not contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; provided, however, that such Selling Stockholder's representation under this Section 6(g) shall only apply to any untrue statement of a material fact

or omission to state a material fact made in reliance upon and in conformity with any information relating to such Selling Stockholder furnished to the Company in writing by such Selling Stockholder expressly for use in the Registration Statement and the Prospectus, it being understood and agreed that the only such information furnished by any Selling Stockholder consists of the information described as such in Section 11(b) hereof.

- (h) *Material Information*. As of the date hereof and as of the Closing Date and as of the Additional Closing Date, as the case may be, the sale of the Option ADSs by such Selling Stockholder is not and will not be prompted by any material information concerning the Company which is not set forth in the Registration Statement, the Pricing Disclosure Package or the Prospectus.
- (i) No Unlawful Payments. Neither such Selling Stockholder nor any of its subsidiaries, nor any director or officer of such Selling Stockholder or any of its subsidiaries nor, to the knowledge of such Selling Stockholder, any employee of, or any agent, affiliate or other person associated with or acting on behalf of, such Selling Stockholder or any of its subsidiaries has (i) used any corporate funds for any unlawful contribution, gift, entertainment or other unlawful expense relating to political activity; (ii) made or taken an act in furtherance of an offer, promise or authorization of any direct or indirect unlawful payment or benefit to any foreign or domestic government official or employee, including of any government-owned or controlled entity or of a public international organization, or any person acting in an official capacity for or on behalf of any of the foregoing, or any political party or party official or candidate for political office; (iii) violated or is in violation of any provision of the Foreign Corrupt Practices Act of 1977, as amended, or any applicable law or regulation implementing the OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions, or committed an offence under the Bribery Act 2010 of the United Kingdom or any other applicable anti-bribery or anti-corruption law; or (iv) made, offered, agreed, requested or taken an act in furtherance of any unlawful bribe or other unlawful benefit, including, without limitation, any rebate, payoff, influence payment, kickback or other unlawful or improper payment or benefit. Such Selling Stockholder and its subsidiaries have instituted, maintain and enforce, policies and procedures designed to promote and ensure compliance with all applicable anti-bribery and anti-corruption laws.
- (j) Compliance with Anti-Money Laundering Laws. The operations of such Selling Stockholder and its subsidiaries are and have been conducted at all times in compliance with the Anti-Money Laundering Laws, and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving such Selling Stockholder or any of its subsidiaries with respect to the Anti-Money Laundering Laws is pending or, to the knowledge of such Selling Stockholder, threatened.
- (k) No Conflicts with Sanctions Laws. Neither such Selling Stockholder nor any of its subsidiaries, directors or officers, nor, to the knowledge of such Selling Stockholder, any employee of, or any agent, affiliate or other person associated with or acting on behalf of, such Selling Stockholder or any of its subsidiaries is currently the subject or the target of any Sanctions, nor is such Selling Stockholder any of its subsidiaries located, organized or resident in a Sanctioned Country; and such Selling Stockholder will not directly or indirectly use the proceeds of the offering of the Option ADSs hereunder, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other person or entity (i) to fund or facilitate any activities of or business with any person that, at the time of such funding or facilitation, is the subject or target of Sanctions, (ii) to fund or facilitate any activities of or business in any Sanctioned Country or (iii) in any other manner that will result in a violation by

any person (including any person participating in the transaction, whether as underwriter, advisor, investor or otherwise) of Sanctions. For the past five years, such Selling Stockholder and its subsidiaries have not knowingly engaged in and are not now knowingly engaged in any dealings or transactions with any person that at the time of the dealing or transaction is or was the subject or the target of Sanctions or with any Sanctioned Country.

- (1) Organization and Good Standing. Such Selling Stockholder has been duly organized and is validly existing under the laws of its jurisdiction of organization.
- (m) *ERISA*. Such Selling Stockholder is not (i) an employee benefit plan subject to Title I of ERISA, (ii) a plan or account subject to Section 4975 of the Code or (iii) an entity deemed to hold "plan assets" of any such plan or account under Section 3(42) of ERISA, 29 C.F.R. 2510.3-101, or otherwise.
- (n) *Stamp Taxes*. No stamp duties or other issuance or transfer taxes (for the avoidance of doubt this does not include any value added tax or similar taxes) are payable by or on behalf of the Underwriters in the Federal Republic of Germany, the United States or any political subdivision or tax authority thereof solely in connection with (A) the execution, delivery and performance of this Agreement, (B) the delivery of the Option ADSs by such Selling Stockholder in the manner contemplated by this Agreement and the Prospectus or (C) the sale and delivery by the Underwriters of the Option ADSs as contemplated herein and in the Prospectus.
- (o) *Enforcement of Foreign Judgments*. Any final judgment for a fixed or determined sum of money rendered by any U.S. federal or New York state court located in the State of New York having jurisdiction under its own laws in respect of any suit, action or proceeding against such Selling Stockholder based upon this Agreement would be declared enforceable against the Selling Stockholder by the courts of the Federal Republic of Germany, without reconsideration or reexamination of the merits.
- (p) *Valid Choice of Law*. The choice of laws of the State of New York as the governing law of this Agreement is a valid choice of law under the laws of the Federal Republic of Germany and will be honored by the courts of the Federal Republic of Germany, subject to the restrictions described under the caption "Service of Process and Enforcement of Liabilities" in the Registration Statement, the Pricing Disclosure Package and the Prospectus. Such Selling Stockholder has the power to submit, and pursuant to Section 20(c) of this Agreement, has legally, validly, effectively and irrevocably submitted, to the personal jurisdiction of each New York state and United States federal court sitting in the City of New York and has validly and irrevocably waived any objection to the laying of venue of any suit, action or proceeding brought in such court.
- (q) *Indemnification and Contribution*. The indemnification and contribution provisions set forth in Section 11 hereof do not contravene German law or public policy.
- (r) *Currency*. To the extent any payment is to be made by such Selling Stockholder pursuant to this Agreement, such Selling Stockholder has access, subject to the laws of the Federal Republic of Germany, to the internal currency market in the Federal Republic of Germany and, to the extent necessary, valid agreements with the Federal Republic of Germany commercial banks for purchasing U.S. dollars to make payments of amounts which may be payable under this Agreement.

Each of the Selling Stockholders represents and warrants that all of the Option ADSs to be sold by such Selling Stockholders hereunder have been placed in custody under a Custody Agreement relating to such Option ADSs, in the form heretofore furnished to you, duly executed and delivered by such Selling Stockholder to Hauck & Aufhauser, as custodian (the "Custodian for the Selling Stockholders"), and that such Selling Stockholder has duly executed and delivered a Power of Attorney, in the form heretofore furnished to you, appointing each of Sierk Poetting and Ryan Richardson as such Selling Stockholder's Attorneys-in-fact (the "Attorneys-in Fact") with authority to execute and deliver this Agreement on behalf of such Selling Stockholder, to determine the Option ADS Purchase Price, to authorize the delivery of the Option ADSs by such Selling Stockholder hereunder and otherwise to act on behalf of such Selling Stockholder in connection with the transactions contemplated by this Agreement and the Custody Agreement.

Each of the Selling Stockholders specifically agrees that the Option ADSs held in custody for such Selling Stockholder under the Custody Agreement are subject to the interests of the Underwriters hereunder, and that the arrangements made by such Selling Stockholder for such custody, and the appointment by such Selling Stockholder of the Attorneys-in-Fact by the Power of Attorney, are to that extent irrevocable. Each of the Selling Stockholders specifically agrees that the obligations of such Selling Stockholder hereunder shall not be terminated by operation of law, whether by the death or incapacity of any individual Selling Stockholder, or, in the case of an estate or trust, by the death or incapacity of any executor or trustee or the termination of such estate or trust, or in the case of a partnership, corporation or similar organization, by the dissolution of such partnership, corporation or organization, or by the occurrence of any other event. If any individual Selling Stockholder or any such executor or trustee should die or become incapacitated, or if any such estate or trust should be terminated, or if any such partnership, corporation or similar organization should be dissolved, or if any other such event should occur, before the delivery of the Option ADSs hereunder, such Option ADSs shall be delivered by or on behalf of such Selling Stockholder in accordance with the terms and conditions of this Agreement and the Custody Agreement, and actions taken by the Attorneys-in-Fact pursuant to the Power of Attorney shall be as valid as if such death, incapacity, termination, dissolution or other event had not occurred, regardless of whether or not the Custodian for the Selling Stockholders, the Attorneys-in-Fact, or any of them, shall have received notice of such death, incapacity, termination, dissolution or other event.

## 7. Further Agreements of the Company. The Company covenants and agrees with each Underwriter that:

- (a) *Required Filings*. The Company will file the final Prospectus with the Commission within the time periods specified by Rule 424(b) and Rule 430A, 430B or 430C under the Securities Act, and will file any Issuer Free Writing Prospectus to the extent required by Rule 433 under the Securities Act; and the Company will furnish copies of the Prospectus and each Issuer Free Writing Prospectus (to the extent not previously delivered) to the Underwriters in New York City prior to 10:00 A.M., New York City time, on the business day next succeeding the date of this Agreement in such quantities as the Representatives may reasonably request. The Company will pay the registration fee for this offering pursuant to Rule 456(b)(1) under the Securities Act or will pay such fee within the time period required by such rule (without giving effect to the proviso therein) and in any event prior to the Closing Date and any Additional Closing Date.
- (b) *Delivery of Copies*. If requested, the Company will deliver, without charge, (i) to the Representatives, two signed copies of the Registration Statement as originally filed and each amendment thereto, in each case including all exhibits and consents filed therewith; and (ii) to each Underwriter (A) a conformed copy of the Registration Statement as originally filed and each amendment thereto (without exhibits) and (B) during the Prospectus Delivery Period (as defined below), as many copies of the Prospectus (including all amendments and supplements thereto and

each Issuer Free Writing Prospectus) as the Representatives may reasonably request. As used herein, the term "Prospectus Delivery Period" means such period of time after the first date of the public offering of the Offered ADSs as in the opinion of counsel for the Underwriters a prospectus relating to the Offered ADSs is required by law to be delivered (or required to be delivered but for Rule 172 under the Securities Act) in connection with sales of the Offered ADSs by any Underwriter or dealer.

- (c) Amendments or Supplements, Issuer Free Writing Prospectuses. Before making, preparing, using, authorizing, approving, referring to or filing any Issuer Free Writing Prospectus, and before filing any amendment or supplement to the Registration Statement, the Pricing Disclosure Package or the Prospectus, the Company will furnish to the Representatives and counsel for the Underwriters a copy of the proposed Issuer Free Writing Prospectus, amendment or supplement for review and will not make, prepare, use, authorize, approve, refer to or file any such Issuer Free Writing Prospectus or file any such proposed amendment or supplement to which the Representatives reasonably object.
- (d) Notice to the Representatives. The Company will advise the Representatives promptly, and confirm such advice in writing (which may be by electronic mail), (i) when the Registration Statement has become effective; (ii) when any amendment to the Registration Statement has been filed or becomes effective; (iii) when any supplement to the Pricing Disclosure Package, the Prospectus, any Issuer Free Writing Prospectus or any Written Testing-the-Waters Communication or any amendment to the Prospectus has been filed or distributed; (iv) of any request by the Commission for any amendment to the Registration Statement or any amendment or supplement to the Prospectus or the receipt of any comments from the Commission relating to the Registration Statement or any other request by the Commission for any additional information including, but not limited to, any request for information concerning any Testing-the-Waters Communication; (v) of the issuance by the Commission or any other governmental or regulatory authority of any order suspending the effectiveness of the Registration Statement or preventing or suspending the use of any Preliminary Prospectus, any of the Pricing Disclosure Package, the Prospectus or any Written Testing-the-Waters Communication or the initiation or, to the knowledge of the Company, threatening of any proceeding for that purpose or pursuant to Section 8A of the Securities Act; (vi) of the occurrence of any event or development within the Prospectus Delivery Period as a result of which the Prospectus, any of the Pricing Disclosure Package, any Issuer Free Writing Prospectus or any Written Testing-the-Waters Communication as then amended or supplemented would include any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances existing when the Prospectus, the Pricing Disclosure Package, any such Issuer Free Writing Prospectus or any Written Testing-the-Waters Communication is delivered to a purchaser, not misleading; and (vii) of the receipt by the Company of any notice with respect to any suspension of the qualification of the Shares or the Offered ADSs for offer and sale in any jurisdiction or the initiation or, to the knowledge of the Company, threatening of any proceeding for such purpose; and the Company will use its reasonable best efforts to prevent the issuance of any such order suspending the effectiveness of the Registration Statement, preventing or suspending the use of any Preliminary Prospectus, any of the Pricing Disclosure Package or the Prospectus or any Written Testing-the-Waters Communication or suspending any such qualification of the Shares or the Offered ADSs and, if any such order is issued, will obtain as soon as possible the withdrawal thereof.
- (e) Ongoing Compliance. (i) If during the Prospectus Delivery Period (A) any event or development shall occur or condition shall exist as a result of which the Prospectus as then amended or supplemented would include any untrue statement of a material fact or omit to state

any material fact necessary in order to make the statements therein, in the light of the circumstances existing when the Prospectus is delivered to a purchaser, not misleading or (B) it is necessary to amend or supplement the Prospectus to comply with law, the Company will promptly notify the Underwriters thereof and forthwith prepare and, subject to paragraph (c) above, file with the Commission and furnish to the Underwriters and to such dealers as the Representatives may designate such amendments or supplements to the Prospectus as may be necessary so that the statements in the Prospectus as so amended or supplemented will not, in the light of the circumstances existing when the Prospectus is delivered to a purchaser, be misleading or so that the Prospectus will comply with law and (ii) if at any time prior to the Closing Date (A) any event or development shall occur or condition shall exist as a result of which the Pricing Disclosure Package as then amended or supplemented would include any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein, in the light of the circumstances existing when the Pricing Disclosure Package is delivered to a purchaser, not misleading or (B) it is necessary to amend or supplement the Pricing Disclosure Package to comply with law, the Company will promptly notify the Underwriters thereof and forthwith prepare and, subject to paragraph (c) above, file with the Commission (to the extent required) and furnish to the Underwriters and to such dealers as the Representatives may designate such amendments or supplements to the Pricing Disclosure Package as may be necessary so that the statements in the Pricing Disclosure Package as on amended or supplemented will not, in the light of the circumstances existing when the Pricing Disclosure Package is delivered to a purchaser, be misleading or so that the Pricing Disclosure Package will comply with law.

- (f) *Blue Sky Compliance*. The Company will use its reasonable best efforts, in cooperation with the Underwriters, to qualify the Shares and Offered ADSs for offer and sale under the applicable securities or Blue Sky laws of such jurisdictions as the Representatives shall reasonably request and will continue such qualifications in effect so long as required for distribution of the Shares and Offered ADSs; <u>provided</u> that the Company shall not be required to (i) qualify as a foreign corporation or other entity or as a dealer in securities in any such jurisdiction where it would not otherwise be required to so qualify, (ii) file any general consent to service of process in any such jurisdiction or (iii) subject itself to taxation in any such jurisdiction if it is not otherwise so subject.
- (g) *Earning Statement*. The Company will make generally available to its shareholders and the Representatives as soon as practicable an earning statement that satisfies the provisions of Section 11(a) of the Securities Act and Rule 158 of the Commission promulgated thereunder covering a period of at least twelve months beginning with the first fiscal quarter of the Company occurring after the "effective date" (as defined in Rule 158) of the Registration Statement; <u>provided</u> that the Company shall be deemed to have furnished such statements to its security holders and the Representatives to the extent they are filed on the Commission's Electronic Data Gathering, Analysis, and Retrieval system ("EDGAR") or any successor to such system.
- (h) Clear Market. For a period of 90 days after the date of the Prospectus, the Company 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 submit to, or file with, the Commission a registration statement under the Securities Act relating to, any Ordinary Shares, ADSs or any securities convertible into or exercisable or exchangeable for Shares, 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 Shares or

ADSs or any such other securities, whether any such transaction described in clause (i) or (ii) above is to be settled by delivery of Shares, ADSs or such other securities, in cash or otherwise, without the prior written consent of J.P. Morgan Securities LLC and BofA Securities, Inc., other than (A) the Shares to be sold hereunder, pursuant to the Rights Offering described in the Registration Statement, Pricing Disclosure Package and Prospectus, or pursuant to the private placement under the Investment Agreements with Temasek Ellington Investments Pte. Ltd. and Heiligeland biotech GmbH, dated June 29, 2020, (B) any Shares of the Company issued upon the exercise of options granted under Company Share Plans, (C) the filing by the Company of any registration statement on Form S-8 or a successor form thereto relating to a Company Share Plan described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, or (D) Shares or other securities issued in connection with a transaction with an unaffiliated third party that includes a bona fide commercial relationship (including joint ventures, marketing or distribution arrangements, collaboration agreements or licensing agreements) or any acquisition of assets of not less than a majority or controlling portion of the equity of another entity, provided that the aggregate number of the shares issued pursuant to clause (D) shall not exceed more than five percent (5%) of the total number of outstanding Shares immediately following the issuance and sale of the Underwritten Shares pursuant to this Agreement.

- (i) *Use of Proceeds*. The Company will apply the net proceeds from the sale of the Shares and the Offered ADSs as described in each of the Registration Statement, the Pricing Disclosure Package and the Prospectus under the heading "Use of Proceeds".
- (j) *No Stabilization*. Neither the Company nor its subsidiaries or affiliates will take, directly or indirectly, any action designed to or that could reasonably be expected to cause or result in any stabilization or manipulation of the price of the ADS.
  - (k) Exchange Listing. The Company will use its reasonable best efforts to maintain the listing of the Offered ADSs on the Nasdaq Market.
- (l) *Reports*. During a period of three (3) years from the date of this Agreement, the Company will furnish to the Representatives, as soon as commercially reasonable after the date that they are available, copies of all reports or other communications (financial or other) furnished to holders of the Offered ADSs, and copies of any reports and financial statements furnished to or filed with the Commission or any national securities exchange or automatic quotation system; <u>provided</u> the Company will be deemed to have furnished such reports and financial statements to the Representatives to the extent they are filed on EDGAR or any successor to such system.
- (m) *Deposit Agreement*. On or prior to the Closing Date and each applicable Additional Closing Date, the Company agrees that it will comply with the Deposit Agreement so that ADRs evidencing the relevant Offered ADSs will, assuming compliance by the Depositary with its obligations under the Deposit Agreement, be executed (and, if applicable, countersigned) and issued by the Depositary against receipt of such Underwritten Shares and delivered to the Settlement Agent at the Closing Date, and (iii) to otherwise comply with the terms of the Deposit Agreement, including without limitation, the covenants set forth in the Deposit Agreement.
- (n) *Record Retention*. The Company will, pursuant to reasonable procedures developed in good faith, retain copies of each Issuer Free Writing Prospectus that is not filed with the Commission in accordance with Rule 433 under the Securities Act.
- (o) *Emerging Growth Company; Foreign Private Issuer*. The Company will promptly notify the Representatives if the Company ceases to be an Emerging Growth Company

or a Foreign Private Issuer at any time prior to the later of (i) completion of the distribution of the Offered ADSs within the meaning of the Securities Act and (ii) completion of the 90-day restricted period referred to in Section 7(h) hereof.

- (p) *Tax Indemnity*. The Company will indemnify and hold harmless the Underwriters against any documentary, stamp, registration or similar issuance tax, including any interest and penalties, on the sale of the Shares or the Offered ADSs by the Company to the Underwriters and on the execution and delivery of this Agreement. All indemnity payments to be made by the Company hereunder in respect of this Section 7(p) shall be made without withholding or deduction for or on account of any present or future German taxes, duties or governmental shares whatsoever unless the Company is compelled by law to deduct or withhold such taxes, duties or charges. In that event, except for any net income, capital gains or franchise taxes imposed on the Underwriters by the Federal Republic of Germany or the United States or any political subdivision of tax authority thereof or therein as a result of any present or former connection (other than any connection resulting from the transactions contemplated by the Transaction Documents) between the Underwriters and the jurisdiction imposing such withholding or deductions, the Company shall pay such additional amounts as may be necessary in order to ensure that the net amounts received after such withholding or deductions shall equal the amounts that would have been received if no withholding or deduction has been made.
- 8. Further Agreements of the Selling Stockholders. Each of the Selling Stockholders severally covenants and agrees with each Underwriter that:
- (a) *No Stabilization*. Such Selling Stockholder will not take, directly or indirectly, any action designed to or that could reasonably be expected to cause or result in any stabilization or manipulation of the price of the Offered ADSs.
- (b) *Tax Form.* It will deliver to the Representatives prior to or at the Closing Date a properly completed and executed United States Treasury Department Form W-9 (or other applicable form or statement specified by the Treasury Department regulations in lieu thereof) in order to facilitate the Underwriters' documentation of their compliance with the reporting and withholding provisions of the Tax Equity and Fiscal Responsibility Act of 1982 with respect to the transactions herein contemplated.
- (c) *Tax Indemnity*. It will indemnify and hold harmless the Underwriters against any documentary, stamp, registration or similar issuance tax, including any interest and penalties, on the sale of the Option ADSs by such Selling Stockholder to the Underwriters and on the execution and delivery of this Agreement. All indemnity payments to be made by such Selling Stockholder hereunder in respect of this Section 8(c) shall be made without withholding or deduction for or on account of any present or future German taxes, duties or governmental shares whatsoever unless such Selling Stockholder is compelled by law to deduct or withhold such taxes, duties or charges. In that event, except for any net income, capital gains or franchise taxes imposed on the Underwriters by the Federal Republic of Germany or the United States or any political subdivision of tax authority thereof or therein as a result of any present or former connection (other than any connection resulting from the transactions contemplated by this Agreement) between the Underwriters and the jurisdiction imposing such withholding or deductions, such Selling Stockholder shall pay such additional amounts as may be necessary in order to ensure that the net amounts received after such withholding or deductions shall equal the amounts that would have been received if no withholding or deduction has been made.
- (d) *Use of Proceeds*. It will not directly or indirectly use the proceeds of the offering of the Option ADSs hereunder, or lend, contribute or otherwise make available such proceeds to a subsidiary, joint venture partner or other person or entity (i) to fund or facilitate any activities of or business with any person that, at the time of such funding or facilitation, is the subject of target of Sanctions, (ii) to fund or facilitate any activities of or business in any Sanctioned Country or (iii) in any other manner that will result in a violation by any person (including any person participating in the transaction, whether as underwriter, advisor, investor or otherwise) of Sanctions.

- 9. Certain Agreements of the Underwriters. Each Underwriter hereby represents and agrees that:
- (a) It has not and will not use, authorize use of, refer to or participate in the planning for use of, any "free writing prospectus", as defined in Rule 405 under the Securities Act (which term includes use of any written information furnished to the Commission by the Company and not incorporated by reference into the Registration Statement and any press release issued by the Company) other than (i) a free writing prospectus that contains no "issuer information" (as defined in Rule 433(h)(2) under the Securities Act) that was not included (including through incorporation by reference) in the Preliminary Prospectus or a previously filed Issuer Free Writing Prospectus, (ii) any Issuer Free Writing Prospectus, if any, listed on Annex A or prepared pursuant to Section 5(c) or Section 7(c) above (including any electronic road show), or (iii) any free writing prospectus prepared by such underwriter and approved by the Company in advance in writing (each such free writing prospectus referred to in clauses (i) or (iii), an "Underwriter Free Writing Prospectus").
- (b) It has not and will not, without the prior written consent of the Company, use any free writing prospectus that contains the final terms of the Offered ADSs unless such terms have previously been included in a free writing prospectus filed with the Commission; provided that Underwriters may use a term sheet substantially in the form of Annex B hereto without the consent of the Company; provided, further, that any Underwriter using such term sheet shall notify the Company, and provide a copy of such term sheet to the Company, prior to, or substantially concurrently with, the first use of such term sheet.
- (c) It is not subject to any pending proceeding under Section 8A of the Securities Act with respect to the offering (and will promptly notify the Company if any such proceeding against it is initiated during the Prospectus Delivery Period).
- 10. <u>Conditions of Underwriters' Obligations</u>. The obligation of each Underwriter to purchase the Underwritten ADSs on the Closing Date or the Option ADSs on each applicable Additional Closing Date, as the case may be, as provided herein is subject to the performance by the Company and each of the Selling Stockholders of their respective covenants and other obligations hereunder and to the following additional conditions:
  - (a) *Registration Compliance; No Stop Order*. No order suspending the effectiveness of the Registration Statement or the ADS Registration Statement shall be in effect, and no proceeding for such purpose or pursuant to Section 8A under the Securities Act shall be pending before or, to the knowledge of the Company, threatened by the Commission; the Prospectus and each Issuer Free Writing Prospectus shall have been timely filed with the Commission under the Securities Act (in the case of an Issuer Free Writing Prospectus, to the extent required by Rule 433 under the Securities Act) and in accordance with Section 5(c) hereof; and all requests by the Commission for additional information shall have been complied with to the reasonable satisfaction of counsel to the Representatives.

- (b) *Representations and Warranties*. The respective representations and warranties of the Company and the Selling Stockholders contained herein shall be true and correct on the date hereof and on and as of the Closing Date or the applicable Additional Closing Date, as the case may be; and the statements of the Company and its officers and of each of the Selling Stockholders and their officers made in any certificates delivered pursuant to this Agreement shall be true and correct on and as of the Closing Date or the applicable Additional Closing Date, as the case may be.
- (c) No Material Adverse Change. Since the date of this Agreement, no event or condition of a type described in Section 5(j) hereof shall have occurred or shall exist, which event or condition is not described in the Pricing Disclosure Package (excluding any amendment or supplement thereto) and the Prospectus (excluding any amendment or supplement thereto) and the effect of which in the judgment of the Representatives makes it impracticable or inadvisable to proceed with the offering, sale or delivery of the Offered ADSs on the Closing Date or the Additional Closing Date, as the case may be, on the terms and in the manner contemplated by this Agreement, the Pricing Disclosure Package and the Prospectus.
- (d) Officer's Certificate. The Representatives shall have received on and as of the Closing Date or the applicable Additional Closing Date, as the case may be, a certificate of the chief financial officer of the Company and one additional member of the management board or another senior executive officer of the Company who is reasonably satisfactory to the Representatives (i) confirming that such officers have carefully reviewed the Registration Statement, the Pricing Disclosure Package and the Prospectus and, to the knowledge of such officers, the representations set forth in Sections 5(a), 5(b) and 5(c) hereof are true and correct, and (ii) confirming that the other representations and warranties of the Company in this Agreement are true and correct and that the Company has complied with all agreements and satisfied all conditions on its part to be performed or satisfied hereunder at or prior to the Closing Date or the applicable Additional Closing Date, as the case may be. The Representatives shall have received on and as of the applicable Additional Closing Date, a certificate of each of the Selling Stockholders, in form and substance reasonably satisfactory to the Representatives, (A) confirming that the representations of such Selling Stockholder set forth in Sections 6(e), 6(f) and 6(g) hereof is true and correct and (B) confirming that the other representations and warranties of such Selling Stockholder in this agreement are true and correct and that such Selling Stockholder has complied with all agreements and satisfied all conditions on its part to be performed or satisfied hereunder at or prior to such Additional Closing Date.
- (e) Comfort Letters. On the date of this Agreement and on the Closing Date or the applicable Additional Closing Date, as the case may be, (i) Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft shall have furnished to the Representatives, at the request of the Company, letters, dated the respective date of delivery thereof and addressed to the Underwriters, in form and substance reasonably satisfactory to the Representatives, containing statements and information of the type customarily included in accountants' "comfort letters" to underwriters with respect to the financial statements and certain financial information of the Company and its consolidated subsidiaries contained in or incorporated by reference in each of the Registration Statement, the Pricing Disclosure Package and the Prospectus and (ii) PricewaterhouseCoopers LLP shall have furnished to the Representatives, at the request of the Company, letters, dated the respective date of delivery thereof and addressed to the Underwriters, in form and substance reasonably satisfactory to the Representatives, containing statements and information of the type customarily included in accountants' "comfort letters" to underwriters with respect to the financial statements and certain financial information of Neon contained in each of the Registration Statement, the Pricing Disclosure Package and the Prospectus; provided, that the

letter delivered by Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft on the Closing Date or the applicable Additional Closing Date, as the case may be, shall use a "cut-off" date no more than two business days prior to such Closing Date or such Additional Closing Date, as the case may be.

#### (f) [Reserved.]

- (g) *Opinion and 10b-5 Statement of U.S. Counsel for the Company*. Covington & Burling LLP, U.S. counsel for the Company, shall have furnished to the Representatives, at the request of the Company, their written opinion and 10b-5 statement including or relating to regulatory matters, dated the Closing Date or the applicable Additional Closing Date, as the case may be, and addressed to the Underwriters, in form and substance reasonably satisfactory to the Representatives, to the effect set forth in <u>Annex C</u> hereto.
- (h) *Opinion of German Counsel for the Company*. Freshfields Bruckhaus Deringer LLP, German counsel for the Company, shall have furnished to the Representatives, at the request of the Company, their written opinion, dated the Closing Date or the applicable Additional Closing Date, as the case may be, and addressed to the Underwriters, in form and substance reasonably satisfactory to the Representatives, to the effect set forth in <u>Annex D</u> hereto.
- (i) *Opinion of Intellectual Property Counsel for the Company*. Each of Choate Hall & Stewart LLP, Wilson Sonsini Goodrich & Rosati and McDonnell Boehnen Hulbert & Berghoff LLP, intellectual property counsel for the Company, shall have furnished to the Representatives, at the request of the Company, their written opinions, dated the Closing Date or the applicable Additional Closing Date, as the case may be, and addressed to the Underwriters, in form and substance reasonably satisfactory to the Representatives, to the effect set forth in <u>Annex E-1</u>, <u>Annex E-2</u> and <u>Annex E-3</u> hereto, respectively.
- (j) *Intellectual Property Certificate of the Company*. The Representatives shall have received on and as of the Closing Date or the applicable Additional Closing Date, as the case may be, an intellectual property certificate of the Vice President, Legal & Intellectual Property of the Company, dated the Closing Date or the applicable Additional Closing Date, as the case may be, and addressed to the Underwriters, in form and substance reasonably satisfactory to the Representatives, to the effect set forth in <u>Annex E-4</u> hereto.
- (k) *Opinion of Counsel for the Depositary*. Emmet, Marvin & Martin, LLP, counsel for the Depositary, shall have furnished to the Representatives, their written opinion, dated the Closing Date or the applicable Additional Closing Date, as the case may be, and addressed to the Underwriters, in form and substance reasonably satisfactory to the Representatives, to the effect set forth in <u>Annex F</u> hereto.
- (l) *Opinion of Counsel for the Selling Stockholders*. Each of Covington & Burling LLP and Freshfields Bruckhaus Deringer LLP, counsel for the Selling Stockholders, shall have furnished to the Representatives their written opinion, dated the applicable Additional Closing Date and addressed to the Underwriters, in form and substance reasonably satisfactory to the Representatives, to the effect set forth in <u>Annex G</u> hereto.
- (m) *Opinion and 10b-5 Statement of Counsel for the Underwriters.* The Representatives shall have received on and as of the Closing Date or the applicable Additional Closing Date, as the case may be, (i) a U.S. opinion and 10b-5 statement, addressed to the Underwriters, of Davis Polk & Wardwell LLP, U.S. counsel for the Underwriters and (ii) a German opinion, addressed to the Underwriters, of Skadden, Arps, Slate, Meagher & Flom LLP, German counsel for the Underwriters with respect to such matters as the Representatives may reasonably request, and such counsel shall have received such documents and information as they may reasonably request to enable them to pass upon such matters.

- (n) *No Legal Impediment to Issuance and Sale*. No action shall have been taken and no statute, rule, regulation or order shall have been enacted, adopted or issued by any federal, state or foreign governmental or regulatory authority that would, as of the Closing Date or the applicable Additional Closing Date, as the case may be, prevent the issuance or sale of the Underwritten ADSs or the sale of the Option ADSs; and no injunction or order of any federal, state or foreign court shall have been issued that would, as of the Closing Date or the applicable Additional Closing Date, as the case may be, prevent the issuance or sale of the Shares or the Offered ADSs.
- (o) *Exchange Listing*. The Offered ADSs to be delivered on the Closing Date or the applicable Additional Closing Date, as the case may be, shall have been duly listed on the Nasdaq Market, subject to official notice of issuance.
- (p) *Lock-up Agreements*. The "lock-up" agreements, each substantially in the form of Exhibit D hereto, between you and officers, directors, members of the management board of the Company and certain shareholders relating to sales and certain other dispositions of Ordinary Shares, ADSs or certain other securities, delivered to you on or before the date hereof, shall be full force and effect on the Closing Date or the applicable Additional Closing Date, as the case may be.
- (q) *Deposit Agreement*. The Company and the Depositary shall have executed and delivered the Deposit Agreement and the Deposit Agreement shall be in full force and effect. The Depositary shall have delivered to the Company certificates reasonably satisfactory to the Underwriters evidencing the deposit with the Depositary or its nominee of the Underwritten Shares being so deposited against issuance of ADRs evidencing the ADSs to be delivered by the Company at the Closing Date or the applicable Additional Closing Date, as the case may be, and the execution, countersignature (if applicable), issuance and delivery of ADRs evidencing such ADSs pursuant to the Deposit Agreement.
- (r) *Corporate Authorizations*. The Representatives shall have received copies of the resolutions of the management board (*Vorstand*) and the supervisory board (*Aufsichtsrat*) of the Company, authorizing the issuance and the sale of the Underwritten Shares on or prior to the Closing Date.
- (s) *Commercial Register Excerpts*. The Company shall have delivered to the German Subscription Agent, in accordance with, and at the time provided for, in Section 2(d) hereof, in case of the Underwritten Shares to be issued on the Closing Date, (i) a duly executed global share certificate evidencing the Underwritten Shares and (ii) a certified excerpt from the commercial register (*Handelsregister*) pertaining to the Company evidencing the capital increase represented by the Underwritten Shares.
- (t) Rights Waiver Agreements. Holders of the Company's ordinary shares, including ordinary shares represented by ADSs, representing [●]% of the Company's outstanding ordinary shares (including ordinary shares represented by ADSs) shall have entered into binding and irrevocable agreements not to exercise and/or transfer any preemptive rights (Bezugsrechte) in the Rights Offering described in the Registration Statement, the Pricing Disclosure Package and the Prospectus. Such agreements constitute valid, legally binding and irrevocable agreements of such holders enforceable against such holders in accordance with their terms, and such agreements shall be in full force and effect.
- (u) *Additional Documents*. On or prior to the Closing Date or the applicable Additional Closing Date, as the case may be, the Company shall have furnished to the Representatives such further certificates and documents as the Representatives may reasonably request.

All opinions, letters, certificates and evidence mentioned above or elsewhere in this Agreement shall be deemed to be in compliance with the provisions hereof only if they are in form and substance reasonably satisfactory to counsel for the Underwriters.

#### 11. Indemnification and Contribution.

(a) *Indemnification of the Underwriters by the Company*. The Company agrees to indemnify and hold harmless each Underwriter, its affiliates, directors and officers and each person, if any, who controls such Underwriter within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, from and against any and all losses, claims, damages and liabilities (including, without limitation, legal fees and other expenses incurred in connection with any suit, action or proceeding or any claim asserted, as such fees and expenses are incurred), joint or several, that arise out of, or are based upon, (i) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement or the ADS Registration Statement, or caused by any omission or alleged omission to state therein a material fact required to be stated therein or necessary in order to make the statements therein, not misleading, or (ii) any untrue statement or alleged untrue statement of a material fact contained in the Prospectus (or any amendment or supplement thereto), any Preliminary Prospectus, any Issuer Free Writing Prospectus, any "issuer information" filed or required to be filed pursuant to Rule 433(d) under the Securities Act, any Written Testing-the-Waters Communication, any road show as defined in Rule 433(h) under the Securities Act (a "road show") or any Pricing Disclosure Package (including any Pricing Disclosure Package that has subsequently been amended), or caused by any omission or alleged omission to state therein a material fact necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading, in each case except insofar as such losses, claims, damages or liabilities arise out of, or are based upon, any untrue statement or omission or alleged untrue statement or omission made in reliance upon and in conformity with any information relating to any Underwriter furnished to the Company in writing by such Underwriter through the Representatives expressly for use therein, it being understood and agreed that the only such information furnished by any Underwriter consists of the information described as such in paragraph (c) below.

(b) Indemnification of the Underwriters by the Selling Stockholders. Each of the Selling Stockholders severally in proportion to the number of Shares to be sold by such Selling Stockholder hereunder agrees to indemnify and hold harmless each Underwriter, its affiliates, directors and officers and each person, if any, who controls such Underwriter within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act to the same extent as the indemnity set forth in paragraph (a) above, in each case except insofar as such losses, claims, damages or liabilities arise out of, or are based upon, any untrue statement or omission or alleged untrue statement or omission made in reliance upon and in conformity with any information relating to any Underwriter furnished to the Company in writing by such Underwriter through the Representatives expressly for use in the Registration Statement, the Prospectus (or any amendment or supplement thereto), any Preliminary Prospectus, any Issuer Free Writing Prospectus, any Written Testing-the-Waters Communication or the Pricing Disclosure Package, it being understood and agreed that the only such information furnished by any Underwriter consists of the information described as such in paragraph (c) below; provided, however, that (i) each Selling Stockholder's agreement to indemnify and hold harmless hereunder shall only apply

insofar as such losses, claims, damages or liabilities arise out of, or are based upon, any untrue statement or omission or alleged untrue statement or omission made in reliance upon and in conformity with any information relating to such Selling Stockholder furnished to the Company in writing by such Selling Stockholder expressly for use in the Registration Statement, the Prospectus, any Issuer Free Writing Prospectus or any Pricing Disclosure Package, it being understood and agreed upon that the only such information furnished by any Selling Stockholder consists of the following information in the Prospectus furnished on behalf of such Selling Stockholder: the name and address of the Selling Stockholder, the number of ADSs held by the Selling Stockholder and the number of Option ADSs offered by the Selling Stockholder and (ii) the aggregate amount of each Selling Stockholder's liability pursuant to this Section 11(b) shall not exceed the aggregate amount of net proceeds (before deducting expenses) received by such Selling Stockholder from the sale of its ADSs hereunder.

- (c) Indemnification of the Company and the Selling Stockholders. Each Underwriter agrees, severally and not jointly, to indemnify and hold harmless the Company, its directors, its officers who signed the Registration Statement and each person, if any, who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act and each of the Selling Stockholders to the same extent as the indemnity set forth in paragraph (a) above, but only with respect to any losses, claims, damages or liabilities that arise out of, or are based upon, any untrue statement or omission or alleged untrue statement or omission made in reliance upon and in conformity with any information relating to such Underwriter furnished to the Company in writing by such Underwriter through the Representatives expressly for use in the Registration Statement, the Prospectus (or any amendment or supplement thereto), any Preliminary Prospectus, any Issuer Free Writing Prospectus, any Written Testing-the-Waters Communication, any road show or any Pricing Disclosure Package (including any Pricing Disclosure Package that has subsequently been amended), it being understood and agreed upon that the only such information furnished by any Underwriter consists of the following information in the Prospectus furnished on behalf of each Underwriter: the concession and reallowance figures appearing in the third paragraph under the caption "Underwriting" and the information contained in the fifteenth, sixteenth and seventeenth paragraphs relating to stabilizing transactions under the caption "Underwriting."
- (d) *Notice and Procedures*. If any suit, action, proceeding (including any governmental or regulatory investigation), claim or demand shall be brought or asserted against any person in respect of which indemnification may be sought pursuant to the preceding paragraphs of this Section 11, such person (the "Indemnified Person") shall promptly notify the person against whom such indemnification may be sought (the "Indemnifying Person") in writing; provided that the failure to notify the Indemnifying Person shall not relieve it from any liability that it may have under the preceding paragraphs of this Section 11 except to the extent that it has been materially prejudiced (through the forfeiture of substantive rights or defenses) by such failure; and provided, further, that the failure to notify the Indemnifying Person shall not relieve it from any liability that it may have to an Indemnified Person otherwise than under the preceding paragraphs of this Section 11. If any such proceeding shall be brought or asserted against an Indemnified Person and it shall have notified the Indemnifying Person thereof, the Indemnifying Person shall retain counsel reasonably satisfactory to the Indemnified Person (who shall not, without the consent of the Indemnified Person, be counsel to the Indemnifying Person may designate in such proceeding and shall pay the reasonable fees and expenses in such proceeding and shall pay the reasonable fees and expenses of such counsel related to such proceeding, as incurred. In any such proceeding, any Indemnified Person shall have the right to retain its own counsel, but the fees and expenses of such counsel

shall be at the expense of such Indemnified Person unless (i) the Indemnifying Person and the Indemnified Person shall have mutually agreed to the contrary; (ii) the Indemnifying Person has failed within a reasonable time to retain counsel reasonably satisfactory to the Indemnified Person; (iii) the Indemnified Person shall have reasonably concluded that there may be legal defenses available to it that are different from or in addition to those available to the Indemnifying Person; or (iv) the named parties in any such proceeding (including any impleaded parties) include both the Indemnifying Person and the Indemnified Person and representation of both parties by the same counsel would be inappropriate due to actual or potential differing interests between them. It is understood and agreed that the Indemnifying Person shall not, in connection with any proceeding or related proceeding in the same jurisdiction, be liable for the fees and expenses of more than one separate firm (in addition to any local counsel) for all Indemnified Persons, and that all such fees and expenses shall be paid or reimbursed as they are incurred. Any such separate firm for any Underwriter, its affiliates, directors and officers and any control persons of such Underwriter shall be designated in writing by the Representatives and any such separate firm for the Company, its directors, its officers who signed the Registration Statement and any control persons of the Company shall be designated in writing by the Company and any such separate firm for the Selling Stockholders shall be designated in writing by the Attorneys-in-Fact. The Indemnifying Person shall not be liable for any settlement of any proceeding effected without its written consent, but if settled with such consent, the Indemnifying Person agrees to indemnify each Indemnified Person from and against any loss or liability by reason of such settlement. Notwithstanding the foregoing sentence, if at any time an Indemnified Person shall have requested that an Indemnifying Person reimburse the Indemnified Person for fees and expenses of counsel as contemplated by this paragraph, the Indemnifying Person shall be liable for any settlement of any proceeding effected without its written consent if (A) such settlement is entered into more than thirty (30) days after receipt by the Indemnifying Person of such request and (B) the Indemnifying Person shall not have reimbursed the Indemnified Person in accordance with such request prior to the date of such settlement. No Indemnifying Person shall, without the written consent of the Indemnified Person, effect any settlement of any pending or threatened proceeding in respect of which any Indemnified Person is or could have been a party and indemnification could have been sought hereunder by such Indemnified Person, unless such settlement (x) includes an unconditional release of such Indemnified Person, in form and substance reasonably satisfactory to such Indemnified Person, from all liability on claims that are the subject matter of such proceeding and (y) does not include any statement as to or any admission of fault, culpability or a failure to act by or on behalf of any Indemnified Person.

(e) Contribution. If the indemnification provided for in paragraphs (a), (b)or (c) above is unavailable to an Indemnified Person or insufficient in respect of any losses, claims, damages or liabilities referred to therein, then each Indemnifying Person under such paragraph, in lieu of indemnifying such Indemnified Person thereunder, shall contribute to the amount paid or payable by such Indemnified Person as a result of such losses, claims, damages or liabilities (i) in such proportion as is appropriate to reflect the relative benefits received by the Company and the Selling Stockholders, on the one hand, and the Underwriters on the other, from the offering of the Offered ADSs or (ii) if the allocation provided by clause (i) is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) but also the relative fault of the Company and the Selling Stockholders, on the one hand, and the Underwriters on the other, in connection with the statements or omissions that resulted in such losses, claims, damages or liabilities, as well as any other relevant equitable considerations. The relative benefits received by the Company and the Selling Stockholders, on the one hand, and the Underwriters on the other, shall be deemed to be in the same respective proportions as the net proceeds (before deducting expenses) received by the Company and the Selling Stockholders from the sale of the Shares and the Offered ADSs and the total underwriting discounts and

commissions received by the Underwriters in connection therewith, in each case as set forth in the table on the cover of the Prospectus, bear to the aggregate initial offering price of the Offered ADSs as set forth on such cover. The relative fault of the Company and the Selling Stockholders, on the one hand, and the Underwriters on the other, shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission or alleged omission to state a material fact relates to information supplied by the Company and the Selling Stockholders or by the Underwriters and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission.

- (f) Limitation on Liability. The Company, the Selling Stockholders and the Underwriters agree that it would not be just and equitable if contribution pursuant to paragraph (e) above were determined by <u>pro rata</u> allocation (even if the Selling Stockholders were treated as one entity or the Underwriters were treated as one entity for such purpose) or by any other method of allocation that does not take account of the equitable considerations referred to in paragraph (d) above. The amount paid or payable by an Indemnified Person as a result of the losses, claims, damages and liabilities referred to in paragraph (e) above shall be deemed to include, subject to the limitations set forth above, any legal or other expenses reasonably incurred by such Indemnified Person in connection with any such action or claim. Notwithstanding the provisions of paragraphs (e) and (f), in no event shall an Underwriter be required to contribute any amount in excess of the amount by which the total underwriting discounts and commissions received by such Underwriter with respect to the offering of the Offered ADSs exceeds the amount of any damages that such Underwriter has otherwise been required to pay by reason of such untrue or alleged untrue statement or omission or alleged omission. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. The Underwriters' obligations to contribute pursuant to paragraphs (e) and (f) are several in proportion to their respective purchase obligations hereunder and not joint.
- (g) *Non-Exclusive Remedies*. The remedies provided for in this Section 11 are not exclusive and shall not limit any rights or remedies which may otherwise be available to any Indemnified Person at law or in equity.
- 12. Effectiveness of Agreement. This Agreement shall become effective as of the date first written above.
- 13. Termination. This Agreement may be terminated in the absolute discretion of the Representatives, by notice to the Company and the Selling Stockholders, if after the execution and delivery of this Agreement and on or prior to the Closing Date or, in the case of the Option ADSs, prior to the applicable Additional Closing Date (i) trading generally shall have been suspended or materially limited on or by the New York Stock Exchange, the Nasdaq Market, or the Frankfurt Stock Exchange; (ii) trading of any securities issued or guaranteed by the Company shall have been suspended on any exchange or in any over-the-counter market; (iii) a general moratorium on commercial banking activities shall have been declared by federal or New York State, European Union or German authorities; or (iv) there shall have occurred any outbreak or escalation of hostilities or any change in financial markets or any calamity or crisis, either within or outside the United States or the Federal Republic of Germany, that, in the judgment of the Representatives, is material and adverse and makes it impracticable or inadvisable to proceed with the offering, sale or delivery of the Offered ADSs on the Closing Date or the applicable Additional Closing Date, as the case may be, on the terms and in the manner contemplated by this Agreement, the Pricing Disclosure Package and the Prospectus (each of the events set forth in clauses (i) through (iv) above, or the non-occurrence of any condition precedent described in Section 10 hereof or a termination pursuant to Section 14 hereof, a "Termination Event"). With respect to the Underwritten ADSs, upon the occurrence of a Termination Event the following shall apply:
  - (a) *Prior to Filing of a Subscription Certificate*. If a Termination Event occurs before the Subscription Certificate for the Underwritten Shares has been filed with the commercial register of the Company, the obligations of the several Underwriters, through the German Subscription Agent, to subscribe for the Underwritten Shares for the account of the several Underwriters and the several obligations of the Underwriters to purchase the Underwritten Shares and the Underwritten ADSs may be canceled and this Agreement may be terminated by the Representatives at their option and in their sole discretion on behalf of the several Underwriters and, in such circumstances, the Company shall return the relevant Subscription Certificate and the relevant Bank Certificate to the German Subscription Agent, and release any funds already credited to the Capital Increase Account for the benefit of the German Subscription Agent, acting for the account of the several Underwriters.

- (b) After Filing of Documents for Registration of Capital Increase. If a Termination Event occurs after all documents required for the registration of the capital increase representing the Underwritten Shares have been filed with the commercial register, the Representatives may at their option and in their sole discretion, on behalf of the several Underwriters, terminate this Agreement and request from the Company by written notification to the Company to employ its best efforts to procure a withdrawal of the relevant application for registration of the capital increase representing the Underwritten Shares from the commercial register. If the application is withdrawn successfully, the obligation of the several Underwriters, through the German Subscription Agent, to subscribe for the Underwritten Shares for the account of the several Underwriters and the several obligations of the Underwriters to purchase the Underwritten Shares and the Underwritten ADSs shall terminate and the Company shall return the relevant Subscription Certificate and the relevant Bank Certificate to the German Subscription Agent, and release any funds already credited to the Capital Increase Account for the benefit of the German Subscription Agent, acting for the account of the several Underwriters.
- (c) After Registration of Capital Increase or After Application for Registration is not Withdrawn. If a Termination Event occurs after the registration of the capital increase representing the Underwritten Shares with the commercial register or on a date on which the application for the registration of the relevant capital increase representing the Underwritten Shares can no longer be withdrawn, or if despite a request a withdrawal does not occur for other reasons, the following shall apply: the Representatives at their option and in their sole discretion, on behalf of the several Underwriters, may terminate this Agreement; provided, however, that the several obligations of the Underwriters to purchase the Underwritten Shares at the Issue Price shall remain in force and survive any such termination. Subject to the foregoing, in the event of any such termination, the several obligations of the Underwritters towards the Company to purchase the Underwritten Shares and the Underwritten ADSs at the Purchase Price shall terminate. In the event of such termination, no ADS shall have been delivered to investors, and the following shall apply:
  - (i) The Shares underlying these Underwritten ADSs shall be "Unsold Shares," as to which the following shall apply:
  - (A) During a period not exceeding five (5) business days after such termination (the "Unsold Share Period"), the Company may designate one or more shareholders existing as of the date hereof to whom all or a part of the Unsold Shares shall be sold at a purchase price per Unsold Share determined by

the Company, which shall be at least an amount equal to the sum of (a) the Issue Price per Unsold Share plus, (b) any costs and expenses per Unsold Share incurred by the Underwriters in connection with the financing of the Issue Price from the date of the subscription of the Unsold Share to the date of such sale, plus (c) any other costs and expenses per Unsold Share incurred by the Underwriters in connection with or arising from the foregoing procedures, as well as (d) any other costs and expenses per Unsold Share reimbursable pursuant to Section 15. Upon any such sale, to the extent permitted by applicable law, the Underwriters shall as soon as practicable forward to the Company any proceeds of such sale of Unsold Shares less an amount equal to the sum of (a) the Issue Price multiplied by the number of Unsold Shares sold in accordance with this Clause, plus (b) any costs and expenses referred to in the preceding sentence. It is understood by the Company that this clause (c)(i)(A) does not constitute a commitment by the Underwriters to sell the Unsold Shares to such designated shareholders and that such commitment will exist only if and when such shareholders, and at the election of the Underwriters, the Company, enter into definitive arrangements (that may include representations and warranties, covenants, conditions and indemnification) with the Underwriters.

(B) To the extent the Unsold Shares are not sold pursuant to the procedures described in clause (c)(i)(A) during the Unsold Share Period, the Underwriters shall be entitled to sell any or all remaining Unsold Shares (in the form of Ordinary Shares or ADS, at the Underwriters election), to any other person or persons as they determine in their sole discretion, to the extent permitted by applicable law and subject to the inclusion of any securities law legends on any Unsold Shares as in the opinion of counsel for the Underwriters may be necessary. Upon any such sale at a price determined by the Underwriters, to the extent permitted by applicable law, the Underwriters shall as soon as practicable forward to the Company any proceeds received by them from such sale less an amount equal to the sum of (a) the Issue Price multiplied by the number of Unsold Shares sold in accordance with this Clause, (b) any costs and expenses incurred by the Underwriters in connection with the financing of the Issue Price from the date of the subscription of the Unsold Share to the date of such sale, multiplied by the number of Unsold Shares sold in accordance with this Clause, plus (c) any other costs and expenses per Unsold Share incurred by the Underwriters in connection with or arising from the foregoing procedures, as well as (d) any other costs and expenses per Unsold Share reimbursable pursuant to Section 15.

(ii) If the Unsold Shares have already been transferred from the German Subscription Agent to the Depositary and been registered in the Depositary's name, the Company shall use its best efforts to assist the Underwriters in effecting the transfer of such shares to the German Subscription Agent or any other entity designated by the Underwriters.

#### 14. Defaulting Underwriter.

(a) If, on the Closing Date or the Additional Closing Date, as the case may be, any Underwriter defaults on its obligation to purchase the Offered ADSs that it has agreed to purchase hereunder on such date, the non-defaulting Underwriters may in their discretion arrange for the

purchase of such Offered ADSs by other persons satisfactory to the Company and the Selling Stockholders on the terms contained in this Agreement. If, within 36 hours after any such default by any Underwriter, the non-defaulting Underwriters do not arrange for the purchase of such Offered ADSs, then the Company and the Selling Stockholders shall be entitled to a further period of 36 hours within which to procure other persons satisfactory to the non-defaulting Underwriters to purchase such Offered ADSs on such terms. If other persons become obligated or agree to purchase the Offered ADSs of a defaulting Underwriter, either the non-defaulting Underwriters or the Company and the Selling Stockholders may postpone the Closing Date or the applicable Additional Closing Date, as the case may be, for up to five (5) full business days in order to effect any changes that in the opinion of counsel for the Company, counsel for the Selling Stockholders or counsel for the Underwriters may be necessary in the Registration Statement and the Prospectus or in any other document or arrangement, and the Company agrees to promptly prepare any amendment or supplement to the Registration Statement and the Prospectus that effects any such changes. As used in this Agreement, the term "Underwriter" includes, for all purposes of this Agreement unless the context otherwise requires, any person not listed in Schedule 1 hereto that, pursuant to this Section14, purchases Offered ADSs that a defaulting Underwriter agreed but failed to purchase.

- (b) If, after giving effect to any arrangements for the purchase of the Offered ADSs of a defaulting Underwriter or Underwriters by the non-defaulting Underwriters and the Company and the Selling Stockholders as provided in paragraph (a) above, the aggregate number of Offered ADSs that remain unpurchased on the Closing Date or the applicable Additional Closing Date, as the case may be, does not exceed one-eleventh of the aggregate number of Offered ADSs to be purchased on such date, then the Company and the Selling Stockholders shall have the right to require each non-defaulting Underwriter to purchase the number of Offered ADSs that such Underwriter agreed to purchase hereunder on such date plus such Underwriter's pro rata share (based on the number of Offered ADSs that such Underwriter agreed to purchase on such date) of the Offered ADSs of such defaulting Underwriter or Underwriters for which such arrangements have not been made.
- (c) If, after giving effect to any arrangements for the purchase of the Offered ADSs of a defaulting Underwriter or Underwriters by the non-defaulting Underwriters and the Company and the Selling Stockholders as provided in paragraph (a) above, the aggregate number of Offered ADSs that remain unpurchased on the Closing Date or the Additional Closing Date, as the case may be, exceeds one-eleventh of the aggregate amount of Offered ADSs to be purchased on such date, or if the Company and the Selling Stockholders shall not exercise the right described in paragraph (b) above, then this Agreement or, with respect to any Additional Closing Date, the obligation of the Underwriters to purchase Offered ADSs on the Additional Closing Date, as the case may be, shall terminate without liability on the part of the non-defaulting Underwriters. Any termination of this Agreement pursuant to this Section 14 shall be without liability on the part of the Company and the Selling Stockholders, except that the Company and the Selling Stockholders will continue to be liable for the payment of expenses as set forth in Sections 13 and 15 hereof and except that the provisions of Sections 11 and 13 hereof shall not terminate and shall remain in effect. Nothing contained herein shall relieve the Company from any of its obligations contained in Section 13 hereof.
- (d) Nothing contained herein shall relieve a defaulting Underwriter of any liability it may have to the Company, the Selling Stockholders or any non-defaulting Underwriter for damages caused by its default.

#### 15. Payment of Expenses.

- (a) Whether or not the transactions contemplated by this Agreement are consummated or this Agreement is terminated, the Company will pay or cause to be paid all costs and expenses incident to the performance of its obligations hereunder, including without limitation, (i) the costs incident to the authorization, issuance, sale, preparation and delivery of the Shares and the Offered ADSs and any taxes payable in that connection; (ii) the costs incident to the preparation, printing and filing under the Securities Act of the Registration Statement, the ADS Registration Statement, the Preliminary Prospectus, any Issuer Free Writing Prospectus, any Pricing Disclosure Package and the Prospectus (including all exhibits, amendments and supplements thereto) and the distribution thereof; (iii) the costs of reproducing and distributing each of the Transaction Documents; (iv) the fees and expenses of the Company's counsel and independent accountants; (v) the fees and expenses incurred in connection with the registration or qualification and determination of eligibility for investment of the Offered ADSs under the securities laws in accordance with the provisions of Section 7(f) hereof, including the preparation, printing and distribution of a Blue Sky Memorandum, and including the related fees and expenses of counsel for the Underwriters in an aggregate amount not to exceed \$5,000; (vi) the costs of preparing share certificates; (vii) the costs and charges of the Depositary and any transfer agent and any registrar; (viii) all expenses and application fees incurred in connection with any filing with, and clearance of the offering by, FINRA (including the fees and expenses of counsel for the Underwriters related to such filings) in an aggregate amount not to exceed \$40,000; (ix) all expenses incurred by the Company in connection with any "road show" presentation to potential investors (provided, however, that the Underwriters and the Company shall each pay 50% of the cost of chartering any aircraft to be used in connection with the road show by both the Company and the Underwriters, and all lodging, commercial airfare and individual expenses of the Underwriters shall be the responsibility of the Underwriters); and (x) all expenses and application fees related to the listing of the Offered ADSs on the Nasdaq Market. The Selling Stockholders will pay or cause to be paid all costs and expenses incident to the performance of their obligations hereunder.
- (b) If (i) this Agreement is terminated pursuant to Section 13, (ii) the Company or the Selling Stockholders for any reason fail to tender the Shares or Offered ADSs for delivery to the Underwriters or (iii) the Underwriters decline to purchase the Shares or the Offered ADSs for any reason permitted under this Agreement, the Company agrees to reimburse the Underwriters for all out-of-pocket costs and expenses (including the fees and expenses of their counsel) reasonably incurred by the Underwriters in connection with this Agreement and the offering contemplated hereby. It is understood that the Company and the Selling Stockholders shall not pay or reimburse any costs, fees or expenses incurred by any Underwriter that defaults on its obligations to purchase the Offered ADSs.
- 16. <u>Persons Entitled to Benefit of Agreement</u>. This Agreement shall inure to the benefit of and be binding upon the parties hereto and their respective successors and the officers and directors and any controlling persons referred to herein, and the affiliates of each Underwriter referred to in Section 11 hereof. Nothing in this Agreement is intended or shall be construed to give any other person any legal or equitable right, remedy or claim under or in respect of this Agreement or any provision contained herein. No purchaser of Offered ADSs from any Underwriter shall be deemed to be a successor merely by reason of such purchase.
- 17. <u>Survival</u>. The respective indemnities, rights of contribution, representations, warranties and agreements of the Company, the Selling Stockholders and the Underwriters contained in this Agreement (including those contained in Section 13 hereof) or made by or on behalf of the Company, the Selling Stockholders or the Underwriters pursuant to this Agreement or any certificate delivered pursuant hereto shall survive the delivery of and payment for the Shares and the Offered ADSs and shall remain in

full force and effect, regardless of any termination of this Agreement or any investigation made by or on behalf of the Company, the Selling Stockholders or the Underwriters or the directors, officers, controlling persons or affiliates referred to in Section 11 hereof.

- 18. <u>Certain Defined Terms</u>. For purposes of this Agreement, (a) except where otherwise expressly provided, the term "affiliate" has the meaning set forth in Rule 405 under the Securities Act; (b) the term "business day" means any day other than a day on which banks are permitted or required to be closed in New York City; and (c) the term "subsidiary" has the meaning set forth in Rule 405 under the Securities Act.
- 19. <u>Compliance with USA Patriot Act</u>. In accordance with the requirements of the USA Patriot Act (Title III of Pub. L. 107-56 (signed into law October 26, 2001)), the Underwriters are required to obtain, verify and record information that identifies their respective clients, including the Company and the Selling Stockholders, which information may include the name and address of their respective clients, as well as other information that will allow the Underwriters to properly identify their respective clients.

#### 20. Miscellaneous.

- (a) *Notices*. All notices and other communications hereunder shall be in writing and shall be deemed to have been duly given if mailed or transmitted and confirmed by any standard form of telecommunication. Notices to the Underwriters shall be given to the Representatives c/o J.P. Morgan Securities LLC, 383 Madison Avenue, New York, New York 10179 (fax: (212) 622-8358), Attention: Equity Syndicate Desk; and c/o BofA Securities, Inc., One Bryant Park, New York, New York 10036 (fax: (646) 855-3073), Attention: Syndicate Department with a copy to ECM Legal (facsimile: (212) 230-8730); c/o Berenberg Capital Markets LLC, 1251 Avenue of the Americas, New York, New York 10020 (fax: [♠]), Attention: [♠]. Notices to the Company shall be given to it at BioNTech SE, An der Goldgrube 12, D-55131 Mainz, Germany; Attention: Dr. James Ryan, Ph.D., Vice President, Legal and Intellectual Property. Notices to the Selling Stockholders shall be given to the Attorneys-in-Fact at BioNTech SE, An der Goldgrube 12, D-55131 Mainz, Germany; Attention: Dr. Sierk Poetting, Chief Financial Officer and Chief Operating Officer, and Ryan Richardson, Chief Strategy Officer.
- (b) *Governing Law*. This Agreement and any claim, controversy or dispute arising under or related to this Agreement shall be governed by and construed in accordance with the laws of the State of New York without regard to its choice of law provisions.
- (c) *Submission to Jurisdiction*. Each of the Company and the Selling Stockholders hereby submit to the exclusive jurisdiction of the U.S. federal and New York state courts in the Borough of Manhattan in The City of New York in any suit or proceeding arising out of or relating to this Agreement or the transactions contemplated hereby. Each of the Company and the Selling Stockholders waive any objection which it may now or hereafter have to the laying of venue of any such suit or proceeding in such courts. Each of the Company and the Selling Stockholders agree that final judgment in any such suit, action or proceeding brought in such court shall be conclusive and binding upon the Company and each Selling Stockholder, as applicable, and may be enforced in any court to the jurisdiction of which Company and each Selling Stockholder, as applicable, is subject by a suit upon such judgment. The Company and each Selling Stockholder irrevocably appoint BioNTech USA Holding, LLC, located at 228 E 45th Street, Suite 9e, New York, New York 10017, as its authorized agent in the Borough of Manhattan in The City of New York upon which process may be served in any such suit or proceeding, and agrees that service of process upon such authorized agent, and written notice of such service to the Company or any such Selling Stockholder, as the case may be, by the person serving the same to the address provided in this Section 20, shall be deemed in every respect effective service of process upon the Company and such Selling Stockholder in any such suit or proceeding. Each of the Company and the Selling Stockholders hereby represent and warrant that

such authorized agent has accepted such appointment and has agreed to act as such authorized agent for service of process. Each of the Company and the Selling Stockholders further agree to take any and all action as may be necessary to maintain such designation and appointment of such authorized agent in full force and effect for a period of seven years from the date of this Agreement.

- (d) *Judgment Currency*. The Company and each Selling Stockholder agree to indemnify each Underwriter, its directors, officers, affiliates and each person, if any, who controls such Underwriter within the meaning of Section 17 of the Securities Act or Section 20 of the Exchange Act, against any loss incurred by such Underwriter as a result of any judgment or order being given or made for any amount due hereunder and such judgment or order being expressed and paid in a currency (the "<u>Judgment Currency</u>") other than U.S. dollars and as a result of any variation as between (i) the rate of exchange at which the U.S. dollar amount is converted into the Judgment Currency for the purpose of such judgment or order, and (ii) the rate of exchange at which such indemnified person is able to purchase U.S. dollars with the amount of the Judgment Currency actually received by the indemnified person. The foregoing indemnity shall constitute a separate and independent obligation of the Company and each Selling Stockholder and shall continue in full force and effect notwithstanding any such judgment or order as aforesaid. The term "rate of exchange" shall include any premiums and costs of exchange payable in connection with the purchase of, or conversion into, the relevant currency.
- (e) Waiver of Immunity. To the extent that the Company or any Selling Stockholder has or hereafter may acquire any immunity (sovereign or otherwise) from jurisdiction of any court of (i) the Federal Republic of Germany, or any political subdivision thereof, (ii) the United States or the State of New York, (iii) any jurisdiction in which it owns or leases property or assets or from any legal process (whether through service of notice, attachment prior to judgment, attachment in aid of execution, execution, set-off or otherwise) with respect to themselves or their respective property and assets or this Agreement, the Company and each Selling Stockholder hereby irrevocably waives such immunity in respect of its obligations under this Agreement to the fullest extent permitted by applicable law.
- (f) Waiver of Jury Trial. EACH OF THE PARTIES HERETO HEREBY WAIVES ANY RIGHT TO TRIAL BY JURY IN ANY SUIT OR PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT.
  - (g) Recognition of the U.S. Special Resolution Regimes.
    - (i) In the event that any Underwriter that is a Covered Entity becomes subject to a proceeding under a U.S. Special Resolution Regime, the transfer from such Underwriter of this Agreement, and any interest and obligation in or under this Agreement, will be effective to the same extent as the transfer would be effective under the U.S. Special Resolution Regime if this Agreement, and any such interest and obligation, were governed by the laws of the United States or a state of the United States.
  - (ii) In the event that any Underwriter that is a Covered Entity or a BHC Act Affiliate of such Underwriter becomes subject to a proceeding under a U.S. Special Resolution Regime, Default Rights under this Agreement that may be exercised against such Underwriter are permitted to be exercised to no greater extent than such Default Rights could be exercised under the U.S. Special Resolution Regime if this Agreement were governed by the laws of the United States or a state of the United States.

As used in this Section 20(g):

"BHC Act Affiliate" has the meaning assigned to the term "affiliate" in, and shall be interpreted in accordance with, 12 U.S.C. § 1841(k).

"Covered Entity" means any of the following:

- (i) a "covered entity" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 252.82(b);
- (ii) a "covered bank" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 47.3(b); or
- (iii) a "covered FSI" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 382.2(b).

"Default Right" has the meaning assigned to that term in, and shall be interpreted in accordance with, 12 C.F.R. §§ 252.81, 47.2 or 382.1, as applicable.

- "U.S. Special Resolution Regime" means each of (i) the Federal Deposit Insurance Act and the regulations promulgated thereunder and (ii) Title II of the Dodd-Frank Wall Street Reform and Consumer Protection Act and the regulations promulgated thereunder.
  - (h) *Counterparts*. This Agreement may be signed in counterparts (which may include counterparts delivered by any standard form of telecommunication), each of which shall be an original and all of which together shall constitute one and the same instrument.
  - (i) *Amendments or Waivers*. No amendment or waiver of any provision of this Agreement, nor any consent or approval to any departure therefrom, shall in any event be effective unless the same shall be in writing and signed by the parties hereto.
  - (j) *Headings*. The headings herein are included for convenience of reference only and are not intended to be part of, or to affect the meaning or interpretation of, this Agreement.

	Very truly yours,
	BIONTECH SE
	By:
	Name: Title:
	Sierk Poetting and Ryan Richardson, as Attorneys-in-Fact
	acting on behalf of each of the Selling Stockholders listed in Schedule 2
	hereto.
	D <sub>771</sub>
	By: Name:
	Title:
	Ву:
	Name:
	Title:
Accepted: As of the date first written above	
For themselves and on behalf of the	
several Underwriters listed	
in Schedule 1 hereto.	
J.P. MORGAN SECURITIES LLC	
Ву:	
Name: Title:	
THC.	
BOFA SECURITIES, INC.	
By:	
Name:	
Title:	
BERENBERG CAPITAL MARKETS LLC	
By:	
Name:	
Title:	

If the foregoing is in accordance with your understanding, please indicate your acceptance of this Agreement by signing in the space provided

below.

#### Schedule 1

<u>Underwriters</u>
J.P. Morgan Securities LLC BofA Securities, Inc.

Berenberg Capital Markets LLC

UBS Securities LLC Canaccord Genuity LLC

COMMERZBANK Aktiengesellschaft

WR Securities, LLC

Bryan, Garnier & Co. Limited

Total

## Number of Underwritten ADSs

- [•]
- [•]
- [ullet]
- [•]
- [•] [ullet]
- [ullet][•]
- [ullet]

Schedule 2

Selling Stockholders
MIG GmbH & Co. Fonds 7 KG
MIG GmbH & Co. Fonds 8 KG MIG GmbH & Co. Fonds 9 KG

Number of Option ADSs

[●]

[•] [•]

a. Pricing Disclosure Package

[None.]

b. Pricing Information Provided Orally by Underwriters

[•]

Annex B

# [PRICING TERM SHEET]

[TBD.]

B-1

Annex C

## FORM OF OPINION OF U.S. COUNSEL FOR THE COMPANY

#### Annex D

## FORM OF OPINION OF GERMAN COUNSEL FOR THE COMPANY

## FORM OF OPINION OF CHOATE HALL & STEWART LLP

## FORM OF OPINION OF WILSON SONSINI GOODRICH & ROSATI

## FORM OF OPINION OF MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP

## FORM OF INTELLECTUAL PROPERTY CERTIFICATE OF THE COMPANY

Annex F

## FORM OF OPINION OF COUNSEL FOR THE DEPOSITARY

#### Annex G

## FORM OF OPINION OF U.S. COUNSEL FOR THE SELLING STOCKHOLDERS

#### Annex H

## FORM OF OPINION OF GERMAN COUNSEL FOR THE SELLING STOCKHOLDERS

Exhibit A

# [FORM OF SUBSCRIPTION CERTIFICATE]

Exh. A-1

Exhibit B

# [FORM OF BANK CERTIFICATE]

Exh. B-1

Exhibit C

# [FORM OF GLOBAL SHARE]

Exh. C-1

#### FORM OF LOCK-UP AGREEMENT

[•], 2020

J.P. Morgan Securities LLC BofA Securities, Inc. Berenberg Capital Markets LLC

As Representatives of the several Underwriters listed in Schedule 1 to the Underwriting Agreement referred to below

c/o J.P. Morgan Securities LLC 383 Madison Avenue New York, New York 10179

c/o BofA Securities, Inc. One Bryant Park New York, New York 10036

c/o Berenberg Capital Markets LLC 1251 Avenue of the Americas New York, New York 10020

Re: BioNTech SE – Public Offering

Ladies and Gentlemen:

The undersigned understands that you, each as one of several Representatives of the several underwriters, propose to enter into an underwriting agreement (the "Underwriting Agreement") with BioNTech SE, a European stock corporation (*Societas Europaea*) incorporated in Germany and governed by the laws of the European Union and the Federal Republic of Germany and registered with the commercial register (*Handelsregister*) of the local court (*Amtsgericht*) of Mainz, the Federal Republic of Germany (the "Company"), providing for the public offering (the "Public Offering") by the several underwriters named in Schedule 1 to the Underwriting Agreement (the "Underwriters"), of ordinary shares with no par value and a nominal value attributable to each share of €1.00 (the "Ordinary Shares") of the Company in the form of American Depositary Shares ("ADSs," and together with Ordinary Shares, the "Securities"). Capitalized terms used herein and not otherwise defined shall have the meanings set forth in the Underwriting Agreement.

In consideration of the Underwriters' agreement to purchase and make the Public Offering of the ADSs, and for other good and valuable consideration receipt of which is hereby acknowledged, the undersigned hereby agrees that, without the prior written consent of J.P. Morgan Securities LLC and BofA Securities, Inc. on behalf of the Underwriters, the undersigned will not, during the period beginning on the date of this letter agreement (this "Letter Agreement") and ending 90<sup>3</sup> days after the date of the prospectus relating to the Public Offering (the "Prospectus") (such period, the "Restricted Period"), (1)

<sup>3</sup> The Restricted Period for the lock-up agreement signed by the Selling Stockholder will be 30 days.

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 Securities of the Company or any securities convertible into or exercisable or exchangeable for Ordinary Shares (including without limitation, Securities, restricted shares, share options or such other securities which may be deemed to be beneficially owned by the undersigned in accordance with the rules and regulations of the Securities and Exchange Commission (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 any Securities or such other securities, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of Securities 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 Securities or any security convertible into or exercisable or exchangeable for Securities. The undersigned acknowledges and agrees that the foregoing precludes the undersigned from engaging in any hedging or other transactions designed or intended, or which could reasonably be expected to lead to or result in, a sale or disposition of any Securities, or securities convertible into or exercisable or exchangeable for Ordinary Shares, even if any such sale or disposition transaction or transactions would be made or executed by or on behalf of someone other than the undersigned. Notwithstanding the foregoing, the terms of this Letter Agreement shall not apply to or prohibit:

- (A) (i) the ADSs to be sold by the undersigned pursuant to the Underwriting Agreement or (ii) the deposit of Ordinary Shares with the Company's depositary in exchange for the issuance of ADSs, or the cancellation of ADSs in exchange for the delivery of underlying Ordinary Shares,
- (B) transfers of Securities or any security convertible into or exercisable or exchangeable for Securities as a bona fide gift or gifts or for bona fide estate planning purposes, including without limitation transfers to charitable organizations,
- (C) transfers or distributions of Securities or any security convertible into or exercisable or exchangeable for Securities to (i) limited partners, members, stockholders or holders of similar equity interests in the undersigned, (ii) any corporation, partnership, limited liability company or other entity, in each case, all of the beneficial ownership interest of which are held by the undersigned or a Family Member of the undersigned, or (iii) another corporation, partnership, limited liability company, trust or other affiliate (as defined in Rule 405 promulgated under the Securities Act of 1933, as amended) of the undersigned, including without limitation any general partner, limited partner, managing member, manager, member, employee, officer or director of such entity or any trust for the benefit of any of the foregoing or any affiliate of the foregoing, or to any investment fund or other entity controlled or managed by the undersigned or affiliates of the undersigned,
- (D) transactions relating to Securities or any security convertible into or exercisable or exchangeable for Securities acquired in the Public Offering, the Rights Offering or open market transactions on or after the date of the Prospectus,
- (E) transfers or dispositions of Securities or any security convertible into or exercisable or exchangeable for Securities (i) by will, other testamentary document or intestacy, (ii) to any Family Member of the undersigned, (iii) to any trust for the direct or indirect benefit of the undersigned or a Family Member of the undersigned is a trust, to the trustee on behalf of the beneficiary or to the beneficiary of such trust or to the estate of a beneficiary of such trust,
- (F) transfers of Securities or any security convertible into or exercisable or exchangeable for Securities by operation of law pursuant to a domestic order, negotiated divorce settlement or other court order, 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 Securities Exchange Act of 1934, as amended (the "Exchange Act") (or the equivalent thereof in non-U.S. jurisdictions), is required to be made, such filing shall include a description of the transfer,

- (G) the exercise of a warrant or the exercise of a stock option granted under an existing or future stock incentive plan for Securities described in the Registration Statement, Pricing Disclosure Package and Prospectus, through a "cashless" exercise, <u>provided</u> that any such Securities received by the undersigned shall be subject to the terms of this Letter Agreement, and <u>provided</u>, <u>further</u>, 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 Securities was made to the Company in connection with a "cashless" exercise,
- (H) transfers or dispositions of Securities or other securities to the Company 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), <u>provided</u> that any such Securities received by the undersigned shall be subject to the terms of this Letter Agreement, and <u>provided</u>, <u>further</u>, 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 Securities was made solely to the Company in connection with a conversion,
- (I) transfers or dispositions of Securities or other securities to the Company 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 undersigned's Securities or a right of first refusal with respect to transfers of such Securities, <u>provided</u> 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 Securities was made solely to the Company,
- (J) the establishment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of Securities, <u>provided</u> that (i) such plan does not provide for the transfer of Securities during the Restricted 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 Restricted Period, and
- (K) transfers pursuant to a bona fide third party tender offer for all outstanding Securities of the Company, merger, consolidation or other similar transaction approved by the Company's supervisory board and made to all holders of the Company's securities involving a Change of Control of the Company (including, without limitation, the entering into of any lock-up, voting or similar agreement pursuant to which the undersigned may agree to transfer, sell, tender or otherwise dispose of Securities or other such securities in connection with such transaction, or vote any Securities or other such securities in favor of any such transaction), <u>provided</u> that in the event that such tender offer, merger, consolidation or other such transaction is not completed, such Securities held by the undersigned shall remain subject to the provisions of this Letter Agreement,

<u>provided</u> that in the case of any transfer, distribution or disposition pursuant to clause (B), (C), (E) or (F), each donee, distributee or transferee shall execute and deliver to the Representatives a lock-up letter in the form of this paragraph; and <u>provided</u>, <u>further</u>, that in the case of any transfer, distribution or disposition pursuant to clause (B), (C), (D) or (E)(ii), (iii) or (iv), 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 13D, 13F or 13G made after the expiration of the Restricted Period), or

other public announcement shall be required or shall be made voluntarily in connection with such transfer, distribution or disposition; and <u>provided</u>, <u>further</u>, in the case of clauses (B), (C) or E(ii), any such transfer shall not involve a disposition for value.

As used herein, "Family Member" shall mean the spouse of the undersigned, an immediate family member of the undersigned's spouse, in each case living in the undersigned's household or whose principal residence is the undersigned's household (regardless of whether such spouse or family member may at the time be living elsewhere due to educational activities, health care treatment, military service, temporary internship or employment or otherwise; an "immediate family member" shall mean any relationship by blood, marriage or adoption, not more remote than first cousin, and "Change of Control" shall mean the transfer (whether by tender offer, merger, consolidation or other similar transaction), in one transaction or a series of related transactions, to a "person" (as defined in Section 13(d)(3) of the Exchange Act) or "group" (as defined in Section 13(d)(3) of the Exchange Act) of affiliated persons, of securities if, after such transfer, such person or group of affiliated persons becomes the "beneficial owner" (as defined in Section 13(d)(3) of the Exchange Act) of more than 50% of the outstanding voting securities of the Company or the surviving entity.

In furtherance of the foregoing, the Company, and any duly appointed common depositary for the registration or transfer of the ADSs described herein, are hereby authorized to decline to make any transfer of securities if such transfer would constitute a violation or breach of this Letter Agreement.

The undersigned hereby represents and warrants that the undersigned has full power and authority to enter into this Letter Agreement. All authority herein conferred or agreed to be conferred and any obligations of the undersigned shall be binding upon the successors, assigns, heirs or personal representatives of the undersigned.

The undersigned understands that, if (i) either the Company or the Representatives notifies the other in writing prior to the execution of the Underwriting Agreement that it does not intend to proceed with the Public Offering, (ii) the Underwriting Agreement does not become effective by September 30, 2020, (iii) the Underwriting Agreement (other than the provisions thereof which survive termination) shall terminate or be terminated prior to payment for and delivery of the ADSs to be sold thereunder or (iv) the registration statement filed with the Securities and Exchange Commission in connection with the Public Offering is withdrawn, the undersigned shall be released from all obligations under this Letter Agreement. The undersigned understands that the Underwriters are entering into the Underwriting Agreement and proceeding with the Public Offering in reliance upon this Letter Agreement.

The undersigned acknowledges and agrees that the Underwriters have not provided any recommendation or investment advice nor have the Underwriters solicited any action from the undersigned with respect to the Public Offering of the Securities and the undersigned has consulted their own legal, accounting, financial, regulatory and tax advisors to the extent deemed appropriate. The undersigned further acknowledges and agrees that, although the Representatives may be required or choose to provide certain Regulation Best Interest and Form CRS disclosures to you in connection with the Public Offering, the Representatives and the other Underwriters are not making a recommendation to you to participate in the Public Offering, enter into this Letter Agreement, or sell any Securities at the price determined in the Public Offering, and nothing set forth in such disclosures is intended to suggest that the Representatives or any Underwriter is making such a recommendation.

This Letter Agreement and any claim, controversy or dispute arising under or related to this Letter Agreement shall be governed by and construed in accordance with the laws of the State of New York, without regard to the conflict of laws principles thereof.

## ARTICLES OF ASSOCIATION OF BIONTECH SE

#### I. General Provisions

## §1 Company Name, Registered Office and Financial Year

- (1) The name of the Company is "BioNTech SE".
- (2) The Company has its registered office in Mainz, Germany.
- (3) The financial year is the calendar year.

# §2 Purpose of Enterprise

- (1) The purpose of the Company is the research and development, manufacture and marketing of immunological and RNA-based drugs and test methods for the diagnosis, prevention and treatment of cancer, infectious diseases and other serious diseases.
- (2) The Company may undertake all transactions and actions that are expedient for serving the Company's purpose. It is also authorized to establish and acquire other companies and to invest in other companies, as well as to manage such companies or to limit itself to the administration of the investment.

#### §3 Announcements

All of the Company's announcements shall be made exclusively in the German Federal Gazette (Bundesanzeiger).

#### II. Share Capital and Shares

## §4 Amount and Division of Share Capital; Deviating Profit Participation

- (1) The Company's share capital totals EUR 238,197,961.00 and is divided into 238,197,961 no-par value shares.
- (2) Any right of the shareholders to request that share certificates be issued is excluded, to the extent permitted by law or unless certification is required under applicable stock exchange rules where the shares or rights or certificates representing them are admitted for trading. Global certificates for shares may be issued. Form and content of these certificates shall be determined by the Management Board.
- (3) The shares are registered shares.
- (4) In the event of a capital increase, the profit participation of new shares may be determined in deviation from section 60(2) sentence 3 German Stock Corporation Act (*AktG*).
- (5) The Management Board is authorized, with the consent of the Supervisory Board, to increase the Company's share capital in the period

up to 18 August 2024 on one occasion or on multiple occasions by up to a total of EUR 99,924,291.00 by issuing up to 99,924,291 new, no-par value registered shares against contributions in cash or in kind (Authorized Capital). In principle, the shareholders are to be granted a subscription right. The shares may also be acquired by one or more banking institution(s) or one or more companies operating according to section 53(1) sentence 1 Banking Act (*Kreditwesengesetz*; *KWG*) or section 53b(1) sentence 1 or (7) KWG, with the requirement that the shares are offered to the Company's shareholders for purchase (so-called indirect subscription right). The Management Board is authorized to exclude the subscription right of shareholders in one or more instance(s) of a capital increase as part of the Authorized Capital, subject to Supervisory Board approval,

- (a) to exclude fractional amounts from the subscription right,
- (b) in the case of a capital increase against cash contributions, if the issue price of the new shares is not significantly lower than the market price of the Company's shares already listed on the stock exchange at the time the issue price is finally determined. However, this authorization shall only apply provided that the shares issued excluding subscription rights in accordance with section 186(3) sentence 4 AktG may not exceed a total of 10% of the share capital either at the time this authorization takes effect or if this amount is lower at the time this authorization is exercised. This limit of 10% of the share capital includes shares which are issued or disposed of during the term of this authorization until the date of its exercise in direct or equivalent application of section 186(3) sentence 4 AktG. Shares which are used to service bonds with convertible or option rights or convertible obligations are to be offset against the 10% limit if these bonds were issued under exclusion of shareholder subscription rights in accordance with section 186(3) sentence 4 AktG during the entitlement period. Treasury shares are to be offset against the 10% limit, where they were disposed of by the Company during the term of this authorization with the exclusion of subscription rights pursuant to or in analogous application of section 186(3) sentence 4 AktG;
- (c) in the case of capital increases in exchange for contributions in kind, in particular in order to be able to offer the shares to third parties when purchasing companies, parts of companies or interests in companies as well as licenses or industrial property rights;
- (d) in order to grant subscription rights to new shares to holders of conversion or option rights in respect of bonds issued by the Company or its subordinated domestic or foreign group companies, to the extent to which they would be entitled after exercising their conversion or option rights or after fulfilling an agreed conversion obligation;

- (e) to implement an election dividend (*scrip dividend*/share dividend) by which shareholders are given the option to contribute their dividend entitlements to the Company (either in whole or part) as a contribution in kind against issuance of new shares in the Company;
- (f) if shares are issued to one or more investors on one or more occasions or in connection therewith to shareholders by way of co-investments (within the meaning of the **Annex to Section 4(5)**) on the basis of agreements concluded by 30 June 2020 at an issue price (including any further payment agreed under the law of obligations) of at least USD 18.10 (to this extent, the more detailed provisions of the Annex to Section 4(5) shall apply) and, in doing so, the provisions of the Annex to Section 4(5) are complied with. However, this authority to exclude the subscription right pursuant to this letter f) shall lapse if the shares of the Company or the rights or certificates representing them have been admitted to trading on a stock exchange or any other multilateral trading system,
- (g) in case shares are to be issued to a member of the Management Board of the Company or to another person who is employed by the Company or one of its affiliates and a minimum holding period of at least one year and the obligation to transfer back the shares in the event that the beneficiary is not employed by the Company or one of its affiliated companies for the entire duration of the holding period or any other agreed period is agreed upon. Additional restrictions with regard to the shares issued may be agreed upon.
- (h) in a capital increase effected after introduction of the Company's shares or certificates representing them to trading on a stock exchange or a multilateral trading system, if excluding subscription rights, according to the written declaration of an internationally renowned investment bank, is expedient to the shares' successful placement in view of the requirements of eligible investors and if the discount by which the issue price of the shares may be below the current stock exchange price at the time the Management Board adopts the resolution on using authorized capital, according to such declaration, does not exceed the extent necessary for a successful placement, and
- (i) to satisfy an option to acquire additional shares or American Depositary Shares agreed with issuing banks in connection with a public offer of the Company's shares in the form of American Depositary Shares.

The total number of new shares issued from the Authorized Capital and under exclusion of subscription rights pursuant to sentence 4 lit. a) to c) and h) above may not exceed 20% of the share capital, either at the time this authorization becomes effective or – if lower – at the time it is utilized. To be taken into account in the aforementioned 20%-limit are:

(i) those shares issued or to be issued to satisfy conversion or option rights or conversion or option obligations or tender rights of the issuer under bonds, if the bonds have been issued during the term of this authorization up to the time of its exercise, excluding the subscription rights of shareholders, as well as (ii) treasury shares that have been disposed under exclusion of subscription rights during the term of this authorization (except in the case of lit. b) para (v), (vi) or (vii) of the resolution to item no. 8 of the General Meeting of 19 August 2019).

The new shares participate in the profits as of the beginning of the first fiscal year for which the annual financial statements have not yet been submitted to the General Meeting at the time of registration of the implementation of the capital increase. The Management Board is authorized to determine further details of the capital increase and its implementation with the consent of the Supervisory Board.

- (6) The share capital is conditionally increased by up to EUR 21,874,806.00 by issuing up to 21,874,806 new registered no-par value shares each representing a notional value of EUR 1.00 of the share capital (Conditional Capital ESOP 2017/2019). The sole purpose of the Conditional Capital ESOP 2017/2019 is the grant of rights to holders of stock options issued by the Company under the authorization granted by the General Meeting of 18 August 2017 under agenda item 5.a), also in the version of such authorization as amended by resolution of the General Meeting of 19 August 2019 on agenda item 6.a) (together the "Authorization 2017/2019"). The shares shall be issued at the strike price determined in accordance with the provisions of the Authorization 2017/2019 in the version applicable at the time of its exercise. The conditional capital increase shall only be implemented to the extent that the holders of the stock options issued by the Company under the Authorization 2017/2019 exercise their subscription rights and the Company does not satisfy the stock options by delivering treasury shares or by a cash payment. The new shares shall be entitled to dividends from the beginning of the previous financial year if they are created by the exercise of subscription rights up until the start of the Annual General Meeting of the Company, and otherwise from the beginning of the financial year in which they are created as a result of the exercise of the stock options.
- (7) The share capital is conditionally increased by up to EUR 87,499,260.00 by issuing up to 87,499,260 new registered no-par value shares, each representing a notional value of EUR 1.00 of the share capital (Conditional Capital WSV 2019). The conditional capital increase shall only be carried out to the extent that the holders or creditors of option rights or conversion rights or those under an obligation to convert under warrant-linked or convertible bonds issued in return for cash contributions and issued or guaranteed by the Company or by a subordinate Company group entity up to, and including, 18 August 2024 based on Management Board authorisation as per the shareholder resolution conferring such authorisation passed at the General Meeting

of 19 August 2019 avail of their option rights or conversion rights or where they are under an obligation to convert, to the extent they satisfy their obligation to convert, or to the extent that the Company exercises a right to choose to grant Company shares, in whole or in part instead of paying a monetary amount due, and to the extent cash compensation is not granted in each relevant case or treasury shares or shares of another stock-listed company are not utilised for servicing. The new shares are issued at the warrant exercise price or conversion price to be determined in each case in accordance with the aforementioned resolution granting authorisation. The new shares shall carry an entitlement to dividends from the beginning of the financial year in which they are created; as far as the law permits, the Management Board can confer dividend rights of new shares in derogation of the foregoing and of section 60(2) AktG and also for a financial year that has already ended. The Management Board is authorised, subject to Supervisory Board approval, to determine the further details for implementing the conditional capital increase.

(8) To the extent that the above paragraphs provide for authorized or conditional capital, the Supervisory Board is authorized to amend the wording of the Articles of Association after expiry of the period for utilization of the authorized capital and in accordance with the extent of capital increases carried out on the basis thereof.

#### III. The Executive Bodies of the Company

## §5 Two-Tier System

- (1) The Company has a two-tier management and supervisory system consisting of a management body (Management Board) and a supervisory body (Supervisory Board).
- (2) The Company's executive bodies are the Management Board, the Supervisory Board and the General Meeting.

#### IV. Management Board

## §6 Composition

- (1) The Management Board shall consist of at least two persons. The members of the Management Board are appointed for a maximum term of five years. Reappointments are permitted.
- (2) The number of members of the Management Board is otherwise determined by the Supervisory Board.
- (3) The appointment of deputy members of the Management Board is permissible.

### §7 Management, Representation

- (1) The members of the Management Board shall conduct the business of the Company in accordance with the law, the Articles of Association and the rules of procedure issued by the Supervisory Board.
- (2) The Company shall be represented by two members of the Management Board or by one member of the Management Board jointly with one holder of a general commercial power of representation (*Prokurist*). If only one member of the Management Board is appointed, the Company will be represented by this individual alone. The Supervisory Board may grant one, several or all members of the Management Board sole power of representation.
- (3) The Supervisory Board may, by resolution, authorize members of the Management Board in general or in individual cases to conclude legal transactions simultaneously for the Company and as representatives of a company affiliated with the Company within the meaning of section 15 AktG as well as in individual cases simultaneously for the Company and as representatives of a third party.
- (4) The Supervisory Board may appoint a spokesman or a chairperson of the Management Board.
- (5) Furthermore, the Supervisory Board shall issue rules of procedure for the Management Board and shall determine in particular which types of business may only be transacted with its consent.

## §8 Passing of Resolutions

- (1) The Management Board is quorate if all members of the Management Board are invited and at least half of its members participate in the adoption of the resolution, unless otherwise required by mandatory law. Members of the Management Board may cast their vote in writing, by telephone, by telefax or by means of electronic media.
- (2) The resolutions of the Management Board are passed by a majority of the votes cast, unless otherwise required by mandatory law.

  Abstentions shall not to be taken into account. In the event of a tie the chairperson shall have a casting vote, if such person has been appointed. This does not apply to a spokesman of the Management Board who may have been appointed.

## V. Supervisory Board

## §9 Composition, Term of Office and Remuneration

- (1) The Supervisory Board shall comprise of four members.
- (2) Unless the General Meeting resolves on a shorter period when electing individual Supervisory Board members to be elected by it or for the full Supervisory Board, the Supervisory Board members shall be elected for a period ending no later than the end of the General Meeting which

- resolves on the discharge for the fourth financial year after the election. The fiscal year in which the term of office begins is not included in this calculation. Re-election is possible.
- (3) The successor to a member who leaves the Supervisory Board before the end of his or her term of office shall only be elected for the remainder of the term of office of the member who has left the Supervisory Board.
- (4) When electing Supervisory Board members, the General Meeting may for the same period elect a substitute member for several or all Supervisory Board members or as many substitute members as Supervisory Board members and determine the order in which they shall replace the Supervisory Board members who leave the Supervisory Board during their term of office for the remaining term of office.
- (5) Each member of the Supervisory Board may resign from office by submitting a written declaration to the Management Board. A period of one month must be observed.
- (6) In addition to reimbursement of their expenses, the members of the Supervisory Board receive an annual remuneration of EUR 50,000, the chairperson three times this amount and the deputy chairperson one and a half times this amount. The chairperson of the Audit Committee receives an additional annual remuneration of EUR 20,000. The members of the Supervisory Board who are only members of the Supervisory Board for part of the fiscal year or who chair or deputy chair the Supervisory Board or the Audit Committee receive the respective remuneration pro rata temporis. The same shall apply if this provision or a specific version of this provision is only in force for part of the financial year. If the reimbursement of out-of-pocket expenses or the remuneration is subject to value-added tax, value-added tax shall be payable in addition.

## §10 Chairperson and deputy

- (1) The Supervisory Board shall elect a chairperson and a deputy chairperson from among its members for the duration of its term of office. In these elections the oldest member of the Supervisory Board in terms of age is the chairperson. The deputy shall have the rights of the chairperson if the latter is prevented from attending or delegates his or her representation to him or her.
- (2) If the chairperson or his/her deputy departs prematurely from their office, then the Supervisory Board shall immediately hold a new election to cover the remaining term of office.

## §11 Convening and passing resolutions

(1) As far as possible, the Supervisory Board shall be convened in each calendar quarter. It must be convened twice every calendar half-year.

- (2) The meetings of the Supervisory Board shall be convened by the chairperson verbally, by telephone, in writing, by fax or by email, stating the agenda.
- (3) The Supervisory Board is quorate if at least three members participate in the adoption of the resolution. A member also participates in the adoption of a resolution if he or she abstains from voting.
- (4) Resolutions require a majority of the votes cast by the members of the Supervisory Board not taking into account any abstentions. In the case of a tie, the votes of the chairperson of the Supervisory Board or, if he does not participate in the passing of the resolution, the vote of the spokesman of the Supervisory Board shall be the casting vote.
- (5) Resolutions of the Supervisory Board are in principle passed at meetings with personal attendance of the members of the Supervisory Board. Absent members of the Supervisory Board may submit their written vote through another member of the Supervisory Board. Unless the chairperson of the Supervisory Board states otherwise in the invitation due to special circumstances of the individual case, it is permissible for Supervisory Board members to participate and cast their vote in a face-to-face meeting by telephone. The Supervisory Board may also vote without convening a meeting by doing so in writing, by telephone, fax, video conference or email, or in a combined resolution. The chairperson shall decide on the form in which resolutions are to be passed. The Rules of Procedure for the Supervisory Board may stipulate that resolutions are to be postponed in individual cases to be specified in more detail.
- (6) Minutes shall be taken of the meetings of the Supervisory Board and signed by the chairperson of the meeting. If resolutions are passed outside meetings, the minutes must be signed by the chairperson of the Supervisory Board and forwarded to all members without delay.
- (7) The chairperson is authorized to on behalf of the Supervisory Board make the declarations required to implement the resolutions and to receive the declarations addressed to the Supervisory Board.
- (8) The Supervisory Board is empowered to resolve upon changes and amendments to the Articles of Association as long as such changes only affect the wording.

# §12 Rules of Procedure

The Supervisory Board may issue Rules of Procedure for itself within the framework of the statutory provisions and the provisions of these Articles of Association.

## §13 Committees

The Supervisory Board may form committees and may refer items for resolution to these committees within the scope of what is permitted by law.

### VI. General Meeting

### §14 Venue and convocation

- (1) The General Meeting shall take place within the first six months of the expiry of the fiscal year at the registered office of the Company or in a German city with at least 500,000 inhabitants.
- (2) The General Meeting shall be convened by the Management Board or by the Supervisory Board.
- (3) Extraordinary General Meetings shall be convened when the best interests of the Company so require.

# §15 Chairing the General Meeting, Right to Participate, Participation of Supervisory Board Members

- (1) The General Meeting shall be chaired by the chairperson of the Supervisory Board or, in his/her absence, by his/her deputy or, in his/her absence, by another person determined by the Supervisory Board. If no such determination has been made, the chairperson of the meeting shall be elected by the General Meeting.
- (2) Shareholders registered in the share register are entitled to participate and exercise their voting rights in the General Meeting if they are registered with the Company in good time. The registration to attend the General Meeting must be in German or English and must be received by the Company at least six days prior to the meeting, unless a shorter period, expressed in days, is provided for in the invitation to the General Meeting, at the address and in the form (written form, text form or another (electronic) form further specified by the Company) as stipulated in such invitation. The day of the General Meeting and the day of receipt shall not be counted.
- (3) The chairperson of the meeting shall determine the order of items on the agenda as well as the type and form of voting. The chairperson is authorized to limit the question and speaking rights of the shareholders, as appropriate and to the extent permitted by law. In particular, he/she is authorized, at the beginning or during the course of the General Meeting, to set a reasonable time limit for the entire General Meeting, for discussion of particular items on the agenda or for any particular speech or question. Furthermore, the chairperson of the General Meeting may prematurely close the list of requests to speak and close the debate, as far as this is necessary for the proper execution of the General Meeting.
- (4) The chairperson of the General Meeting may permit the video and audio transmission of the General Meeting in whole or in part, including a transmission via the Internet.

## §16 Procedure, Minutes

- (1) Each share carries one vote.
- (2) Voting rights may be exercised by representatives. The power of attorney must be granted in text form by other means. The details shall be determined by the Company. They will be announced with the invitation to the General Meeting.
- (3) The Management Board is authorized to provide for shareholders to vote without attendance in the General Meeting in written form or by way of electronic communication (postal vote) as well as participate in the General Meeting and exercise all or some of their rights in whole or in part by means of electronic communication without physical participation and without being represented by a proxy (online participation). The Management Board determines the details of the postal vote as well as the scope and procedure of online participation in the invitation to the General Meeting. Minutes shall be kept of the proceedings and shall be signed by the chairperson of the Supervisory Board unless a notarial record is required by law.

#### §17 Resolution

- (1) Unless a larger majority is required by law or these Articles of Association, resolutions of the General Meeting shall be adopted by a simple majority of the votes cast. To the extent that statutory provisions also require a majority of the share capital present at the time the resolution is adopted, a simple majority of the share capital present shall suffice, unless a larger majority is required by law. In the event of an undecided vote, an agenda item shall be deemed rejected.
- (2) However, unless a larger majority is required by law, resolutions to amend the Articles of Association require a majority of at least two-thirds of the votes cast and of the share capital represented, if at least half of the share capital is not represented.
- (3) Should no majority be obtained in the first ballot in elections, the candidates with the two highest numbers of votes reached shall be put on a shortlist. If the election results in a tie between these two candidates, the decision shall be made by lot.

#### VII. Annual Financial Statements, Appropriation of Profits

## §18 Annual Financial Statements, Management Report

- (1) The Management Board shall prepare the Annual Financial Statements and any Management Report as well as the Consolidated Financial Statements and any Group Management Report for the past financial year within the statutory period.
- (2) The Management Board shall submit the Annual Financial Statements and any Management Report as well as the Consolidated Financial Statements and any Group Management Report to the Supervisory Board immediately after they have been prepared, together with its proposal to the General Meeting for the appropriation of net profit.

(3) The Supervisory Board shall examine the Annual Financial Statements, any Management Report of the Management Board, the Consolidated Financial Statements and any Group Management Report and the proposal for the appropriation of net profits, and shall report the results of its examination in writing to the General Meeting. It must forward its report to the Management Board within one month of receipt of the documents. Should the Supervisory Board approve the Annual Financial Statements after examination, they shall be adopted unless the Management Board and Supervisory Board decide to leave the adoption of the Annual Financial Statements to the General Meeting.

## §19 Retained Earnings

- (1) Should the Management Board and the Supervisory Board adopt the Annual Financial Statements, they may transfer amounts of up to half of the net profit for the year to retained earnings. In addition, they are authorized to transfer amounts to retained earnings of up to a further quarter of the net profit for the year, as long as the retained earnings do not exceed half of the share capital or insofar as they would not exceed half of the share capital after the transfer.
- (2) When calculating the portion of the net profit to be transferred to retained earnings in accordance with paragraph (1), allocations to the statutory reserve and accumulated losses carried forward shall be taken into account in advance.
- (3) The General Meeting shall resolve on the appropriation of profits retained resulting from the adopted Annual Financial Statements. It may allocate further portions of the profits retained to retained earnings, carry these profits forward to a new account also by way of distribution in kind or distribute them among the shareholders.

# VIII. Legal Disputes

#### §20 Jurisdiction of the US Federal Courts

In the case of litigation on the grounds of or in connection with federal or state capital market laws of the United States of America, only the United States District Court for the Southern District of New York or, in the case of it being replaced by any other first-instance Federal Court of the United States of America having judiciary over the borough of Manhattan, such court, shall be the competent court of jurisdiction, in each case insofar as this may be determined by these Articles of Association. This shall not affect any exclusive international jurisdiction under German or European law of the court located at the Company's registered office.

# IX. Expenses

# §21 Formation expenses

- (1) The formation costs of the Company shall be borne by FORATIS AG.
- (2) The Company shall bear the expenses of the formation of BioNTech SE by conversion of BioNTech AG into a European company (SE) in the amount of up to EUR 100,000.

### Annex to Section 4(5) of the Articles of Association

# Stipulations which are to be fulfilled in the event of an exclusion of the subscription right pursuant to Section 4(5) Sentence 4 Subsection (f) (the "new investor clause")

- (i) The portion of shares issued on the basis of the respective Management Board resolution on the utilization of the authorized capital (including the shares issued to shareholders on the basis of co-investments pursuant to item (iv)) should not exceed one tenth of the share capital existing at the time of the resolution. In the event that shares have already been issued previously using the authorization to exclude subscription rights in accordance with the new investor clause, said tenth shall be replaced by the aforementioned tenth less the fractions which the shares issued in each case represented in relation to the share capital existing at the time of the respective resolution of the Management Board.
- (ii) The issue price in US dollars (including any further payment agreed under the law of obligations) shall be converted into euros for the purpose of determining an issue price in euros on the basis of an exchange rate that is determined by the Management Board in its dutiful discretion and that is current at the time of the resolution on the issuance or, in the case of further payments agreed under the law of obligations, at the time of the request for further payment.
- (iii) Shareholders who hold a total of 60% of the Company's shares and among whom are Medine GmbH, the AT Impf GmbH, at least one Fidelity fund and at least one Redmile fund, have to approve the issuance of shares by declaration in text form. "Fidelity fund" or "Redmile fund" means any investment fund managed or advised by Fidelity Management & Research Company or any of its affiliates or, respectively, by Redmile Group LLC or any of its affiliates on the basis of a contract.
- (iv) In connection with any capital increase under exclusion of subscription rights pursuant to the new investor clause either (x) no shareholder nor any company affiliated with a shareholder will be given the opportunity to participate in the envisaged share issue, or (y) the Company will announce the envisaged share issue to each shareholder by email notifying the number of shares that the respective new investor intends to subscribe for, the issue price per share (including any further payment agreed under the law of obligations) and the total issue price to be paid by the respective investor (including, if applicable, the further payment), will request each shareholder, with a deadline of at least one week, to make a binding declaration in text form as to the extent to which he/she himself/herself wishes to subscribe for shares in the context of the relevant capital increase

("co-investment"), and offer those who have submitted the declaration in due time to conclude a corresponding subscription agreement by submitting a proper draft subscription form. Each shareholder may transfer or assign his or her right to co-invest to companies affiliated with him or, in the case of an investment fund, to another investment fund advised directly or indirectly by the same investment advisor or by an investment advisor affiliated to the same. The invitation and the offer shall be restricted (in the cases set out in letters b. and c. below in the event that a determination of the relevant content is made) to the extent that:

- a. the pro-rata amount of the share capital represented by the total shares to be subscribed for by way of co-investments in the context of the capital increase in question may not exceed the fraction set out in item (i) with the proviso that existing subscription requests are initially taken into account in proportion to the pro-rata shareholdings and are otherwise disregarded to the extent that this amount would otherwise be exceeded,
- b. the pro-rata amount of the share capital represented by the total number of shares to be subscribed for by way of co-investments within the framework of the capital increase in question may not exceed the amount determined in the invitation and the offer (which amounts to at least half of the total envisaged amount of the capital increase); in such a case, the provisions of letter a shall apply mutatis mutandis, and
- c. the co-investment is subject to the condition that, upon penalty of exclusion from the co-investment, within a period of at least five banking days to be determined by the Company, starting from the date of availability of the proper draft of the subscription form corresponding to the declaration (x) the Company receives the duly signed subscription form in two originals, and (y) that the issue amount (in whole or the part claimed by the Company) is fully paid.

	[Execution Copy]
BIONTECH SE	
AND	
THE BANK OF NEW YORK MELLON	
	As Depositary
AND	
OWNERS AND HOLDERS OF AMERICAN DEPOSITARY SHARES	
Deposit Agreement	
October 9, 2019	
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#### DEPOSIT AGREEMENT

DEPOSIT AGREEMENT dated as of October 9, 2019 among BIONTECH SE, a European stock corporation (*Societas Europea*) incorporated in Germany and governed by the laws of the European Union and the Federal Republic of Germany and registered with the commercial register (*Handelsregister*) of the local court (*Amtsgericht*) of Mainz, the Federal Republic of Germany, under number HRB 48720 (herein called the Company), THE BANK OF NEW YORK MELLON, a New York banking corporation (herein called the Depositary), and all Owners and Holders (each as hereinafter defined) from time to time of American Depositary Shares issued hereunder.

#### WITNESSETH:

WHEREAS, the Company desires to provide, as set forth in this Deposit Agreement, for the deposit of Shares (as hereinafter defined) of the Company from time to time with the Depositary or with the Custodian (as hereinafter defined) under this Deposit Agreement, for the creation of American Depositary Shares representing the Shares so deposited and for the execution and delivery of American Depositary Receipts evidencing the American Depositary Shares; and

WHEREAS, the American Depositary Receipts are to be substantially in the form of Exhibit A annexed to this Deposit Agreement, with appropriate insertions, modifications and omissions, as set forth in this Deposit Agreement;

NOW, THEREFORE, in consideration of the premises, it is agreed by and between the parties hereto as follows:

#### ARTICLE 1. DEFINITIONS

The following definitions shall for all purposes, unless otherwise clearly indicated, apply to the respective terms used in this Deposit Agreement:

## SECTION 1.1. American Depositary Shares.

The term "American Depositary Shares" shall mean the securities created under this Deposit Agreement representing rights with respect to the Deposited Securities. American Depositary Shares may be certificated securities evidenced by Receipts or uncertificated securities. The form of Receipt annexed as Exhibit A to this Deposit Agreement shall be the prospectus required under the Securities Act of 1933 for sales of both certificated and uncertificated American Depositary Shares. Except for those provisions of this Deposit Agreement that refer specifically to Receipts, all the provisions of this Deposit Agreement shall apply to both certificated and uncertificated American Depositary Shares.

Each American Depositary Share shall represent the number of Shares specified in Exhibit A to this Deposit Agreement, except that, if there is a distribution upon Deposited Securities covered by Section 4.3, a change in Deposited Securities covered by Section 4.8 with respect to which additional American Depositary Shares are not delivered or a sale of Deposited Securities under Section 3.2 or 4.8, each American Depositary Share shall thereafter represent the amount of Shares or other Deposited Securities that are then on deposit per American Depositary Share after giving effect to that distribution, change or sale.

## SECTION 1.2. Commission.

The term "Commission" shall mean the Securities and Exchange Commission of the United States or any successor governmental agency in the United States.

## SECTION 1.3. Company.

The term "<u>Company</u>" shall mean BioNTech SE, a European stock corporation (*Societas Europea*) incorporated in Germany and governed by the laws of the European Union and the Federal Republic of Germany and registered with the commercial register (*Handelsregister*) of the local court (*Amtsgericht*) of Mainz, the Federal Republic of Germany, under number HRB 48720, and its successors.

#### SECTION 1.4. Custodian.

The term "<u>Custodian</u>" shall mean The Bank of New York Mellon SA/NV, as custodian for the Depositary in the Federal Republic of Germany for the purposes of this Deposit Agreement, and any other firm or corporation the Depositary appoints under Section 5.5 as a substitute or additional custodian under this Deposit Agreement, and shall also mean all of them collectively.

## SECTION 1.5. Deliver; Surrender.

- (a) The term "<u>deliver</u>", or its noun form, when used with respect to Shares or other Deposited Securities, shall mean (i) book-entry transfer of those Shares or other Deposited Securities to an account maintained by an institution authorized under applicable law to effect transfers of such securities designated by the person entitled to that delivery or (ii) physical transfer of certificates evidencing those Shares or other Deposited Securities registered in the name of, or duly endorsed or accompanied by proper instruments of transfer to, the person entitled to that delivery.
- (b) The term "<u>deliver</u>", or its noun form, when used with respect to American Depositary Shares, shall mean (i) registration of those American Depositary Shares in the name of DTC or its nominee and book-entry transfer of those American Depositary Shares to an account at DTC designated by the person entitled to that

delivery, (ii) registration of those American Depositary Shares not evidenced by a Receipt on the books of the Depositary in the name requested by the person entitled to that delivery and mailing to that person of a statement confirming that registration or (iii) if requested by the person entitled to that delivery, execution and delivery at the Depositary's Office to the person entitled to that delivery of one or more Receipts evidencing those American Depositary Shares registered in the name requested by that person.

(c) The term "<u>surrender</u>", when used with respect to American Depositary Shares, shall mean (i) one or more book-entry transfers of American Depositary Shares to the DTC account of the Depositary, (ii) delivery to the Depositary at its Office of an instruction to surrender American Depositary Shares not evidenced by a Receipt or (iii) surrender to the Depositary at its Office of one or more Receipts evidencing American Depositary Shares.

## SECTION 1.6. Deposit Agreement.

The term "<u>Deposit Agreement</u>" shall mean this Deposit Agreement, as it may be amended from time to time in accordance with the provisions of this Deposit Agreement.

#### SECTION 1.7. Depositary; Depositary's Office.

The term "Depositary" shall mean The Bank of New York Mellon, a New York banking corporation, and any successor as depositary under this Deposit Agreement. The term "Office", when used with respect to the Depositary, shall mean the office at which its depositary receipts business is administered, which, at the date of this Deposit Agreement, is located at 240 Greenwich Street, New York, New York 10286.

## SECTION 1.8. Deposited Securities.

The term "<u>Deposited Securities</u>" as of any time shall mean Shares at such time deposited or deemed to be deposited under this Deposit Agreement, including without limitation, Shares that have not been successfully delivered upon surrender of American Depositary Shares, and any and all other securities, property and cash received by the Depositary or the Custodian in respect of Deposited Securities and at that time held under this Deposit Agreement.

#### SECTION 1.9. Disseminate.

The term "<u>Disseminate</u>," when referring to a notice or other information to be sent by the Depositary to Owners, shall mean (i) sending that information to Owners in paper form by mail or another means or (ii) with the consent of Owners, another procedure that has the effect of making the information available to Owners, which may include (A) sending the information by electronic mail or electronic messaging or (B)

sending in paper form or by electronic mail or messaging a statement that the information is available and may be accessed by the Owner on an Internet website and that it will be sent in paper form upon request by the Owner, when that information is so available and is sent in paper form as promptly as practicable upon request.

## SECTION 1.10. Dollars.

The term "Dollars" shall mean United States dollars.

#### SECTION 1.11. DTC.

The term "DTC" shall mean The Depository Trust Company or its successor.

#### SECTION 1.12. Foreign Registrar.

The term "<u>Foreign Registrar</u>" shall mean the entity that carries out the duties of registrar for the Shares and any other agent of the Company for the transfer and registration of Shares, including, without limitation, any securities depository for the Shares.

## SECTION 1.13. Holder.

The term "Holder" shall mean any person holding a Receipt or a security entitlement or other interest in American Depositary Shares, whether for its own account or for the account of another person, but that is not the Owner of that Receipt or those American Depositary Shares.

## SECTION 1.14. Owner.

The term "Owner" shall mean the person in whose name American Depositary Shares are registered on the books of the Depositary maintained for that purpose.

## SECTION 1.15. Receipts.

The term "Receipts" shall mean the American Depositary Receipts issued under this Deposit Agreement evidencing certificated American Depositary Shares, as the same may be amended from time to time in accordance with the provisions of this Deposit Agreement.

## SECTION 1.16. Registrar.

The term "Registrar" shall mean any corporation or other entity that is appointed by the Depositary to register American Depositary Shares and transfers of American Depositary Shares as provided in this Deposit Agreement.

## SECTION 1.17. Replacement.

The term "Replacement" shall have the meaning assigned to it in Section 4.8.

#### SECTION 1.18. Restricted Securities.

The term "Restricted Securities" shall mean Shares that (i) are "restricted securities," as defined in Rule 144 under the Securities Act of 1933, except for Shares that could be resold in reliance on Rule 144 without any conditions, (ii) are beneficially owned by an officer, director (or person performing similar functions) or other affiliate of the Company, (iii) otherwise would require registration under the Securities Act of 1933 in connection with the public offer and sale thereof in the United States or (iv) are subject to other restrictions on sale or deposit under the laws of the European Union or the Federal Republic of Germany, a shareholder agreement or the articles of association or similar document of the Company.

## SECTION 1.19. Securities Act of 1933.

The term "Securities Act of 1933" shall mean the United States Securities Act of 1933, as from time to time amended.

#### SECTION 1.20. Shares.

The term "Shares" shall mean ordinary shares of the Company that are validly issued and outstanding, fully paid and nonassessable and that were not issued in violation of any pre-emptive or similar rights of the holders of outstanding securities of the Company; <u>provided</u>, however, that, if there shall occur any change in nominal or par value, a split-up or consolidation or any other reclassification or, upon the occurrence of an event described in Section 4.8, an exchange or conversion in respect of the Shares of the Company, the term "Shares" shall thereafter also mean the successor securities resulting from such change in nominal value, split-up or consolidation or such other reclassification or such exchange or conversion.

## SECTION 1.21. SWIFT.

The term "<u>SWIFT</u>" shall mean the financial messaging network operated by the Society for Worldwide Interbank Financial Telecommunication, or its successor.

# SECTION 1.22. Termination Option Event.

The term "Termination Option Event" shall mean any of the following events or conditions:

- (i) the Company institutes proceedings to be adjudicated as bankrupt or insolvent, consents to the institution of bankruptcy or insolvency proceedings against it, files a petition or answer or consent seeking reorganization or relief under any applicable law in respect of bankruptcy or insolvency, consents to the filing of any petition of that kind or to the appointment of a receiver, liquidator, assignee, trustee, custodian or sequestrator (or other similar official) of it or any substantial part of its property or makes an assignment for the benefit of creditors, or if information becomes publicly available indicating that unsecured claims against the Company are not expected to be paid;
- (ii) the American Depositary Shares are delisted from a stock exchange in the United States on which the American Depositary Shares were listed and, 30 days after that delisting, the American Depositary Shares have not been listed on another stock exchange in the United States, nor is there a symbol available for over-the-counter trading of the American Depositary Shares in the United States;
- (iii) the Depositary has received notice of facts that indicate, or otherwise has reason to believe, that the American Depositary Shares have become ineligible for registration on Form F-6 under the Securities Act of 1933; or
  - (iv) an event or condition that is defined as a Termination Option Event in Section 4.1, 4.2 or 4.8.

# ARTICLE 2. FORM OF RECEIPTS, DEPOSIT OF SHARES, DELIVERY, TRANSFER AND SURRENDER OF AMERICAN DEPOSITARY SHARES

SECTION 2.1. Form of Receipts; Registration and Transferability of American Depositary Shares.

Definitive Receipts shall be substantially in the form set forth in Exhibit A to this Deposit Agreement, with appropriate insertions, modifications and omissions, as permitted under this Deposit Agreement. No Receipt shall be entitled to any benefits under this Deposit Agreement or be valid or obligatory for any purpose, unless that Receipt has been (i) executed by the Depositary by the manual signature of a duly authorized officer of the Depositary or (ii) executed by the facsimile signature of a duly authorized officer of the Depositary and countersigned by the manual signature of a duly authorized signatory of the Depositary or the Registrar or a co-registrar. The Depositary shall maintain books on which (x) each Receipt so executed and delivered as provided in this Deposit Agreement and each transfer of that Receipt and (y) all American Depositary Shares delivered as provided in this Deposit Agreement and all registrations of transfer of American Depositary Shares, shall be registered. A Receipt bearing the facsimile signature of a person that was at the time of signing a proper officer of the Depositary shall, subject to the other provisions of this paragraph, bind the Depositary, even if that person was not a proper officer of the Depositary on the date of issuance of that Receipt.

The Receipts and statements confirming registration of American Depositary Shares may, following consultation with the Company to the extent practicable, have incorporated in or attached to them such legends or recitals or modifications not inconsistent with the provisions of this Deposit Agreement as may be reasonably required by the Depositary or required to comply with any applicable law or regulations thereunder or with the rules and regulations of any securities exchange upon which American Depositary Shares may be listed or to conform with any usage with respect thereto, or to indicate any special limitations or restrictions to which any particular Receipts and American Depositary Shares are subject by reason of the date of issuance of the underlying Deposited Securities or otherwise.

American Depositary Shares evidenced by a Receipt, when the Receipt is properly endorsed or accompanied by proper instruments of transfer, shall be transferable as certificated registered securities under the laws of the State of New York. American Depositary Shares not evidenced by Receipts shall be transferable as uncertificated registered securities under the laws of the State of New York. The Depositary, notwithstanding any notice to the contrary, may treat the Owner of American Depositary Shares as the absolute owner thereof for the purpose of determining the person entitled to distribution of dividends or other distributions or to any notice provided for in this Deposit Agreement and for all other purposes, and neither the Depositary nor the Company shall have any obligation or be subject to any liability under this Deposit Agreement to any Holder of American Depositary Shares (but only to the Owner of those American Depositary Shares).

## SECTION 2.2. Deposit of Shares.

Subject to the terms and conditions of this Deposit Agreement, Shares or evidence of rights to receive Shares may be deposited under this Deposit Agreement by delivery thereof to any Custodian, accompanied by any appropriate instruments or instructions for transfer, or endorsement, in form satisfactory to the Custodian.

As conditions of accepting Shares for deposit, the Depositary may require (i) any certification reasonably required by the Depositary or the Custodian in accordance with the provisions of this Deposit Agreement, (ii) a written order directing the Depositary to deliver to, or upon the written order of, the person or persons stated in that order American Depositary Shares representing those deposited Shares, (iii) evidence satisfactory to the Depositary that those Shares have been re-registered in the books of the Company or the Foreign Registrar in the name of the Depositary, a Custodian or a nominee of the Depositary or a Custodian, (iv) evidence satisfactory to the Depositary that any necessary approval for the transfer or deposit has been granted by any governmental body in each applicable jurisdiction and (v) an agreement or assignment, or other instrument satisfactory to the Depositary, that provides for the prompt transfer to the Custodian of any dividend, or right to subscribe for additional Shares or to receive other property, that any person in whose name those Shares are or have been recorded may thereafter receive upon or in respect of those Shares, or, in lieu thereof, such agreement of indemnity or other agreement as shall be satisfactory to the Depositary.

At the request and risk and expense of a person proposing to deposit Shares, and for the account of that person, the Depositary may receive certificates for Shares to be deposited, together with the other instruments specified in this Section, for the purpose of forwarding those Share certificates to the Custodian for deposit under this Deposit Agreement.

The Depositary shall instruct each Custodian that, upon each delivery to a Custodian of a ce1iificate or certificates for Shares to be deposited under this Deposit Agreement, together with the other documents specified in this Section, that Custodian shall, as soon as transfer and recordation can be accomplished, present that certificate or those certificates to the Company or the Foreign Registrar, if applicable, for transfer and recordation of the Shares being deposited in the name of the Depositary or its nominee or that Custodian or its nominee.

Deposited Securities shall be held by the Depositary or by a Custodian for the account and to the order of the Depositary or at such other place or places as the Depositary shall determine. The Depositary shall, as soon as practicable, provide written notice to the Company if Deposited Securities will be held other than by the Depositary or a Custodian.

The Depositary shall make reasonable efforts to comply with written instructions received from the Company not to knowingly accept for deposit under this Deposit Agreement any Shares identified in those instructions at the times and the circumstances specified in those instructions, in order to facilitate the Company's compliance with the securities laws of the United States.

## SECTION 2.3. Delivery of American Depositary Shares.

The Depositary shall instruct each Custodian that, upon receipt by that Custodian of any deposit pursuant to Section 2.2, together with the other documents or evidence required under that Section, that Custodian shall notify the Depositary of that deposit and the person or persons to whom or upon whose written order American Depositary Shares are deliverable in respect thereof. Upon receiving a notice of a deposit from a Custodian, or upon the receipt of Shares or evidence of the right to receive Shares by the Depositary, the Depositary, subject to the terms and conditions of this Deposit Agreement, shall deliver, to or upon the order of the person or persons entitled thereto, the number of American Depositary Shares issuable in respect of that deposit, but only upon payment to the Depositary of the fees and expenses of the Depositary for the delivery of those American Depositary Shares as provided in Section 5.9, and of all taxes and governmental charges and fees payable in connection with that deposit and the transfer of the deposited Shares. However, the Depositary shall deliver only whole numbers of American Depositary Shares.

# SECTION 2.4. <u>Registration of Transfer of American Depositary Shares; Combination and Split-up of Receipts; Interchange of Certificated</u> and Uncertificated American Depositary Shares.

The Depositary, subject to the terms and conditions of this Deposit Agreement, shall, without unreasonable delay, register a transfer of American Depositary Shares on its transfer books upon (i) in the case of certificated American Depositary Shares, surrender of the Receipt evidencing those American Depositary Shares, by the Owner or by a duly authorized attorney, properly endorsed or accompanied by proper instruments of transfer or (ii) in the case of uncertificated American Depositary Shares, receipt from the Owner of a proper instruction (including, for the avoidance of doubt, instructions through DRS and Profile as provided in Section 2.9), and, in either case, duly stamped as may be required by the laws of the State of New York and of the United States of America. Upon registration of a transfer, the Depositary shall, without unreasonable delay, deliver the transferred American Depositary Shares to or upon the order of the person entitled thereto.

The Depositary, subject to the terms and conditions of this Deposit Agreement, shall upon surrender of a Receipt or Receipts for the purpose of effecting a split-up or combination of such Receipt or Receipts, without unreasonable delay, execute and deliver a new Receipt or Receipts for any authorized number of American Depositary Shares requested, evidencing the same aggregate number of American Depositary Shares as the Receipt or Receipts surrendered.

The Depositary, upon surrender of certificated American Depositary Shares for the purpose of exchanging for uncertificated American Depositary Shares, shall, without unreasonable delay, cancel the Receipt evidencing those certificated American Depositary Shares and send the Owner a statement confirming that the Owner is the owner of the same number of uncertificated American Depositary Shares. The Depositary, upon receipt of a proper instruction (including, for the avoidance of doubt, instructions through DRS and Profile as provided in Section 2.9) from the Owner of uncertificated American Depositary Shares for the purpose of exchanging for certificated American Depositary Shares, shall, without unreasonable delay, cancel those uncertificated American Depositary Shares and register and deliver to the Owner a Receipt evidencing the same number of certificated American Depositary Shares.

The Depositary may appoint one or more co-transfer agents for the purpose of effecting registration of transfers of American Depositary Shares and combinations and split-ups of Receipts at designated transfer offices on behalf of the Depositary. In carrying out its functions, a co-transfer agent may require evidence of authority and compliance with applicable laws and other requirements by Owners or persons entitled to American Depositary Shares and will be entitled to protection and indemnity to the same extent as the Depositary.

#### SECTION 2.5. Surrender of American Depositary Shares and Withdrawal of Deposited Securities.

Upon surrender of American Depositary Shares for the purpose of withdrawal of the Deposited Securities represented thereby and payment of the fee of the Depositary for the surrender of American Depositary Shares as provided in Section 5.9 and payment of all taxes and governmental charges payable in connection with that surrender and withdrawal of the Deposited Securities, and subject to the terms and conditions of this Deposit Agreement, the Owner of those American Depositary Shares shall be entitled to delivery (to the extent delivery can then be lawfully and practicably made), to or as instructed by that Owner, of the amount of Deposited Securities at the time represented by those American Depositary Shares, but not any money or other property as to which a record date for distribution to Owners has passed (since money or other property of that kind will be delivered or paid on the scheduled payment date to the Owner as of that record date), and except that the Depositary shall not be required to accept surrender of American Depositary Shares for the purpose of withdrawal to the extent it would require delivery of a fraction of a Deposited Security. That delivery shall be made, as provided in this Section, without unreasonable delay.

As a condition of accepting a surrender of American Depositary Shares for the purpose of withdrawal of Deposited Securities, the Depositary may require (i) that each surrendered Receipt be properly endorsed in blank or accompanied by proper instruments of transfer in blank and (ii) that the surrendering Owner execute and deliver to the Depositary a written order directing the Depositary to cause the Deposited Securities being withdrawn to be delivered to or upon the written order of a person or persons designated in that order.

Thereupon, the Depositary shall direct the Custodian to deliver, subject to Sections 2.6, 3.1 and 3.2, the other terms and conditions of this Deposit Agreement and local market rules and practices, to the surrendering Owner or to or upon the written order of the person or persons designated in the order delivered to the Depositary as above provided, the amount of Deposited Securities represented by the surrendered American Depositary Shares, and the Depositary may charge the surrendering Owner a fee and its expenses for giving that direction by cable (including SWIFT) or facsimile transmission.

If Deposited Securities are delivered physically upon surrender of American Depositary Shares for the purpose of withdrawal, that delivery will be made at the Custodian's office, except that, at the request, risk and expense of an Owner surrendering American Depositary Shares for withdrawal of Deposited Securities, and for the account of that Owner, the Depositary shall direct the Custodian to forward any cash or other property comprising, and forward a certificate or certificates, if applicable, and other proper documents of title, if any, for, the Deposited Securities represented by the surrendered American Depositary Shares to the Depositary for delivery at the Depositary's Office or to another address specified m the order received from the surrendering Owner.

#### SECTION 2.6. Limitations on Delivery, Registration of Transfer and Surrender of American Depositary Shares.

As a condition precedent to the delivery, registration of transfer or surrender of any American Depositary Shares or split-up or combination of any Receipt or withdrawal of any Deposited Securities, the Depositary, Custodian or Registrar may require payment from the depositor of Shares or the presenter of the Receipt or instruction for registration of transfer or surrender of American Depositary Shares not evidenced by a Receipt of a sum sufficient to reimburse it for any tax or other governmental charge and any stock transfer or registration fee with respect thereto (including any such tax or charge and fee with respect to Shares being deposited or withdrawn) and payment of any applicable fees as provided in this Deposit Agreement, may require the production of proof satisfactory to it as to the identity and genuineness of any signature and may also require compliance with any regulations the Depositary may establish consistent with the provisions of this Deposit Agreement, including, without limitation, this Section 2.6.

The Depositary may refuse to accept deposits of Shares for delivery of American Depositary Shares or to register transfers of American Depositary Shares in particular instances, or may suspend deposits of Shares or registration of transfer generally, whenever it or the Company considers it necessary or advisable to do so. The Depositary may refuse surrenders of American Depositary Shares for the purpose of withdrawal of Deposited Securities in particular instances, or may suspend surrenders for the purpose of withdrawal generally, but, notwithstanding anything to the contrary in this Deposit Agreement, only for (i) temporary delays caused by closing of the Depositary's register or the register of holders of Shares maintained by the Company or the Foreign Registrar, or the deposit of Shares, in connection with voting at a shareholders' meeting or the payment of dividends, (ii) the payment of fees, taxes and similar charges, (iii) compliance with any U.S. or foreign laws or governmental regulations relating to the American Depositary Shares or to the withdrawal of the Deposited Securities or (iv) any other reason that, at the time of the Depositary's refusal or suspension, is permitted under paragraph I(A)(l) of the General Instructions to Form F-6 under the Securities Act of 1993 or any successor to that provision. In each case of (i)-(iv), the Depositary shall notify the Company as promptly as practicable of any such refusal, suspension or delay that is outside the ordinary course of business.

The Depositary shall not knowingly accept for deposit under this Deposit Agreement any Shares that, at the time of deposit, are Restricted Securities.

## SECTION 2.7. Lost Receipts, etc.

If a Receipt is mutilated, destroyed, lost or stolen, the Depositary shall deliver to the Owner the American Depositary Shares evidenced by that Receipt in uncertificated form or, if requested by the Owner, execute and deliver a new Receipt of like tenor in exchange and substitution for such mutilated Receipt, upon surrender and cancellation of that mutilated Receipt, or in lieu of and in substitution for that destroyed, lost or stolen Receipt. However, before the Depositary will deliver American Depositary Shares in uncertificated form or execute and deliver a new Receipt, in substitution for a destroyed, lost or stolen Receipt, the Owner must (a) file with the Depositary (i) a request for that replacement before the Depositary has notice that the Receipt has been acquired by a bona fide purchaser and (ii) a sufficient indemnity bond and (b) satisfy any other reasonable requirements imposed by the Depositary.

## SECTION 2.8. Cancellation and Destruction of Surrendered Receipts.

The Depositary shall cancel all Receipts surrendered to it and is authorized to destroy Receipts so cancelled.

## SECTION 2.9. DTC Direct Registration System and Profile Modification System.

(a) Notwithstanding the provisions of Section 2.4, the parties acknowledge that DTC's Direct Registration System ("<u>DRS</u>") and Profile Modification System ("<u>Profile</u>") apply to the American Depositary Shares upon acceptance thereof to DRS by DTC. DRS is the system administered by DTC that facilitates interchange between registered holding of uncertificated securities and holding of security entitlements in those securities through DTC and a DTC participant. Profile is a required feature of DRS that allows a DTC participant, claiming to act on behalf of an Owner of American Depositary Shares, to direct the Depositary to register a transfer of those American Depositary Shares to DTC or its nominee and to deliver those American Depositary Shares to the DTC account of that DTC participant without receipt by the Depositary of prior authorization from the Owner to register that transfer.

(b) In connection with DRS/Profile, the parties acknowledge that the Depositary will not determine whether the DTC participant that is claiming to be acting on behalf of an Owner in requesting a registration of transfer and delivery as described in paragraph (a) above has the actual authority to act on behalf of that Owner (notwithstanding any requirements under the Uniform Commercial Code). For the avoidance of doubt, the provisions of Sections 5.3 and 5.8 apply to the matters arising from the use of the DRS/Profile. The parties agree that the Depositary's reliance on and compliance with instructions received by the Depositary through the DRS/Profile system and otherwise in accordance with this Deposit Agreement shall not constitute negligence or bad faith on the part of the Depositary.

#### ARTICLE 3. CERTAIN OBLIGATIONS OF OWNERS AND HOLDERS OF AMERICAN DEPOSITARY SHARES

SECTION 3.1. Filing Proofs, Certificates and Other Information.

Any person presenting Shares for deposit or any Owner or Holder may be required from time to time to file with the Depositary or the Custodian such proof of citizenship or residence, exchange control approval, or such information relating to the registration on the books of the Company or the Foreign Registrar, if applicable, to execute such certificates and to make such representations and warranties, as the Depositary may deem necessary or proper. The Depositary may withhold the delivery or registration of transfer of American Depositary Shares, the distribution of any dividend or other distribution or of the proceeds thereof or the delivery of any Deposited Securities until that proof or other information is filed or those certificates are executed or those representations and warranties are made. The Depositary shall provide the Company with copies of any information or other materials that it receives pursuant to this Section 3.1, to the extent that disclosure is permitted under applicable law.

## SECTION 3.2. Liability of Owner for Taxes.

If any tax or other governmental charge shall become payable by the Custodian or the Depositary with respect to or in connection with any American Depositary Shares or any Deposited Securities represented by any American Depositary Shares or in connection with a transaction to which Section 4.8 applies, that tax or other governmental charge shall be payable by the Owner of those American Depositary Shares to the Depositary. The Depositary may refuse to register any transfer of those American Depositary Shares or any withdrawal of Deposited Securities represented by those American Depositary Shares until that payment is made, and may withhold any dividends or other distributions or the proceeds thereof, or may sell for the account of the Owner any part or all of the Deposited Securities represented by those American Depositary Shares and apply those dividends or other distributions or the net proceeds of any sale of that kind in payment of that tax or other governmental charge but, even after a sale of that kind, the Owner of those American Depositary Shares shall remain liable for any deficiency. Neither the Company nor the Depositary shall be liable for failure of an Owner or Holder to comply with applicable tax laws or to pay applicable governmental charges. The Depositary shall distribute any net proceeds of a sale made under this Section that are not used to pay taxes or governmental charges to the Owners entitled to them in accordance with Section 4.1. If the number of Shares represented by each American Depositary Share decreases as a result of a sale of Deposited Securities under this Section, the Depositary may call for surrender of the American Depositary Shares to be exchanged on a mandatory basis for a lesser number of American Depositary Shares in that exchange and distribute the net proceeds of that sale to the Owners entitled to them.

#### SECTION 3.3. Warranties on Deposit of Shares.

Every person depositing Shares under this Deposit Agreement shall be deemed thereby to represent and warrant that those Shares and each certificate therefor, if applicable, are validly issued, fully paid and nonassessable and were not issued in violation of any preemptive or similar rights of the holders of outstanding securities of the Company and that the person making that deposit is duly authorized so to do. Every depositing person shall also be deemed to represent that the Shares, at the time of deposit, are not Restricted Securities. All representations and warranties deemed made under this Section shall survive the deposit of Shares and delivery of American Depositary Shares.

#### SECTION 3.4. Disclosure of Interests.

Owners and Holders may be subject to German and European Union law notification and mandatory transfer ("squeeze-out") requirements regarding their holdings of American Depositary Shares and Shares and should acquaint themselves with applicable German and European Union law regarding such requirements.

When required in order to comply with applicable laws and regulations (including the rules and requirements of any stock exchange on which the American Depositary Shares are or will be traded or listed, or the rules and requirements of any clearing system through which transactions in the American Depositary Shares may be settled) or the articles of association or similar document of the Company, the Company may from time to time request each Owner and Holder to provide to the Depositary information relating to: (a) the capacity in which it holds American Depositary Shares, (b) the identity of any Holders or other persons or entities then or previously interested in those American Depositary Shares and the nature of those interests and (c) any other matter where disclosure of such matter is required for that compliance, in each case within the time period prescribed by the Company. Each Owner and Holder agrees to provide all information known to it in response to a request made pursuant to this Section. Each Holder consents to the disclosure by the Depositary and the Owner or any other Holder through which it holds American Depositary Shares, directly or indirectly, of all information responsive to a request made pursuant to this Section relating to that Holder that is known to that Owner or other Holder. The Depositary agrees to use reasonable efforts to comply with written instructions requesting that the Depositary forward any request authorized under this Section to the Owners and to forward to the Company any responses it receives in response to that request. The Depositary may charge the Company a fee and its expenses for complying with requests under this Section 3.4.

Each Owner and Holder of American Depositary Shares further agrees to comply with the laws and regulations of the European Union and the Federal Republic of Germany (if and to the extent applicable) with respect to the disclosure requirements regarding ownership or potential for ownership of Shares, all as if the American Depositary Shares were the Shares represented thereby, which is deemed to include, inter alia, requirements to make notifications and filings within the required timeframes to the Company and any other authorities of the European Union and the Federal Republic of Germany.

#### ARTICLE 4. THE DEPOSITED SECURITIES

#### SECTION 4.1. Cash Distributions.

Whenever the Depositary receives any cash dividend or other cash distribution on Deposited Securities, the Depositary shall, subject to the provisions of Section 4.5, convert that dividend or other distribution into Dollars and distribute the amount thus received (net of the fees and expenses of the Depositary as provided in Section 5.9) to the Owners entitled thereto, in proportion to the number of American Depositary Shares representing those Deposited Securities held by them respectively; <a href="mailto:provided">provided</a>, however, that if the Custodian or the Depositary shall be required to withhold and does withhold from that cash dividend or other cash distribution an amount on account of taxes or other governmental charges, the amount distributed to the Owners of the American Depositary Shares representing those Deposited Securities shall be reduced accordingly. <a href="However">However</a>, the Depositary will not pay any Owner a fraction of one cent, but will round each Owner's entitlement to the nearest whole cent.

The Company or its agent will remit to the appropriate governmental agency in each applicable jurisdiction all amounts withheld and owing to such agency.

If a cash distribution would represent a return of all or substantially all the value of the Deposited Securities underlying American Depositary Shares, the Depositary may require surrender of those American Depositary Shares and may require payment of or deduct the fee for surrender of American Depositary Shares (whether or not it is also requiring surrender of American Depositary Shares) as a condition of making that cash distribution. A distribution of that kind shall be a <u>Termination Option Event</u>.

## SECTION 4.2. Distributions Other Than Cash, Shares or Rights.

Subject to the provisions of Sections 4.11 and 5.9, whenever the Depositary receives any distribution other than a distribution described in Section 4.1, 4.3 or 4.4 on Deposited Securities (but not in exchange for or in conversion or in lieu of Deposited Securities), the Depositary shall, as promptly as practicable, cause the securities or property received by it to be distributed to the Owners entitled thereto, after deduction or upon payment of any fees and expenses of the Depositary and any taxes or other governmental charges, in proportion to the number of American Depositary Shares representing such Deposited Securities held by them respectively, in any manner that the Depositary reasonably deems equitable and practicable for accomplishing that distribution (which may be a distribution of depositary shares representing the securities received); provided, however, that if in the reasonable opinion of the Depositary such distribution cannot be made proportionately among the Owners entitled thereto, or if for

any other reason (including, but not limited to, any requirement that the Company or the Depositary withhold an amount on account of taxes or other governmental charges or that securities received must be registered under the Securities Act of 1933 in order to be distributed to Owners or Holders) the Depositary deems such distribution not to be lawful and feasible, the Depositary may adopt, after consultation with the Company to the extent practicable, such other method as it may deem equitable and practicable for the purpose of effecting such distribution, including, but not limited to, the public or private sale of the securities or property thus received, or any part thereof, and distribution of the net proceeds of any such sale (net of the fees and expenses of the Depositary as provided in Section 5.9), as promptly as practicable, to the Owners entitled thereto, all in the manner and subject to the conditions set forth in Section 4.1. The Depositary may withhold any distribution of securities under this Section 4.2 if it has not received reasonably satisfactory assurances from the Company that the distribution does not require registration under the Securities Act of 1933. The Depositary may sell, by public or private sale, an amount of securities or other property it would otherwise distribute under this Section 4.2 that is sufficient to pay its fees and expenses in respect of that distribution.

If a distribution under this Section 4.2 would represent a return of all or substantially all the value of the Deposited Securities underlying American Depositary Shares, the Depositary may require surrender of those American Depositary Shares and may require payment of or deduct the fee for surrender of American Depositary Shares (whether or not it is also requiring surrender of American Depositary Shares) as a condition of making that distribution. A distribution of that kind shall be a <u>Termination Option Event</u>.

#### SECTION 4.3. <u>Distributions in Shares.</u>

Whenever the Depositary receives any distribution on Deposited Securities consisting of a dividend in, or free distribution of, Shares, the Depositary may, and shall if the Company so requests in writing, deliver to the Owners entitled thereto, in proportion to the number of American Depositary Shares representing those Deposited Securities held by them respectively, an aggregate number of American Depositary Shares representing the amount of Shares received as that dividend or free distribution, subject to the terms and conditions of this Deposit Agreement with respect to the deposit of Shares and issuance of American Depositary Shares, including withholding of any tax or governmental charge as provided in Section 4.11 and payment of the fees and expenses of the Depositary as provided in Section 5.9 (and the Depositary may sell, by public or private sale, an amount of the Shares received (or American Depositary Shares representing those Shares) sufficient to pay its fees and expenses in respect of that distribution). In lieu of delivering fractional American Depositary Shares, the Depositary may sell the amount of Shares represented by the aggregate of those fractions (or American Depositary Shares representing those Shares) and distribute the net proceeds, as promptly as practicable, all in the manner and subject to the conditions described in

Section 4.1. If and to the extent that additional American Depositary Shares are not delivered and Shares or American Depositary Shares are not sold, each American Depositary Share shall thenceforth also represent the additional Shares distributed on the Deposited Securities represented thereby.

If the Company declares a distribution in which holders of Deposited Securities have a right to elect whether to receive cash, Shares or other securities or a combination of those things, or a right to elect to have a distribution sold on their behalf, the Depositary may, after consultation with the Company, make that right of election available for exercise by Owners in any manner the Depositary reasonably considers to be lawful and practical. As a condition of making a distribution election right available to Owners, the Depositary may require reasonably satisfactory assurances from the Company that doing so does not require registration of any securities under the Securities Act of 1933.

## SECTION 4.4. Rights.

(a) If rights are granted to the Depositary in respect of deposited Shares to purchase additional Shares or other securities, the Company and the Depositary shall endeavor to consult as to the actions, if any, the Depositary should take in connection with that grant of rights. The Depositary may, to the extent reasonably deemed by it to be lawful and practical (i) if requested in writing by the Company, grant to all or certain Owners rights to instruct the Depositary to purchase the securities to which the rights relate and deliver those securities or American Depositary Shares representing those securities to Owners, (ii) if requested in writing by the Company, deliver the rights to or to the order of certain Owners, or (iii) sell the rights to the extent practicable and distribute the net proceeds of that sale to Owners entitled to those proceeds. To the extent rights are not exercised, delivered or disposed of under (i), (ii) or (iii) above, the Depositary shall permit the rights to lapse unexercised.

(b) If the Depositary will act under (a)(i) above, the Company and the Depositary will enter into a separate agreement setting forth the conditions and procedures applicable to the particular offering. Upon instruction from an applicable Owner in the form the Depositary specified and upon payment by that Owner to the Depositary of an amount equal to the purchase price of the securities to be received upon the exercise of the rights, the Depositary shall, on behalf of that Owner, exercise the rights and purchase the securities. The purchased securities shall be delivered to, or as instructed by, the Depositary. The Depositary shall (i) deposit the purchased Shares under this Deposit Agreement and deliver American Depositary Shares representing those Shares to that Owner or (ii) deliver or cause the purchased Shares or other securities to be delivered to or to the order of that Owner. The Depositary will not act under (a)(i) above unless the offer and sale of the securities to which the rights relate are registered under the Securities Act of 1933 or the Depositary has received an opinion of United States counsel that is reasonably satisfactory to it to the effect that those securities may be sold and delivered to the applicable Owners without registration under the Securities Act of 1933.

- (c) If the Depositary will act under (a)(ii) above, the Company and the Depositary will enter into a separate agreement setting forth the conditions and procedures applicable to the particular offering. Upon (i) the request of an applicable Owner to deliver the rights allocable to the American Depositary Shares of that Owner to an account specified by that Owner to which the rights can be delivered and (ii) receipt of such documents as the Company and the Depositary agreed to require to comply with applicable law, the Depositary will deliver those rights as requested by that Owner.
- (d) If the Depositary will act under (a)(iii) above, the Depositary will use reasonable efforts to sell the rights in proportion to the number of American Depositary Shares held by the applicable Owners and pay the net proceeds to the Owners otherwise entitled to the rights that were sold, upon an averaged or other practical basis without regard to any distinctions among such Owners because of exchange restrictions or the date of delivery of any American Depositary Shares or otherwise.
- (e) Payment or deduction of the fees of the Depositary as provided in Section 5.9 and payment or deduction of the expenses of the Depositary and any applicable taxes or other governmental charges shall be conditions of any delivery of securities or payment of cash proceeds under this Section 4.4.
- (:f) The Depositary shall not be responsible for any failure to determine that it may be lawful or feasible to make rights available to or exercise rights on behalf of Owners in general or any Owner in particular, or to sell rights.

## SECTION 4.5. Conversion of Foreign Currency.

Whenever the Depositary or the Custodian receives foreign currency, by way of dividends or other distributions or the net proceeds from the sale of securities, property or rights, and if at the time of the receipt thereof the foreign currency so received can in the judgment of the Depositary be converted on a reasonable basis into Dollars and the resulting Dollars transferred to the United States, the Depositary shall, as promptly as reasonably practicable, convert or cause to be converted by sale or in any other manner that it may determine that foreign currency into Dollars, and those Dollars shall be distributed, as promptly as practicable, to the Owners entitled thereto. A cash distribution may be made upon an averaged or other practicable basis without regard to any distinctions among Owners based on exchange restrictions, the date of delivery of any American Depositary Shares or otherwise and shall be net of any expenses of conversion into Dollars incurred by the Depositary as provided in Section 5.9.

If a conversion of foreign currency or the repatriation or distribution of Dollars can be effected only with the approval or license of any government or agency thereof, the Depositary may, but will not be required to, file an application for that approval or license.

If the Depositary, after consultation with the Company to the extent practicable, determines that in its reasonable judgment any foreign currency received by the Depositary or the Custodian is not convertible on a reasonable basis into Dollars transferable to the United States, or if any approval or license of any government or agency thereof that is required for such conversion is not filed or sought by the Depositary or is not obtained within a reasonable period as determined by the Depositary, the Depositary may distribute the foreign currency received by the Depositary to, or in its discretion may hold such foreign currency uninvested and without liability for interest thereon for the respective accounts of, the Owners entitled to receive the same.

If any conversion of foreign currency, in whole or in part, cannot be effected for distribution to some of the Owners entitled thereto, the Depositary may in its discretion make that conversion and distribution in Dollars to the extent practicable and permissible to the Owners entitled thereto and may distribute the balance of the foreign currency received by the Depositary to, or hold that balance uninvested and without liability for interest thereon for the respective accounts of, the Owners entitled thereto.

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 this 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 this 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 Owners, subject to the Depositary's obligations under Section 5.3. The methodology used to determine exchange rates used in currency conversions is available upon request.

## SECTION 4.6. Fixing of Record Date.

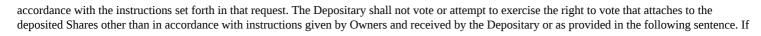
Whenever a cash dividend, cash distribution or any other distribution is made on Deposited Securities or rights to purchase Shares or other securities are issued with respect to Deposited Securities (which rights will be delivered to or exercised or sold on behalf of Owners in accordance with Section 4.4) or the Depositary receives notice that a distribution or issuance of that kind will be made, or whenever the Depositary receives notice that a meeting of holders of Shares will be held in respect of which the Company has requested the Depositary to send a notice under Section 4.7, or whenever the Depositary will assess a fee or charge against the Owners, or whenever the Depositary causes a change in the number of Shares that are represented by each

American Depositary Share, or whenever the Depositary otherwise finds it necessary or convenient, the Depositary shall fix a record date, which shall be the same as, or as near as practicable to, any corresponding record date set by the Company with respect to Shares, (a) for the determination of the Owners (i) who shall be entitled to receive the benefit of that dividend or other distribution or those rights, (ii) who shall be entitled to give instructions for the exercise of voting rights at that meeting, (iii) who shall be responsible for that fee or charge or (iv) for any other purpose for which the record date was set, or (b) on or after which each American Depositary Share will represent the changed number of Shares. Subject to the provisions of Sections 4.1 through 4.5 and to the other terms and conditions of this Deposit Agreement, the Owners on a record date fixed by the Depositary shall be entitled to receive the amount distributable by the Depositary with respect to that dividend or other distribution or those rights or the net proceeds of sale thereof in proportion to the number of American Depositary Shares held by them respectively, to give voting instructions or to act in respect of the other matter for which that record date was fixed, or be responsible for that fee or charge, as the case may be.

## SECTION 4.7. Voting of Deposited Shares.

(a) Upon receipt of notice of any meeting of holders of Shares at which holders of Shares will be entitled to vote, if requested in writing by the Company, the Depositary shall, as soon as practicable thereafter, Disseminate to the Owners a notice, the form of which shall be in the sole discretion of the Depositary, that shall contain (i) the information contained in the notice of meeting received by the Depositary, (ii) a statement that the Owners as of the close of business on a specified record date will be entitled, subject to any applicable provision of European Union or German law and of the articles of association or similar documents of the Company, to instruct the Depositary as to the exercise of the voting rights pertaining to the amount of Shares represented by their respective American Depositary Shares, (iii) a statement as to the manner in which those instructions may be given, including an express indication that instructions may be given or deemed given in accordance with the last sentence of paragraph (b) below, if no instruction is received, to the Depositary to vote those Shares or cause them to be voted in favor of any resolution that has been proposed (*Beschlussvorschlag*) in the formal notice of the meeting pursuant to § 121 of the Stock Corporation Act (*Einberufung*) (each such resolution being referred to as a "Proposal") and (iv) the last date on which the Depositary will accept instructions (the "Instruction Cutoff Date").

(b) Upon the written request of an Owner of American Depositary Shares, as of the date of the request or, if a record date was specified by the Depositary, as of that record date, received on or before any Instruction Cutoff Date established by the Depositary, the Depositary may, and if the Depositary sent a notice under the preceding paragraph shall, endeavor, in so far as practicable, to vote or cause to be voted the amount of deposited Shares represented by those American Depositary Shares in



- (i) the Company instructed the Depositary to Disseminate a notice under paragraph (a) above and complied with paragraph (d) below,
- (ii) no instructions are received by the Depositary from an Owner with respect to a Proposal and an amount of American Depositary Shares of that Owner on or before the Instruction Cutoff Date, and
- (iii) the Depositary has received from the Company, by the business day following the Instruction Cutoff Date, a written confirmation that, as of the Instruction Cutoff Date, (x) the Company wishes the Depositary to vote or cause to be voted Shares under this sentence, (y) the Company reasonably does not know of any substantial opposition to the Proposal and (z) the Proposal is not materially adverse to the interests of shareholders

then, the Depositary shall deem that Owner to have instructed the Depositary to vote, and the Depositary shall endeavor, insofar as practicable, to vote or cause to be voted that amount of deposited Shares in favor of the Proposal.

- (c) There can be no assurance that Owners generally or any Owner in particular will receive the notice described in paragraph (a) above in time to enable Owners to give instructions to the Depositary prior to the Instruction Cutoff Date.
- (d) In order to give Owners a reasonable opportunity to instruct the Depositary as to the exercise of voting rights relating to Shares, if the Company will request the Depositary to Disseminate a notice under paragraph (a) above, the Company shall give the Depositary notice of the meeting, details concerning the matters to be voted upon, including the resolutions, copies of materials to be made available to holders of Shares in connection with the meeting and an indication whether each of those matters is a Proposal, not less than 30 days prior to the meeting date.

## SECTION 4.8. Tender and Exchange Offers; Redemption, Replacement or Cancellation of Deposited Securities.

(a) The Depositary shall not tender any Deposited Securities in response to any voluntary cash tender offer, exchange offer or similar offer made to holders of Deposited Securities (a "<u>Voluntary Offer</u>"), except when instructed in writing to do so by an Owner surrendering American Depositary Shares and subject to any conditions or procedures the Depositary may require.

(b) If the Depositary receives a written notice that Deposited Securities have been redeemed for cash or otherwise purchased for cash in a transaction that is mandatory and binding on the Depositary as a holder of those Deposited Securities (a "Redemption"), the Depositary, at the expense of the Company (unless otherwise agreed between the Company and the Depositary in writing), shall (i) if required, surrender Deposited Securities that have been redeemed to the issuer of those securities or its agent on the redemption date, (ii) Disseminate a notice to Owners (A) notifying them of that Redemption, (B) calling for surrender of a corresponding number of American Depositary Shares and (C) notifying them that the called American Depositary Shares have been converted into a right only to receive the money received by the Depositary upon that Redemption and those net proceeds shall be the Deposited Securities to which Owners of those converted American Depositary Shares shall be entitled upon surrenders of those American Depositary Shares in accordance with Section 2.5 or 6.2 and (iii) distribute the money received upon that Redemption, as promptly as practicable, to the Owners entitled to it upon surrender by them of called American Depositary Shares in accordance with Section 2.5 (and, for the avoidance of doubt, Owners shall not be entitled to receive that money under Section 4.1). If the Redemption affects less than all the Deposited Securities, the Depositary shall call for surrender a corresponding portion of the outstanding American Depositary Shares and only those American Depositary Shares will automatically be converted into a right to receive the net proceeds of the Redemption. The Depositary shall allocate the American Depositary Shares converted under the preceding sentence among the Owners pro-rata to their respective holdings of American Depositary Shares is allocated to any Owner. A Redemption of all or substantially all of the Deposited Securities shall be a Termination Option Event.

(c) If the Depositary is notified of or there occurs any change in nominal value or any subdivision, combination or any other reclassification of the Deposited Securities or any recapitalization, reorganization, sale of assets substantially as an entirety, merger or consolidation affecting the issuer of the Deposited Securities or to which it is a party that is mandatory and binding on the Depositary as a holder of Deposited Securities and, as a result, securities or other property have been or will be delivered in exchange, conversion, replacement or in lieu of, Deposited Securities (a "Replacement"), the Depositary shall, if required, surrender the old Deposited Securities affected by that Replacement of Shares and hold, as new Deposited Securities under this Deposit Agreement, the new securities or other property delivered to it in that Replacement. However, the Depositary may elect to sell those new Deposited Securities if in the reasonable opinion of the Depositary it is not lawful or not practical for it to hold those new Deposited Securities under this Deposit Agreement because those new Deposited Securities may not be distributed to Owners without registration under the Securities Act of 1933 or for any other reason, at public or private sale, at such places and on such terms as it reasonably deems proper and proceed as if those new Deposited Securities had been Redeemed under paragraph (b) above. A Replacement shall be a Termination Option Event.

(d) In the case of a Replacement where the new Deposited Securities will continue to be held under this Deposit Agreement, the Depositary may call for the surrender of outstanding Receipts to be exchanged for new Receipts specifically describing the new Deposited Securities and the number of those new Deposited Securities represented by each American Depositary Share. If the number of Shares represented by each American Depositary Share decreases as a result of a Replacement, the Depositary may call for surrender of the American Depositary Shares to be exchanged on a mandatory basis for a lesser number of American Depositary Shares and may sell American Depositary Shares to the extent necessary to avoid distributing fractions of American Depositary Shares in that exchange and distribute the net proceeds of that sale, as promptly as practicable, to the Owners entitled to them.

(e) If there are no Deposited Securities with respect to American Depositary Shares, including if the Deposited Securities are cancelled, or the Deposited Securities with respect to American Depositary Shares have become apparently worthless, (i) the Depositary may (A) call for surrender of those American Depositary Shares or (B) cancel those American Depositary Shares, upon notice to Owners, and (ii) that condition shall be a <u>Termination Option Event</u>.

## SECTION 4.9. Reports.

The Depositary shall make available for inspection by Owners at its Office any reports and communications, including any proxy solicitation material, received from the Company which are both (a) received by the Depositary as the holder of the Deposited Securities and (b) made generally available to the holders of those Deposited Securities by the Company. The Company shall furnish reports and communications, including any proxy soliciting material to which this Section applies, to the Depositary in English, to the extent those materials are required to be translated into English pursuant to any regulations of the Commission.

## SECTION 4.10. Lists of Owners.

Upon written request by the Company, the Depositary shall, as promptly as practicable and at the expense of the Company, furnish to it a list, as of a recent date, of the names, addresses and American Depositary Share holdings of all Owners.

## SECTION 4.11. Withholding,

If the Depositary determines that any distribution received or to be made by the Depositary (including Shares and rights to subscribe therefor) is subject to any tax or other governmental charge that the Depositary is obligated to withhold, the Depositary may sell, by public or private sale, all or a portion of the distributed property (including

Shares and rights to subscribe therefor) in the amounts and manner the Depositary deems necessary and practicable to pay those taxes or charges, and the Depositary shall distribute the net proceeds of that sale, after deduction of those taxes or charges, to the Owners entitled thereto in proportion to the number of American Depositary Shares held by them respectively.

Services for Owners and Holders that may permit them to obtain reduced rates of tax withholding at source or reclaim excess tax withheld, and the fees and costs associated with using services of that kind, are not provided under, and are outside the scope of, this Deposit Agreement.

Each Owner and Holder agrees to indemnify the Company, the Depositary, the Custodian and their respective directors, employees, agents and affiliates for, and hold each of them harmless against, any claim by any governmental authority with respect to taxes, additions to tax, penalties or interest arising out of any refund of taxes, reduced withholding at source or other tax benefit received by it.

## ARTICLE 5. THE DEPOSITARY, THE CUSTODIANS AND THE COMPANY

# SECTION 5.1. Maintenance of Office and Register by the Depositary.

Until termination of this Deposit Agreement in accordance with its terms, the Depositary shall maintain facilities for the delivery, registration of transfers and surrender of American Depositary Shares in accordance with the provisions of this Deposit Agreement.

The Depositary shall keep a register of all Owners and all outstanding American Depositary Shares, which shall be open for inspection by the Owners at the Depositary's Office during regular business hours, but only for the purpose of communicating with Owners regarding the business of the Company or a matter related to this Deposit Agreement or the American Depositary Shares.

The Depositary may close the register for delivery, registration of transfer or surrender for the purpose of withdrawal from time to time as provided in Section 2.6.

If any American Depositary Shares are listed on one or more stock exchanges, the Depositary shall act as Registrar or appoint a Registrar or one or more co-registrars for registration of those American Depositary Shares in accordance with any requirements of that exchange or those exchanges.

The Company shall have the right, at all reasonable times, to inspect transfer and registration records of the Depositary relating the American Depositary Shares and to require the Depositary to supply, at the Company's expense, copies of any part of those records that it reasonably requests.

SECTION 5.2. Prevention or Delay of Performance by the Company or the Depositary.

Neither the Depositary nor the Company nor any of their respective directors, employees, agents or affiliates shall incur any liability to any Owner or Holder:

- (i) if by reason of (A) any provision of any present or future law or regulation or other act of the government of the United States or the Federal Republic of Germany, the European Union, any State of the United States or any other state or jurisdiction, or of any governmental or regulatory authority or stock exchange; (B) (in the case of the Depositary only) any provision, present or future, of the articles of association or similar document of the Company, or any provision of any securities issued or distributed by the Company, or any offering or distribution thereof; or (C) any event or circumstance, whether natural or caused by a person or persons, that is beyond the ability of the Depositary or the Company, as the case may be, to prevent or counteract by reasonable care or effort (including, but not limited to, earthquakes, floods, severe storms, fires, explosions, war, terrorism, civil unrest, labor disputes or criminal acts; interruptions or malfunctions of utility services, Internet or other communications lines or systems; unauthorized access to or attacks on computer systems or websites; or other failures or malfunctions of computer hardware or software or other systems or equipment), the Depositary or the Company is, directly or indirectly, prevented from, forbidden to or delayed in, or could be subject to any civil or criminal penalty on account of doing or performing and therefore does not do or perform, any act or thing that, by the terms of this Deposit Agreement or the Deposited Securities, it is provided shall be done or performed;
- (ii) for any exercise of, or failure to exercise, any discretion provided for in this Deposit Agreement (including any determination by the Depositary to take, or not take, any action that this Deposit Agreement provides the Depositary may take);
- (iii) for the inability of any Owner or Holder to benefit from any distribution, offering, right or other benefit that is made available to holders of Deposited Securities but is not, under the terms of this Deposit Agreement, made available to Owners or Holders; or
  - (iv) for any special, consequential or punitive damages for any breach of the terms of this Deposit Agreement.

Where, by the terms of a distribution to which Section 4.1, 4.2 or 4.3 applies, or an offering to which Section 4.4 applies, or for any other reason, that distribution or offering may not be made available to Owners, and the Depositary may not dispose of that distribution or offering on behalf of Owners and make the net proceeds available to Owners, then the Depositary shall not make that distribution or offering available to Owners, and shall allow any rights, if applicable, to lapse.

## SECTION 5.3. Obligations of the Depositary and the Company.

The Company, its supervisory board members, management board members, employees, agents and affiliates assume no obligation nor shall any of them be subject to any liability under this Deposit Agreement to any Owner or Holder, except that the Company agrees to perform its obligations specifically set forth in this Deposit Agreement without negligence or bad faith.

The Depositary, its officers, directors, employees, agents and affiliates assume no obligation nor shall any of them be subject to any liability under this Deposit Agreement to any Owner or Holder (including, without limitation, liability with respect to the validity or worth of the Deposited Securities), except that the Depositary agrees to perform its obligations specifically set forth in this Deposit Agreement without negligence or bad faith, and the Depositary shall not be a fiduciary or have any fiduciary duty to Owners or Holders.

Neither the Depositary nor the Company shall be under any obligation to appear in, prosecute or defend any action, suit or other proceeding in respect of any Deposited Securities or in respect of the American Depositary Shares on behalf of any Owner or Holder or any other person.

Each of the Depositary and the Company may rely, and shall be protected in relying upon, any written notice, request, direction or other document believed by it to be genuine and to have been signed or presented by the proper party or parties.

Neither the Depositary nor the Company shall be liable for any action or non-action by it in reliance upon the advice of or information from legal counsel, accountants, any person presenting Shares for deposit, any Owner or any other person believed by it in good faith to be competent to give such advice or information.

The Depositary shall not be liable for any acts or omissions made by a successor depositary whether in connection with a previous act or omission of the Depositary or in connection with any matter arising wholly after the removal or resignation of the Depositary, provided that in connection with the issue out of which such potential liability arises the Depositary performed its obligations without negligence or bad faith while it acted as Depositary.

The Depositary shall not be liable for the acts or omissions of any securities depository, clearing agency or settlement system in connection with or arising out of book-entry settlement of American Depositary Shares or Deposited Securities or otherwise.

In the absence of bad faith on its part, the Depositary shall not be responsible for any failure to carry out any instructions to vote any of the Deposited Securities, or for the manner in which any such vote is cast or the effect of any such vote.

The Depositary shall have no duty to make any determination or provide any information as to the tax status of the Company or any liability for any tax consequences that may be incurred by Owners or Holders as a result of owning or holding American Depositary Shares. The Depositary shall not be liable for the inability or failure of an Owner or 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.

No disclaimer of liability under the United States federal securities laws is intended by any provision of this Deposit Agreement.

## SECTION 5.4. Resignation and Removal of the Depositary.

The Depositary may at any time resign as Depositary hereunder by written notice of its election so to do delivered to the Company, to become effective upon the appointment of a successor depositary and its acceptance of that appointment as provided in this Section. The effect of resignation if a successor depositary is not appointed is provided for in Section 6.2.

The Depositary may at any time be removed by the Company by 90 days' prior written notice of that removal, to become effective upon the later of (i) the 90th day after delivery of the notice to the Depositary and (ii) the appointment of a successor depositary and its acceptance of its appointment as provided in this Section.

If the Depositary resigns or is removed, the Company shall use commercially reasonable efforts to appoint a successor depositary, which shall be a bank or trust company having an office in the Borough of Manhattan, The City of New York. Every successor depositary shall execute and deliver to the Company an instrument in writing accepting its appointment under this Deposit Agreement. If the Depositary receives notice from the Company that a successor depositary has been appointed following its resignation or removal, the Depositary, upon payment of all sums due it from the Company, shall deliver to its successor a register listing all the Owners and their respective holdings of outstanding American Depositary Shares and shall deliver the Deposited Securities to or to the order of its successor. When the Depositary has taken the actions specified in the preceding sentence (i) the successor shall become the Depositary and shall have all the rights and shall assume all the duties of the Depositary under this Deposit Agreement and (ii) the predecessor depositary shall cease to be the Depositary and shall be discharged and released from all obligations under this Deposit Agreement, except for its duties under Section 5.8 with respect to the time before that discharge. A successor Depositary shall notify the Owners of its appointment as soon as practical after assuming the duties of Depositary.

Any corporation or other entity into or with which the Depositary may be merged or consolidated shall be the successor of the Depositary without the execution or filing of any document or any further act.

## SECTION 5.5. The Custodians.

The Custodian shall be subject at all times and in all respects to the directions of the Depositary and shall be responsible solely to it. The Depositary in its discretion may at any time appoint a substitute or additional custodian or custodians, each of which shall thereafter be one of the Custodians under this Deposit Agreement. If the Depositary receives notice that a Custodian is resigning and, upon the effectiveness of that resignation there would be no Custodian acting under this Deposit Agreement, the Depositary shall, as promptly as practicable after receiving that notice, appoint a substitute custodian or custodians, each of which shall thereafter be a Custodian under this Deposit Agreement. The Depositary shall require any Custodian that resigns or is removed to deliver all Deposited Securities held by it to another Custodian.

## SECTION 5.6. Notices and Reports.

If the Company takes or decides to take any corporate action of a kind that is addressed in Sections 4.1 to 4.4, or 4.6 to 4.8, or that effects or will effect a change of the name or legal structure of the Company, or that effects or will effect a change to the Shares, the Company shall notify the Depositary and the Custodian of that action or decision as soon as it is lawful and practical to give that notice. The notice shall be in English and shall include all details that the Company is required to include in any notice to any governmental or regulatory authority or securities exchange or is required to make available generally to holders of Shares by publication or otherwise.

The Company will arrange for the translation into English, if not already in English, to the extent required pursuant to any regulations of the Commission, and the prompt transmittal by the Company to the Depositary and the Custodian of all notices and any other reports and communications which are made generally available by the Company to holders of its Shares. If requested in writing by the Company, the Depositary will Disseminate, as promptly as practicable, at the Company's expense, those notices, reports and communications to all Owners or otherwise make them available to Owners in a manner that the Company specifies as substantially equivalent to the manner in which those communications are made available to holders of Shares and compliant with the requirements of any securities exchange on which the American Depositary Shares are listed. The Company will timely provide the Depositary with the quantity of such notices, reports, and communications, as requested by the Depositary from time to time, in order for the Depositary to effect that Dissemination.

The Company represents that as of the date of this Deposit Agreement, the statements in Article 11 of the Receipt with respect to the Company's obligation to file periodic reports under the United States Securities Exchange Act of 1934, as amended, are true and correct. The Company agrees to promptly notify the Depositary upon becoming aware of any change in the truth of any of those statements.

## SECTION 5.7. Distribution of Additional Shares, Rights, etc.

If the Company or any affiliate of the Company determines to make any issuance or distribution of (1) additional Shares, (2) rights to subscribe for Shares, (3) securities convertible into Shares, or (4) rights to subscribe for such securities (each a "<u>Distribution</u>"), the Company shall notify the Depositary in writing in English as promptly as practicable and in any event before the Distribution starts and, if requested in writing by the Depositary, the Company shall promptly furnish to the Depositary either (i) evidence reasonably satisfactory to the Depositary that the Distribution is registered under the Securities Act of 1933 or (ii) a written opinion from U.S. counsel for the Company that is reasonably satisfactory to the Depositary, stating that the Distribution does not require, or, if made in the United States, would not require, registration under the Securities Act of 1933.

Nothing in this Section 5.7 or elsewhere in this Deposit Agreement shall create any obligation of the Company or the Depositary to file a registration statement under the Securities Act of 1933 in respect of any securities or rights.

The Company agrees with the Depositary that neither the Company nor any company controlled by, controlling or under common control with the Company will at any time deposit any Shares that, at the time of deposit, are Restricted Securities.

## SECTION 5.8. Indemnification.

The Company agrees to indemnify the Depositary, its directors, employees, agents and affiliates and each Custodian against, and hold each of them harmless from, any liability or expense (including, but not limited to any fees and expenses incurred in seeking, enforcing or collecting such indemnity and the reasonable fees and expenses of counsel) that may arise out of or in connection with (a) any registration with the Commission of American Depositary Shares or Deposited Securities or the offer or sale thereof or (b) acts performed or omitted, pursuant to the provisions of or in connection with this Deposit Agreement and the American Depositary Shares, as the same may be amended, modified or supplemented from time to time, (i) by either the Depositary or a Custodian or their respective directors, employees, agents and affiliates, except for any liability or expense arising out of the negligence or bad faith of either of them, or (ii) by the Company or any of its directors, employees, agents and affiliates.

The Depositary agrees to indemnify the Company, its directors, employees, agents and affiliates and hold them harmless from any liability or expense (including, but not limited to any fees and expenses incurred in seeking, enforcing or collecting such indemnity and the reasonable fees and expenses of counsel) that may arise out of acts performed or omitted by the Depositary or any Custodian or their respective directors, employees, agents and affiliates due to their negligence or bad faith.

Any person seeking indemnification hereunder (an "Indemnified Person") shall notify the person from whom it is seeking indemnification (the "Indemnifying Person") of the commencement of any indemnifiable action or claim promptly after such Indemnified Person becomes aware of such commencement and shall consult in good faith with the Indemnifying Person as to the conduct of the defense of such action or claim, which defense shall be reasonable under the circumstances. No Indemnified Person shall compromise or settle any such action or claim without the consent in writing of the Indemnifying Person (which shall not be unreasonably withheld).

## SECTION 5.9. Charges of Depositary.

The following charges shall be incurred by any party depositing or withdrawing Shares or by any party surrendering American Depositary Shares or to whom American Depositary Shares are issued (including, without limitation, issuance pursuant to a stock dividend or stock split declared by the Company or an exchange of stock regarding the American Depositary Shares or Deposited Securities or a delivery of American Depositary Shares pursuant to Section 4.3), or by Owners, as applicable: (1) taxes and other governmental charges, (2) such registration fees as may from time to time be in effect for the registration of transfers of Shares generally on the Share register of the Company or Foreign Registrar and applicable to transfers of Shares to or from the name of the Depositary or its nominee or the Custodian or its nominee on the making of deposits or withdrawals hereunder, (3) such cable (including SWIFT) and facsimile transmission fees and expenses as are expressly provided in this Deposit Agreement, (4) such expenses as are incurred by the Depositary in the conversion of foreign currency pursuant to Section 4.5, (5) a fee of \$5.00 or less per 100 American Depositary Shares (or portion thereof) for the delivery of American Depositary Shares pursuant to Section 2.3, 4.3 or 4.4 and the surrender of American Depositary Shares pursuant to Section 2.5 or 6.2, (6) a fee of \$.05 or less per American Depositary Share (or portion thereof) for any cash distribution made pursuant to this Deposit Agreement, including, but not limited to Sections 4.1 through 4.4 and Section 4.8, (7) a fee for the distribution of securities pursuant to Section 4.2 or of rights pursuant to Section 4.4 (where the Depositary will not exercise or sell those rights on behalf of Owners), such fee being in an amount equal to the fee for the execution and delivery of American Depositary Shares referred to above which would have been charged as a result of the deposit of such securities under this Deposit Agreement (for purposes of this item 7 treating all such securities as if they were Shares) but which securities are instead distributed by the Depositary to Owners, (8) in addition to any fee charged under item 6 above, a fee of \$.05 or less per American Depositary Share (or portion thereof) per annum for depositary services, which will be payable as provided in item 9 below, and (9) any other charges payable by the Depositary or the Custodian, any of the Depositary's or Custodian's agents or the agents of the Depositary's or Custodian's agents, in connection with the servicing of Shares or other Deposited Securities (which charges shall be assessed against Owners as of the date or dates set by the Depositary in accordance with Section 4.6 and shall be payable at the sole discretion of the Depositary by billing those Owners for those charges or by deducting those charges from one or more cash dividends or other cash distributions).

The Depositary may collect any of its fees by deduction from any cash distribution payable, or by selling a portion of any securities to be distributed, to Owners that are obligated to pay those fees.

In performing its duties under this 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 own and deal in any class of securities of the Company and its affiliates and in American Depositary Shares.

## SECTION 5.10. Retention of Depositary Documents.

The Depositary is authorized to destroy those documents, records, bills and other data compiled during the term of this Deposit Agreement at the times permitted by the laws or regulations governing the Depositary.

## SECTION 5.11. Exclusivity.

Without prejudice to the Company's rights under Section 5.4, the Company agrees not to appoint any other depositary for issuance of depositary shares, depositary receipts or any similar securities or instruments so long as The Bank of New York Mellon is acting as Depositary under this Deposit Agreement.

## SECTION 5.12. Information for Regulatory Compliance.

Each of the Company and the Depositary shall provide to the other, as promptly as practicable, information from its records or otherwise available to it that is reasonably requested by the other to permit the other to comply with applicable law or requirements of governmental or regulatory authorities.

## ARTICLE 6. AMENDMENT AND TERMINATION

## SECTION 6.1. Amendment.

The form of the Receipts and any provisions of this Deposit Agreement may at any time and from time to time be amended by agreement between the Company and the Depositary without the consent of Owners or Holders in any respect that they may deem necessary or desirable. Any amendment that would impose or increase any fees or charges (other than taxes and other governmental charges, registration fees, cable (including SWIFT) or facsimile transmission costs, delivery costs or other such

expenses), or that would otherwise prejudice any substantial existing right of Owners, shall, however, not become effective as to outstanding American Depositary Shares until the expiration of 30 days after notice of that amendment has been Disseminated to the Owners of outstanding American Depositary Shares. Every Owner and Holder, at the time any amendment so becomes effective, shall be deemed, by continuing to hold American Depositary Shares or any interest therein, to consent and agree to that amendment and to be bound by this Deposit Agreement as amended thereby. Upon the effectiveness of an amendment to the form of Receipt, including a change in the number of Shares represented by each American Depositary Share, the Depositary may call for surrender of Receipts to be replaced with new Receipts in the amended form or call for surrender of American Depositary Shares to effect that change of ratio. In no event shall any amendment impair the right of the Owner to surrender American Depositary Shares and receive delivery of the Deposited Securities represented thereby, except in order to comply with mandatory provisions of applicable law.

## SECTION 6.2. Termination.

- (a) The Company may initiate termination of this Deposit Agreement by notice to the Depositary. The Depositary may initiate termination of this Deposit Agreement if (i) at any time 60 days shall have expired after the Depositary delivered to the Company a written resignation notice and a successor depositary has not been appointed and accepted its appointment as provided in Section 5.4 or (ii) a Termination Option Event has occurred. If termination of this Deposit Agreement is initiated, the Depositary shall Disseminate a notice of termination to the Owners of all American Depositary Shares then outstanding setting a date for termination (the "Termination Date"), which shall be at least 90 days after the date of that notice, and this Deposit Agreement shall terminate on that Termination Date.
- (b) After the Termination Date, the Company shall be discharged from all obligations under this Deposit Agreement except for its obligations to the Depositary under Sections 5.8 and 5.9.
- (c) At any time after the Termination Date, the Depositary may sell the Deposited Securities then held under this Deposit Agreement and may thereafter hold uninvested the net proceeds of any such sale, together with any other cash then held by it hereunder, unsegregated and without liability for interest, for the pro rata benefit of the Owners of American Depositary Shares that remain outstanding, and those Owners will be general creditors of the Depositary with respect to those net proceeds and that other cash. After making that sale, the Depositary shall be discharged from all obligations under this Deposit Agreement, except (i) to account for the net proceeds and other cash (after deducting, in each case, the fee of the Depositary for the surrender of American Depositary Shares, any expenses for the account of the Owner of such American Depositary Shares in accordance with the terms and conditions of this Deposit Agreement and any applicable taxes or governmental charges) and (ii) for its obligations under Section 5.8 and (iii) to act as provided in paragraph (d) below.

(d) After the Termination Date, the Depositary shall continue to receive dividends and other distributions pertaining to Deposited Securities (that have not been sold), may sell rights and other property as provided in this Deposit Agreement and shall deliver Deposited Securities (or sale proceeds) upon surrender of American Depositary Shares (after payment or upon deduction, in each case, of the fee of the Depositary for the surrender of American Depositary Shares, any expenses for the account of the Owner of those American Depositary Shares in accordance with the terms and conditions of this Deposit Agreement and any applicable taxes or governmental charges). After the Termination Date, the Depositary shall not accept deposits of Shares or deliver American Depositary Shares. After the Termination Date, (i) the Depositary may refuse to accept surrenders of American Depositary Shares for the purpose of withdrawal of Deposited Securities (that have not been sold) or reverse previously accepted surrenders of that kind that have not settled if in its judgment the requested withdrawal would interfere with its efforts to sell the Deposited Securities, (ii) the Depositary will not be required to deliver cash proceeds of the sale of Deposited Securities until all Deposited Securities have been sold and (iii) the Depositary may discontinue the registration of transfers of American Depositary Shares and suspend the distribution of dividends and other distributions on Deposited Securities to the Owners and need not give any further notices or perform any further acts under this Deposit Agreement except as provided in this Section.

#### ARTICLE 7. MISCELLANEOUS

## SECTION 7.1. Counterparts; Signatures; Delivery.

This Deposit Agreement may be executed in any number of counterparts, each of which shall be deemed an original and all of those counterparts shall constitute one and the same instrument. Copies of this Deposit Agreement shall be filed with the Depositary and the Custodians and shall be open to inspection by any Owner or Holder during regular business hours.

The exchange of copies of this Deposit Agreement and signature pages by facsimile, or email attaching a pdf or similar bit-mapped image, shall constitute effective execution and delivery of this Deposit Agreement as to the parties to it; copies and signature pages so exchanged may be used in lieu of the original Deposit Agreement and signature pages for all purposes and shall have the same validity, legal effect and admissibility in evidence as an original manual signature; the parties to this Deposit Agreement hereby agree not to argue to the contrary.

## SECTION 7.2. No Third Party Beneficiaries.

This Deposit Agreement is for the exclusive benefit of the Company, the Depositary, the Owners and the Holders and their respective successors and shall not be deemed to give any legal or equitable right, remedy or claim whatsoever to any other person.

## SECTION 7.3. Severability.

In case any one or more of the provisions contained in this Deposit Agreement or in a Receipt should be or become invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained in this Deposit Agreement or that Receipt shall in no way be affected, prejudiced or disturbed thereby.

## SECTION 7.4. Owners and Holders as Parties; Binding Effect.

The Owners and Holders from time to time shall be parties to this Deposit Agreement and shall be bound by all of the terms and conditions of this Deposit Agreement and of the Receipts by acceptance of American Depositary Shares or any interest therein.

# SECTION 7.5. Notices.

Any and all notices to be given to the Company shall be in writing and shall be deemed to have been duly given if personally delivered or sent by domestic first class or international air mail or air courier or sent by facsimile transmission or email attaching a pdf or similar bit-mapped image of a signed writing, <u>provided</u> that receipt of the facsimile transmission or email has been confirmed by the recipient, addressed to BioNTech SE, An der Goldgrube 12, D55131 Mainz, Germany, Attention: Vice President, Legal and Intellectual Property, or any other place to which the Company may have transferred its principal office with notice to the Depositary.

Any and all notices to be given to the Depositary shall be in writing and shall be deemed to have been duly given if in English and personally delivered or sent by first class domestic or international air mail or air courier or sent by facsimile transmission or email attaching a pdf or similar bit-mapped image of a signed writing, addressed to The Bank of New York Mellon, 240 Greenwich Street, New York, New York 10286, Attention: Depositary Receipt Administration, or any other place to which the Depositary may have transferred its Office with notice to the Company.

Delivery of a notice to the Company or Depositary by mail or air courier shall be deemed effected when deposited, postage prepaid, in a post-office letter box or received by an air courier service. Delivery of a notice to the Company or Depositary sent by facsimile transmission or email shall be deemed effected when the recipient acknowledges receipt of that notice.

A notice to be given to an Owner shall be deemed to have been duly given when Disseminated to that Owner. Dissemination in paper form will be effective when personally delivered or sent by first class domestic or international air mail or air courier, addressed to that Owner at the address of that Owner as it appears on the transfer books for American Depositary Shares of the Depositary, or, if that Owner has filed with the Depositary a written request that notices intended for that Owner be mailed to some other address, at the address designated in that request. Dissemination in electronic form will be effective when sent in the manner consented to by the Owner to the electronic address most recently provided by the Owner for that purpose.

## SECTION 7.6. Appointment of Agent for Service of Process; Submission to Jurisdiction; Jury Trial Waiver.

The Company hereby (i) designates and appoints the person named in Exhibit A to this Deposit Agreement as the Company's authorized agent in the United States upon which process may be served in any suit or proceeding arising out of or relating to the Shares or Deposited Securities, the American Depositary Shares, the Receipts or this Deposit Agreement (a "Proceeding"), (ii) consents and submits to the jurisdiction of any state or federal court in the State of New York in which any Proceeding may be instituted and (iii) agrees that service of process upon said authorized agent shall be deemed in every respect effective service of process upon the Company in any Proceeding. The Company agrees to deliver to the Depositary, upon the execution and delivery of this Deposit Agreement, a written acceptance by the agent named in Exhibit A to this Deposit Agreement of its appointment as process agent. The Company further agrees to take any and all action, including the filing of any and all such documents and instruments, as may be necessary to continue that designation and appointment in full force and effect, or to appoint and maintain the appointment of another process agent located in the United States as required above, and to deliver to the Depositary a written acceptance by that agent of that appointment, for so long as any American Depositary Shares or Receipts remain outstanding or this Deposit Agreement remains in force. In the event the Company fails to maintain the designation and appointment of a process agent in the United States in full force and effect, the Company hereby waives personal service of process upon it and consents that a service of process in connection with a Proceeding may be made by certified or registered mail, return receipt requested, directed to the Company at its address last specified for notices under this Deposit Agreement, and service so made shall be deemed completed five (5) days after the same shall have been so mailed.

EACH PARTY TO THIS DEPOSIT AGREEMENT (INCLUDING, FOR AVOIDANCE OF DOUBT, EACH OWNER AND HOLDER) HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY

APPLICABLE LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN ANY SUIT, ACTION OR PROCEEDING AGAINST THE COMPANY AND/OR THE DEPOSITARY DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THE SHARES OR OTHER DEPOSITED SECURITIES, THE AMERICAN DEPOSITARY SHARES OR THE RECEIPTS, THIS DEPOSIT AGREEMENT OR ANY TRANSACTION CONTEMPLATED HEREIN OR THEREIN, OR THE BREACH HEREOF OR THEREOF, INCLUDING, WITHOUT LIMITATION, ANY QUESTION REGARDING EXISTENCE, VALIDITY OR TERMINATION (WHETHER BASED ON CONTRACT, TORT OR ANY OTHER THEORY).

## SECTION 7.7. Waiver of Immunities.

To the extent that the Company or any of its properties, assets or revenues may have or may hereafter become entitled to, or have attributed to it, any right of immunity, on the grounds of sovereignty or otherwise, from any legal action, suit or proceeding, from the giving of any relief in any respect thereof, from setoff or counterclaim, from the jurisdiction of any court, from service of process, from attachment upon or prior to judgment, from attachment in aid of execution or judgment, or from execution of judgment, or other legal process or proceeding for the giving of any relief or for the enforcement of any judgment, in any jurisdiction in which proceedings may at any time be commenced, with respect to its obligations, liabilities or any other matter under or arising out of or in connection with the Shares or Deposited Securities, the American Depositary Shares, the Receipts or this Deposit Agreement, the Company, to the fullest extent permitted by law, hereby irrevocably and unconditionally waives, and agrees not to plead or claim, any immunity of that kind and consents to relief and enforcement as provided above.

## SECTION 7.8. Governing Law.

This Deposit Agreement and the Receipts shall be interpreted in accordance with and all rights hereunder and thereunder and provisions hereof and thereof shall be governed by the laws of the State of New York.

IN WITNESS WHEREOF, BIONTECH SE and THE BANK OF NEW YORK MELLON have duly executed this Deposit Agreement as of the day and year first set forth above and all Owners and Holders shall become parties hereto upon acceptance by them of American Depositary Shares or any interest therein.

# BIONTECH SE

By: /s/ Dr. Sierk Poetting

Name: Dr. Sierk Poetting Title: Managing Director

THE BANK OF NEW YORK MELLON, as Depositary

By: /s/ Robert W. Goad

Name: Robert W. Goad Title: Managing Director

[Signature Page to Deposit Agreement]

## EXHIBIT A

AMERICAN DEPOSITARY SHARES (Each American Depositary Share represents one deposited Share)

THE BANK OF NEW YORK MELLON
AMERICAN DEPOSITARY RECEIPT
FOR ORDINARY SHARES OF
BIONTECH SE
(INCORPORATED IN GERMANY AND GOVERNED BY THE LAWS OF THE
EUROPEAN UNION AND THE FEDERAL REPUBLIC OF GERMANY)

The Bank of New York Mellon, as depositary (hereinafter called the "Depositary"), hereby certifies that	,
or registered assigns IS THE OWNER OF	

## AMERICAN DEPOSITARY SHARES

representing deposited ordinary shares (herein called "Shares") of BioNTech SE, a European stock corporation (*Societas Europea*) incorporated in Germany and governed by the laws of the European Union and the Federal Republic of Germany (herein called the "<u>Company</u>"). At the date hereof, each American Depositary Share represents one Share deposited or subject to deposit under the Deposit Agreement (as such term is hereinafter defined) with a custodian for the Depositary (herein called the "<u>Custodian</u>") that, as of the date of the Deposit Agreement, was The Bank of New York Mellon SA/NV located in Germany. The Depositary's Office and its principal executive office are located at 240 Greenwich Street, New York, N.Y. 10286.

THE DEPOSITARY'S OFFICE ADDRESS IS 240 GREENWICH STREET, NEW YORK, N.Y. 10286

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#### THE DEPOSIT AGREEMENT.

This American Depositary Receipt is one of an issue (herein called "Receipts"), all issued and to be issued upon the terms and conditions set forth in the Deposit Agreement dated as of October 9, 2019 (herein called the "Deposit Agreement") among the Company, the Depositary, and all Owners and Holders from time to time of American Depositary Shares issued thereunder, each of whom by accepting American Depositary Shares agrees to become a party thereto and become bound by all the terms and conditions thereof. The Deposit Agreement sets forth the rights of Owners and Holders and the rights and duties of the Depositary in respect of the Shares deposited thereunder and any and all other securities, property and cash from time to time received in respect of those Shares and held thereunder (those Shares, securities, property, and cash are herein called "Deposited Securities"). Copies of the Deposit Agreement are on file at the Depositary's Office in New York City and at the office of the Custodian.

The statements made on the face and reverse of this Receipt are summaries of certain provisions of the Deposit Agreement and are qualified by and subject to the detailed provisions of the Deposit Agreement, to which reference is hereby made. Capitalized terms defined in the Deposit Agreement and not defined herein shall have the meanings set forth in the Deposit Agreement.

## 2. SURRENDER OF AMERICAN DEPOSITARY SHARES AND WITHDRAWAL OF SHARES.

Upon surrender of American Depositary Shares for the purpose of withdrawal of the Deposited Securities represented thereby and payment of the fee of the Depositary for the surrender of American Depositary Shares as provided in Section 5.9 of the Deposit Agreement and payment of all taxes and governmental charges payable in connection with that surrender and withdrawal of the Deposited Securities, and subject to the terms and conditions of the Deposit Agreement, the Owner of those American Depositary Shares shall be entitled to delivery (to the extent delivery can then be lawfully and practicably made), to or as instructed by that Owner, of the amount of Deposited Securities at the time represented by those American Depositary Shares, but not any money or other property as to which a record date for distribution to Owners has passed (since money or other property of that kind will be delivered or paid on the scheduled payment date to the Owner as of that record date), and except that the Depositary shall not be required to accept surrender of American Depositary Shares for the purpose of withdrawal to the extent it would require delivery of a fraction of a Deposited Security. The Depositary shall direct the Custodian with respect to delivery of Deposited Securities and may charge the surrendering Owner a fee and its expenses for giving that direction by cable (including SWIFT) or facsimile transmission. If Deposited Securities are delivered physically upon surrender of American Depositary Shares for the purpose of withdrawal, that delivery will be made at the Custodian's office, except that, at the request, risk and expense of the surrendering Owner, and for the account of that Owner,

the Depositary shall direct the Custodian to forward any cash or other property comprising, and forward a certificate or certificates, if applicable, and other proper documents of title, if any, for, the Deposited Securities represented by the surrendered American Depositary Shares to the Depositary for delivery at the Depositary's Office or to another address specified in the order received from the surrendering Owner.

# 3. REGISTRATION OF TRANSFER OF AMERICAN DEPOSITARY SHARES; COMBINATION AND SPLIT-UP OF RECEIPTS; INTERCHANGE OF CERTIFICATED AND UNCERTIFICATED AMERICAN DEPOSITARY SHARES.

The Depositary, subject to the terms and conditions of the Deposit Agreement, shall, without unreasonable delay, register a transfer of American Depositary Shares on its transfer books upon (i) in the case of certificated American Depositary Shares, surrender of the Receipt evidencing those American Depositary Shares, by the Owner or by a duly authorized attorney, properly endorsed or accompanied by proper instruments of transfer or (ii) in the case of uncertificated American Depositary Shares, receipt from the Owner of a proper instruction (including, for the avoidance of doubt, instructions through DRS and Profile as provided in Section 2.9 of that Agreement), and, in either case, duly stamped as may be required by the laws of the State of New York and of the United States of America. Upon registration of a transfer, the Depositary shall, without unreasonable delay, deliver the transferred American Depositary Shares to or upon the order of the person entitled thereto.

The Depositary, subject to the terms and conditions of the Deposit Agreement, shall upon surrender of a Receipt or Receipts for the purpose of effecting a split-up or combination of such Receipt or Receipts, without unreasonable delay, execute and deliver a new Receipt or Receipts for any authorized number of American Depositary Shares requested, evidencing the same aggregate number of American Depositary Shares as the Receipt or Receipts surrendered.

The Depositary, upon surrender of certificated American Depositary Shares for the purpose of exchanging for uncertificated American Depositary Shares, shall, without unreasonable delay, cancel the Receipt evidencing those certificated American Depositary Shares and send the Owner a statement confirming that the Owner is the owner of the same number of uncertificated American Depositary Shares. The Depositary, upon receipt of a proper instruction (including, for the avoidance of doubt, instructions through DRS and Profile as provided in Section 2.9 of the Deposit Agreement) from the Owner of uncertificated American Depositary Shares for the purpose of exchanging for certificated American Depositary Shares, shall, without unreasonable delay, cancel those uncertificated American Depositary Shares and register and deliver to the Owner a Receipt evidencing the same number of certificated American Depositary Shares.

As a condition precedent to the delivery, registration of transfer, or surrender of any American Depositary Shares or split-up or combination of any Receipt or withdrawal of any Deposited Securities, the Depositary, the Custodian, or Registrar may require payment from the depositor of the Shares or the presenter of the Receipt or instruction for registration of transfer or surrender of American Depositary Shares not evidenced by a Receipt of a sum sufficient to reimburse it for any tax or other governmental charge and any stock transfer or registration fee with respect thereto (including any such tax or charge and fee with respect to Shares being deposited or withdrawn) and payment of any applicable fees as provided in the Deposit Agreement, may require the production of proof satisfactory to it as to the identity and genuineness of any signature and may also require compliance with any regulations the Depositary may establish consistent with the provisions of the Deposit Agreement.

The Depositary may refuse to accept deposits of Shares for delivery of American Depositary Shares or to register transfers of American Depositary Shares in particular instances, or may suspend deposits of Shares or registration of transfer generally, whenever it or the Company considers it necessary or advisable to do so. The Depositary may refuse surrenders of American Depositary Shares for the purpose of withdrawal of Deposited Securities in particular instances, or may suspend surrenders for the purpose of withdrawal generally, but, notwithstanding anything to the contrary in the Deposit Agreement, only for (i) temporary delays caused by closing of the Depositary's register or the register of holders of Shares maintained by the Company [or the Foreign Registrar], or the deposit of Shares, in connection with voting at a shareholders' meeting or the payment of dividends, (ii) the payment of fees, taxes and similar charges, (iii) compliance with any U.S. or foreign laws or governmental regulations relating to the American Depositary Shares or to the withdrawal of the Deposited Securities or (iv) any other reason that, at the time of the Depositary's refusal or suspension, is permitted under paragraph l(A)(l) of the General Instructions to Form F-6 under the Securities Act of 1993 or any successor to that provision. In each case of (i)-(iv), the Depositary shall notify the Company as promptly as practicable of any such refusal, suspension or delay that is outside the ordinary course of business.

The Depositary shall not knowingly accept for deposit under the Deposit Agreement any Shares that, at the time of deposit, are Restricted Securities.

## 4. LIABILITY OF OWNER FOR TAXES.

If any tax or other governmental charge shall become payable by the Custodian or the Depositary with respect to or in connection with any American Depositary Shares or any Deposited Securities represented by any American Depositary Shares or in connection with a transaction to which Section 4.8 of the Deposit Agreement applies, that tax or other governmental charge shall be payable by the Owner of those American Depositary Shares to the Depositary. The Depositary may refuse to register any transfer of those American Depositary Shares or any withdrawal of Deposited Securities

represented by those American Depositary Shares until that payment is made, and may withhold any dividends or other distributions or the proceeds thereof, or may sell for the account of the Owner any part or all of the Deposited Securities represented by those American Depositary Shares, and may apply those dividends or other distributions or the net proceeds of any sale of that kind in payment of that tax or other governmental charge but, even after a sale of that kind, the Owner shall remain liable for any deficiency. Neither the Company nor the Depositary shall be liable for failure of an Owner or Holder to comply with applicable tax laws or to pay applicable governmental charges. The Depositary shall distribute any net proceeds of a sale made under Section 3.2 of the Deposit Agreement that are not used to pay taxes or governmental charges to the Owners entitled to them in accordance with Section 4.1 of the Deposit Agreement. If the number of Shares represented by each American Depositary Share decreases as a result of a sale of Deposited Securities under Section 3.2 of the Deposit Agreement, the Depositary may call for surrender of the American Depositary Shares to be exchanged on a mandatory basis for a lesser number of American Depositary Shares and may sell American Depositary Shares to the extent necessary to avoid distributing fractions of American Depositary Shares in that exchange and distribute the net proceeds of that sale to the Owners entitled to them.

## 5. WARRANTIES ON DEPOSIT OF SHARES.

Every person depositing Shares under the Deposit Agreement shall be deemed thereby to represent and warrant that those Shares and each certificate therefor, if applicable, are validly issued, fully paid and nonassessable and were not issued in violation of any preemptive or similar rights of the holders of outstanding securities of the Company and that the person making that deposit is duly authorized so to do. Every depositing person shall also be deemed to represent that the Shares, at the time of deposit, are not Restricted Securities. All representations and warranties deemed made under Section 3.3 of the Deposit Agreement shall survive the deposit of Shares and delivery of American Depositary Shares.

## 6. FILING PROOFS, CERTIFICATES, AND OTHER INFORMATION.

Any person presenting Shares for deposit or any Owner or Holder may be required from time to time to file with the Depositary or the Custodian such proof of citizenship or residence, exchange control approval, or such information relating to the registration on the books of the Company or the Foreign Registrar, if applicable, to execute such certificates and to make such representations and warranties, as the Depositary may deem necessary or proper. The Depositary may withhold the delivery or registration of transfer of any American Depositary Shares, the distribution of any dividend or other distribution or of the proceeds thereof or the delivery of any Deposited Securities until that proof or other information is filed or those certificates are executed or those representations and warranties are made. As conditions of accepting Shares for deposit, the Depositary may require (i) any certification required by the Depositary or the

Custodian in accordance with the provisions of the Deposit Agreement, (ii) a written order directing the Depositary to deliver to, or upon the written order of, the person or persons stated in that order, the number of American Depositary Shares representing those deposited Shares, (iii) evidence satisfactory to the Depositary that those Shares have been re-registered in the books of the Company or the Foreign Registrar in the name of the Depositary, a Custodian or a nominee of the Depositary or a Custodian, (iv) evidence satisfactory to the Depositary that any necessary approval has been granted by any governmental body in each applicable jurisdiction and (v) an agreement or assignment, or other instrument satisfactory to the Depositary, that provides for the prompt transfer to the Custodian of any dividend, or right to subscribe for additional Shares or to receive other property, that any person in whose name those Shares are or have been recorded may thereafter receive upon or in respect of those Shares, or, in lieu thereof, such agreement of indemnity or other agreement as shall be satisfactory to the Depositary.

## CHARGES OF DEPOSITARY.

The following charges shall be incurred by any party depositing or withdrawing Shares or by any party surrendering American Depositary Shares or to whom American Depositary Shares are issued (including, without limitation, issuance pursuant to a stock dividend or stock split declared by the Company or an exchange of stock regarding the American Depositary Shares or Deposited Securities or a delivery of American Depositary Shares pursuant to Section 4.3 of the Deposit Agreement), or by Owners, as applicable: (1) taxes and other governmental charges, (2) such registration fees as may from time to time be in effect for the registration of transfers of Shares generally on the Share register of the Company or Foreign Registrar and applicable to transfers of Shares to or from the name of the Depositary or its nominee or the Custodian or its nominee on the making of deposits or withdrawals hereunder, (3) such cable (including SWIFT) and facsimile transmission fees and expenses as are expressly provided in the Deposit Agreement, (4) such expenses as are incurred by the Depositary in the conversion of foreign currency pursuant to Section 4.5 of the Deposit Agreement, (5) a fee of \$5.00 or less per 100 American Depositary Shares (or portion thereof) for the delivery of American Depositary Shares pursuant to Section 2.3, 4.3 or 4.4 of the Deposit Agreement and the surrender of American Depositary Shares pursuant to Section 2.5 or 6.2 of the Deposit Agreement, (6) a fee of \$.05 or less per American Depositary Share (or portion thereof) for any cash distribution made pursuant to the Deposit Agreement, including, but not limited to Sections 4.1 through 4.4 and 4.8 of the Deposit Agreement, (7) a fee for the distribution of securities pursuant to Section 4.2 of the Deposit Agreement or of rights pursuant to Section 4.4 of that Agreement (where the Depositary will not exercise or sell those rights on behalf of Owners), such fee being in an amount equal to the fee for the execution and delivery of American Depositary Shares referred to above which would have been charged as a result of the deposit of such securities under the Deposit Agreement (for purposes of this item 7 treating all such securities as if they were Shares) but which securities are instead distributed by the Depositary to Owners, (8) in addition

to any fee charged under item 6, a fee of \$.05 or less per American Depositary Share (or portion thereof) per annum for depositary services, which will be payable as provided in item 9 below, and (9) any other charges payable by the Depositary or the Custodian, any of the Depositary's or Custodian's agents or the agents of the Depositary's or Custodian's agents, in connection with the servicing of Shares or other Deposited Securities (which charges shall be assessed against Owners as of the date or dates set by the Depositary in accordance with Section 4.6 of the Deposit Agreement and shall be payable at the sole discretion of the Depositary by billing those Owners for those charges or by deducting those charges from one or more cash dividends or other cash distributions).

The Depositary may collect any of its fees by deduction from any cash distribution payable, or by selling a portion of any securities to be distributed, to Owners that are obligated to pay those fees.

The Depositary may own and deal in any class of securities of the Company and its affiliates and in American Depositary Shares.

From time to time, the Depositary may make payments to the Company to reimburse the Company for costs and expenses generally arising out of establishment and maintenance of the American Depositary Shares program, waive fees and expenses for services provided by the Depositary or share revenue from the fees collected from Owners or 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.

#### DISCLOSURE OF INTERESTS.

Owners and Holders may be subject to German and European Union law notification and mandatory transfer ("squeeze-out") requirements regarding their holdings of American Depositary Shares and Shares and should acquaint themselves with applicable German and European Union law regarding such requirements.

When required in order to comply with applicable laws and regulations (including the rules and requirements of any stock exchange on which the American Depositary Shares are or will be traded or listed, or the rules and requirements of any clearing system through which transactions in the American Depositary Shares may be settled) or the articles of association or similar document of the Company, the Company may from time to time request each Owner and Holder to provide to the Depositary information relating to: (a) the capacity in which it holds American Depositary Shares, (b) the identity of any Holders or other persons or entities then or previously interested in those American Depositary Shares and the nature of those interests and (c) any other matter where disclosure of such matter is required for that compliance, in each case within the time period prescribed by the Company. Each Owner and Holder agrees to provide all information known to it in response to a request made pursuant to

this Section. Each Holder consents to the disclosure by the Depositary and the Owner or any other Holder through which it holds American Depositary Shares, directly or indirectly, of all information responsive to a request made pursuant to this Section relating to that Holder that is known to that Owner or other Holder. The Depositary agrees to use reasonable efforts to comply with written instructions requesting that the Depositary forward any request authorized under this Section to the Owners and to forward to the Company any responses it receives in response to that request. The Depositary may charge the Company a fee and its expenses for complying with requests under Section 3.4 of the Deposit Agreement.

Each Owner and Holder of American Depositary Shares further agrees to comply with the laws and regulations of the European Union and the Federal Republic of Germany (if and to the extent applicable) with respect to the disclosure requirements regarding ownership or potential for ownership of Shares, all as if the American Depositary Shares were the Shares represented thereby, which is deemed to include, inter alia, requirements to make notifications and filings within the required timeframes to the Company and any other authorities of the European Union and the Federal Republic of Germany.

## 9. TITLE TO AMERICAN DEPOSITARY SHARES.

It is a condition of the American Depositary Shares, and every successive Owner and Holder of American Depositary Shares, by accepting or holding the same, consents and agrees that American Depositary Shares evidenced by a Receipt, when the Receipt is properly endorsed or accompanied by proper instruments of transfer, shall be transferable as certificated registered securities under the laws of the State of New York, and that American Depositary Shares not evidenced by Receipts shall be transferable as uncertificated registered securities under the laws of the State of New York. The Depositary, notwithstanding any notice to the contrary, may treat the Owner of American Depositary Shares as the absolute owner thereof for the purpose of determining the person entitled to distribution of dividends or other distributions or to any notice provided for in the Deposit Agreement and for all other purposes, and neither the Depositary nor the Company shall have any obligation or be subject to any liability under the Deposit Agreement to any Holder of American Depositary Shares, but only to the Owner.

## 10. VALIDITY OF RECEIPT.

This Receipt shall not be entitled to any benefits under the Deposit Agreement or be valid or obligatory for any purpose, unless this Receipt shall have been (i) executed by the Depositary by the manual signature of a duly authorized officer of the Depositary or (ii) executed by the facsimile signature of a duly authorized officer of the Depositary and countersigned by the manual signature of a duly authorized signatory of the Depositary or the Registrar or a co-registrar.

## 11. REPORTS; INSPECTION OF TRANSFER BOOKS.

The Company is subject to the periodic reporting requirements of the Securities Exchange Act of 1934 and, accordingly, files certain reports with the Securities and Exchange Commission. Those reports will be available for inspection and copying through the Commission's EDGAR system or at public reference facilities maintained by the Commission in Washington, D.C.

The Depositary will make available for inspection by Owners at its Office any reports, notices and other communications, including any proxy soliciting material, received from the Company which are both (a) received by the Depositary as the holder of the Deposited Securities and (b) made generally available to the holders of those Deposited Securities by the Company. The Company shall furnish reports and communications, including any proxy soliciting material to which Section 4.9 of the Deposit Agreement applies, to the Depositary in English, to the extent such materials are required to be translated into English pursuant to any regulations of the Commission.

The Depositary will keep books for the registration of American Depositary Shares and transfers of American Depositary Shares, which shall be open for inspection by the Owners at the Depositary's Office during regular business hours, <u>provided</u> that such inspection shall not be for the purpose of communicating with Owners in the interest of a business or object other than the business of the Company or a matter related to the Deposit Agreement or the American Depositary Shares.

#### 12. DIVIDENDS AND DISTRIBUTIONS.

Whenever the Depositary receives any cash dividend or other cash distribution on Deposited Securities, the Depositary will, if at the time of receipt thereof any amounts received in a foreign currency can in the judgment of the Depositary be converted on a reasonable basis into Dollars transferable to the United States, and subject to the Deposit Agreement, convert that dividend or other cash distribution into Dollars and distribute, as promptly as practicable, the amount thus received (net of the fees and expenses of the Depositary as provided in Article 7 hereof and Section 5.9 of the Deposit Agreement) to the Owners entitled thereto; <u>provided</u>, however, that if the Custodian or the Depositary is required to withhold and does withhold from that cash dividend or other cash distribution an amount on account of taxes or other governmental charges, the amount distributed to the Owners of the American Depositary Shares representing those Deposited Securities shall be reduced accordingly. If a cash distribution would represent a return of all or substantially all the value of the Deposited Securities underlying American Depositary Shares, the Depositary may require surrender of those American Depositary Shares and may require payment of or deduct the fee for surrender of American Depositary Shares (whether or not it is also requiring surrender of American Depositary Shares) as a condition of making that cash distribution. A distribution of that kind shall be a <u>Termination Option Event</u>.

Subject to the provisions of Section 4.11 and 5.9 of the Deposit Agreement, whenever the Depositary receives any distribution other than a distribution described in

Section 4.1, 4.3 or 4.4 of the Deposit Agreement on Deposited Securities (but not in exchange for or in conversion or in lieu of Deposited Securities), the Depositary will, as promptly as practicable, cause the securities or property received by it to be distributed to the Owners entitled thereto, after deduction or upon payment of any fees and expenses of the Depositary and any taxes or other governmental charges, in any manner that the Depositary deems equitable and practicable for accomplishing that distribution (which may be a distribution of depositary shares representing the securities received); provided, however, that if in the reasonable opinion of the Depositary such distribution cannot be made proportionately among the Owners entitled thereto, or if for any other reason the Depositary deems such distribution not to be lawful and feasible, the Depositary may adopt, following consultation with the Company to the extent reasonably practicable, such other method as it may deem equitable and practicable for the purpose of effecting such distribution, including, but not limited to, the public or private sale of the securities or property thus received, or any part thereof, and distribution of the net proceeds of any such sale (net of the fees and expenses of the Depositary as provided in Article 7 hereof and Section 5.9 of the Deposit Agreement) to the Owners entitled thereto all in the manner and subject to the conditions set forth in Section 4.1 of the Deposit Agreement. The Depositary may withhold any distribution of securities under Section 4.2 of the Deposit Agreement if it has not received satisfactory assurances from the Company that the distribution does not require registration under the Securities Act of 1933. The Depositary may sell, by public or private sale, an amount of securities or other property it would otherwise distribute under this Article that is sufficient to pay its fees and expenses in respect of that distribution. If a distribution under Section 4.2 of the Deposit Agreement would represent a return of all of substantially all the value of the Deposited Securities underlying American Depositary Shares, the Depositary may require surrender of those American Depositary Shares and may require payment of or deduct the fee for surrender of American Depositary Shares (whether or not it is also requiring surrender of American Depositary Shares) as a condition of making that distribution. A distribution of that kind shall be a <u>Termination Option Event</u>.

Whenever the Depositary receives any distribution consisting of a dividend in, or free distribution of, Shares, the Depositary may, and shall if the Company so requests in writing, deliver to the Owners entitled thereto, an aggregate number of American Depositary Shares representing the amount of Shares received as that dividend or free distribution, subject to the terms and conditions of the Deposit Agreement with respect to the deposit of Shares and issuance of American Depositary Shares, including the withholding of any tax or other governmental charge as provided in Section 4.11 of the Deposit Agreement and the payment of the fees and expenses of the Depositary as provided in Article 7 hereof and Section 5.9 of the Deposit Agreement (and the Depositary may sell, by public or private sale, an amount of Shares received (or American Depositary Shares representing those Shares) sufficient to pay its fees and expenses in respect of that distribution). In lieu of delivering fractional American Depositary Shares, the Depositary may sell the amount of Shares represented by the aggregate of those fractions (or American Depositary Shares representing those Shares)

and distribute the net proceeds, as promptly as practicable, all in the manner and subject to the conditions described in Section 4.1of the Deposit Agreement. If and to the extent that additional American Depositary Shares are not delivered and Shares or American Depositary Shares are not sold, each American Depositary Share shall thenceforth also represent the additional Shares distributed on the Deposited Securities represented thereby.

If the Company declares a distribution in which holders of Deposited Securities have a right to elect whether to receive cash, Shares or other securities or a combination of those things, or a right to elect to have a distribution sold on their behalf, the Depositary may, after consultation with the Company, make that right of election available for exercise by Owners in any manner the Depositary reasonably considers to be lawful and practical. As a condition of making a distribution election right available to Owners, the Depositary may require reasonably satisfactory assurances from the Company that doing so does not require registration of any securities under the Securities Act of 1933.

If the Depositary determines that any distribution received or to be made by the Depositary (including Shares and rights to subscribe therefor) is subject to any tax or other governmental charge that the Depositary is obligated to withhold, the Depositary may sell, by public or private sale, all or a portion of the distributed property (including Shares and rights to subscribe therefor) in the amounts and manner the Depositary reasonably deems necessary and practicable to pay those taxes or charges, and the Depositary shall distribute the net proceeds of that sale, after deduction of those taxes or charges, to the Owners entitled thereto in proportion to the number of American Depositary Shares held by them respectively.

Each Owner and Holder agrees to indemnify the Company, the Depositary, the Custodian and their respective directors, employees, agents and affiliates for, and hold each of them harmless against, any claim by any governmental authority with respect to taxes, additions to tax, penalties or interest arising out of any refund of taxes, reduced withholding at source or other tax benefit received by it. Services for Owners and Holders that may permit them to obtain reduced rates of tax withholding at source or reclaim excess tax withheld, and the fees and costs associated with using services of that kind, are not provided under, and are outside the scope of, the Deposit Agreement.

## 13. RIGHTS.

(a) If rights are granted to the Depositary in respect of deposited Shares to purchase additional Shares or other securities, the Company and the Depositary shall endeavor to consult as to the actions, if any, the Depositary should take in connection with that grant of rights. The Depositary may, to the extent reasonably deemed by it to be lawful and practical (i) if requested in writing by the Company, grant to all or certain Owners rights to instruct the Depositary to purchase the securities to which the rights relate and deliver those securities or American Depositary Shares representing those

securities to Owners, (ii) if requested in writing by the Company, deliver the rights to or to the order of certain Owners, or (iii) sell the rights to the extent practicable and distribute the net proceeds of that sale to Owners entitled to those proceeds. To the extent rights are not exercised, delivered or disposed of under (i), (ii) or (iii) above, the Depositary shall permit the rights to lapse unexercised.

- (b) If the Depositary will act under (a)(i) above, the Company and the Depositary will enter into a separate agreement setting forth the conditions and procedures applicable to the particular offering. Upon instruction from an applicable Owner in the form the Depositary specified and upon payment by that Owner to the Depositary of an amount equal to the purchase price of the securities to be received upon the exercise of the rights, the Depositary shall, on behalf of that Owner, exercise the rights and purchase the securities. The purchased securities shall be delivered to, or as instructed by, the Depositary. The Depositary shall (i) deposit the purchased Shares under the Deposit Agreement and deliver American Depositary Shares representing those Shares to that Owner or (ii) deliver or cause the purchased Shares or other securities to be delivered to or to the order of that Owner. The Depositary will not act under (a)(i) above unless the offer and sale of the securities to which the rights relate are registered under the Securities Act of 1933 or the Depositary has received an opinion of United States counsel that is reasonably satisfactory to it to the effect that those securities may be sold and delivered to the applicable Owners without registration under the Securities Act of 1933.
- (c) If the Depositary will act under (a)(ii) above, the Company and the Depositary will enter into a separate agreement setting forth the conditions and procedures applicable to the particular offering. Upon (i) the request of an applicable Owner to deliver the rights allocable to the American Depositary Shares of that Owner to an account specified by that Owner to which the rights can be delivered and (ii) receipt of such documents as the Company and the Depositary agreed to require to comply with applicable law, the Depositary will deliver those rights as requested by that Owner.
- (d) If the Depositary will act under (a)(iii) above, the Depositary will use reasonable efforts to sell the rights in proportion to the number of American Depositary Shares held by the applicable Owners and pay the net proceeds to the Owners otherwise entitled to the rights that were sold, upon an averaged or other practical basis without regard to any distinctions among such Owners because of exchange restrictions or the date of delivery of any American Depositary Shares or otherwise.
- (e) Payment or deduction of the fees of the Depositary as provided in Section 5.9 of the Deposit Agreement and payment or deduction of the expenses of the Depositary and any applicable taxes or other governmental charges shall be conditions of any delivery of securities or payment of cash proceeds under Section 4.4 of that Agreement.

(f) The Depositary shall not be responsible for any failure to determine that it may be lawful or feasible to make rights available to or exercise rights on behalf of Owners in general or any Owner in particular, or to sell rights.

#### 14. CONVERSION OF FOREIGN CURRENCY.

Whenever the Depositary or the Custodian receives foreign currency, by way of dividends or other distributions or the net proceeds from the sale of securities, property or rights, and if at the time of the receipt thereof the foreign currency so received can in the judgment of the Depositary be converted on a reasonable basis into Dollars and the resulting Dollars transferred to the United States, the Depositary shall, as promptly as reasonably practicable, convert or cause to be converted by sale or in any other manner that it may determine that foreign currency into Dollars, and those Dollars shall be distributed, as promptly as practicable, to the Owners entitled thereto. A cash distribution may be made upon an averaged or other practicable basis without regard to any distinctions among Owners based on exchange restrictions, the date of delivery of any American Depositary Shares or otherwise and shall be net of any expenses of conversion into Dollars incurred by the Depositary as provided in Section 5.9 of the Deposit Agreement.

If a conversion of foreign currency or the repatriation or distribution of Dollars can be effected only with the approval or license of any government or agency thereof, the Depositary may, but will not be required to, file an application for that approval or license.

If the Depositary, after consultation with the Company to the extent practicable determines that in its reasonable judgment any foreign currency received by the Depositary or the Custodian is not convertible on a reasonable basis into Dollars transferable to the United States, or if any approval or license of any government or agency thereof that is required for such conversion is not filed or sought by the Depositary or is not obtained within a reasonable period as determined by the Depositary, the Depositary may distribute the foreign currency received by the Depositary to, or in its discretion may hold such foreign currency uninvested and without liability for interest thereon for the respective accounts of, the Owners entitled to receive the same.

If any conversion of foreign currency, in whole or in part, cannot be effected for distribution to some of the Owners entitled thereto, the Depositary may in its discretion make that conversion and distribution in Dollars to the extent practicable and permissible to the Owners entitled thereto and may distribute the balance of the foreign currency received by the Depositary to, or hold that balance uninvested and without liability for interest thereon for the respective accounts of, the Owners entitled thereto.

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 Owners, subject to the Depositary's obligations under Section 5.3 of that Agreement. The methodology used to determine exchange rates used in currency conversions is available upon request.

## 15. RECORD DATES.

Whenever a cash dividend, cash distribution or any other distribution is made on Deposited Securities or rights to purchase Shares or other securities are issued with respect to Deposited Securities (which rights will be delivered to or exercised or sold on behalf of Owners in accordance with Section 4.4 of the Deposit Agreement) or the Depositary receives notice that a distribution or issuance of that kind will be made, or whenever the Depositary receives notice that a meeting of holders of Shares will be held in respect of which the Company has requested the Depositary to send a notice under Section 4.7 of the Deposit Agreement, or whenever the Depositary will assess a fee or charge against the Owners, or whenever the Depositary causes a change in the number of Shares that are represented by each American Depositary Share, or whenever the Depositary otherwise finds it necessary or convenient, the Depositary shall fix a record date, which shall be the same as, or as near as practicable to, any corresponding record date set by the Company with respect to Shares, (a) for the determination of the Owners (i) who shall be entitled to receive the benefit of that dividend or other distribution or those rights, (ii) who shall be entitled to give instructions for the exercise of voting rights at that meeting, (iii) who shall be responsible for that fee or charge or (iv) for any other purpose for which the record date was set, or (b) on or after which each American Depositary Share will represent the changed number of Shares. Subject to the provisions of Sections 4.1 through 4.5 of the Deposit Agreement and to the other terms and conditions of the Deposit Agreement, the Owners on a record date fixed by the Depositary shall be entitled to receive the amount distributable by the Depositary with respect to that dividend or other distribution or those rights or the net proceeds of sale thereof in proportion to the number of American Depositary Shares held by them respectively, to give voting instructions or to act in respec

## 16. VOTING OF DEPOSITED SHARES.

(a) Upon receipt of notice of any meeting of holders of Shares at which holders of Shares will be entitled to vote, if requested in writing by the Company, the Depositary shall, as soon as practicable thereafter, Disseminate to the Owners a notice,

the form of which shall be in the sole discretion of the Depositary, that shall contain (i) the information contained in the notice of meeting received by the Depositary, (ii) a statement that the Owners as of the close of business on a specified record date will be entitled, subject to any applicable provision of European Union or German law and of the articles of association or similar documents of the Company, to instruct the Depositary as to the exercise of the voting rights pertaining to the amount of Shares represented by their respective American Depositary Shares, (iii) a statement as to the manner in which those instructions may be given, including an express indication that instructions may be given or deemed given in accordance with the last sentence of paragraph (b) below, if no instruction is received, to the Depositary to vote those Shares or cause them to be voted in favor of any resolution that has been proposed (*Beschlussvorschlag*) in the formal notice of the meeting pursuant to§ 121 of the Stock Corporation Act (*Einberufung*) (each such resolution being referred to as a "<u>Proposal</u>") and (iv) the last date on which the Depositary will accept instructions (the "<u>Instruction Cutoff Date</u>").

- (b) Upon the written request of an Owner of American Depositary Shares, as of the date of the request or, if a record date was specified by the Depositary, as of that record date, received on or before any Instruction Cutoff Date established by the Depositary, the Depositary may, and if the Depositary sent a notice under the preceding paragraph shall, endeavor, in so far as practicable, to vote or cause to be voted the amount of deposited Shares represented by those American Depositary Shares in accordance with the instructions set forth in that request. The Depositary shall not vote or attempt to exercise the right to vote that attaches to the deposited Shares other than in accordance with instructions given by Owners and received by the Depositary or as provided in the following sentence. If
  - (i) the Company instructed the Depositary to Disseminate a notice under paragraph (a) above and complied with paragraph (d) below,
- (ii) no instructions are received by the Depositary from an Owner with respect to a Proposal and an amount of American Depositary Shares of that Owner on or before the Instruction Cutoff Date, and
- (iii) the Depositary has received from the Company, by the business day following the Instruction Cutoff Date, a written confirmation that, as of the Instruction Cutoff Date, (x) the Company wishes the Depositary to vote or cause to be voted Shares under this sentence, (y) the Company reasonably does not know of any substantial opposition to the Proposal and (z) the Proposal is not materially adverse to the interests of shareholders

then, the Depositary shall deem that Owner to have instructed the Depositary to vote, and the Depositary shall endeavor, insofar as practicable, to vote or cause to be voted that amount of deposited Shares in favor of the Proposal.

- (c) There can be no assurance that Owners generally or any Owner in particular will receive the notice described in paragraph (a) above in time to enable Owners to give instructions to the Depositary prior to the Instruction Cutoff Date.
- (d) In order to give Owners a reasonable opportunity to instruct the Depositary as to the exercise of voting rights relating to Shares, if the Company will request the Depositary to Disseminate a notice under paragraph (a) above, the Company shall give the Depositary notice of the meeting, details concerning the matters to be voted upon, including the resolutions, copies of materials to be made available to holders of Shares in connection with the meeting and an indication whether each of those matters is a Proposal, not less than 30 days prior to the meeting date.

#### 17. TENDER AND EXCHANGE OFFERS; REDEMPTION, REPLACEMENT OR CANCELLATION OF DEPOSITED SECURITIES.

- (a) The Depositary shall not tender any Deposited Securities in response to any voluntary cash tender offer, exchange offer or similar offer made to holders of Deposited Securities (a "Voluntary Offer"), except when instructed in writing to do so by an Owner surrendering American Depositary Shares and subject to any conditions or procedures the Depositary may require.
- (b) If the Depositary receives a written notice that Deposited Securities have been redeemed for cash or otherwise purchased for cash in a transaction that is mandatory and binding on the Depositary as a holder of those Deposited Securities (a "Redemption"), the Depositary, at the expense of the Company (unless otherwise agreed between the Company and the Depositary in writing), shall (i) if required, surrender Deposited Securities that have been redeemed to the issuer of those securities or its agent on the redemption date, (ii) Disseminate a notice to Owners (A) notifying them of that Redemption, (B) calling for surrender of a corresponding number of American Depositary Shares and (C) notifying them that the called American Depositary Shares have been converted into a right only to receive the money received by the Depositary upon that Redemption and those net proceeds shall be the Deposited Securities to which Owners of those converted American Depositary Shares shall be entitled upon surrenders of those American Depositary Shares in accordance with Section 2.5 or 6.2 of the Deposit Agreement and (iii) distribute the money received upon that Redemption, as promptly as practicable, to the Owners entitled to it upon surrender by them of called American Depositary Shares in accordance with Section 2.5 of that Agreement (and, for the avoidance of doubt, Owners shall not be entitled to receive that money under Section 4.1 of that Agreement). If the Redemption affects less than all the Deposited Securities, the Depositary shall call for surrender a corresponding portion of the outstanding American Depositary Shares and only those American Depositary Shares will automatically be converted into a right to receive the net proceeds of the Redemption. The Depositary shall allocate the American Depositary Shares converted under the preceding sentence among the Owners pro-rata to their respective holdings of American Depositary Shares immediately prior to the Redemption, except that the allocations may be adjusted so that no fraction of a converted American Depositary Share is allocated to any Owner. A Redemption of all or substantially all of the Deposited Securities shall be a Termination Option Event.

- (c) If the Depositary is notified of or there occurs any change in nominal value or any subdivision, combination or any other reclassification of the Deposited Securities or any recapitalization, reorganization, sale of assets substantially as an entirety, merger or consolidation affecting the issuer of the Deposited Securities or to which it is a party that is mandatory and binding on the Depositary as a holder of Deposited Securities and, as a result, securities or other property have been or will be delivered in exchange, conversion, replacement or in lieu of, Deposited Securities (a "Replacement"), the Depositary shall, if required, surrender the old Deposited Securities affected by that Replacement of Shares and hold, as new Deposited Securities under the Deposit Agreement, the new securities or other property delivered to it in that Replacement. However, the Depositary may elect to sell those new Deposited Securities if in the reasonable opinion of the Depositary it is not lawful or not practical for it to hold those new Deposited Securities under the Deposit Agreement because those new Deposited Securities may not be distributed to Owners without registration under the Securities Act of 1933 or for any other reason, at public or private sale, at such places and on such terms as it reasonably deems proper and proceed as if those new Deposited Securities had been Redeemed under paragraph (b) above. A Replacement shall be a Termination Option Event.
- (d) In the case of a Replacement where the new Deposited Securities will continue to be held under the Deposit Agreement, the Depositary may call for the surrender of outstanding Receipts to be exchanged for new Receipts specifically describing the new Deposited Securities and the number of those new Deposited Securities represented by each American Depositary Share. If the number of Shares represented by each American Depositary Share decreases as a result of a Replacement, the Depositary may call for surrender of the American Depositary Shares to be exchanged on a mandatory basis for a lesser number of American Depositary Shares and may sell American Depositary Shares to the extent necessary to avoid distributing fractions of American Depositary Shares in that exchange and distribute the net proceeds, as promptly as practicable, of that sale to the Owners entitled to them.
- (e) If there are no Deposited Securities with respect to American Depositary Shares, including if the Deposited Securities are cancelled, or the Deposited Securities with respect to American Depositary Shares have become apparently worthless, (i) the Depositary may (A) call for surrender of those American Depositary Shares or (B) cancel those American Depositary Shares, upon notice to Owners, and (ii) that condition shall be a Termination Option Event.

#### 18. LIABILITY OF THE COMPANY AND DEPOSITARY.

Neither the Depositary nor the Company nor any of their respective directors, employees, agents or affiliates shall incur any liability to any Owner or Holder:

- (i) if by reason of (A) any provision of any present or future law or regulation or other act of the government of the United States or the Federal Republic of Germany, the European Union, any State of the United States or any other state or jurisdiction, or of any governmental or regulatory authority or stock exchange; (B) (in the case of the Depositary only) any provision, present or future, of the articles of association or similar document of the Company, or by reason of any provision of any securities issued or distributed by the Company, or any offering or distribution thereof; or (C) any event or circumstance, whether natural or caused by a person or persons, that is beyond the ability of the Depositary or the Company, as the case may be, to prevent or counteract by reasonable care or effort (including, but not limited to earthquakes, floods, severe storms, fires, explosions, war, terrorism, civil unrest, labor disputes or criminal acts; interruptions or malfunctions of utility services, Internet or other communications lines or systems; unauthorized access to or attacks on computer systems or websites; or other failures or malfunctions of computer hardware or software or other systems or equipment), the Depositary or the Company is, directly or indirectly, prevented from, forbidden to or delayed in, or could be subject to any civil or criminal penalty on account of doing or performing and therefore does not do or perform, any act or thing that, by the terms of the Deposit Agreement or the Deposited Securities, it is provided shall be done or performed;
- (ii) for any exercise of, or failure to exercise, any discretion provided for in the Deposit Agreement (including any determination by the Depositary to take, or not take, any action that the Deposit Agreement provides the Depositary may take);
- (iii) for the inability of any Owner or Holder to benefit from any distribution, offering, right or other benefit that is made available to holders of Deposited Securities but is not, under the terms of the Deposit Agreement, made available to Owners or Holders; or
  - (iv) for any special, consequential or punitive damages for any breach of the terms of the Deposit Agreement.

Where, by the terms of a distribution to which Section 4.1, 4.2 or 4.3 of the Deposit Agreement applies, or an offering to which Section 4.4 of that Agreement applies, or for any other reason, that distribution or offering may not be made available to Owners, and the Depositary may not dispose of that distribution or offering on behalf of Owners and make the net proceeds available to Owners, then the Depositary shall not make that distribution or offering available to Owners, and shall allow any rights, if applicable, to lapse.

Neither the Company nor the Depositary assumes any obligation or shall be subject to any liability under the Deposit Agreement to Owners or Holders, except that they agree to perform their obligations specifically set forth in the Deposit Agreement

without negligence or bad faith. The Depositary shall not be a fiduciary or have any fiduciary duty to Owners or Holders. The Depositary shall not be subject to any liability with respect to the validity or worth of the Deposited Securities. Neither the Depositary nor the Company shall be under any obligation to appear in, prosecute or defend any action, suit, or other proceeding in respect of any Deposited Securities or in respect of the American Depositary Shares, on behalf of any Owner or Holder or other person. Neither the Depositary nor the Company shall be liable for any action or non-action by it in reliance upon the advice of or information from legal counsel, accountants, any person presenting Shares for deposit, any Owner or Holder, or any other person believed by it in good faith to be competent to give such advice or information. Each of the Depositary and the Company may rely, and shall be protected in relying upon, any written notice, request, direction or other document believed by it to be genuine and to have been signed or presented by the proper party or parties. The Depositary shall not be liable for any acts or omissions made by a successor depositary whether in connection with a previous act or omission of the Depositary or in connection with a matter arising wholly after the removal or resignation of the Depositary, provided that in connection with the issue out of which such potential liability arises, the Depositary performed its obligations without negligence or bad faith while it acted as Depositary. The Depositary shall not be liable for the acts or omissions of any securities depository, clearing agency or settlement system in connection with or arising out of book-entry settlement of American Depositary Shares or Deposited Securities or otherwise. In the absence of bad faith on its part, the Depositary shall not be responsible for any failure to carry out any instructions to vote any of the Deposited Securities or for the manner in which any such vote is cast or the effect of any such vote. The Depositary shall have no duty to make any determination or provide any information as to the tax status of the Company or any liability for any tax consequences that may be incurred by Owners or Holders as a result of owning or holding American Depositary Shares. The Depositary shall not be liable for the inability or failure of an Owner or 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. No disclaimer of liability under the United States federal securities laws is intended by any provision of the Deposit Agreement.

#### 19. RESIGNATION AND REMOVAL OF THE DEPOSITARY; APPOINTMENT OF SUCCESSOR CUSTODIAN.

The Depositary may at any time resign as Depositary under the Deposit Agreement by written notice of its election so to do delivered to the Company, to become effective upon the appointment of a successor depositary and its acceptance of such appointment as provided in the Deposit Agreement. The Depositary may at any time be removed by the Company by 90 days' prior written notice of that removal, to become effective upon the later of (i) the 90th day after delivery of the notice to the Depositary and (ii) the appointment of a successor depositary and its acceptance of its appointment as provided in the Deposit Agreement. The Depositary in its discretion may at any time appoint a substitute or additional custodian or custodians.

#### 20. AMENDMENT.

The form of the Receipts and any provisions of the Deposit Agreement may at any time and from time to time be amended by agreement between the Company and the Depositary without the consent of Owners or Holders in any respect which they may deem necessary or desirable. Any amendment that would impose or increase any fees or charges (other than taxes and other governmental charges, registration fees, cable (including SWIFT) or facsimile transmission costs, delivery costs or other such expenses), or that would otherwise prejudice any substantial existing right of Owners, shall, however, not become effective as to outstanding American Depositary Shares until the expiration of 30 days after notice of that amendment has been Disseminated to the Owners of outstanding American Depositary Shares. Every Owner and Holder, at the time any amendment so becomes effective, shall be deemed, by continuing to hold American Depositary Shares or any interest therein, to consent and agree to that amendment and to be bound by the Deposit Agreement as amended thereby. Upon the effectiveness of an amendment to the form of Receipt, including a change in the number of Shares represented by each American Depositary Share, the Depositary may call for surrender of Receipts to be replaced with new Receipts in the amended form or call for surrender of American Depositary Shares to effect that change of ratio. In no event shall any amendment impair the right of the Owner to surrender American Depositary Shares and receive delivery of the Deposited Securities represented thereby, except in order to comply with mandatory provisions of applicable law.

#### 21. TERMINATION OF DEPOSIT AGREEMENT.

- (a) The Company may initiate termination of the Deposit Agreement by notice to the Depositary. The Depositary may initiate termination of the Deposit Agreement if (i) at any time 60 days shall have expired after the Depositary delivered to the Company a written resignation notice and a successor depositary has not been appointed and accepted its appointment as provided in Section 5.4 of that Agreement or
- (ii) a Termination Option Event has occurred. If termination of the Deposit Agreement is initiated, the Depositary shall Disseminate a notice of termination to the Owners of all American Depositary Shares then outstanding setting a date for termination (the "Termination Date"), which shall be at least 90 days after the date of that notice, and the Deposit Agreement shall terminate on that Termination Date.
- (b) After the Termination Date, the Company shall be discharged from all obligations under the Deposit Agreement except for its obligations to the Depositary under Sections 5.8 and 5.9 of that Agreement.
- (c) At any time after the Termination Date, the Depositary may sell the Deposited Securities then held under the Deposit Agreement and may thereafter hold uninvested the net proceeds of any such sale, together with any other cash then held by it hereunder, unsegregated and without liability for interest, for the pro rata benefit of the Owners of American Depositary Shares that remain outstanding, and those Owners will

be general creditors of the Depositary with respect to those net proceeds and that other cash. After making that sale, the Depositary shall be discharged from all obligations under the Deposit Agreement, except (i) to account for the net proceeds and other cash (after deducting, in each case, the fee of the Depositary for the surrender of American Depositary Shares, any expenses for the account of the Owner of such American Depositary Shares in accordance with the terms and conditions of the Deposit Agreement and any applicable taxes or governmental charges) and (ii) for its obligations under Section 5.8 of that Agreement and (iii) to act as provided in paragraph (d) below.

(d) After the Termination Date, the Depositary shall continue to receive dividends and other distributions pertaining to Deposited Securities (that have not been sold), may sell rights and other property as provided in the Deposit Agreement and shall deliver Deposited Securities (or sale proceeds) upon surrender of American Depositary Shares (after payment or upon deduction, in each case, of the fee of the Depositary for the surrender of American Depositary Shares, any expenses for the account of the Owner of those American Depositary Shares in accordance with the terms and conditions of the Deposit Agreement and any applicable taxes or governmental charges). After the Termination Date, the Depositary shall not accept deposits of Shares or deliver American Depositary Shares. After the Termination Date, (i) the Depositary may refuse to accept surrenders of American Depositary Shares for the purpose of withdrawal of Deposited Securities (that have not been sold) or reverse previously accepted surrenders of that kind that have not settled if in its judgment the requested withdrawal would interfere with its efforts to sell the Deposited Securities, (ii) the Depositary will not be required to deliver cash proceeds of the sale of Deposited Securities until all Deposited Securities have been sold and (iii) the Depositary may discontinue the registration of transfers of American Depositary Shares and suspend the distribution of dividends and other distributions on Deposited Securities to the Owners and need not give any further notices or perform any further acts under the Deposit Agreement except as provided in Section 6.2 of that Agreement.

#### 22. DTC DIRECT REGISTRATION SYSTEM AND PROFILE MODIFICATION SYSTEM.

(a) Notwithstanding the provisions of Section 2.4 of the Deposit Agreement, the parties acknowledge that DTC's Direct Registration System ("<u>DRS</u>") and Profile Modification System ("<u>Profile</u>") apply to the American Depositary Shares upon acceptance thereof to DRS by DTC. DRS is the system administered by DTC that facilitates interchange between registered holding of uncertificated securities and holding of security entitlements in those securities through DTC and a DTC participant. Profile is a required feature of DRS that allows a DTC participant, claiming to act on behalf of an Owner of American Depositary Shares, to direct the Depositary to register a transfer of those American Depositary Shares to DTC or its nominee and to deliver those American Depositary Shares to the DTC account of that DTC participant without receipt by the Depositary of prior authorization from the Owner to register that transfer.

(b) In connection with DRS/Profile, the parties acknowledge that the Depositary will not determine whether the DTC participant that is claiming to be acting on behalf of an Owner in requesting registration of transfer and delivery as described in paragraph (a) above has the actual authority to act on behalf of that Owner (notwithstanding any requirements under the Uniform Commercial Code). For the avoidance of doubt, the provisions of Sections 5.3 and 5.8 of the Deposit Agreement apply to the matters arising from the use of the DRS/Profile. The parties agree that the Depositary's reliance on and compliance with instructions received by the Depositary through the DRS/Profile system and otherwise in accordance with the Deposit Agreement, shall not constitute negligence or bad faith on the part of the Depositary.

### 23. APPOINTMENT OF AGENT FOR SERVICE OF PROCESS; SUBMISSION TO JURISDICTION; JURY TRIAL WAIVER; WAIVER OF IMMUNITIES.

The Company has (i) appointed BioNTech USA Holding, LLC, 228 E 45th Street, Suite 9e, New York, NY 10017 as the Company's authorized agent in the United States upon which process may be served in any suit or proceeding arising out of or relating to the Shares or Deposited Securities, the American Depositary Shares, the Receipts or this Agreement, (ii) consented and submitted to the jurisdiction of any state or federal court in the State of New York in which any such suit or proceeding may be instituted, and (iii) agreed that service of process upon said authorized agent shall be deemed in every respect effective service of process upon the Company in any such suit or proceeding.

EACH PARTY TO THE DEPOSIT AGREEMENT (INCLUDING, FOR AVOIDANCE OF DOUBT, EACH OWNER AND HOLDER) THEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN ANY SUIT, ACTION OR PROCEEDING AGAINST THE COMPANY AND/OR THE DEPOSITARY DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THE SHARES OR OTHER DEPOSITED SECURITIES, THE AMERICAN DEPOSITARY SHARES OR THE RECEIPTS, THE DEPOSIT AGREEMENT OR ANY TRANSACTION CONTEMPLATED HEREIN OR THEREIN, OR THE BREACH HEREOF OR THEREOF, INCLUDING, WITHOUT LIMITATION, ANY QUESTION REGARDING EXISTENCE, VALIDITY OR TERMINATION (WHETHER BASED ON CONTRACT, TORT OR ANY OTHER THEORY).

To the extent that the Company or any of its properties, assets or revenues may have or hereafter become entitled to, or have attributed to it, any right of immunity, on the grounds of sovereignty or otherwise, from any legal action, suit or proceeding, from the giving of any relief in any respect thereof, from setoff or counterclaim, from the jurisdiction of any court, from service of process, from attachment upon or prior to judgment, from attachment in aid of execution or judgment, or other legal process or proceeding for the giving of any relief or for the enforcement of any judgment, in any jurisdiction in which proceedings may at any time be commenced, with respect to its

obligations, liabilities or any other matter under or arising out of or in connection with the Shares or Deposited Securities, the American Depositary Shares, the Receipts or the Deposit Agreement, the Company, to the fullest extent permitted by law, hereby irrevocably and unconditionally waives, and agrees not to plead or claim, any such immunity and consents to such relief and enforcement.



55131 Mainz Germany

July 21, 2020

#### BioNTech SE - Form F-1 Registration Statement

Ladies and Gentlemen

BioNTech SE An der Goldgrube 12 **Hamburg** Freshfields Bruckhaus Deringer LLP Hohe Bleichen 7 20354 Hamburg T +49 40 36 90 60 (Zentrale)

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Doc ID DAC31877923

Our Ref

We are acting as legal advisers to BioNTech SE, a European stock corporation (SE) with its business address at An der Goldgrube 12, 55131 Mainz, Germany and registered with the commercial register (*Handelsregister*) of the local court (*Amtsgericht*) of Mainz, Germany, (the *Commercial Register*) under number HRB 48720 (the *Company*) as to matters of German law in connection with the public offering and sale of up to 5,000,000 American Depository Shares (the *ADS*), with each ADS representing one no par value registered share of the Company (the *New Shares*), each such share having a notional par value of EUR 1.00 per Share.

In this opinion, "Germany" means the Federal Republic of Germany.

#### 1. **Documents Reviewed**

For the purpose of rendering this legal opinion, we have examined the following documents (together, the *Opinion Documents*):

- a copy of the Company's articles of association (Satzung), as in effect as of the date of this opinion (the Articles of Association); (a)
- (b) a copy of an electronic excerpt (Handelsregisterauszug) from the Commercial Register relating to the Company dated July 21, 2020 (the Register Excerpt);
- a copy of the registration statement (as amended) the *Registration Statement*) on Form F-1 filed by the Company with the Securities and (c) Exchange Commission on July 21, 2020 pursuant to the Securities Act of 1933, as amended;
- (d) draft copies of the minutes of the resolutions of the management board (Vorstand) of the Company and the supervisory board (Aufsichtsrat) of the Company, resolving upon the increase of the Company's share capital from the Company's authorized capital by issuing new no par value registered shares at an issuance price of EUR 1.00 per share (together the Capital Increase Resolutions, with said capital increase being referred to as the Authorized Capital Increase); and

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(e) any such certificates, corporate records and other documents, and such matters of law, as we have deemed necessary or appropriate for the purposes of this opinion. We have not reviewed any other documents for the purposes of this opinion.

#### 2. Assumptions

As to questions of fact material to this opinion that we did not independently establish or verify, we have relied on certificates or comparable documents of public officials and of officers and representatives of the Company.

In considering the Opinion Documents and rendering this opinion we have assumed without further inquiry:

- (a) the conformity of all copies of documents supplied to us with the relevant originals and the authenticity and completeness of all documents submitted to us whether as originals or as copies;
- (b) that all signatures on Opinion Documents are genuine signatures of those individuals from whom they purport to stem;
- (c) that Opinion Documents examined by us in draft form have been or, as the case may be, will be executed in the form of the draft examined by us by the party that in the respective draft is envisaged to so execute the respective Opinion Document, save for the proper supplementation of certain of the Opinion Documents on the basis of the maximum number and the actual number of the New Shares to be issued pursuant to the Capital Increase Resolutions (which numbers will be set after the date hereof);
- (d) that all individuals who have executed and delivered or will execute and deliver any of the Opinion Documents had or will have, at the relevant times, (i) full legal capacity (*Geschäftsfähigkeit*) and (ii) power to validly represent (*Vertretungsmacht*) the respective party (other than individuals executing, passing or delivering on behalf of the Company), in executing and delivering the relevant Opinion Document;
- (e) that none of the Opinion Documents has been or, as the case may be, will be revoked, rescinded, repealed, terminated (whether in whole or in part), amended or supplemented;
- (f) the correctness and completeness of all factual matters expressed in the Opinion Documents;
- (g) that the Register Excerpt is accurate and complete as at its date and that no changes to the facts related therein have occurred between the date the Register Excerpt was issued and the date hereof;
- (h) that the Articles of Association are true and accurate as of the date of this opinion;

- (i) that the Capital Increase Resolutions are not affected by any factual circumstance not apparent from the Opinion Documents (unless known to us); and
- (j) that no other arrangements between any of the parties to the Capital Increase Resolutions in respect of the transaction contemplated thereby or other declaration or act which modifies or supersedes any of the terms of a Capital Increase Resolution exist (unless known by us).

#### 3. Laws Considered

The undersigned is admitted to the bar association (*Rechtsanwaltskammer*) in Hamburg, Germany, and licensed as attorney (*Rechtsanwalt*) in Germany. This opinion is, therefore, limited to matters of German law as presently in effect and applied by the German courts (including the law of the European Union to the extent it is directly applicable in Germany). We have not investigated and do not express or imply any opinion with respect to the laws of any other jurisdiction.

#### 4. Opinion Statements

Based upon and subject to the foregoing and the qualifications set out below, we are of the opinion that:

- (a) The Company is a European stock corporation (SE) duly established and validly existing under the laws of Germany and registered with the Commercial Register under number HRB 48720.
- (b) Following the due execution of the Capital Increase Resolutions, the due execution and delivery of a subscription form by the relevant subscriber, the payment to the Company of the issuance price of EUR 1.00 per New Share and the registration of the implementation of the Authorized Capital Increase with the Commercial Register, the relevant New Shares will be validly issued to the relevant subscriber and fully paid (subject to the payment of the difference between the nominal amount and the final offer price).

#### 5. Qualifications

The foregoing opinion statements are subject to the following qualifications:

In this opinion, concepts of German law are addressed in the English language and not in the original German terms, which may differ in their exact legal meaning. This opinion may only be relied upon under the express condition that this opinion and any issues of interpretation arising hereunder are exclusively governed by German law.

This opinion speaks of its date only, and we do not assume any obligation to update this opinion or to inform you of any changes to any of the facts or laws of other matters referred to herein. This opinion is limited to the matters addressed herein and should not be read as opinion in respect to any other matter.

We hereby consent to the filing of this opinion letter as an exhibit to the Registration Statement and to the references to this firm under the caption "Legal Matters" contained in the prospectus included in the Registration Statement. In giving such consent, we do not admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations promulgated thereunder.

This opinion is for your benefit in connection with the Registration Statement and may be relied upon by you and by persons entitled to rely upon it pursuant to the applicable provisions of the Securities Act.

Very truly yours,

/s/ Dr. Peter Versteegen

Dr. Peter Versteegen

Freshfields Bruckhaus Der

Freshfields Bruckhaus Deringer LLP

## 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 4

to

the License and Collaboration Agreement of 19th May 2015

by and between

BioNTech SE

and

Genmab A/S

1

#### **EXECUTION COPY**

This Amendment No 4 is made and entered into as of 25<sup>th</sup> day of November ("<u>Amendment No 4 Effective Date</u>") by and between BioNTech SE, a German corporation having its principal office at An der Goldgrube 12, 55131 Mainz, Germany ("<u>Biontech</u>") and Genmab A/S, CVR no. 21023884, a Danish corporation having its principal office at Kalvebod Brygge 43, DK-1560 Copenhagen V, Denmark, ("<u>Genmab</u>") (Biontech and Genmab each a "<u>Parties</u>").

#### **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, Amendment No 2 dated August 4, 2017 and Amendment No. 3 dated May 18, 2018 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 as well as Amendment No 2 to Side letter No 2 dated May 18, 2018) and a Side Letter No 3 dated September 25, 2017 (jointly referred to as the "Agreement");

**WHEREAS**, the Parties have included in the collaboration Biontech's proprietary [\*\*\*];

WHEREAS, the [\*\*\*] have been developed on behalf of Biontech by the company [\*\*\*] subject to a separate agreement between Biontech and [\*\*\*];

**WHEREAS,** Genmab has requested, and Biontech is willing to give, certain additional representations and warranties with respect to Biontech's legal ownership of the [\*\*\*];

**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 4.
- 2. The following provision is included in the Agreement as a new subsection (h) to Section 12.2 (Biontech Representations and Warranties):
  - "Biontech is the sole and legal owner of the [\*\*\*], including all and any rights and interest therein, and that Biontech has complied with, and for the duration of the Term will comply with, all and any obligations, including payment obligations, to [\*\*\*] as required for Biontech to retain the full legal ownership of the [\*\*\*]."

#### **EXECUTION COPY**

3. The following sentence is included at the end of Section 7.3:

"[...] For avoidance of doubt, Biontech shall bear all and any costs, fees, royalties and other payments payable to [\*\*\*] relating to Biontech's [\*\*\*] including the [\*\*\*], identified in Exhibit 4, tables 1, 4 and 7, as well as [\*\*\*] (as such list may be updated from time to time) and such payments shall not be included in the calculation of Shared Costs."

The remainder of Section 7.3 shall remain unchanged.

4. The following sentence is included at the end of Section 14.7.a:

"[...] For avoidance of doubt, Biontech shall bear all and any costs, fees, royalties and other payments payable to [\*\*\*] relating to Biontech's [\*\*\*], identified in Exhibit 4, tables 1, 4 and 7, as well as [\*\*\*] (as such [\*\*\*] may be updated from time to time) and such payments shall not be included in the calculation of Shared Costs."

The remainder of Section 14.7.a shall remain unchanged.

- 5. Save as set forth in this Amendment No 4, all other terms and conditions of the Agreement shall remain in full force and effect.
- 6. This Amendment No 4 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 4.

IN WITNESS WHEREOF, authorized representatives of the Parties have duly executed this Amendment No 4 as of the Amendment No 4 Effective Date.

For BioNTech SE:		Genmab A/S		
Date:	[***]	Date:	[***]	
Signature:	[***]	Signature:	[***]	
Print name:	[***]	Print name:	[***]	
Title:	[***]	Title:	<u>[***]</u>	

## 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 5

to

the License and Collaboration Agreement of 19th May 2015

by and between

BioNTech SE

and

Genmab A/S

1

This Amendment No 5 is made and entered into as of May 08th, 2020 (Amendment No 5 Effective Date) by and between BioNTech SE, 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 SE and Genmab A/S, as amended by the Amendment No 1 dated May 18, 2017, Amendment No 2 dated August 4, 2017, Amendment No. 3 dated May 18, 2018 and Amendment No. 4 dated November 25th 2019 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 as well as Amendment No 2 to Side letter No 2 dated May 18, 2018), a Side Letter No 3 dated September 25, 2017 and Letter Agreement dated February 4, 2020 (jointly referred to as the "Agreement);

WHEREAS, Biontech and Genmab wish to extend the Duration of Phase A as well as the date of yearly adjustment of the FTE rate;

**WHEREAS,** Biontech and Genmab wish to include [\*\*\*] as shared costs;

**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 5.
- 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** <u>Duration of Phase A.</u> 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. Section 7.2 of the Agreement is deleted in its entirety and replaced by the below new Section 7.2 with effect from the Amendment No. 5 Effective Date:
  - **"7.2 FTE Rate.** The Parties agree that the [\*\*\*] of either Party who performs research, Development, consultation or support work under any Research or Development Plan is [\*\*\*]. Commencing upon April 1 2019 and upon every anniversary thereafter, the fee will be adjusted in accordance with the percentage change over the applicable annual period in the [\*\*\*]."

- 4. Section 8.6 of the Agreement is deleted in its entirety and replaced by the below new Section 8.6 with effect from the Amendment No. 5 Effective Date.
  - **"8.6 [\*\*\*].** The costs and expenses of R&D representatives (including members of the Joint Research Committee, Joint Steering Committee, Joint Development Team members, scientists and Joint Commercialization Committee, patent attorneys, project managers) associated with [\*\*\*] under this Section 8 ("[\*\*\*]") shall [\*\*\*] (Shared Costs). Shared Costs shall be those related to any [\*\*\*] as of the 1st of July 2019 and until expiry or termination of this Agreement. For the sake of clarity: [\*\*\*].
- 5. Save as set forth in this Amendment No 5, all other terms and conditions of the Agreement shall remain in full force and effect.
- 6. This Amendment No 5 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 5.
- 7. The Parties agree that this Agreement can be signed using a DocuSign® electronic signature. Such electronic signature is the legally binding equivalent to a Party's handwritten signature and it has the same validity, enforceability and meaning as a handwritten signature and the Parties hereby waive any objection to the contrary.

IN WITNESS WHEREOF, authorized representatives of the Parties have duly executed this Amendment No 5 as of the Amendment No 5 Effective Date.

For BioNTech SE:	Genmab A/S
Date:	Date:
Signature:	Signature:
Print name:	Print name:
Title:	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

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.

**Lease No.:** 20 - 0351 - 1 -

#### 22nd 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 01.06.2020 as follows:

**Extension** 

Building: 03.51, Volmerstraße 5-9 Premises: 1327 Office (17.82m²)

Rent office: €9.38m<sup>2</sup>

Period:	un 31.05.		from 01. extend		from 01. tot	
Rental space	1,522	2.87m <sup>2</sup>	1	7.82m <sup>2</sup>	1,54	0.69m <sup>2</sup>
Rent	€	[***]	€	[***]	€	[***]
monthly advances for:						
Building utilities/building operating costs						
- 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,

**WISTA Management GmbH** 

**List of Rental Spaces** 

Lessee: JPT Peptide Technologies GmbH, Volmerstraße 5

Berlin, 13.05.2020 [signatures]

#### JPT Peptide Technologies GmbH

#### Appendix 1

#### Bilingual Key

#### DE-EN

Geschoss – Floor

Raum-Nr. – Room No.

Nutzung – Use

Fläche – Surface area

1. OG – First floor

2. OG – Second floor

3. OG – Third floor

Büro – Office

Labor-Laboratory

 $Lager-Storage\ area\ b\"uro\"ahnlich-$ 

office-like

Summe – Total

Flächenerweiterung ab 01.06.2020

– Expansion of area from 01.06.2020

**Aufstellung Mietflächen** Mieter: **JPT Peptide Technologies GmbH, Volmerstraße** 5

Geschoss	Raum-NR.	Nutzung	Fläche (m²)
1.OG	1137	Büro	20,14
1.OG	1138	Büro	23,97
1.OG	1220	Büro	17,91
1.OG	1222	Büro	17,78
1.OG	1223	Büro	17,98
1.OG	1224	Büro	17,78
1.OG	1242	Labor	28,84
1.OG	1239	Labor	29,11
1.OG	1241	Labor	21,45
1.OG	1243	Büro	15,05
1.OG	1320	Büro	23,87
1.OG	1322	Büro	17,91
1.OG	1325	Büro	17,82
1.OG	1326	Büro	17,98
1.OG	1327	Büro	17,82
1.OG	1328	Büro	17,98
2.OG	2120	Büro	16,26
2.OG	2121	Lager	18,20
2.OG	2122	Labor	17,85
2.OG	2123	Büro	23,82
2.OG	2124	Büro	17,98
2.OG	2126	Büro	11,79
2.OG	2127	Büro	17,91
2.OG	2128	Büro	11,79
2.OG	2129	Lager	25,75
2.OG	2130	Büro	14,09
2.OG	2131	Büro	17,91
2.OG	2132	Büro	39,43
2.OG	2134	Büro	20,74
2.OG	2135	Labor	21,17
2.OG	2137	Labor	39,72
2.OG	2138	Labor	22,09
2.OG	2139	Labor	29,00
2.OG	2140	Büro	17,73
2.OG	2141	Labor	23,77
2.OG	2142	Labor	25,59
2.OG	2434	Labor	29,11
3.OG	3120	Büro	17,85
3.OG	3121	Lager	29,34
3.OG	3122	Buro	17,91
3.OG	3123	Büro	17,78
3.OG	3124	Büro	17,98
3.OG	3126	Büro	11,79
3.OG	3127	Büro	17,91
3.OG	3128	Büro	11,79
3.OG	3129	Lager	25,75
3.OG	3130	Büro	14,09
3.OG	3131	Büro	17,91
3.0G	3132	Labor	39,43
3.OG	3134	Labor	20,74
3.OG	3135 3137	Labor	21,17
3.OG	3137	Labor	39,72
3.OG	3138	Labor	22,09
3.OG	3140	Labor	29,05
3.OG	3141	Labor	29,25
3.OG	3142	Labor bÿroãhligh	28,85
3.OG	3143	büroãhlich Labor	13,38
3.OG	3320 3321	Labor	17,91
3.OG	3321	Labor	17,82
3.OG	3323	Büro	30,06
3.OG	3325	Büro	24,10 17.75
3.OG	3326	Büro	17,75
3.OG	3327	Büro	17,85
3.OG	3328	Labor	23,81
3.OG	3329	Büro	11,73
3.OG	3330	Labor	23,81
3.OG	3332	Büro	17,69
3.OG	3333	Büro	17,91
3.OG	3335	Büro	15,12 26.14
3.OG	3422	Büro	36,14

 3.OG
 3424
 Büro
 22,30

 3.OG
 3735
 Büro
 17,82

 Summe
 1540,69

Flãchenerweiterung ab 01.06.2020

# 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

by and between

PFIZER INC.

and

**BIONTECH SE** 

March 17, 2020

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#### **COLLABORATION AGREEMENT**

This Collaboration Agreement (the "<u>Agreement</u>") is entered into as of March 17, 2020 (the "<u>Effective Date</u>"), 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 ("<u>Pfizer</u>") and BioNTech SE, 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 ("<u>BioNTech</u>"). Pfizer and BioNTech may each be referred to herein individually as a "<u>Party</u>" 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) in the Field (as defined below) for delivery via Delivery Technology (as defined below);

WHEREAS, Pfizer has extensive experience and expertise in the development and commercialization of pharmaceutical and biopharmaceutical products;

WHEREAS, in view of the current COVID-19 crisis, Pfizer and BioNTech wish to engage in expedited collaborative research and development pursuant to the Research and Development Plan (as defined below) to identify and develop Candidates for inclusion in the Product, seek expedited regulatory approval for such Product, and launch such Product in all countries of the Territory (as defined below) as quickly as reasonably possible; and

WHEREAS, Pfizer and BioNTech wish that Pfizer Commercializes the Product in all countries of the Territory, subject to BioNTech having the right to exclusively commercialize the Product in the BioNTech Commercialization Territory.

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 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 SE or any entity that is directly or indirectly controlled by BioNTech SE) (collectively, the "Impf Group") shall not be considered Affiliates of BioNTech.

- 1.2. "<u>Anti-Corruption Laws</u>" means all applicable anti-bribery and anti-corruption laws and regulations, including the U.S. Foreign Corrupt Practices Act of 1977, the U.K. Bribery Act 2010, and the local laws and regulations of any countries in which Candidates or Products, payments or services will be provided or procured under or pursuant to this Agreement.
- 1.3. "Applicable Data Protection Law" means all applicable personal data protection laws, rules and regulations, including the EU General Data Protection Regulation ("GDPR").
- 1.4. "<u>Bankruptcy Code</u>" 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. "<u>Binding Obligation</u>" 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 Commercialization Territory" means (a) Germany and Turkey, until such time, on a country by country basis, a BioNTech Territory Exit Option is exercised by BioNTech in respect of one or both of those countries; (b) those countries, on a country by country basis, which become Pfizer Exit Countries (if any); and (c) those countries within the Developing Countries Territory for so long as BioNTech or its Affiliate or designee pursuant to the relevant Third Party Funder agreement undertakes Commercialization of the Product in such countries.
- 1.7. "BioNTech Improvement" means any Research and Development 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 in addition to or other than the Candidates or Products (b) is not predominantly directed to the Pfizer Technology and (c) could have reasonably been developed without the aid, use or application of Pfizer Materials, Pfizer Improvements or Pfizer's Confidential Information or any improvements or enhancements thereto.
  - 1.8. "BioNTech Know-How" means [\*\*\*].
- 1.9. "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.

- 1.10. "BioNTech Patent Right" means any Patent Right (other than Pfizer Patent Rights or Patent Rights jointly owned by BioNTech and Pfizer pursuant to Section 10.2) 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 Term (other than, in either case, through the grant of a license by Pfizer) and (b) claims any BioNTech Know-How.
- 1.11. "<u>BioNTech Technology</u>" means the BioNTech Patent Rights, BioNTech Materials, BioNTech Know-How. For avoidance of doubt, BioNTech Technology includes all Intellectual Property Rights Controlled by BioNTech pursuant to the Fosun Agreement.
  - 1.12. "BioNTech Territory Exit Option" is defined in Schedule 4.1.
- 1.13. "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 and Development Program Technology, or (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.
- 1.14. "<u>Biologics License Application</u>" or "<u>BLA</u>" 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.
- 1.15. "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.
- 1.16. "Business Day" means a day other than a Saturday, Sunday or bank or other public holiday in New York, New York, USA or Mainz, Germany.
- 1.17. "<u>Candidate</u>" means an immunogenic composition in the Field that comprises Unmodified RNA Technology, Modified RNA Technology or Replicon Technology that (a) is Developed pursuant to the Research and Development Plan, (b) is Controlled by BioNTech as of the Effective Date or from time to time during the Term or (c) subject to Section 4.1, is Exploited by any of the Parties or their Affiliates pursuant to this Agreement, the Commercialization Terms and the Commercialization Agreement. Those Candidates Controlled by BioNTech and existing as of the Effective Date are set forth in Schedule 1.17.
- 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. "Capex Costs" means any capital expenditure costs associated with (a) the Research and Development Program or (b) the build-out, establishment, construction, expansion or investment in any Manufacturing facilities.

- 1.21. "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 13.7).
- 1.22. "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 III Clinical Trial or other expedited clinical trial conducted by or on behalf of one or both Parties in connection with this Agreement.
- 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. "<u>Commercialization Agreement</u>" means the definitive agreement pursuant to which (i) Pfizer shall be licensed to Commercialize the Product on the Commercialization Terms and (ii) BioNTech shall retain and have rights to Commercialize the Product in the BioNTech Commercialization Territory; such agreement to be entered into between the Parties in accordance with the provisions of Section 4 and Schedule 4.1.
- 1.25. "Commercialize" or "Commercializing" means to market, promote, distribute, offer for sale, sell, have sold, import, have imported, export, have exported or otherwise commercialize a compound or product. When used as a noun, "Commercialization" and "Commercialized" means any and all activities involved in Commercializing.
- 1.26. "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, in particular taking into account the then-current urgency of the COVID-19 crisis. 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 having regard to the circumstances, 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.

- 1.27. "Compassionate Use Purposes" means, with respect to the Product, providing Product under compassionate or emergency use or expanded access programs, including pursuant to an emergency use authorization granted by a Governmental Authority or Regulatory Authority, or in jurisdictions or to vulnerable populations experiencing emergency pandemic, or crisis epidemic, coronavirus conditions.
- 1.28. "Competitive Product" means a pharmaceutical product that incorporates an immunogenic composition comprising RNA in the Field that is intended to be, has been, or is being Exploited by a Third Party. For avoidance of doubt, Competitive Product does not include Product (a) Commercialized by or on behalf of BioNTech in the BioNTech Commercialization Territory pursuant to this Agreement or the Commercialization Agreement, as applicable; or (b) Commercialized outside of the Territory in accordance with the terms of the Fosun Agreement.
- 1.29. "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.
- 1.30. "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 Effective 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.

- 1.31. "Controll" 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.
  - 1.32. "Conversion Costs" means [\*\*\*].
- 1.33. "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.
- 1.34. "Cover", "Covered" or "Covering" means, with respect to (a) 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 and (b) a given Candidate or Product and Know-How, that such Know-How would, absent a license thereunder or ownership thereof, be misappropriated or misused by the use or making 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. "<u>Current Licenses</u>" means any agreement (a) that BioNTech or its Affiliates has entered 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 <u>Schedule 1.36</u>.
  - 1.37. "Current Licensor" means any Third Party that is a party to a Current License.

- 1.38. "<u>Delivery Technology</u>" 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 [\*\*\*].
- 1.39. "<u>Developed</u>" or "<u>Developing</u>" 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 or any research or development conducted after receipt of Regulatory Approval, including those required by any Regulatory Authority to maintain any Regulatory Approval. When used as a noun, "Development" means any and all activities involved in Developing.
- 1.40. "Developing Countries Territory." means, to the extent BioNTech or any of its Affiliates receive Third Party funding from [\*\*\*] to fund Development or Manufacturing of the Candidates or Products pursuant to this Agreement, those countries listed in Schedule 1.40 which are also defined in the relevant funding documents as "Developing Countries"; provided that if prior to the execution of such funding documents, the price of any medicinal product (including the Product) in any country within Schedule 1.40 is made relevant as a reference price for the sale of the Product in any country outside of the countries listed within Schedule 1.40, then such country shall be automatically removed as a country within Schedule 1.40, unless otherwise mutually agreed in writing by the Parties.
- 1.41. "<u>Development Budget</u>" means the budget to be agreed and updated by the JSC for all activities, costs and expenses that are to be funded as Shared Development Costs, and which initial budget for the first [\*\*\*] of this Agreement is to be agreed between the Parties in accordance with Section 2.2.
  - 1.42. "EMA" means the European Medicines Agency or any successor agency thereto.
- 1.43. "Expedited Trial Pathway" means a Clinical Trial protocol or pathway recognized or authorized by any Regulatory Authority for the emergency or expedited approval of medicines for human use, as opposed to a traditional Clinical Trial.
- 1.44. "Exploit" means to Develop, Manufacture, Commercialize, use or otherwise exploit. Cognates of the word "Exploit" will have correlative meanings.
- 1.45. "FD&C Act" means the United States Federal Food, Drug, and Cosmetic Act, as amended, and the rules and regulations promulgated thereunder.
  - 1.46. "FDA" means the United States Food and Drug Administration or any successor agency thereto.
- 1.47. "Field" means immunogenic compositions comprising RNA encoding a SARS-CoV-2 polypeptide or fragment thereof, including naturally occurring or engineered variants thereof, for prophylaxis against COVID-19 in humans.
- 1.48. "<u>Flu Collaboration License</u>" means the separate research collaboration and license agreement between, inter alia, the Parties for the development and commercialization of immunogenic compositions comprising RNA that encodes at least one Antigen for prophylaxis against influenza in humans dated July 20, 2018, as amended.

- 1.49. "Fosun" means Shanghai Fosun Pharmaceutical Industrial Development, Co. Ltd, a company incorporated in China, and having a place of business at No. 1289 Yishan Road, Shanghai, China.
  - 1.50. "Fosun Agreement" means the Development and License Agreement concluded between BioNTech and Fosun on March 13, 2020.
- 1.51. "<u>Funding Event</u>" means (a) the BioNTech Deferred Development Costs have been repaid in full (other than solely through the payment of the Regulatory Approval Milestone in the event that the then-current Development Budget contemplates the expenditure of additional funds for the continued Development of the Product); (b) a Change of Control of BioNTech; or (c) the date notice is served by either Party to terminate this Agreement in accordance with Section 13.
- 1.52. "<u>Future License</u>" means an agreement approved by the Parties (a) that BioNTech or its Affiliates enters into on or after the Effective Date with a Third Party or (b) that Pfizer or its Affiliates enters into on or after the Effective Date; which in the case of (a) and (b) grants a license (sublicensable in accordance with the licenses granted hereunder) to that Third Party's ("<u>Future Licensor</u>") Patent Rights for the Commercialization of the Candidates or Products by BioNTech and Pfizer in the Field, and which license is applicable to the Candidates or Products and is necessary to avoid, overcome or settle any potential or actual infringement of those Third Party Patent Rights.
  - 1.53. "GAAP" means United States generally accepted accounting principles, consistently applied.
  - 1.54. "GEIA" means the German Employee Invention Act.
- 1.55. "<u>GEIA Technology</u>" means all BioNTech Technology and Research and Development Program Technology invented by employees of BioNTech or its Affiliates (solely or jointly with employees of Third Parties) under the jurisdiction of GEIA.
- 1.56. "Government" or "Governmental Authority" is to be broadly interpreted and includes (a) any national, federal, state, local, regional or foreign government, or level, branch, or subdivision thereof; (b) any multinational or public international organization or authority; (c) any ministry, department, bureau, division, authority, agency, commission, or body entitled to exercise any administrative, executive, judicial, legislative, police, regulatory, or taxing authority or power; (d) any court, tribunal, or governmental arbitrator or arbitral body; (e) any government-owned or controlled institution or entity; (f) any enterprise or instrumentality performing a governmental function; and (g) any political party.
- 1.57. "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, (d) any member of a military or a royal or ruling family, and (e) 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 or -controlled hospitals, or a person serving on a healthcare committee that advises a Government, will be considered Government Officials.
  - 1.58. "Gross Profit" means [\*\*\*].

- 1.59. "GxP" means, collectively, all relevant good practice quality guidelines and regulations, encompassing such internationally recognized standards as Good Manufacturing Practice (GMP), Good Clinical Practice (GCP), Good Laboratory Practice (GLP), Good Distribution Practice (GDP), and Good Review Practice (GRP).
- 1.60. "HCP" or "Healthcare Professional" includes any physician, nurse, pharmacist, or other person who may administer, prescribe, purchase or recommend pharmaceutical products or other healthcare products.
- 1.61. "<u>Human Material</u>" means any biological samples of one or more Subjects collected, provided or utilized by BioNTech during the Research and Development Plan pursuant to this Agreement.
- 1.62. "<u>ICF</u>" means an informed consent form that was approved by a qualified Institutional Review Board or Independent Ethics Committee ("<u>IRB / IEC</u>") in accordance with all applicable Laws and recognized international standards for the protection of human research subjects.
- 1.63. "IFRS" means International Financing Reporting Standards, as in effect from time to time, together with its pronouncements thereon from time to time, consistently applied.
- 1.64. "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.
- 1.65. "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.
  - 1.66. "Joint Steering Committee" or "JSC" means the steering committee described in Section 7.3.1.
- 1.67. "<u>Joint Know-How</u>" means any Research and Development 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, which does not constitute BioNTech Know-How, Product Know-How or Pfizer Know-How.
- 1.68. "Joint Patent Rights" means Research and Development Program Patent Rights that claim or disclose any invention included in Joint Know-How.
  - 1.69. "Joint Technology" means the Joint Know-How and the Joint Patent Rights.
- 1.70. "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.

- 1.71. "Law" means any law, statute, rule, regulation, order, judgment or ordinance of any Governmental Authority, including all applicable Anti-Corruption Laws, accounting and recordkeeping laws, and laws relating to interactions with HCPs and Government Officials. For the avoidance of doubt, any specific references to any applicable Law or any portion thereof shall be deemed to include all then-current amendments thereto or any replacement or successor law, statute, standard, ordinance, code, rule, regulation, resolution, promulgation, order, writ, judgment, injunction, decree, stipulation, ruling or determination thereto.
- 1.72. "MA Holder" means, on a country by country basis within the Territory, the Party (or its Affiliate or designee under its control) that holds the Regulatory Approval required for the Commercialization of the Product in such country.
  - 1.73. "Major EU Market Country" means any of France, Germany, Italy, Spain or the United Kingdom.
  - 1.74. "Major Market Country" means the Major EU Market Countries, the United States and Japan.
- 1.75. "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", "Manufactured" or "Manufacturing" means any and all activities involved in Manufacturing a compound or protein, device or product or any component thereof.
  - 1.76. "Manufacturing Costs" means [\*\*\*].
- 1.77. "Manufacturing Plan" means the plan for establishing Manufacturing and the Manufacturing facilities, as well as the Manufacturing obligations of each Party, in respect of the Candidates and Products, as such plan may be updated and modified from time to time with the unanimous consent of the JSC, and which initial plan for the first [\*\*\*] of this Agreement is to be agreed between the Parties in accordance with Section 2.2.

- 1.78. "Manufacturing Variances" means [\*\*\*].
- 1.79. "Materials" means the Pfizer Materials or the BioNTech Materials, as the context requires.
- 1.80. "Modified RNA" means an mRNA that has been modified by the incorporation of one or more modified nucleosides, excluding the 5' CAP.
- 1.81. "Modified RNA Technology." means the BioNTech Know-How applicable to Modified RNA. For clarity, Modified RNA Technology does not include [\*\*\*].
  - 1.82. "Mutation" means [\*\*\*].
  - 1.83. "Net Sales" means with respect to a Product [\*\*\*].

[\*\*\*]

[\*\*\*]

- 1.84. "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.
- 1.85. "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.
- 1.86. "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.
- 1.87. "Personal Data" means any information relating to an identified or identifiable natural person as further specified in Art. 4 no. 1 of the GDPR.
- 1.88. "Pfizer Commercialization Territory," means the Territory, except for countries within the BioNTech Commercialization Territory from time to time.
- 1.89. "<u>Pfizer Exit Countries</u>" means, on a country by country basis, those countries out of the United Arab Emirates and South-East Asia where Pfizer elects, pursuant to the Commercialization Terms or Commercialization Agreement, not to Commercialize the Product pursuant to any Pfizer Exit Option.
- 1.90. "Pfizer Improvements" means any Research and Development 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 in addition to or 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 Know-How or BioNTech's Confidential Information or any improvements or enhancements thereto.
  - 1.91. "Pfizer Know-How" means [\*\*\*]

[\*\*\*]

- 1.92. "Pfizer Patent Right" means any Patent Right (other than Patent Rights jointly owned by BioNTech and Pfizer pursuant to Section 10.2) in any form and whether pending or issued 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, in either case, through the grant of a license by BioNTech), and (b) claims any Pfizer Know-How.
- 1.93. "<u>Pfizer Quarter</u>" 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. Wherever non-country specific timelines are specified in this Agreement in reference to a Pfizer Quarter, such reference shall be deemed to be made to the Pfizer Year applicable in the United States.
  - 1.94. "Pfizer Technology" means the Pfizer Patent Rights, Pfizer Materials and Pfizer Know-How.
- 1.95. "<u>Pfizer Year</u>" means the twelve (12) month fiscal periods observed by Pfizer (a) commencing on January 1 with respect to the USA; and (b) commencing on December 1 with respect to any country in the Territory other than the USA.
- 1.96. "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.
- 1.97. "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 it 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.
- 1.98. "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.
- 1.99. "<u>Price Approval</u>" 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).
  - 1.100. "Product" means any pharmaceutical product in a formulation suitable for administration to humans that [\*\*\*].

- 1.101. "Product Know-How" means any Research and Development Program Know-How 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 and is not generally applicable to compositions or products in addition to or other than a Candidate or Product.
- 1.102. "<u>Product Materials</u>" means all raw materials (including, without limitation, active pharmaceutical ingredients and excipients, vectors, plasmids and mRNA), labeling or packaging materials and components needed for the Manufacture and supply of a given Candidate or Product.
  - 1.103. "Product Patent Rights" means any Patent Right that claims any invention included in Product Know-How.
  - 1.104. "Product Technology" means the Product Know-How and Product Patent Rights.
- 1.105. "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.
  - 1.106. "RNA" means ribonucleic acid.
  - 1.107. "RNA Process Technology" means the BioNTech Know-How used to Manufacture Candidates or Products.
- 1.108. "RNA Technology." means Replicon Technology, Unmodified RNA Technology, Modified RNA Technology and Delivery Technology that is, in each case, used by BioNTech in the Research and Development Program
- 1.109. "Regulatory Approval" means all technical, medical and scientific licenses, registrations, authorizations and approvals (including approvals of INDs, NDAs, BLAs, 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.
- 1.110. "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.
- 1.111. "Relevant Factors" means all relevant factors that may affect the Development, Regulatory Approval or Commercialization of a Candidate or Product, including (as applicable): [\*\*\*]

[\*\*\*]

- 1.112. "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 or a sequence encoding at least one non-human polypeptide that is capable of eliciting an immune response (an "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.
  - 1.113. "Replicon Product" means any Product comprising Replicon Technology.
- 1.114. "Replicon Technology" means the BioNTech Know-How applicable to Replicons. For clarity, Replicon Technology does not include Modified RNA Technology, Unmodified RNA Technology or Delivery Technology.
- 1.115. "Representatives" means (a) with respect to Pfizer, Pfizer, its Affiliates, its Sublicensees and subcontractors, and each of their respective officers, directors, employees, consultants, contractors and agents and (b) with respect to BioNTech, BioNTech, its Affiliates, its Sublicensees and subcontractors, and each of their respective officers, directors, employees, consultants, contractors and agents.
- 1.116. "Research and Development Plan" means the research and development plan to define the Development activities pursuant to the collaboration anticipated under this Agreement, which plan is initially to be agreed between the Parties in accordance with Section 2.2 for the first [\*\*\*] of activities under this Agreement, and as may be amended from time to time pursuant to Section 6.1.
- 1.117. "Research and Development 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 and Development Plan.
- 1.118. "Research and Development 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 and Development Plan or made jointly by or on behalf of (a) BioNTech or its Representatives and (b) Pfizer or its Representatives in the conduct of activities under the Research and Development Plan.
- 1.119. "Research and Development Program Patent Rights" means any and all Patent Rights claiming or disclosing any invention included in Research and Development Program Know-How.
- 1.120. "Research and Development Program Technology" means the Research and Development Program Patent Rights and Research and Development Program Know-How.
- 1.121. "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.

- 1.122. "Shared Development Cost" means [\*\*\*].
- 1.123. "Signing Date" means April 9, 2020.
- 1.124. "South-East Asia" means [\*\*\*].
- 1.125. "Subject" means the individual donor of the Human Material or of the original tissues from which the Human Material was derived.
- 1.126. "<u>Sublicensee</u>" means any Person to whom a Party grants or has granted, directly or indirectly, a license or sublicense of any of the same Intellectual Property Rights licensed to such Party by the other Party under this Agreement in accordance with Section 3.6. For the avoidance of doubt, distributors used by a Party to Commercialize Product in a country or region shall not be regarded a Sublicensees.
- 1.127. "Tax" means all corporation tax, advance corporation tax, income tax, capital gains tax, value added tax, customs and other import duties, inheritance tax, purchase tax, capital duties, social insurance contributions, foreign taxation and duties and all penalties, charges and interest relating to any of the foregoing or resulting from a failure to comply with the provisions of any enactment relating to any of the foregoing.
  - 1.128. "Territory" means worldwide, except for the People's Republic of China (including Hong Kong SAR and Macau SAR) and Taiwan.
  - 1.129. "Third Party" means any Person other than Pfizer, BioNTech or their respective Affiliates.
- 1.130. "Third Party License Payment" shall mean a payment due to a Third Party Licensor or Future Licensor pursuant to a Current License or Future License, as applicable, that is [\*\*\*]. For the avoidance of doubt, [\*\*\*]

[\*\*\*].

- 1.131. "<u>Trademark</u>" 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.
- 1.132. "<u>Transfer Price</u>" shall mean [\*\*\*] of the Manufacturing Cost of such Candidate or Product, subject to any different percentage between [\*\*\*] as determined by the JCC, to be applied for Products to be supplied to the Developing Countries Territory or to take account of any supply requirements of any Governmental Authority within the Territory or pursuant to the terms and conditions of any funding agreement with a Third Party Funder.
  - 1.133. "Unmodified RNA" means an mRNA that [\*\*\*].
- 1.134. "<u>Unmodified RNA Technology</u>" means the BioNTech Know-How applicable to Unmodified RNA. For clarity, Unmodified RNA Technology does not include Replicon Technology, Modified RNA Technology or Delivery Technology.
- 1.135. "<u>UPC Agreement</u>" means the treaty Agreement on the Unified Patent Court signed 19 February 2013, as may be amended or superseded from time.
  - 1.136. The following terms are defined in the section of this Agreement listed opposite each term:

Defined Term	Section in Agreement
Acquirer	14.2.2
Acquisition Program	14.1.1
Additional Patent Jurisdictions	10.3.1.1
Affected Party	14.1
Agreement	Preamble
Alliance Managers	7.1
Audited Party	5.10
Auditing Party	5.10
BARDA	5.5.1
BioNTech	Preamble
BioNTech Deferred Development Costs	5.4.2
BioNTech Enforcement Patent Rights	10.4.2
BioNTech Indemnified Party	15.2
BioNTech JSC Members	7.3.1
BioNTech Prosecution Patent Rights	10.3.1.1
Capex Funding	5.5.1

<b>Defined Term</b> Change of Control Party	Section in Agreement 11.7
Commercialization Terms	4.1
Consequential Damages	15.1
Competitive Product Infringement	10.4.3
Continuing Party	10.3.2
Cure Plan	3.7.3
Debtor	13.7.1
Declining Party	10.3.2
Disputed Matter	7.3.5
Disclosing Party	11.1
Enforcement Action	10.4.1
Effective Date	Preamble
Equity Investment	5.2
Force Majeure	16.3
FTO Action	10.7.1
Global Trade Control Laws	16.10
Impf Group	1.1
Incremental Withholding Tax	5.7.1
Indemnified Party	15.4.1
Indemnifying Party	15.4.1
Infringement Claim	10.8
IRB / IEC	1.62
JSC Chair	7.3.2
Key Patent Jurisdictions	10.3.1.1
Lead Development Party	9.1.1
Lead Party	5.5.1
Liabilities	15.2
Licensed Activities	10.7.1
Litigation Conditions	15.4.2
Marketing Authorization Applications	9.2.2
Notice of Dispute	16.11.1
Party or Parties	Preamble
Patent Committee	10.1
Patent Term Extension	10.3.4
Pfizer	Preamble
Pfizer Indemnified Party	15.3
Pfizer JSC Members	7.3.1
Pfizer Materials	7.4.1
Pharmacovigilance Agreement	9.2.7
Prosecution Proceedings	10.3.5
Policies	12.3.20
Program Director and Program Directors	7.2
Reference Product Sponsor	10.4.6.2
Receiving Party	11.1
Regulatory Approval Milestone	5.3
Restricted Market	16.10.1
Restricted Parties	16.10.2
Restricted Party List	16.10.2
Review Period	11.5.2
ROW	9.1.1

Defined Term	Section in Agreement
Term	13.2
Third Party Claim	15.4.1
Third Party Funder	5.5.1
Third Party Licensor	1.12
Upfront Payment	5.1
VAT	5.7.2
Withholding Tax	5.7.1

#### 2. SCOPE OF COLLABORATION

- 2.1. <u>Scope of Collaboration</u>. Subject to the terms and conditions of this Agreement, the Parties shall (a) cooperate in good faith to conduct their respective activities under the Agreement; and (b) establish one or more committees as described in Article 7 of this Agreement to oversee and coordinate the Development, Manufacture and Commercialization of Candidates and Products in the Territory.
- 2.2. <u>Initial Research and Development Plan and Manufacturing Plan</u>. Commencing on the Signing Date each Party shall, acting reasonably and in good faith, negotiate and seek to agree binding versions of the Research and Development Plan, Development Budget and the Manufacturing Plan, which shall be agreed by [\*\*\*]. The Research and Development Plan to be agreed shall reflect the requirements described in Sections 6.1 and 6.2.

### 3. <u>LICENSES.</u>

### 3.1. Research Licenses.

- 3.1.1. **Research 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 a sole license under the BioNTech Technology to use, have used, Develop, have Developed, Manufacture, and have Manufactured [\*\*\*] Candidates and Products within the Territory [\*\*\*].
- 3.1.2. Research License from Pfizer to BioNTech. Subject to the terms and conditions of this Agreement, effective as of the Effective Date, Pfizer on behalf of itself and its Affiliates hereby grants (and will procure that its Affiliates grant) to BioNTech a sole license under the Pfizer Technology to use, have used, Develop, have Developed, Manufacture, and have Manufactured [\*\*\*] (a) Candidates and Products and within the Territory [\*\*\*], and (b) Candidates or products identical to any Product within the Field for their Development (but not Manufacture) outside the Territory by or on behalf of BioNTech (including by Fosun or its Affiliates) pursuant to the Fosun Agreement. With respect to (b) above, such license shall (i) exclude and prohibit the disclosure and license by BioNTech of Pfizer Technology used for Manufacture or formulation of the Candidate or Products, other than to the extent necessary for Fosun or its Affiliates to undertake fill/finish of a product identical to any Product in China or to comply with information requirements of the China National Medical Products Administration relating to such product required under applicable Law; and (ii) automatically terminate on the termination or expiration of the Fosun Agreement and will, unless earlier terminated, survive the termination or expiration of this Agreement in those circumstances described in Section 13.

3.1.3. **Scope of Research Licenses**. Each of the licenses granted under Section 3.1.1 and 3.1.2 is (a) a sole license, such that the applicable licensor Party shall not grant a Third Party (unless it is necessary for the Third Party undertaking a fee-for-service Development or Manufacturing activity on its behalf pursuant to this Agreement) a license under the same Intellectual Property Rights for any Exploitation within the Field and within the Territory in respect of any product, whether or not it is a Candidate or Product; (b) royalty-free; (c) sub-licensable in accordance with and subject to Section 3.6; (d) non-assignable, in whole or part, other than where a Party's benefit under this Agreement may be assigned pursuant to Section 16.1; and (e) granted subject to the provisions of this Agreement, and for the duration of the Term or until termination or expiry of this Agreement if earlier, unless otherwise specified herein.

#### 3.2. Licenses for Commercial Manufacturing.

- 3.2.1. 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 a non-exclusive license under the BioNTech Technology to Manufacture and have Manufactured Candidates and Products for use within the Territory and, subject to Section 3.4, Commercialization within the Territory in any indication.
- 3.2.2. License from Pfizer to BioNTech. Subject to the terms and conditions of this Agreement, effective as of the Effective Date, Pfizer on behalf of itself and its Affiliates hereby grants (and will procure that its Affiliates grant) to BioNTech a non-exclusive license under the Pfizer Technology to Manufacture and have Manufactured (a) Candidates and Products for Commercialization within the Territory in accordance with Section 3.4 in any indication and (b) Candidates and products identical to any Product within the Field for their use and Commercialization outside the Territory by BioNTech or Fosun and its Affiliates pursuant to the Fosun Agreement. With respect to (b) above, such license shall (i) exclude and prohibit the disclosure and license by BioNTech of Pfizer Technology used for Manufacture or formulation of the Candidate or Product, other than to the extent necessary for Fosun or its Affiliates to (x) undertake fill/finish of a product identical to any Product in China or (y) comply with information requirements of the China National Medical Products Administration relating to such product required under applicable Law; and (ii) shall automatically terminate on the termination or expiration of the Fosun Agreement and will, unless earlier terminated, survive the termination or expiration of this Agreement in those circumstances described in Section 13.
- 3.2.3. **Scope of Commercial Manufacturing Licenses**. Each of the licenses granted under Section 3.2.1 and 3.2.2 is (a) royalty-free; (b) sub-licensable in accordance with and subject to Section 3.6; (c) non-assignable, in whole or part, other than where a Party's benefit under this Agreement may be assigned pursuant to Section 16.1; and (d) granted subject to the provisions of this Agreement, and for the duration of the Term or until termination or expiry of this Agreement if earlier, unless otherwise specified herein.

#### 3.3. Regulatory Dossier Licenses.

3.3.1. License from BioNTech to Pfizer. Effective as of the Effective Date, in respect of the Drug Master Files, Regulatory Approvals and Regulatory Documentation (as defined in the Fosun Agreement), BioNTech hereby grants to Pfizer a sole license to rely upon and make reference to such Drug Master Files, Regulatory Approvals and Regulatory Documentation (and the data referenced therein), to use the same in respect of any application for, and maintaining, any Regulatory Approvals (as defined in this Agreement) filed by Pfizer pursuant to this Agreement in respect of Candidates or Products. The license granted under this Section 3.3.1 is (a) royalty-free; (b) sub-licensable in accordance with and subject to Section 3.6; (c) non-assignable, in whole or part, other than where a Party's benefit under this Agreement may be assigned pursuant to Section 16.1; and (d) granted subject to the provisions of this Agreement, and for the duration of the Term or until termination or expiry of this Agreement if earlier, unless otherwise specified herein. BioNTech shall procure disclosure of such Drug Master Files, Regulatory Approvals and Regulatory Documentation upon Pfizer's request. Without limiting any of the foregoing, but subject to Section 3.10, BioNTech shall be permitted to use such Drug Master Files, Regulatory Approvals and Regulatory Documentation (to the extent not comprising Pfizer's Technology or Pfizer's Confidential Information) with respect to any application for or maintenance of any Regulatory Approvals outside the Field.

#### 3.4. Commercialization Licenses.

- 3.4.1. License from BioNTech to Pfizer. Subject to the terms and conditions of this Agreement, and the terms of Schedule 4.1 until the Parties execute the Commercialization Agreement, BioNTech on behalf of itself and its Affiliates hereby grants (and will procure that its Affiliates grant) to Pfizer an exclusive (even as to BioNTech) license under the BioNTech Technology to Commercialize and have Commercialized Products within the Pfizer Commercialization Territory in any indication. The foregoing license shall be subject to the terms of the Commercialization Agreement once executed.
- 3.4.2. **License from Pfizer to BioNTech**. Subject to the terms and conditions of this Agreement, and the terms of Schedule 4.1 until the Parties execute the Commercialization Agreement, Pfizer on behalf of itself and its Affiliates hereby grants (and will procure that its Affiliates grant) to BioNTech a license under the Pfizer Technology to Commercialize and have Commercialized (a) Products within the BioNTech Commercialization Territory in any indication, which license shall be granted on a sole basis; and (b) products identical to any Product within the Field but outside the Territory by BioNTech or by Fosun or its Affiliates pursuant to the Fosun Agreement. With respect to (b) above, such license shall (i) be sole; (ii) royalty-bearing; (iii) exclude and prohibit the disclosure and license by BioNTech of Pfizer Technology used for Manufacture or formulation of any Candidate or Product, other than to the extent necessary for Fosun or its Affiliates to (x) undertake fill/finish of a product identical to any Product in China or (y) comply with information requirements of the China National Medical Products Administration relating to such product required under applicable Law; and (iv) shall automatically terminate on the termination or expiration of the Fosun Agreement and will, unless earlier terminated, survive the termination or expiration of this Agreement in those circumstances described in Section 13.
- 3.4.3. **Scope of Commercialization Licenses**. Each of the licenses granted under Section 3.4.1 and 3.4.2 is (a) sub-licensable in accordance with and subject to Section 3.6; (b) non-assignable, in whole or part, other than where a Party's benefit under this Agreement may be assigned pursuant to Section 16.1; and (c) granted subject to the provisions of this Agreement, the Commercialization Agreement upon its execution, Schedule 4.1 and for the duration of the Term or until termination or expiry of this Agreement if earlier, unless otherwise specified herein. Furthermore, [\*\*\*].

#### 3.4.4. **Financial Provisions for Commercialization**. The license under:

- 3.4.4.1. Section 3.4.1 and 3.4.2(a) is royalty-free but each is subject to the Gross Profit share set out in the Commercialization Terms; and
- 3.4.4.2. Section 3.4.2(b) shall be royalty bearing at a rate of (i) [\*\*\*] percent of net sales of the product(s) sold pursuant to the Fosun Agreement where such product(s) is Covered by any Pfizer Patent Right or any Joint Patent Rights (ii) if, or when, (i) does not apply, then [\*\*\*] percent of net sales of the product(s) sold pursuant to the Fosun Agreement where such product(s) is Covered by any Pfizer Know-How or any Joint Know-How with net sales having the same definition, *mutatis mutandis*, to Net Sales under this Agreement, with sales and royalty reporting every Pfizer Quarter, payments on a Pfizer Quarter basis, and Pfizer having audit rights comparable with those under this Agreement); *provided*, *however*, that (a) during the period in which a generic or biosimilar equivalent to such product(s) is Commercialized in any part of the territory that is the subject of the Fosun Agreement, the royalty under (i) above shall be reduced by [\*\*\*]; or (b) if the gross profit share earned by BioNTech in connection with sale of products under the Fosun Agreement is lower than the royalty amount to be paid to Pfizer hereunder in respect of those same sales, then no royalty shall be payable hereunder for those sales. The foregoing royalty obligations shall commence on the first commercial sale of the product(s) sold pursuant to the Fosun Agreement, and extend (a) with respect to the royalty under (i) for so long as such product(s) is Covered by any such Patent Rights (until such Patent Right expires, is surrendered, or is otherwise irrevocably revoked or declared invalid), and (b) with respect to the royalty under (ii), the [\*\*\*] anniversary of the date of the first commercial sale of such product(s) in the territory that is the subject of the Fosun Agreement; and in each case, such provision shall survive the termination or expiry of this Agreement.

### 3.5. Additional Licenses.

3.5.1. **To Pfizer**. Without limiting any other license or sublicense granted under this Agreement or the Commercialization 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 and Product Technology that were solely or jointly made or invented by Pfizer Representatives to use, have used, Develop, have Developed, Manufacture, have Manufactured, Commercialize, have Commercialized and otherwise Exploit any products or processes outside the Field. In addition to the obligations set forth in Section 3.10 for the avoidance of doubt, the license granted in this Section 3.5.1 shall not include or imply a right of Pfizer to use any of BioNTech's Confidential Information (that is not a BioNTech Improvement or Product Technology) outside the Field.

#### 3.5.2. **To BioNTech**.

3.5.2.1. Without limiting any other license or sublicense granted under this Agreement or the Commercialization 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.

- 3.5.2.2. Without limiting any other license or sublicense granted under this Agreement or the Commercialization 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 Pfizer's interest in the Research and Development Program Technology to use, have used, Develop, have Developed, Manufacture, have Manufactured, Commercialize, have Commercialized and otherwise Exploit any products or processes outside the Field.
- 3.5.2.3. For the avoidance of doubt, the licenses granted in this Section 3.5.2 shall not include or imply a right of BioNTech to use any Pfizer Confidential Information (that is not a Pfizer Improvement or Research and Development Program Technology) outside the Field, but remain subject to the obligations set forth in Section 3.10.

3.6. <u>Sublicensees</u>. Either Party shall have the right to grant sublicenses and, as applicable, sub-sublicenses under and subject to the rights granted to it under this Section 3 to (a) its Affiliates; (b) permitted Third Party subcontractors which such Party uses to undertake services for, or to perform its obligations under, this Agreement, the Commercialization Terms and the Commercialization Agreement; (c) Sublicensees in respect of Manufacturing, provided that, other than where a sublicense is required by a Governmental Authority or pursuant to a Third Party Funder agreement, the sublicensing Party shall (i) discuss the proposed use of a Third Party with the other Party, and take into account any reasonable views, objections or comments with respect to the proposed Third Party; (ii) impose industry standard obligations of confidentiality and non-use on the Third Party with respect to the other Party's Confidential Information, and limit the disclosure of that other Party's Confidential Information so far as is reasonably necessary; and (iii) not, where Pfizer is the sublicensing Party, subcontract Manufacturing of the Product [\*\*\*] without BioNTech's prior consent (such consent not to be unreasonably withheld); and (d) distributors of the Product in the Territory; and (e) in the case of BioNTech, and subject to the restrictions in Sections 3.1, 3.2, and 3.4 and the terms of Section 11, Fosun and any of Fosun's Affiliates pursuant to the Fosun Agreement for Commercialization in the Field outside the Territory. In respect of any and all such sublicenses (or sub-sublicenses):

- 3.6.1. the sublicensing Party shall be responsible for failure by its Sublicensees to comply with the terms and conditions of this Agreement;
- 3.6.2. the rights sublicensed under the sublicense may not be further sublicensed by the Sublicensee;
- 3.6.3. the sublicensing Party shall notify the other Party in writing of any sublicenses granted to Third Parties (other than Fosun);

- 3.6.4. in the event of a sublicense in respect of the Commercialization of Product, shall provide a copy of the relevant sublicense agreement to the other Party upon request which may be redacted to delete provisions not applicable to the calculation of Gross Profits; and
- 3.6.5. unless otherwise agreed between the Parties on a case-by-case basis, all sublicenses shall automatically terminate (and the sublicensing Party shall ensure that all sublicenses automatically terminate) upon termination (for whatever reason) or expiry of a license granted hereunder, but only to the extent necessary to terminate the sublicense in so far as it corresponds to any terminated or expired licenses granted in this Agreement.

#### 3.7. BioNTech Current Licenses.

- 3.7.1. **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 (including any increase in Third Party License Payments) 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.
- 3.7.2. **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 3 and will use Commercially Reasonable Efforts to cause each applicable Current Licensor to perform all of its obligations under the applicable Current License.
- 3.7.3. **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, under the Commercialization Agreement, 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 payme

- 3.7.4. **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:
  - 3.7.4.1. 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 (a) 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 (b) the amount that would have to be reimbursed by Pfizer to BioNTech in accordance with the terms of the Commercialization Agreement; or
  - 3.7.4.2. 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 the Commercialization Agreement.
- 3.7.5. 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.
- 3.7.6. **Exceptions to the Fosun Agreements**. If BioNTech (as opposed to Pfizer) has breached the Fosun Agreement [\*\*\*]. In addition, in respect of the Fosun Agreement (i) [\*\*\*]; and (ii) [\*\*\*].

- 3.7.7. **Reduction in Royalties**. BioNTech shall use reasonable efforts to obtain any reductions or waivers in royalties or other payments due under the Current Licenses that could constitute Third Party License Payments due to the pandemic status of COVID-19 or with respect to countries or populations experiencing emergency pandemic or crisis epidemic, coronavirus conditions, including taking into account any restrictions on pricing for the Product based on applicable Law and funding agreements with Third Party Funders. For the avoidance of doubt, BioNTech does not guarantee that any such reductions or waivers can be obtained from such licensors.
- 3.8. Third Party Agreements. Each Party will be solely responsible for all obligations (including royalty and payment obligations) that relate to Candidates, Products, BioNTech Technology or Pfizer Technology under its or its Affiliates' own agreements with Third Parties that are in effect on or prior to the Effective Date, including the Current Licenses for which BioNTech has sole responsibility.
- 3.9. <u>No Implied Rights</u>. 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.

#### 3.10. Exclusivity.

- 3.10.1. **Mutual Exclusivity.** Except if otherwise permitted by the unanimous consent of the JSC, during the Term, neither Party shall, and shall procure that its Affiliates shall not, itself or with or on behalf of a Third Party, Develop, have Developed, Manufacture, have Manufactured, Commercialize, have Commercialized or otherwise Exploit or have Exploited any [\*\*\*] in the Field within the Territory, except that each Party may continue any existing agreement with a Third Party for non-clinical research within the Field with academic institutions and consortia. For avoidance of doubt, the foregoing exclusivity obligation shall not apply to (a) [\*\*\*]; (b) [\*\*\*]; (c) [\*\*\*].
- 3.10.2. **Exclusivity of the Licenses**. Without prejudice to the licenses granted by BioNTech pursuant to this Section 3 or pursuant to the Commercialization Agreement, BioNTech shall not, and shall procure that its Affiliates shall not, grant any license, permission, waiver, covenant not to sue, or other right to use or Exploit any of the BioNTech Technology within the Field and within the Territory that would conflict with or erode any of Pfizer's rights hereunder.

3.10.3. Exclusivity in the Product. Except pursuant to this Agreement or the Commercialization Terms or Commercialization Agreement, neither Party shall, and shall procure that its respective Affiliates shall not, itself or with or on behalf of a Third Party, Develop, have Developed, Manufacture, have Manufactured, Commercialize, have Commercialized or otherwise Exploit (a) any Candidate Controlled by BioNTech as of the Effective Date within the Field; or (b) any Candidate that, as a consequence of the Development under this Agreement, becomes Controlled by BioNTech after the Effective Date, for any field; or (c) any Product for any field or application; in each case (a), (b) and (c) other than for non-clinical research purposes, or within the Field pursuant to the Fosun Agreement.

### 4. <u>COMMERCIALIZATION</u>

- 4.1. <u>Commercialization Agreement</u>. With respect to Commercialization, the Parties have agreed to the terms set forth in Schedule 4.1 ("<u>Commercialization Terms</u>") and will, for [\*\*\*] following the Signing Date (or any other time period agreed by the Parties in writing), negotiate and execute a definitive Commercialization Agreement reflecting such Commercialization Terms. Such agreement shall be negotiated in good faith and acting reasonably, and shall set forth the rights and responsibilities of the Parties in connection with the Commercialization of the Products and which shall be consistent with the Commercialization Terms. If the Commercialization Agreement is not executed within the [\*\*\*] period the Parties will prioritize and engage in additional discussions to conclude and execute the Commercialization Agreement as soon as possible.
- 4.2. <u>Commercialization Rights Pending Agreement</u>. If a definitive Commercialization Agreement is not executed before the Product is first ready to be Commercialized in the Territory, each Party may still commence and continue with the Commercialization of the Product in its respective Commercialization territory, but shall do so subject to the provisions of the Commercialization Terms until the Commercialization Agreement is executed.

#### 5. PAYMENTS AND FUNDING.

- 5.1. <u>Upfront Payment</u>. Pfizer shall make a one-time, non-refundable (without limiting Pfizer's right to claim for damages under this Agreement) payment of Seventy-two Million Dollars (\$72,000,000) to BioNTech ("<u>Upfront Payment</u>") within thirty (30) days of receipt of BioNTech's invoice (such invoice to be delivered on or following the Signing Date), but not before the Research and Development Plan, Development Budget and Manufacturing Plan are agreed between the Parties in accordance with Section2.2, which payment shall be dedicated to activities to be performed under the Research and Development Plan.
- 5.2. <u>Equity Investment</u>. Pfizer and BioNTech shall enter into an "Investment Agreement" contemporaneously with this Agreement pursuant to which Pfizer agrees to subscribe for shares in BioNTech in consideration for an investment amount of One Hundred and Thirteen Million Dollars (\$113,000,000) based on a price per share of \$47.53, subject to the conditions as prescribed in such Investment Agreement ("Equity Investment").
- 5.3. <u>Regulatory Milestone Payment</u>. Within [\*\*\*] of the date upon which either BioNTech or Pfizer first obtains all Regulatory Approvals required for the Commercialization of the Product in a Major Market Country in the Territory, Pfizer shall pay BioNTech a one-time, non-refundable (without limiting Pfizer's right to claim for damages under this Agreement) milestone payment of [\*\*\*] Dollars (US\$[\*\*\*]) ("<u>Regulatory Approval Milestone</u>"), which shall be automatically applied to repayment of, and offset against, the BioNTech Deferred Development Costs, and to the extent that at such time the BioNTech Deferred Development Costs are less than the value of the Regulatory Approval Milestone any difference shall be paid to BioNTech.

#### 5.4. Sharing of Development Costs.

- 5.4.1. **Shared Development Costs.** Except as otherwise provided herein, each Party shall bear fifty percent (50%) of all Shared Development Costs.
- 5.4.2. **BioNTech Deferred Development Costs**. Without prejudice to Section 5.4.1, BioNTech's share of the Shared Development Costs incurred in accordance with the binding parts of the Development Budget, Research and Development Plan and the Manufacturing Plan, and this Agreement, and which are not funded by a Third Party Funder, shall be funded initially by way of an interest free repayable loan from Pfizer unless and until there is a Funding Event ("<u>BioNTech Deferred Development Costs</u>"). Following a Funding Event, BioNTech shall thereafter fund its share of the Shared Development Costs in accordance with Section 5.4.4. The BioNTech Deferred Development Costs shall be funded by Pfizer but shall be subject to the reporting and reconciliation provisions of Section 5.4.4. The BioNTech Deferred Development Costs shall be repayable through (a) the Regulatory Approval Milestone, if paid pursuant to Section 5.3; (b) a proportion of the Commercialization Sales Milestone Payments (as defined and described in <u>Schedule 4.1</u>); (c) Pfizer's retention of the Enhanced Profit Share element of Gross Profits pursuant to the Commercialization Terms set out in the Commercialization Terms and (d) an immediate lump sum paid by BioNTech upon (i) Change of Control of BioNTech pursuant to Section 14.1.3.3, provided that the most recent published annual group net income, published prior to the date of such Change of Control, of the Third Party acquiring BioNTech is [\*\*\*] Dollars or (ii) termination of this Agreement for BioNTech's breach or its bankruptcy or insolvency. If this Agreement is terminated by Pfizer pursuant to its right under Section 13.4, the BioNTech Deferred Development Costs shall cease to be repayable by BioNTech.
- 5.4.3. **Budgeting of Shared Development Costs.** The Parties shall agree on, and regularly update (if required), the Development Budget through the JSC. As soon as either Party determines that it is likely to overspend on the binding part of the Development Budget that is allocated to that Party by more than [\*\*\*], it shall inform the JSC accordingly, and shall only be entitled to incur such overrun costs as Shared Development Costs pursuant to Section 5.4.1 and 5.4.2 upon the JSC's mutual consent.
- 5.4.4. **Reporting and Reconciliation.** Wherever possible and practicable, prior to any Funding Event any external Shared Development Costs incurred in accordance with the binding parts of the Development Budget shall initially be invoiced to and borne by Pfizer, but shall be subject to reimbursement in accordance with this Section 5.4.4. All other Shared Development Costs incurred in accordance with the binding parts of the Development Budget shall initially be borne by the Party incurring such costs and shall thereafter be subject to reimbursement in accordance with this Section 5.4.4. Each Party shall report to the other Party, within [\*\*\*] after the end of each Pfizer US Quarter, the Shared Development Costs incurred by such Party during such Pfizer Quarter. Such report shall specify in reasonable detail all amounts included in such Shared Development Costs during such Pfizer Quarter (broken down by activity), and out-of-pocket costs shall be allocated to the extent possible to a specific activity in the applicable binding part of the Research and Development Plan. Each such report shall enable the receiving Party to compare the reported Shared Development Costs against the applicable binding part of the Development Budget previously approved by the JSC, on both a quarterly basis and a cumulative basis for each activity. The Parties shall seek to resolve any questions related to such accounting statements within [\*\*\*] following receipt by each Party of the other Party's report hereunder. Following such resolution, BioNTech shall prepare a reconciliation report for the Shared Development Costs for such Pfizer Quarter (including as against the binding parts of the Development Budget) and shall either (a) deliver an invoice to Pfizer for any amounts due to

BioNTech as a result of reconciliation or (b) notify Pfizer that it should issue an invoice to BioNTech for any amounts due to Pfizer as a result of reconciliation. Any such invoice from BioNTech to Pfizer shall be payable within [\*\*\*] from receipt by Pfizer. Prior to any Funding Event, any such invoice from Pfizer to BioNTech shall not be payable upon receipt, but shall be accounted as BioNTech Deferred Development Costs and shall be payable in accordance with the mechanism described in Section 5.4.2. Following any Funding Event, any such such invoice from Pfizer to BioNTech shall be payable within [\*\*\*] from receipt by Pfizer.

- 5.4.5. **Capex Costs**. Notwithstanding anything else in this Agreement, each Party shall be solely responsible for its own Capex Costs and any capital expenditures required in connection with this Agreement or the Commercialization Agreement.
- 5.4.6. **Other Costs.** Except as expressly set forth otherwise in this Agreement), each Party will bear all costs and expenses it incurs in connection with its activities under this Agreement.

#### 5.5. Third Party Funding.

- 5.5.1. **Third Party Funders.** Pfizer and BioNTech shall, in good faith and acting collaboratively, seek funding from one or more Third Parties for such Third Party to provide financial support to the collaboration between the Parties under this Agreement (each, a "<u>Third Party Funder</u>"). For each potential Third Party Funder, the Parties will agree on (a) the Party to lead the communications and discussions with such Third Party Funder (the "<u>Lead Party</u>.") and (b) the activities, costs or expenses for which funding support shall be sought (e.g. funding for Development costs, funding in support of a Party's Capex Costs ("<u>Capex Funding</u>") or both). An initial list of potential Third Party Funders and their allocation as between the Parties is set forth in Schedule 5.5. Notwithstanding the foregoing, Pfizer shall be entitled to secure funding from, and shall be the Lead Party in discussions with, [\*\*\*], in the event that Pfizer, in its sole discretion, [\*\*\*], and BioNTech shall be entitled to secure funding from, and shall be the Lead Party in discussions with, [\*\*\*], in the event that BioNTech, in its sole discretion, chooses to seek funding from [\*\*\*].
- 5.5.2. **Discussions with Funders.** The Lead Party will lead any discussions with such Third Parties in any country, provided that the Lead Party will provide regular updates to the JSC and keep the JSC reasonably informed of the status and any developments in such discussions, and shall, at the other Party's reasonable request, update the other Party on any such discussions. The Lead Party shall conduct any such discussions and draft and file any applications for any Third Party Funding in good faith and acting reasonably with respect to its requests for such funding. Where legally possible and unless otherwise agreed between the Parties, each application for any Third Party funding shall be made in both Parties' name unless the Parties have agreed in advance pursuant to Section 5.5.1 that such application shall be in respect of one Party's Capex Funding alone, in which case such application may be made in that Party's own name alone. The Lead Party shall not enter into a written agreement with any Third Party Funder without prior written consent of the other Party (such consent not to be unreasonably withheld, conditioned or delayed) unless the Parties have agreed in advance pursuant to Section 5.5.1 that such agreement shall be in respect of that Lead Party's Capex Funding alone, in which case the Lead Party can conclude such Third Party Funder agreement without consent from the other Party. Notwithstanding the foregoing, (a) Pfizer shall be entitled to seek any funding from [\*\*\*] without requiring BioNTech's consent; and (b) BioNTech shall be entitled to seek any funding from [\*\*\*] without requiring Pfizer's consent. Pfizer and BioNTech acknowledge and agree that there is no guaranty that any Lead Party will be successful in securing any funding from any Third Party Funder or that any specific amount of funding will be obtained.

- 5.5.3. **Allocation of Funds and Balancing Payment.** To the extent possible, any Third Party funding to the extent it relates to activities in relation to which the Parties have agreed to treat the associated Development costs as Shared Development Cost shall be shared equally between the Parties. If such sharing is not possible, a balancing adjustment shall be made in favor of the other Party to the Shared Development Costs to reflect [\*\*\*] percent of such funding that that Party receives from the Third Party Funder provided that doing so does not breach any applicable Laws or the terms of such funding. Each Party shall promptly report to the other Party in writing if and when it receives any payments from any Third Party Funder funding that relates to activities, costs or expenses that are Shared Development Costs.
- 5.5.4. **Not Applicable to Loans.** For the avoidance of doubt, this Section 5.5 shall not apply to any traditional loans provided by any Third Party to a Party provided that (a) such loans are repayable by the borrower Party and not, directly or indirectly, by the other Party; (b) this Agreement, the Commercialization Agreement, any other agreement ancillary to this Agreement or the Commercialization Agreement, the BioNTech Technology, Product Technology and Product are not provided as security for, or otherwise encumbered by way of, such loan (excluding, for clarity, any tangible assets). Each Party shall be entitled to seek any such loans from any Third Party without any obligations to the other Party.
- 5.6. Records and Accounting Principles. Each Party shall keep books and records of any of Shared Development Costs and any Third Party funding in accordance with good industry practice and GAAP or IFRS, as applicable. Each Party shall determine Shared Development Costs using its standard accounting procedures, consistently applied and in accordance with GAAP or IFRS, as applicable (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). All personnel costs of either Party or its Affiliates are excluded from Shared Development Costs.

#### 5.7. <u>Taxes</u>.

5.7.1. Withholding Taxes. The Parties agree to use 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 compensation under this Agreement, the liability for such Withholding Taxes shall be the sole responsibility of the receiving Party, and the paying Party shall (a) deduct or withhold such Withholding Taxes from the payment made to the receiving Party, (b) timely pay such Withholding Taxes to the proper taxing authority, and (c) send proof of payment to the receiving Party within [\*\*\*] 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 5.6 (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.

- 5.7.2. **Value Added Tax**. All payments between the Parties under this Agreement are exclusive of applicable statutory value added tax or similar taxes ("<u>VAT</u>"), 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.
- 5.7.3. **Other.** Except as otherwise set forth in this Section 5.7, 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.
- 5.8. <u>Currency, Source of Payments</u>. All amounts payable and calculations under this Agreement will be in United States dollars, [\*\*\*]. As applicable, all costs and expenses will be translated into United States dollars at the exchange rate used by the relevant Party 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 under this Section 5.8, 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 the Party owing the relevant payment may elect, in its sole discretion, to deliver such payment in the relevant jurisdiction and in the local currency of the relevant jurisdiction.
- 5.9. Method of Payment. Except as permitted pursuant to Section 5.8, 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 the paying Party's election, to such bank account as the receiving Party will designate in writing to the other Party within [\*\*\*] of the Signing Date, and thereafter at least [\*\*\*] before the payment is due. All invoice or billing related questions in relation to Pfizer should be referred to Pfizer's Accounting Department at 800.601.1357 or go to the Accounts Payable Invoice Portal at ap.pfizer.com. Unless otherwise specified herein, each invoice is payable within [\*\*\*] of receipt of the relevant invoice.
- 5.10. Audits. Upon [\*\*\*] prior notice from a Party (the "Auditing Party"), the other Party (the "Audited Party") will permit an independent certified public accounting firm of nationally recognized standing selected by the Auditing Party and reasonably acceptable to the Audited Party, to examine, [\*\*\*], the relevant books and records of the Audited Party and its Affiliates (and where possible, its subcontractors) as may be reasonably necessary to verify the amounts reported by the Audited Party in accordance with Sections 5.4 and 5.5. An examination by the Auditing Party under this Section 5.10 will occur not more than [\*\*\*] and will be limited to the pertinent books and records for any Calendar Year ending not more than [\*\*\*] before the date of the request. The accounting firm will be provided access to such books and records at the Audited Party's or its Affiliates' facility(ies) where such books and records are normally kept and such examination will be conducted during the Audited Party's or its Affiliates' normal business hours. The Audited Party may require the accounting firm to sign a reasonably acceptable non-disclosure agreement before providing the accounting firm with access to the Audited Party's or its Affiliates' 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 the Audited Party, and, in each case, the specific details concerning any discrepancies. No other information will be provided to the Auditing Party.

- 5.10.1. **Underpayments/Overpayments**. If such accounting firm concludes that there are errors in how Shared Development Costs have been charged, allocated or reclaimed, or Third Party funding has not been allocated in accordance with this Agreement by the Audited Party, then adjustments shall be made in accordance with the accounting firm's recommendations in a reconciliation of Shared Development Costs and any overpayment or underpayment by the Audited Party shall be rectified either by a refund to, or payment by, the Audited Party from or to the Auditing Party within [\*\*\*] of the date the Audited Party receives such accountant's written report. Further, if the amount of any overpayment or overallocation to the Audited Party exceeds more than [\*\*\*] of the amount that was properly payable due or allocated to the Audited Party, then the Audited Party will reimburse the Auditing Party for the Auditing Party's out-of-pocket costs in connection with the audit.
- 5.10.2. **Confidentiality**. Notwithstanding any provision of this Agreement to the contrary, all reports and financial information of the Audited Party or its Affiliates which are provided to or subject to review by the Auditing Party will be deemed to be Confidential Information of the Audited Party and subject to the provisions of Section 11.1.

#### 5.11. No Guaranty of Success.

- 5.11.1. Pfizer and BioNTech acknowledge and agree that any milestone payments pursuant to BioNTech hereunder or under the Commercialization Terms: (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 accordance with the applicable milestone or event, 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 and BioNTech; (c) are not intended to be used as a measure of damages if this Agreement is terminated for any reason; and (d) will only be triggered, and will only be relevant as provided, in accordance with the terms and conditions of such provisions.
- 5.11.2. 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 (a) the successful Development or Commercialization of any Product under this Agreement, (b) the number of Products that will or may be successfully Developed or Commercialized under this Agreement, (c) anticipated sales or the actual value of any Products that may be successfully Developed or Commercialized under this Agreement or (d) the damages, if any, that may be payable if this Agreement is terminated for any reason.
- 5.11.3. Neither Party makes any representation, warranty or covenant, either express or implied, to the other Party 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) it will devote, or cause to be devoted, any level of diligence or resources to Developing, Manufacturing or Commercializing any Product in any country, or in the Territory.

#### 6. RESEARCH AND DEVELOPMENT PLAN

- 6.1. Scope of Development and Updating of Plans. Pfizer and BioNTech will collaborate during the Term to conduct research to identify, Develop and evaluate Candidates and Products within the Field in accordance with the binding parts of the Research and Development Plan, the Development Budget, the Manufacturing Plan, and the terms and conditions set forth in this Section 6. The Research and Development Plan may be modified by agreement and approval of the JSC pursuant to Section 7, provided that the JSC shall have no right or authority to (a) modify the Research and Development Plan in a way not permitted under Section 7.3; or (b) modify the Research and Development Plan so as to amend the contractual provisions of this Agreement. The initial [\*\*\*] of each of the Research and Development Plan, the Manufacturing Plan and the Development Budget shall be agreed between the Parties by [\*\*\*], the first [\*\*\*] of each are binding upon the Parties and the second [\*\*\*] are indicative but non-binding. At least [\*\*\*] prior to the expiration of such initial [\*\*\*] binding period, the JSC shall decide and mutually agree on the following [\*\*\*] period of each of the Research and Development Plan, the Manufacturing Plan and the Development Budget which period, upon agreement, shall be binding upon the Parties subject to Section 7.3.4. At least [\*\*\*] days prior to the expiration of the initial [\*\*\*] period following the Effective Date, the JSC shall establish a rolling [\*\*\*] process to decide on and update each of the Research and Development Plan, the Development Budget and the Manufacturing Plan for subsequent [\*\*\*] periods, each of which shall be updated by the JSC no later than [\*\*\*] prior to the expiration of the then binding [\*\*\*] period.
- 6.2. Research and Development Plan. The Research and Development Plan shall (a) include a broad non-binding overview of the first [\*\*\*] of the planned Development program (specifying in reasonable detail all material Development activities) to generate the preclinical, clinical, CMC, regulatory and other information required for submitting a marketing authorization application for Regulatory Approval for the Candidate or Product and to achieve such Regulatory Approval for the Candidate or Product in one or more selected country(ies) of the Territory; (b) include a more detailed and binding part of the plan for the initial binding period described in Section 6.1, which will be updated in accordance with Section 6.1; and (c) set forth those obligations assigned to each Party with respect to the performance of the Development activities contemplated by such Research and Development Plan.

# 6.3. Allocation of Responsibilities.

- 6.3.1. **General**. Each Party will use Commercially Reasonable Efforts to perform its obligations and activities identified under the binding parts of the Research and Development Plan or as allocated to it by the JSC in a professional manner in accordance with any target dates set forth in Research and Development Plan. Further, each Party will perform its obligations under the binding parts of the Research and Development Plan or as allocated to it by the JSC in compliance with all Laws applicable to its activities under the Research and Development Plan.
  - 6.3.2. **Mutations**. If and to the extent Mutations of the SARS-CoV-2 virus arise [\*\*\*]
- 6.3.3. **Label Extensions**. If a Party wishes to extend the label or approved indication of any Product Developed hereunder to other indications (including any outside of the Field), it may so notify the JSC. In such event, the JSC shall discuss such label extension in good faith. If the JSC agrees by unanimous consent that Development should be undertaken to support the label extension, the Parties shall include the Development activities required to be undertaken to support

such label extension in the Research and Development Plan and, if appropriate, amend the Field accordingly to cover such extension. Any external cost or expense (other than Capex Cost) incurred by either Party (or its Affiliates) solely and specifically in connection with such Development activities [\*\*\*].

- 6.3.4. **Subcontractors**. Either Party may subcontract its responsibilities under the binding parts of the Research and Development Plan or those allocated to it by the JSC without the other Party's prior written consent; *provided* that such Party shall be responsible for the management of all permitted subcontractors (which will include any Affiliate of a Party). The engagement of any Third Party subcontractor by a Party shall be in writing. The engagement of any subcontractor (whether Affiliate or Third Party) shall not relieve such Party of its obligations under this Agreement or the binding parts of the Research and Development Plan. Any agreement between the Party or its Affiliate and a subcontractor pertaining to the Research and Development Plan activities shall be consistent with the provisions of this Agreement including (a) an obligation to assign all Intellectual Property Rights generated during its performance of such Research and Development Plan to the Party free of any encumbrance such that the Party may fulfil its obligations hereunder and (b) terms and conditions under which such Third Party is obligated to preserve the confidentiality of the Research and Development Program, Research and Development Program Technology and any Confidential Information are at least as restrictive as those described in Section 11.2.1.
- 6.3.5. **Flexibility of Resources**. Due to practical consequences arising from the outbreak of the virus that is the subject of the Field, it may become difficult or temporarily impossible (including as classified as a force majeure event) for a Party to fulfil all of its responsibilities under the Research and Development Plan or as allocated to it by the JSC. Accordingly, a Party, in its effort to collaborate, may therefore agree to swap, substitute or perform any of the other Party's responsibilities that were allocated to it in the Research and Development Plan or by the JSC. The JSC shall be responsible for coordinating any such changes, which must be finally approved in writing by the Parties where the change results in a Party taking on additional financial cost and responsibility.
- 6.3.6. **Personnel Matters**. Each Party acknowledges and agrees that it is solely responsible for the compensation of its personnel assigned to the Research and Development 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 and Development Plan activities are not nor shall they be deemed to be employees of Pfizer, and Pfizer personnel assigned to the Research and Development Plan activities are not nor shall they be deemed to be employees of BioNTech.

## 7. CONTRACT GOVERNANCE.

7.1. <u>Alliance Managers</u>. Each Party will appoint a single individual to act as the primary point of contact between the Parties to support the activities under the Research and Development Plan and the Manufacturing Plan (the "<u>Alliance Managers</u>"). Each Party may change its designated Alliance Manager at any time upon written notice to the other Party. As of the Effective Date, the Alliance Manager for Pfizer will be [\*\*\*] and the Alliance Manager for BioNTech will be [\*\*\*]. The Alliance Managers will:

- 7.1.1. use good faith efforts to attend (either in person or by telecommunications) all meetings of the JSC, but will be non-voting members at such meetings; and
  - 7.1.2. be the first point of referral for all matters of conflict resolution and bring disputes to the attention of the JSC in a timely manner.
- 7.2. <u>Program Directors</u>. Each Party will appoint a program director to oversee all activities conducted under the Research and Development Plan (each, a "<u>Program Director</u>"). 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 and Development Plan. As of the Effective Date, the Program Directors for Pfizer and BioNTech are [\*\*\*], respectively.

### 7.3. Joint Steering Committee.

7.3.1. **Composition**. As of the Effective Date, the Parties will establish a Joint Steering Committee, comprised of at least [\*\*\*] representatives of BioNTech (including the Alliance Manager for BioNTech) and at least [\*\*\*] representatives of Pfizer (including the Alliance Manager for Pfizer). The JSC representatives for each of Pfizer and BioNTech will be referred to herein as the "<u>Pfizer JSC Members</u>" and the "<u>BioNTech JSC Members</u>" respectively. As of the Effective Date, the Pfizer JSC Members shall be [\*\*\*] and the BioNTech JSC Members shall [\*\*\*].

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 and Development Program. 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.

- 7.3.2. **Committee Chair**. The JSC will be chaired by a BioNTech JSC Member (the "<u>JSC Chair</u>"). BioNTech may replace the JSC Chair at any time upon notice to Pfizer. The responsibilities of the JSC Chair will be:
  - 7.3.2.1. to notify each Party at least [\*\*\*] Business Days in advance of each JSC meeting;
  - 7.3.2.2. to collect and organize agenda items for each JSC meeting; and

- 7.3.2.3. 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.
- 7.3.3. **Meetings**. Until the initiation of a Phase I Clinical Trial or Expedited Trial Pathway, the JSC shall meet at least weekly, unless otherwise unanimously agreed. Thereafter, the JSC will meet on at least bi-weekly 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. Any sub-committees or working groups established in accordance with Section 7.3.4 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 two representatives of each Party are 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 JSC Chair will use good faith efforts to (a) prepare and circulate to BioNTech and Pfizer each JSC meeting agenda on or before the day prior to the scheduled date for each JSC meeting and (b) circulate for review and approval by BioNTech and Pfizer written minutes of each JSC meeting within [\*\*\*] Business Days after such meeting. The Parties will agree on the minutes of each meeting promptly, but in no event later than the day before the next meeting of the JSC.
- 7.3.4. **Responsibilities**. The JSC will coordinate and provide operational and strategic oversight of the Development and Manufacturing activities to be performed under the Research and Development Plan and the Manufacturing Plan by each Party and, within such scope will:
  - 7.3.4.1. review and approve all proposals of whether to seek funding from a Third Party Funder, and the terms of any proposed agreement with a Third Party Funder, which (with the exceptions specified in Section 5.5.2 for [\*\*\*] and [\*\*\*]) will require unanimous consent of the JSC;
  - 7.3.4.2. monitor and assess the progress of activities under the Research and Development Plan and the Manufacturing Plan;
  - 7.3.4.3. decide on the Candidates or Products that will be studied in the Clinical Trials;
  - 7.3.4.4. decide on the design of the Clinical Trials, including the protocol governing the Clinical Trials;
  - 7.3.4.5. decide on and revise and approve any revisions of the Research and Development Plan, the Development Budget and the Manufacturing Plan (including in accordance with the mechanism described in Section 6.1 and any adjustments pursuant to Section 6.3.3 and 6.3.5), each of which shall require unanimous consent of the JSC except as expressly set forth in Section 7.3.5;

- 7.3.4.6. discuss any Intellectual Property Rights of a Third Party which may be relevant to Candidates and Products;
- 7.3.4.7. oversee the Development of Manufacturing processes relating to the Candidates or Products, establishment of Manufacturing capacity, and endorse a strategy for Manufacturing Candidates and Product for both the Clinical Trials and planned Commercialization;
- 7.3.4.8. review and discuss all preclinical data and data arising from Clinical Trials investigating the Candidate or Product in the Territory, including adverse events;
- 7.3.4.9. review and discuss all preclinical data and data arising from Clinical Trials under the Fosun Agreement, including adverse events;
- 7.3.4.10. form such other committees and sub-committees as the JSC may deem appropriate, such as a Joint Development Committee, a Joint Manufacturing Committee and the like, *provided that* the JSC may, with unanimous consent, delegate decision-making authority (that is within the JSC's own authority) relevant to such committee's and sub-committee's area of expertise only (and the Parties agree that they will form Joint Manufacturing Committee within [\*\*\*] days of the Effective Date);
- 7.3.4.11. address such other matters relating to the activities of the Parties under the Research and Development Plan or the Manufacturing 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;
- 7.3.4.12. agree on a Development Budget, as well as any amendments to such budgets, provided that the Development Budget and any amendments to it shall require unanimous consent of the JSC;
- 7.3.4.13. discuss, collaborate on and oversee any applications for Regulatory Approvals in respect of the Candidates and Products, both within and outside the Territory;
- 7.3.4.14. discuss, collaborate on and agree on mutations pursuant to Section 6.3.2 or any label extension pursuant to Section 6.3.3, each of which must be agreed by unanimous consent of the JSC; and
- 7.3.4.15. attempt to resolve any disputes between the Parties with respect to (a) the performance of activities under the Research and Development Plan or the Manufacturing Plan on an informal basis or (b) matters before the Patent Committee, in each case subject to Section 7.3.5.
- 7.3.5. **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 "<u>Disputed Matter</u>"), then:

- 7.3.5.1. Pfizer will have final decision making authority in relation to all decisions applicable to the Execution Task where the Decision Making Right is allocated to Pfizer as set out in Schedule 7.3.5; and
- 7.3.5.2. BioNTech will have final decision-making authority in relation to all decisions applicable to the Execution Task where the Decision Making Right is allocated to BioNTech as set out in Schedule 7.3.5; and
- 7.3.5.3. all other Disputed Matters (including those for which the Decision Making Right is identified as Mutual) shall be subject to the Parties reaching unanimous or mutual consent (including in respect of the Development Budget).

The Parties agree that the JSC will further refine the details of the decision-making rights and processes in accordance with Schedule 7.3.5 and the terms of this Agreement.

7.3.6. Limits on JSC Authority. Notwithstanding any provision of this Section 7 to the contrary, (a) 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, (b) except with respect to modifications to the Research and Development Plan or Manufacturing Plan permitted as set forth in Section 7.3.4.5, the JSC will not have the power to amend this Agreement or otherwise modify or waive compliance with this Agreement in any manner and (c) neither Party will require the other Party to (i) 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 Effective Date or (ii) perform any activities that are materially different or greater in scope or more costly than those provided for in the Research and Development Plan then in effect. For avoidance of doubt, a joint committee will be formed under the Commercialization Agreement to provide operational and strategic oversight of the Commercialization.

7.3.7. **JSC Term**. The JSC will be dissolved upon expiration of the Term.

### 7.4. Materials and Permitted Activities.

7.4.1. **Transfer**. From time to time during the Term, Pfizer shall provide BioNTech with tangible chemical or biological materials (the "<u>Pfizer Materials</u>") and BioNTech may provide Pfizer with BioNTech Materials for the other Party's use in accordance with binding parts of the Research and Development Plan. The Party providing its Materials represents and warrants to the other Party that, as of the date of delivery of the Material (a) [\*\*\*], (b) [\*\*\*] and (c) [\*\*\*].

- 7.4.2. **Title to Materials**. All right, title and interest in and to the providing Party's Materials (including any modifications or progeny thereof) will remain the sole and exclusive property of such Party notwithstanding the transfer to and use by other Party of the same.
- 7.4.3. **Permitted Activities.** Notwithstanding anything to the contrary in this Agreement save for each Party's exclusivity obligations and restrictions (including those at Sections 3.1 and 3.10), 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.
- 7.4.4. **Return of Proprietary Materials**. Upon termination or expiration of the Term, each Party receiving the other Party's Materials hereunder shall, either destroy or return all unused Materials to the providing Party.

#### 8. MANUFACTURING

- 8.1. <u>Development of Manufacture Process</u>. BioNTech and Pfizer shall jointly Develop a scalable process for Manufacture of Candidates and Products in the Field in the Territory in accordance with the binding parts of the Research and Development Plan and the Manufacturing Plan.
- 8.2. Manufacture of Candidates and Products. Each Party will use Commercially Reasonable Efforts to perform its obligations and activities identified under the binding parts of the Manufacturing Plan or as allocated to it by the JSC in a professional manner in accordance with any target dates set forth in the Manufacturing Plan. Further, each Party will perform its obligations under the binding parts of the Manufacturing Plan or as allocated to it by the JSC in compliance with all Laws applicable to its activities under the Manufacturing Plan. Pfizer and BioNTech will collaborate in the build-up of Manufacturing capacity for the Manufacturing of Candidates and Products for clinical and commercial purposes in accordance with the binding parts of the Manufacturing Plan and the terms and conditions set forth in this Section 8. The Manufacturing Plan may be modified by unanimous consent of the JSC pursuant to Section 7. Unless otherwise agreed in the Manufacturing Plan, at a minimum Pfizer will be responsible for the build-up of its Manufacturing site(s) in the USA for quantities of Product to be agreed as part of the Manufacturing Plan and the commercial supply agreement for such site, and at a minimum BioNTech will be responsible for the extension of its Manufacturing sites in Mainz and Idar-Oberstein for quantities of Product to be agreed as part of the Manufacturing Plan may also consider one or both Parties engaging Third Party contract manufacturing organizations as a source of Manufacturing. In addition, promptly after the Effective Date, the Parties will agree on a technology transfer plan and continue to perform the technology transfer that the Parties have already started prior to the Effective Date to enable Manufacturing by Pfizer. For the avoidance of doubt, to the extent the technology transferred under this Agreement is identical to the technology to be transferred pursuant to the Flu Collaboration License, the Parties shall cooperate to minimize any duplication of technology transfer efforts under t

8.3. <u>Quality Requirements</u>. Each Party that undertakes or subcontracts any Manufacturing activities in respect of the Candidates or Products, whether for the purposes of this Agreement, the Clinical Trials or pursuant to the commercial supply agreements shall ensure that all Manufacturing activities are undertaken in accordance with (a) applicable GxP standards, applicable Laws, and other regulatory and manufacturing good practice (including record and sample keeping, deviation reporting, testing and quality requirements); and (b) the requirements of the applicable Quality Agreement.

### 8.4. Manufacturing Agreements.

- 8.4.1. **Clinical Supply**. Within [\*\*\*] following the Effective Date, the Parties shall enter into an agreement for clinical supply, as required to ensure the Clinical Trials planned can proceed on the timelines set forth in the binding parts of the Research and Development Plan. All clinical supply of Candidates and Products shall be charged at the Manufacturing Costs. In addition, the Parties will negotiate in good faith and mutually agree on a Quality Agreement with respect to such clinical supply agreement.
- 8.4.2. **Commercial Supply**. Furthermore, the Parties will negotiate in good faith and mutually agree on one or more commercial supply agreement(s) and Quality Agreement(s) simultaneously with the negotiation of the Commercialization Terms. The commercial supply agreement(s) shall be in accordance with the following commercial terms:
  - 8.4.2.1. The Manufacturing Party shall be entitled to charge the Transfer Price for each batch of Product delivered in accordance with the relevant commercial supply agreement. Such Transfer Price shall be invoiced by the Manufacturing Party upon delivery of the Products and shall be payable by the other Party within [\*\*\*] from receipt of such invoice.
  - 8.4.2.2. The Transfer Price shall be adjusted on a yearly basis for all commercial supply agreements in accordance with relevant cost developments.
  - 8.4.2.3. The Parties will work together, subject to and observing applicable Laws, and agree the volumes of Product Materials to be purchased from Third Party suppliers for the purposes of this Agreement and to [\*\*\*] of either Party to source the other Party's requirements for such Product Materials for its Manufacturing activities pursuant to this Agreement and the Commercialization Agreement, which sourced Product Materials shall then be sold, at cost, to that other Party [\*\*\*].
  - 8.4.2.4. [\*\*\*]

- 8.4.3. The supply agreements to be entered into between the Parties pursuant to Sections 8.4.1 and 8.4.2, or the Commercialization Agreements if more appropriate, shall include appropriate accounting mechanisms to allow for true-up payments in respect of (i) Manufacturing Costs, including to account for any mark up on the Manufacturing Costs of Product Materials where permitted in the definition of Manufacturing Costs, and (ii) Manufacturing Variances.
- 8.5. <u>Allocation of Responsibilities</u>. Section 6.3.1 and Sections 6.3.4 to 6.3.6 shall apply *mutatis mutandis* in respect of each Party's responsibilities under the Manufacturing Plan.

### 9. <u>DEVELOPMENT, REGULATORY AND PHARMACOVIGILANCE.</u>

- 9.1. Development Matters.
- 9.1.1. Allocation of Development and Regulatory Responsibility. The Development of Candidates and Products shall be conducted by the Parties, under the direction and oversight of the JSC (and, as applicable, the Joint Development Committee), in accordance with the applicable Research and Development Plan and Development Budget. Pursuant to the initial Research and Development Plan, the Parties shall identify a strategy for Development of the Candidates and Products in the Territory that identifies the Party that is leading the clinical Development of the Candidates or Products in a country in the Territory (the "Lead Development Party"). Notwithstanding the foregoing, the Parties have agreed that (a) Pfizer shall lead the clinical aspects of Development of Candidates and Products in the USA, and (b) BioNTech shall lead the clinical aspects of Development of Candidates and Products in the EU. BioNTech shall be the sponsor and IND/CTA holder for all Clinical Trials in the Territory, in each case, subject to a mutually agreeable strategy with respect to the Development of Candidates and Products. For any Clinical Trial for which Pfizer is the Lead Development Party (but is not the sponsor of such Clinical Trials), BioNTech shall have delegated to Pfizer operational and day-to-day Development activities, decision-making authority and responsibility for such Clinical Trial, including those activities described in Schedule 9.1.1, subject to a protocol approved by unanimous consent by the JSC. For avoidance of doubt, the Lead Development Party shall conduct its Development activities in collaboration with and with active review of the other Party.
- 9.1.2. **Appointment of Lead Development Party for Future Clinical Trials.** At any time during the term of this Agreement, the JSC may determine by mutual consent that additional clinical Development of the Candidate and Product are warranted and, in such event, unless otherwise agreed by the JSC, (a) Pfizer shall be the Lead Development Party for each additional Clinical Trial in the USA, (b) BioNTech shall be the Lead Development Party for each additional Clinical Trial in the EU and (c) the JSC shall mutually agree on the appointment of one of the Parties to be the Lead Development Party for each additional Clinical Trial on a Clinical Trial-by-Clinical Trial basis in a country or region in the Territory other than the USA and EU ("ROW"), and subject to the mutually agreed upon strategy.
  - 9.1.3. Clinical Trials. In respect of Clinical Trials for the Candidates or Products pursuant to this Agreement, the following shall apply:
    - 9.1.3.1. *GxP Standards*. Subject to Section 9.1.3.7, BioNTech as the sponsor for any Clinical Trial in respect of any Candidate or Product pursuant to this Agreement shall ensure the Clinical Trial is conducted in accordance with GxP and all applicable Laws, and will provide to the other Party any significant GxP or non-compliance issues relating to the protocol for such Clinical Trial, which arise or may be identified through monitoring,

- 9.1.3.2. *Monitoring Plans*. A high-level strategy for monitoring Clinical Trials in respect of any Candidate or Product pursuant to this Agreement will be agreed by the JSC within [\*\*\*] following the Effective Date. The Lead Development Party of the Clinical Trial will notify the other Party if there are any amendments required to such monitoring plan, and provide such other Party with an opportunity to review and comment on any such amendments, and any amendments shall only be made following approval by the JSC.
- 9.1.3.3. *IRB/IEC Approval*. BioNTech as the sponsor and Regulatory Approval holder of the Clinical Trials shall ensure that the Clinical Trial is approved by and subject to continuing oversight by an appropriate Institutional Review Board (IRB) or Independent Ethics Committee (IEC), except that BioNTech shall delegate this responsibility to Pfizer for any Clinical Trial for which Pfizer is the Lead Development Party. The Lead Development Party shall provide documentation of both the initial IRB/IEC approval of the final protocol to the other Party and annual renewals of that approval if such renewals are required. To the extent a Party receives notice of any withdrawal or suspension of IRB/IEC approval during the term of this Agreement, it will promptly inform the other Party
- 9.1.3.4. *Informed Consent*. BioNTech as the sponsor and Regulatory Approval holder for each applicable Clinical Trial will obtain informed consent for each Clinical Trial subject in accordance with the applicable informed consent document and applicable Law and will inform and obtain express consent from each Clinical Trial subject that the data arising from such Clinical Trial may be used in accordance with the terms of this Agreement (including its export from the European Union and its processing by Pfizer or other Third Parties in accordance with the terms of this Agreement and Law), provided however, that BioNTech shall delegate this responsibility to Pfizer for those Clinical Trials for which Pfizer is the Lead Development Party. Notwithstanding the foregoing, the Lead Development Party will share the informed consent document with the other Party for such other Party's review and comment prior to its use in a Clinical Trial in a country in the Territory.
- 9.1.3.5. *Sponsorshi*p. Where the Lead Development Party (or its Affiliate or designee) is not the sponsor of a Clinical Trial or Regulatory Approval holder, such Lead Development Party shall not represent to any Third Party, including any Clinical Trial subjects, that the Lead Development Party or its Affiliates are a sponsor.
- 9.1.3.6. *Reporting*. BioNTech is solely responsible for any and all safety reporting and regulatory obligations associated with the conduct of the Clinical Trial for which it is the sponsor, including, but not limited to, obtaining and maintaining Regulatory Approvals for the conduct of the Clinical Trials, provided, however, that BioNTech shall delegate the safety reporting and regulatory obligations associated with the conduct of each Clinical Trial in the Territory to Pfizer subject to Section 9.3.

9.1.3.7. *Delegation.* Notwithstanding the responsibilities of BioNTech as IND/CTA holder or sponsor of Clinical Trials, where Pfizer is the Lead Development Party for a Clinical Trial Pfizer shall conduct its activities in compliance with GxP and applicable Law with respect to each of the activities which have been delegated to Pfizer pursuant to Schedule 9.1.1.

### 9.2. Regulatory Matters.

9.2.1. **Lead Development Party.** The JSC shall agree on a strategy to allocate operational responsibility for regulatory activities relating to each Candidate or Product to a Lead Development Party by reference to the country or region within the Territory for which that Party is to act as the Lead Development Party in respect of a Clinical Trial for one or more Candidates or Products. The JSC's initial allocation shall be that Lead Development Party for regulatory activities relating to each Candidate or Product in the EU shall be BioNTech, and the Lead Development Party for regulatory activities relating to each Candidate or Product in the USAshall be Pfizer. Subject to the JSC's mutual consent to seek Regulatory Approval in one or more countries or regions in the ROW, Pfizer shall be the Lead Development Party for regulatory activities relating to each Candidate or Product in such country or region in the ROW, the Party that wishes to seek Regulatory Approval in such country or region shall be entitled to be the Lead Development Party for regulatory activities relating to each Candidate or Product in such country or region and seek such Regulatory Approval at its own cost. The JSC may vary from the foregoing allocations by mutual consent. The other Party shall cooperate with the Lead Development Party, at its reasonable request, with respect to any regulatory matters for which the Regulatory Approval holder is responsible or to whom regulatory matters have been delegated.

9.2.2. **Regulatory Communications and Filings.** Pfizer shall prepare, file in BioNTech's name, diligently prosecute to grant, and maintain all applications for Regulatory Approvals ("Marketing Authorization Applications") and all Regulatory Approvals obtained therefrom in respect of any Candidates or Products in USA and, subject to Section 9.2.1, the ROW. BionTech shall prepare, file in BioNTech's name, diligently prosecute to grant, and maintain all applications for Marketing Authorization Applications and all Regulatory Approvals obtained therefrom in respect of any Candidates or Products in EU. The JSC may vary from the foregoing allocations by mutual consent. In accordance with Section 9.2.1, each Party shall cooperate with the other Party with respect to any and all regulatory matters for which the other Party is responsible pursuant to this Agreement or the Research and Development Plan. Unless exigent action is required with respect to a given filing before a Regulatory Authority concerning a Candidate or Product, or a material communication with a Regulatory Authority concerning the same, the Party submitting such Marketing Authorization Application prior to submission within a reasonable amount of time (but not less than [\*\*\*] Business Days) to allow such Party to review and comment on such filings, and the Party submitting such Marketing Authorization Application shall consider all comments and proposed revisions from the other Party in good faith prior to submission. The Party responsible for filing such Regulatory Approvals shall consult with the other Party regarding, and keep the other Party informed of, the status of the preparation of all Marketing Authorization Applications and the prosecution thereof, including any material communications

that it receives with respect to the same. Upon request of the other Party, the Lead Development Party responsible for filing applications for such Regulatory Approvals shall provide to the other Party copies of all final Marketing Authorization Applications and filings relating thereto that it submits. The foregoing provisions of this Section 9.2.2 shall also apply to material and substantive communications with Regulatory Authorities.

- 9.2.3. **Regulatory Meetings.** The Lead Development Party shall consult with the other Party reasonably in advance of the date of any anticipated meeting with a Regulatory Authority relating to any Marketing Authorization Applications or Regulatory Approvals in respect of any Candidate or Product and shall consider any timely and reasonable recommendations made by the other Party in preparation for such meeting. The Parties agree that Pfizer, as the Lead Development Party for the regulatory activities in the USA and ROW shall lead interactions with the Regulatory Authority in the USA and ROW, while BioNTech as the Lead Development Party for the EU, shall lead interactions with the Regulatory Authority in Germany and the EU. The Parties agree that the Party who has been appointed by the JSC as the Lead Development Party shall lead interactions with respect to countries or regions in the Territory. Upon the request of the other Party, and to the extent legally permissible and not opposed by the relevant Regulatory Authority, the Lead Development Party shall permit the other Party to attend any and all meetings with the applicable Regulatory Authority concerning the Candidate or Product. [\*\*\*]
- 9.2.4. **Manufacturing Matters.** Where Pfizer is the Lead Development Party and responsible for preparing the filings for Regulatory Approval, BioNTech shall provide all reasonable assistance to Pfizer in such filings, including preparation of the CMC portions of the Common Technical Document in English and supporting ancillary cGMP documents and analytical data as required to meet specific regulatory filing and approval requirements. Each Party shall promptly provide the other with copies of material written correspondence as reasonably necessary to permit each Party to comply with its relevant regulatory obligations described in the Agreement or as otherwise reasonably requested.
- 9.2.5. Ownership of Regulatory Filings, Market Authorization Approvals and Pricing and Reimbursement Approvals. Unless otherwise required under applicable Law or determined by unanimous consent of the JSC (or the JCC with respect to Commercialization Agreement, as applicable), all Regulatory Approvals directed to a Candidate or Product in a country in the Territory and all applications therefor shall be made or held in the name of and owned by BioNTech. Notwithstanding the foregoing BioNTech may, upon giving reasonable notice to Pfizer, elect to transfer to Pfizer or any of its Affiliates one or more Regulatory Approvals in the Territory directed to a Candidate or Product and Pfizer will not withhold its agreement to such transfer if Pfizer or any of its Affiliates is already Commercializing a Pfizer vaccine product in such country and is permitted to hold Regulatory Approvals in such country. Recognizing that the transfer of the foregoing responsibilities or the responsibilities described in 9.2.1 and 9.2.2 and Regulatory Approvals as the case may be requires time, coordination and effort, the Parties will agree a reasonable transition plan for each such transfer and during the transfer period BioNTech shall continue to perform its obligations as Lead Development Party or owner of the Regulatory Approval.

9.2.6. **Notice of Regulatory Investigation or Inquiry.** If any Regulatory Authority (i) contacts a Party with respect to the alleged improper Development, Manufacture, or Commercialization of a Candidate or Product in the Territory, (ii) conducts, or gives notice of its intent to conduct, an inspection at a Party's facilities used in the Development or Manufacturing of a Candidate or Product, or (iii) takes, or gives notice of its intent to take, any other regulatory action with respect to any activity of a Party that could reasonably be expected to adversely affect any Development, Manufacture or Commercialization activities with respect to a Candidate or Product in the Territory, then such Party shall promptly notify the other Party of such contact, inspection or notice. The inspected Party shall provide such other Party with copies of all pertinent information and documentation issued by any such Regulatory Authority within [\*\*\*] Business Days of receipt, and, to the extent practicable, the JSC or appropriate subcommittee. Such other Party shall have the right to (a) be present at any such inspection, and (b) review and comment upon in advance any responses of the inspected Party that pertain to a Candidate or Product or a Party's activities hereunder.

### 9.2.7. Pharmacovigilance and Pharmacovigilance Agreement.

- 9.2.7.1. As soon as practicably possible following the Signing Date the Parties shall form a Joint Safety Committee to (a) review and approve each investigator's brochure for the clinical Development of Candidates and Products, (b) review and approve all aggregated data Drug Safety Update Reports, annual IND reports, and other period reports to Governmental Authorities information regarding patient safety (including adverse drug) experiences that are or may be associated with Candidates or Products, (c) review, discuss and agree the outputs of each Party's periodic Candidate and Product related benefit/risk analysis, and (d) such other patient safety-related activities as the Parties may delegate to it from time to time.
- 9.2.7.2. So long as BioNTech holds the necessary INDs/CTAs/Regulatory Approvals and is acting as sponsor in a country or region in the Territory, BioNTech may initiate clinical Development of the Candidates and Products in the EU prior to the Parties entering into a pharmacovigilance agreement. In such circumstances BioNTech shall be responsible for collecting, monitoring, evaluating, sharing and reporting to applicable Governmental Authorities in the EU information regarding patient safety (including adverse drug) experiences that are or may be associated with Candidates or Products. BioNTech shall be responsible for maintaining a suitable safety database.
- 9.2.7.3. By no later than the approval of the Investigational New Drug (IND) for Candidate(s) with FDA, the Parties shall have entered into a pharmacovigilance agreement ("Pharmacovigilance Agreement") reflecting the terms set forth in Section 9.3 and Schedule 9.2.7.
- 9.2.7.4. Following the filing of the IND for Candidate(s) with FDA:

- (a) should BioNTech require Pfizer to take over certain activities in relation to collecting, monitoring, evaluating, sharing and reporting to applicable Governmental Authorities, but excluding Ethics Committees, information regarding patient safety (including adverse drug) experiences that are or may be associated with Candidates or Products in the EU, the Parties shall agree and execute an amendment to the Pharmacovigilance Agreement to (i) reflect the additional activities and responsibilities the Parties have agreed Pfizer will perform in the EU, and (ii) set out the procedures the Parties have agreed upon to allow for the reconciliation of BioNTech's safety database with Pfizer's safety database. The effectiveness of the amendment shall be conditional upon BioNTech delivering to Pfizer (x) confirmation from the relevant Governmental Authorities in the EU that they have accepted an amendment to the clinical trial protocol for any on-going clinical trial of Candidates or Product in the EU to reflect the necessary changes (as agreed with Pfizer) in responsibilities and contact information for collecting, monitoring, evaluating, sharing and reporting of information regarding patient safety (including adverse drug) experiences, and (y) written confirmation from BioNTech that it has amended the relevant clinical trial agreements to reflect the change in pharmacovigilance provider and trained the investigators on the new reporting procedures; and,
- (b) BioNTech through their Agreement with Fosun shall ensure that Fosun, via BioNTech, deliver to Pfizer (x) a copy of a due diligence report on Fosun's safety data reporting system reasonably acceptable to Pfizer in terms of findings made, (y) a copy of the pharmacovigilance agreement between BioNTech and Fosun which, inter alia, provides for delivery to Pfizer of fully assessed, translated (into English) CIOMS forms for all SAEs: Death / life threatening SUSARs 5 Business Days from Day 0 (Day 0 being receipt by Fosun from the clinical investigator), or 10 days for all other SAEs, [\*\*\*] and (z) details of the quality management system used with Fosun to ensure that if late inbound reports are received BioNTech can request root cause analysis and implementation of corrective and preventive actions by Fosun. The Parties agree that prior to Fosun's commencement of clinical activities by Fosun, BioNTech shall have entered into a written agreement with Fosun, reflecting the foregoing.
- 9.2.7.5. The Pharmacovigilance Agreement and each amendment to it from time to time shall set forth the responsibilities and procedures for (i) collecting, monitoring, evaluating, sharing and reporting to applicable Governmental Authorities information regarding patient safety (including adverse drug) experiences that are or may be associated with Candidates or Products in the countries covered by that agreement and (ii) providing regulatory information to and support of the other Party

with regard to regulatory obligations, provided, that, each such agreement shall include the following guiding principles: acting as BioNTech's delegate for regulatory interactions, Pfizer shall primarily control the regulatory process and regulatory interactions in the countries covered by that agreement, provided, however that the Parties shall work together collaboratively to further the purposes of the collaboration and the activities described in this Agreement. Subject to the proviso in the foregoing sentence, to the extent there is any conflict between the terms and conditions of the Pharmacovigilance Agreement (as amended from time to time) and this Agreement with respect to safety or regulatory matters, the Pharmacovigilance Agreement shall control.

- 9.2.8. **Audits.** Each Party shall have the right, at its sole cost and expense, to perform audits of the other Party's pharmacovigilance, regulatory, and environmental, health and safety activities concerning any Candidates or Products under this Agreement, including each Party's oversight of any Third Party contracted to perform pharmacovigilance, regulatory or environmental health and safety activities as outlined in this Agreement and in compliance with applicable Laws, which audit right is exercisable at any time during the Term. Upon request, BioNTech shall provide Pfizer with a copy if its latest audit report on Fosun's pharmacovigilance activities.
- 9.3. Global Safety Database and Safety Reporting. Subject to Section 9.2.7, Pfizer shall maintain the global safety database for the Candidates and Products pursuant to this Agreement and the Commercialization Agreement. Provided that (a) BioNTech (subject to Section 9.1) will be the Lead Development Party with respect to Clinical Trials conducted in the EU, (b) BioNTech will hold a safety database to meet its sponsor responsibilities and regulatory responsibilities in the EU and to hold safety data reports received from China; (c) information shall be exchanged between Pfizer and BioNTech as described in the Pharmacovigilance Agreement to ensure alignment of information between the databases and (d) BioNTech will delegate its responsibilities for the collection, processing, assessment and safety reporting to Regulatory Authorities for all Clinical Trial(s) conducted pursuant to the Research and Development Plan in the Territory upon the approval of the IND for Candidate(s) with FDA. Notwithstanding the foregoing, such responsibility can only be delegated to and Pfizer can only accept this responsibility if the Clinical Trial sites for the Candidates and Products are reporting the safety data, including all individual Serious Adverse Events, translated into English, to Pfizer and for so long as Pfizer has access to all safety data, including products identical to Candidates or Products conducted under the terms and conditions of the Fosun Agreement (or subsequent agreements with other development partners) to allow Pfizer to meet its regulatory obligations as Lead Development Party in the Territory.
- 9.4. <u>Product Complaints and Returns.</u> The Parties' rights and obligations with respect to non-conformance and returns of Products shall be governed by, as and to the extent applicable, the applicable supply agreement, the global Quality Agreement, or the Pharmacovigilance Agreement.
- 9.5. <u>Clinical Trial Register</u>. BioNTech shall, in accordance with Law and its internal policies, register, and publish the summaries and results of, Clinical Trials relating to the Candidate or Product on a clinical trial register maintained by it (or an equivalent register), or as otherwise required by Law. If Pfizer is the Lead Development Party for a Clinical Trial, Pfizer shall prepare such summaries and results in accordance with its internal policies and in a timely manner so as to allow the summaries and results to be published within the mandatory time period, and provide such summaries and results to BioNTech for review and comment. Pfizer will give reasonable consideration to any such comments. BioNTech shall publish such summaries and results on a clinical trial register maintained by it (or an equivalent register), within the mandatory time period.

- 9.6. <u>Regulatory Exclusivity.</u> The JSC shall oversee the process of applying for and securing exclusivity rights that may be available under the Law of countries in the Territory, including any data or market exclusivity periods such as those periods listed in the FDA's Orange Book or Purple Book (as applicable) or periods under national implementations of Article 10.1(a)(iii) of Directive 2001/EC/83 (including any pediatric exclusivity extensions or other forms of regulatory exclusivity that may be available), and all international equivalents.
- 9.7. <u>Liability</u>. Subject to Pfizer and its Affiliates compliance with the obligations set forth in Section 9.1.3.7 above, Pfizer and its Affiliates, employees, agents or representatives will not be liable to BioNTech or its Affiliates in respect of any act, omission, default or neglect on the part of Pfizer, its Affiliates, or their respective employees, agents or representatives in connection with the activities undertaken as a Lead Development Party where such activities are undertaken in good faith, unless liability arises from Pfizer's or its Affiliates, employees, agents or representatives gross negligence or willful misconduct.
- 9.8. <u>Objection Right</u>. Notwithstanding any other provision of this Section 9, as Regulatory Approval holder, BioNTech shall have the right to object to and oppose any intended action of Pfizer as Lead Development Party if BioNTech reasonably believes Pfizer's intended action to be contrary to applicable Law.
- 9.9. <u>Personal Data.</u> To the extent the Parties shall be required to share Personal Data in connection with this Agreement or the Commercialization Agreement, the Parties shall enter into a legally binding written agreement governing the Parties relationship and their processing activities as required by Applicable Data Protection Law.

#### 10. INTELLECTUAL PROPERTY

- 10.1. <u>Patent Committee</u>. Within the first [\*\*\*] following the Effective Date, or as otherwise agreed by the Parties, the Parties will establish a patent committee (the "<u>Patent Committee</u>"), 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:
  - 10.1.1. coordinate all activities in relation to the filing and prosecution of Patent Rights relating to this Agreement pursuant to Sections 10.2.1 and 10.3.1 of this Agreement,
    - 10.1.2. discuss any actual, potential or suspected infringement of such Patent Rights pursuant to Section 10.4.1, and
    - 10.1.3. regularly review which BioNTech Patent Rights may be relevant to Candidates and Products.
  - 10.1.4. 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 Patent Committee member chosen by mutual agreement. The Patent Committee shall operate in good faith and acting reasonably. Sections 7.3.2 and 7.3.3, 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 to the JSC for final resolution and decisions of the JSC in this regard must be made by unanimous consent.

#### 10.2. Ownership of Intellectual Property.

- 10.2.1. Ownership of Product Technology. [\*\*\*]
- 10.2.2. **Ownership of BioNTech Improvements and Pfizer Improvements**. As between the Parties, (a) BioNTech will own all BioNTech Improvements and (b) Pfizer will own all Pfizer Improvements.
- 10.2.3. **Ownership of other Research and Development Program Technology**. Except for BioNTech Improvements, Pfizer Improvements and [\*\*\*] the ownership of other Research and Development Program Technology, will be allocated based on inventorship as defined under the Laws of the United States. Notwithstanding the foregoing, during the Term, and without prejudice to Section 10.3 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 and Development Program Technology.
- 10.2.4. **Ownership of Joint Technology**. Subject to Section 10.2.1, 10.2.2 and 10.2.3, the Parties will jointly own any Joint Technology. Subject to (a) the grant of licenses or sublicenses under Section 3, (b) BioNTech's representations, warranties and covenants under Section 12 and (c) the Parties' other rights and obligations under this Agreement (including Section 3.10), 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.
- 10.2.5. **Ownership of Other Intellectual Property**. Except as set forth in Sections 10.2.1, 10.2.4, 10.2.2 and 10.2.1, 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.

#### 10.3. Patent Rights.

# 10.3.1. Filing, Prosecution and Maintenance of Patent Rights.

10.3.1.1. *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 including the Major EU Market Countries, Japan, the United States, Brazil, Russia, India, 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 (a) 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 (b) 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, as relevant, 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 [\*\*\*] 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 [\*\*\*] after written request by Pfizer, by written notice to Pfizer update Schedule 12.3.4 to identify all BioNTech Patent Rights to be added thereto.

- 10.3.1.2. Other Patent Rights. Except as provided in Section 10.3.1.1, each Party will have the sole right, but not the obligation, to file, prosecute and maintain the Research and Development Program Patent Rights or other Patent Rights that it solely owns under this Agreement or to which it otherwise has control of prosecution rights in its sole discretion, provided that at a Party's reasonable request, the other Party will provide status or other requested information for any Research and Development Program Patent Right and will consider in good faith any recommendations made by such Party in regard to the filing, prosecution or maintenance of any such Patent Right.
- 10.3.1.3. *Reference of Research and Development Program Know-How.* If a Party chooses to file, and thereafter prosecute and maintain, Patent Rights after the expiration of the Term, including any extension to the Term, that Party may use or incorporate Research and Development Program Know-How in the filing or prosecution of such Patent Rights filed after the Term, if it determines in its sole discretion that it is necessary or useful to use or incorporate such Research and Development Program Know-How.

10.3.2. 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: (a) 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 (b) 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 (a) and (b) with the respective provisions of Section 10.3.1.1 to apply mutatis mutandis except as provided in this Section 10.3.2. 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 Pfizer 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; 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.

- 10.3.3. **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 or [\*\*\*] in the Field in the Territory, 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.
- 10.3.4. **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, [\*\*\*]. [\*\*\*]
- 10.3.5. **Clarifications**. For clarity, prosecution under this Section 10.3 includes opposition, revocation and post-grant review proceedings before the granting patent office or other patent office proceedings ("<u>Prosecution Proceeding</u>"). If such Prosecution Proceedings are concurrent with Third Party litigation under Section 10.4 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 10.5 (including the right for one Party to have final control as stipulated in Section 10.5).
- 10.3.6. **Liability**. To the extent that a Party is obtaining, prosecuting or maintaining a Patent Right or otherwise exercising its rights under this Section 10.3, 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.

- 10.3.7. **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, 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.
- 10.3.8. **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.

#### 10.4. Enforcement of Patent Rights.

- 10.4.1. **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 and Development 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.
- 10.4.2. Enforcement of BioNTech Patent Rights and Product Patent Rights. Subject to Section 10.4.1, 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 BioNTech Patent Rights [\*\*\*] in the Field in the Territory (the "BioNTech Enforcement Patent Rights"), 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 consent to join any such Enforcement Action upon BioNTech's request, or where required by Law or where Pfizer or its Affiliates are enjoined by the counterparty. BioNTech shall not name as a party Pfizer or its Affiliates in any Enforcement Action without Pfizer's prior written consent. In any event, BioNTech will not, without the prior written consent of Pfizer, enter into any compromise or settlement relating to such litigation that (a) admits the invalidity or unenforceability of any BioNTech Enforcement Patent Right or (b) requires BioNTech to abandon any BioNTech Enforcement Patent Right. Upon the request of BioNTech, Pfizer shall have the sole discretion to decide whether or not to join as a party in any such Enforcement Action, and where it elects to do so it shall, at BioNTech's expense, join and cooperate with BioNTech in such Enforcement Action. Pfizer will have the right to consult with, and provide comments to, BioNTech about such Enforcement Action (irrespective of Pfizer or its Affiliate being a party to 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 15) as a consequence of any Enforcement Action initiated or pursued pursuant to this Section 10.4 or any unfavorable decision resulting therefrom, including any decision holding any BioNTech Enforcement Patent Rights 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 treated as Gross Profits for the purposes of the Commercialization Agreement.

10.4.3. **Pfizer's Enforcement Rights**. In respect of an infringement of any BioNTech Enforcement Patent Right in the Field in the Territory in connection with a Competitive Product ("Competitive Product Infringement"), if, following (a) discussion of any potential Enforcement Action pursuant to Section 10.4.1 and (b) 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 and any such Enforcement Action will be at Pfizer's expense and the provisions set forth in the first paragraph of this Section 10.4.2 shall apply *mutatis mutandis*. Pfizer's rights with respect to an Enforcement Action for BioNTech Enforcement Patent Rights other than Product Patent Rights shall be limited to (i) Major Market Countries; (ii) Enforcement Actions in countries in which a Competitive Product (or part thereof) reasonably believed to be designated for any Major Market Country is Manufactured; and (iii) Enforcement Actions in Belgium, Ireland or the Netherlands that are in parallel with Enforcement Actions in any of the Major EU Market Countries. [\*\*\*]

10.4.4. BioNTech Enforcement outside the Field and/or outside the Territory. Subject to Section 10.4.1 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 outside the Field and/or outside the Territory in connection with any BioNTech Enforcement Patent Rights), 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 consent to join any such Enforcement Action upon BioNTech's request, where required by Law or where Pfizer or its Affiliates are enjoined by the counterparty. BioNTech shall not name as a party Pfizer or its Affiliates in any Enforcement Action without Pfizer's prior written consent. In any event, 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 Enforcement Patent Rights or (ii) requires BioNTech to abandon any BioNTech Enforcement Patent Rights. Upon the request of BioNTech, Pfizer shall have the sole discretion to decide whether or not to join as a party in any such Enforcement Action, and where it elects to do so it shall, at BioNTech's expense, join and cooperate with BioNTech in such Enforcement Action.

Pfizer will have the right to consult with, and provide comments to, BioNTech about such Enforcement Action (irrespective of Pfizer or its Affiliate being a party to 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 15 or otherwise in this sub-section) as a consequence of any Enforcement Action initiated or pursued pursuant to this Section 10.4.3 or any unfavorable decision resulting therefrom, including any decision holding any BioNTech Enforcement Patent Rights invalid or unenforceable.

10.4.5. **Pfizer Patent Rights.** Pfizer shall have the sole right, but not the obligation, to institute litigation or take other steps to remedy infringement in connection with 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.

#### 10.4.6. Biosimilar Notices.

- 10.4.6.1. *BioNTech Cooperation*. Upon Pfizer's request, BioNTech and Pfizer will use Commercially Reasonable Efforts to assist and cooperate with each other 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 or BioNTech; *provided* that BioNTech will make the final decisions with respect to such strategy and any such responses.
- 10.4.6.2. Compliance with Biosimilar Notices. The MA Holder 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 from any Third Party regarding any Product that is being Commercialized in the Field in the Territory in the applicable jurisdiction, and the exchange of information between any Third Party and such MA Holder pursuant to such requirements; provided that, prior to any submission of information by MA Holder to a Third Party, the other Party will have the right to review the patent information included in such proposed submission, and to make suggestions as to any changes to such patent information that Pfizer reasonably believes to be necessary; provided further that MA Holder 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, the MA Holder, as the sponsor of the application for the Product, will be the "reference product sponsor" under the PHS Act. The MA Holder will give written notice to the other Party of receipt of a Biosimilar Notice received by MA Holder with respect to a Product, and MA Holder will consult with the other Party

with respect to the selection of any Patent Rights to be submitted pursuant to 42 U.S.C. § 262(1) (or any similar law in any country of the Territory outside the United States); *provided* that the MA Holder will have final say on such selection of Patent Rights. Such other Party 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(1)(1)(B)(iii). In connection with any action brought by such other Party under this Section 10.4.6, such other Party, upon the MA Holder'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 MA Holder in any such action, including timely commencing or joining in any action brought by MA Holder under this Section 10.4.6.

- 10.4.7. **Unified Patent Court.** In respect of BioNTech Enforcement 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, BioNTech shall have the sole discretion to decide whether to (a) 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 (b) 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).
- 10.4.8. **Settlement Cross-Licensing**. If pursuant to a bona fide settlement of any Enforcement Action or Infringement Claim controlled by Pfizer, Pfizer, with BioNTech's prior written consent, which shall not be unreasonably withheld, conditioned or delayed, 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 (a) 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 3), 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 Third Party Competitive Product and (b) all other royalties received by Pfizer shall be deemed Gross Profits. For the avoidance of doubt, should the Third Party as part of the same agreement grant any cross-license to Pfizer (sublicensable to BioNTech for the purposes of this Agreement) for any Candidates or Products, such cross-license shall not be deemed "non-cash" consideration for the purpose of the Net Sales definition.

10.5. 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 Enforcement Patent Rights 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 10.3.1), and the provisions of Section 10.3.1 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 10.4, 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.

10.6. <u>Purple Book Listings</u>. To the extent of any BioNTech Enforcement Patent Rights, the Parties shall cooperate with each other to enable BioNTech to make filings with Regulatory Authorities, as required or allowed in connection with (a) in the United States, the FDA's Purple Book and the Biologics Price Competition and Innovation Act and (b) outside the United States, under the national implementations of Article 10.1(a)(iii) of Directive 2001/EC/83 or other international equivalents thereof within the Territory. 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.

# 10.7. Allegations of Infringement and Right to Seek Third Party Licenses.

- 10.7.1. **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 and Development 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 "<u>Licensed Activities</u>") 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 (collectively, an "<u>FTO Action</u>"), such Party will, as soon as reasonably practicable, notify the other Party in writing and the Parties will discuss the FTO Action in good faith to determine and agree upon a resolution of the same.
- 10.7.2. **Option to Negotiate.** If the Parties determine that to resolve the FTO Action 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, then [\*\*\*]; will negotiate and enter into a license or other agreement with such Third Party in close coordination with the other Party. If the Parties do not agree that a license from a Third Party is necessary or useful to resolve the FTO Action, the Party who considers a license is necessary or useful to resolve the FTO Action shall be entitled to negotiate and enter into a license or other agreement with such Third Party, but shall do so keeping the other Party reasonably informed. [\*\*\*] [\*\*\*]

10.8. 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 and Development 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 their respective 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 15.3 to indemnify Pfizer (including any Pfizer Indemnified Party) with respect to such Infringement Claim, then (a) Pfizer will bear 100% of its own attorneys' fees incurred in investigating, preparing or defending such Infringement Claim notwithstanding the provisions of Section 15.3 and (b) BioNTech will otherwise indemnify Pfizer and any applicable Pfizer Indemnified Parties to the full extent provided for under Section 15.3, provided that Pfizer shall not enter into any compromise or settlement with the Third Party in respect of such Infringement Claim without BioNTech's prior written consent (such consent not to be unreasonably withheld, conditioned or delayed) where such compromise or settlement requires the payment of monetary penalty or damages that are indemnified by BioNTech under this Agreement. 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 and Development Program Technology infringes Third Party patents without the other Party's written consent.

# 11. CONFIDENTIALITY

11.1. 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).

#### 11.2. Authorized Disclosure.

11.2.1. **Disclosure to Party Representatives**. Notwithstanding the foregoing provisions of Section 11.1, 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 10.1.

- 11.2.2. **Disclosure to Third Parties**. Notwithstanding the foregoing provisions of Section 11.1, each Party may disclose Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary:
  - 11.2.2.1. to Governmental Authorities to the extent useful, to (a) obtain or maintain Regulatory Approvals for any Candidate or Product within the Territory; or (b) obtain or maintain Regulatory Approvals for a product comprising a Candidate in the Field outside of the Territory; and (c) in order to respond to inquiries, requests or investigations (i) relating to Candidates or Products or this Agreement within the Territory; or (ii) relating to any product comprising a Candidate in the Field outside of the Territory; *provided*, *however*, that BioNTech may not disclose any Pfizer Confidential Information to Fosun or its Affiliates without the prior written consent of Pfizer, other than to the extent necessary for Fosun or its Affiliates (or such other collaboration partner in or for China) to undertake fill/finish of a product identical to any Product in China or to comply with information requirements of the China National Medical Products Administration relating to such product required under applicable Law, in each case so far as such use is licensed under Sections 3.4.2(b) or 3.4.4(b);
  - 11.2.2.2. 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 within the Territory; *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;
  - 11.2.2.3. in connection with filing or prosecuting Research and Development Program Patent Rights, Product Patent Rights or Trademark rights as permitted by this Agreement;
  - 11.2.2.4. in connection with any prosecution or litigation actions or defenses undertaken pursuant to Section 10 or any other litigation directly related to a Candidate or Product in the Field in the Territory;
  - 11.2.2.5. subject to the provisions of Section 11.5.2, 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;
  - 11.2.2.6. by either Party in respect of Confidential Information belonging to the other Party (including the terms of the Agreement) to any bona fide or potential subcontractor under this Agreement in connection with the Development of the Candidate or Product in the Territory, 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 10.1; and

11.2.2.7. to the extent necessary or useful in order to enforce its rights under this Agreement.

Notwithstanding anything herein to the contrary, each Party acknowledges and agrees that the use by a Party of the other Party's Confidential Information disclosed under the Flu Collaboration License in the performance of this Agreement is not a breach of the confidentiality obligations under this Agreement or the Flu Collaboration License, and vice versa. 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 11.2.2, 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.

- 11.3. 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. Before disclosing this Agreement or any of the terms hereof pursuant to this Section 11.3, 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 11.3 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 11.3, 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.
- 11.4. <u>Residual Knowledge Exception</u>. Notwithstanding any provision of this Agreement to the contrary, Residual Knowledge will not be considered Confidential Information for purposes of this Section 10.1; <u>provided</u> 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.

# 11.5. Public Announcements; Publications.

- 11.5.1. **Announcements**. Except as may be expressly permitted under Section 11.3, neither Party will make any public announcement regarding this Agreement without the prior written approval of the other Party. The Parties agree that the Parties will issue a mutually agreed upon joint press release regarding the signing of this Agreement following the Signing Date.
- 11.5.2. **Publications**. During the Term, each Party will submit to the other Party for review and approval (such approval not to be unreasonably withheld, delayed or conditioned) any proposed publication or public presentation proposed by a Party or its Affiliates or any of their respective Representatives that relates to the activities conducted under this Agreement, including the Research and Development Plan; *provided* that notwithstanding the requirement for approval (a) neither Party shall be prevented from submitting any publication or making a presentation in respect of a Clinical Trial for which the Party is either the IND holder or the Lead Development Party to

the extent such publication or presentation is required under applicable Law or such Party's internal publication policies, but such publishing Party shall not disclose the other Party's confidential information in respect of its technology and Intellectual Property Rights, and shall take on board and reasonably consider any reasonable requests of the other Party with respect to such proposed publication or presentation; (b) the Party whose approval is sought shall not unreasonably withhold or condition such approval; and (c) nothing shall prohibit a Party from making any press release or statement where required pursuant to applicable Law or stock exchange rule, subject to such publishing Party shall take on board and reasonably consider any reasonable requests of the other Party with respect to such proposed publication or presentation. Each Party's review and approval will be conducted only for the purposes of identifying if confidential information should be modified or deleted so as to preserve the value of the technology owned by such Party or its Affiliates and the rights granted to each Party hereunder. Written copies of such proposed publication or presentation required to be submitted hereunder will be submitted as soon as practically possible before submission for publication or presentation (the "Review Period"). The reviewing Party will provide its comments with respect to such publications and presentations within 7 Business Days of its receipt of such written copy. The Review Period may be extended for an additional 10 Business Days in the event a Party can, within 7 Business Days of receipt of the written copy, demonstrate reasonable need for such extension including for the preparation and filing of patent applications. Each Party 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 11.5.2, including International Committee of Medical Journal Editors standards rega

- 11.6. Non-Disclosure in China. For the avoidance of doubt, nothing in this Agreement authorizes or permits BioNTech to disclose to Fosun, its Affiliates or any other collaboration partner in or for China any Pfizer Confidential Information without the prior written consent of Pfizer other than to the extent necessary for Fosun or its Affiliates (or such other collaboration partner in or for China) to undertake fill/finish of a product identical to any Product in China or to comply with information obligations required by the China National Medical Products Administration relating to such product in accordance with applicable Law, in each case so far as such use is licensed under Sections 3.4.2(b) or 3.4.4(b).
- 11.7. Obligations in Connection with Change of Control. If a Party is subject to a Change of Control or if a Party or any of its Affiliates acquires or merges with a Third Party during the Term ("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 11. 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.

### 2. REPRESENTATIONS AND WARRANTIES

- 12.1. Mutual Representations and Warranties. Each of BioNTech and Pfizer hereby represents and warrants to the other Party that:
  - 12.1.1. it is duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization;
- 12.1.2. 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;
  - 12.1.3. it has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder;
- 12.1.4. 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
- 12.1.5. 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 Effective Date.
- 12.2. <u>Mutual Covenants</u>. 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 Effective Date until expiration or termination of this Agreement it will perform its obligations under this Agreement in compliance with applicable Laws.
- 12.3. Representations and Warranties of BioNTech. BioNTech hereby represents and warrants to Pfizer that, unless otherwise disclosed in Schedule 12.3 (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 1.36 shall be deemed disclosed against the representations and warranties given by BioNTech at sections 12.3.1, 12.3.2, 12.3.4, 12.3.10 and 12.3.11 of this Agreement and provided further that all disclosures made under the Flu Collaboration License shall be deemed disclosed also under this Agreement:
  - 12.3.1. as of the Signing 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;
  - 12.3.2. as of the Signing Date, BioNTech has, and to its knowledge will have, the full right, power and authority to (a) 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 (b) perform its obligations under this Agreement;
  - 12.3.3. <u>Schedule 1.17</u> sets forth a true and complete list of all Candidates relevant to the Field discovered, developed or Controlled by BioNTech or its Affiliates on or prior to the Signing Date;
  - 12.3.4. as of the Signing Date, (a) <u>Schedule 12.3.4</u> 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 and Development Program, (b) each such Patent Right is in full force and effect and, so far as BioNTech is aware, valid and enforceable, (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; (d) BioNTech Controls all Patent Rights listed in <u>Schedule 12.3.4</u>; and (e) other than those licensed hereunder, there are no other Patent Rights owned or Controlled by BioNTech that Candidates or Products would infringe;

- 12.3.5. as of the Signing Date, BioNTech is not aware of any material adverse event, or medical or scientific concern or doubt regarding the safety, contraindications or effectiveness of the use of the BioNTech Technology or the Candidates that have not previously been disclosed in writing to Pfizer;
- 12.3.6. to BioNTech's knowledge as of the Signing Date, (a) 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);
- 12.3.7. as of the Signing 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;
- 12.3.8. 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 Signing 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);
- 12.3.9. in respect of BioNTech Technology solely or jointly owned by BioNTech existing as of the Signing Date, neither BioNTech nor its Affiliates are subject to any funding agreement with any government or Governmental Authority;
- 12.3.10. as of the Effective Date (a) there are no BioNTech Third Party Agreements other than the Current Licenses set forth in Schedule 1.36, (b) true and complete copies of each Current License (other than the Fosun Agreement) 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;
- 12.3.11. as of the Signing 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 1.17 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;

- 12.3.12. as of the Effective 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;
- 12.3.13. as of the Signing Date, BioNTech and its Affiliates (a) have claimed and remunerated all employee inventions of their respective employees comprised within the GEIA Technology in accordance with the provisions of the GEIA; and (b) are entitled to unrestrictedly claim all rights to employee inventions of their employees comprised within the GEIA Technology;
- 12.3.14. as of the Signing Date, BioNTech has obtained all necessary assignment documents for the BioNTech 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 and Development 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;
- 12.3.15. as of the Signing 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;
- 12.3.16. as of the Signing 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;
- 12.3.17. 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;
- 12.3.18. 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;

- 12.3.19. 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-Corruption Laws, accounting and record keeping laws, and laws relating to interactions with HCPs, Governments and Government Officials;
- 12.3.20. BioNTech has implemented 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;
- 12.3.21. 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.

#### 12.4. Accuracy of Representations and Warranties.

- 12.4.1. BioNTech will take no action which would render any representation or warranty made by BioNTech and contained in Section 12.1 or Section 12.2 inaccurate or untrue; <u>provided</u> that such covenant shall not apply to representations and warranties expressly given as of the Effective Date;
- 12.4.2. 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
- 12.4.3. 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 12.1, Section 12.2, Section 16.10 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 16.10, 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 Effective Date.

- 12.5. <u>BioNTech Covenants</u>. In addition to the covenants made by BioNTech elsewhere in this Agreement, BioNTech hereby covenants to Pfizer that, from the Effective Date until expiration or termination of this Agreement:
  - 12.5.1. 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 16.1) 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 and Development 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 and Development 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;
  - 12.5.2. 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 and Development 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 and Development 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 12.5.2 due to any reasonable act or position taken in connection with the filing, prosecution, maintenance, defense or enforcement of BioNTech Technology or Research and Development Program Technology as permitted in Section 10);
  - 12.5.3. 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 Effective 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
  - 12.5.4. 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

- 12.5.5. BioNTech and its Affiliates will maintain or obtain valid and enforceable agreements with or from all inventors of BioNTech Technology or Research and Development 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 and Development Program Technology (except to the extent applicable Law provides that all right, title and interest in and to such BioNTech Technology or Research and Development Program Technology automatically vests in BioNTech or its Affiliates by operation of law).
- 12.5.6. 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.
- 12.5.7. 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);
- 12.5.8. To the extent BioNTech Technology or Research and Development 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 (a) 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 and Development Program Technology (except to the extent applicable Law provides that all right, title and interest in and to such BioNTech Technology or Research and Development Program Technology automatically vests in the Third Party subcontractor by operation of law) and, (b) to the extent GEIA applies to such BioNTech Technology or Research and Development Program Technology, use Commercially Reasonable Efforts to obtain a waiver of inventor in his rights in Sec. 14, 16 and 17 GEIA;
- 12.5.9. with respect to any BioNTech Technology or Research and Development 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 and Development Program Technology made by the

- inventor, (b) the inventor assigns its rights, title and interest in and to that BioNTech Technology or Research and Development 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;
- 12.5.10. with respect to animals used in conducting activities under this Agreement, BioNTech will, and will cause its Affiliates and permitted subcontractors to, comply with its policies on animal care and use which shall be no less strict than Pfizer's Corporate Policy regarding Animal Care and Use, attached hereto as <a href="Exhibit C"><u>Exhibit C</u></a> (except where in conflict with applicable Law);
- 12.5.11. 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 binding part of the Research and Development Plan 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 and Development Plan is in accordance with all applicable Laws and recognized international standards for the protection of human research subjects;
- 12.5.12. BioNTech shall, at all times, maintain and enforce a compliance and ethics program containing adequate systems, policies and procedures for the detection, investigation, documentation, and remediation of any allegations, reports or findings related to a potential violation of applicable Law, including Anti-Corruption Laws, with respect to the Candidates, Products, payments and services under this Agreement, which policies shall be not less strict than Pfizer's Anti-Bribery and Anti-Corruption Principles attached hereto as Exhibit B. Such policies and procedures should set out rules governing interactions with HCPs, Government Officials, the engagement of Third Parties, and where appropriate, conducting due diligence, and the investigation, documentation and remediation of any allegations, reports or findings related to a potential violation of applicable Laws, and BioNTech shall, upon Pfizer's request, require any persons acting on behalf of BioNTech in connection with this Agreement to complete anti-corruption compliance training provided by Pfizer, and will notify Pfizer of any persons that require or may require such training during the Term of this Agreement;
- 12.5.13. if BioNTech finds, following an investigation, credible evidence of a violation of any applicable policies and procedures that are designed to ensure compliance with any applicable Laws, including any criminal, civil or administrative laws or regulations, or violations of policies or procedures related to scientific misconduct or data integrity, BioNTech shall promptly inform Pfizer of the occurrence and the steps taken by BioNTech to remediate the occurrence; and
- 12.5.14. in it undertaking, sponsoring, or having regulatory oversight over any Clinical Trials, BioNTech shall ensure and procure that all documentation for such Clinical Trials shall comply with, and take advantage of, any applicable Laws that serve to limit product liability claims and losses having regard to the pandemic status of COVID-19, including any requirements under any declarations pursuant to the Public Readiness and Emergency Preparedness (PREP) Act in the USA or any equivalent, similar or comparable legislation in the Territory.

- 12.6. <u>Pfizer Covenants</u>. In addition to the covenants made by Pfizer elsewhere in this Agreement, Pfizer hereby covenants to BioNTech that, from the Effective Date until expiration or termination of this Agreement,
  - 12.6.1. Pfizer and its Affiliates maintain or will obtain valid and enforceable agreements with or from all inventors of Pfizer Improvements or Research and Development Program 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 or Research and Development Program Technology (except to the extent applicable Law provides that all right, title and interest in and to such Pfizer Improvements or Research and Development Program Technology 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 or Research and Development Program Technology or any other Person that is required in connection with the creation or exploitation of or transfer of rights to such Pfizer Improvements or Research and Development Program Technology;
  - 12.6.2. 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 and Development Plan is in accordance with all applicable Laws and recognized international standards for the protection of human research subjects; and
  - 12.6.3. Pfizer will comply with the provisions of the Current Licenses set forth in <u>Schedule 1.36</u> in respect of BioNTech Technology sublicensed to Pfizer under the respective Current Licenses insofar as Pfizer is using such BioNTech Technology;
  - 12.6.4. Pfizer shall comply with its Anti-Bribery and Anti-Corruption Principles attached hereto as <u>Exhibit B</u> and its Corporate Policy regarding Animal Care and Use, attached hereto as <u>Exhibit C</u>; and
  - 12.6.5. in it undertaking, sponsoring, or having regulatory oversight over any Clinical Trials, Pfizer shall ensure and procure that all documentation for such Clinical Trials shall comply with, and take advantage of, any applicable Laws that serve to limit product liability claims and losses having regard to the pandemic status of COVID-19, including any requirements under any declarations pursuant to the Public Readiness and Emergency Preparedness (PREP) Act in the USA or any equivalent, similar or comparable legislation in the Territory.
  - 12.7. Notifications. During the Term. BioNTech will promptly notify Pfizer in writing or orally in the event that it learns of:
  - 12.7.1. 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 and Development Program Patent Rights; or

- 12.7.2. any inequitable conduct or fraud on the patent office with respect to any of the BioNTech Patent Rights or Research and Development Program Patent Rights; or
- 12.7.3. any Person (other than Persons identified as inventors of inventions disclosed in the BioNTech Patent Rights or Research and Development Program Patent Rights) who claims to be an inventor of an invention disclosed in the BioNTech Patent Rights or Research and Development Program Patent Rights; and
- 12.7.4. any lawsuits, claims, administrative actions, government inquiries or investigations, or other proceedings related to the activities contemplated under this Agreement.
- 12.8. <u>Representation by Legal Counsel</u>. 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.
- 12.9. <u>BioNTech's knowledge</u>. All references in this Section 12 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 <u>Schedule 12.9</u>.
- 12.10. <u>Disclaimer</u>. 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.

# 13. GOVERNMENT APPROVALS; TERM AND TERMINATION

- 13.1. <u>Government Approvals</u>. 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.
- 13.2. <u>Term.</u> The term of this Agreement (the "<u>Term</u>") will commence on the Effective Date and shall continue, unless terminated earlier in accordance with this Section 13, until the later of (a) completion of all Development and Manufacturing obligations of each Party set out herein; and (b) the termination or expiry of the Commercialization Agreement or, in the absence of a Commercialization Agreement, Pfizer ceasing to pursue Commercialization activities pursuant to the Commercialization Terms.
- 13.3. Termination for Cause by a Party. Either Party may terminate this Agreement for cause, at any time during the Term, by giving written notice to the other Party in the event that such other Party commits a material breach of its obligations under this Agreement and such material breach remains uncured for at least 90 days, 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 [\*\*\*] and if the Party accused of breach 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 the Party accused of a breach 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.

- 13.4. <u>Termination by Pfizer Convenience</u>. [\*\*\*], Pfizer may terminate this Agreement for convenience upon [\*\*\*] prior written notice (which notice period may be shortened by BioNTech in BioNTech's sole discretion through written notice to Pfizer at any time after BioNTech's receipt of such termination notice) without any liability to BioNTech.
  - 13.5. Termination by Pfizer for [\*\*\*]

# 13.6. Effects of Termination.

- 13.6.1. **Termination for Cause by a Party.** In the event that a Party terminates this Agreement for cause pursuant to Section 13.3, 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), except as otherwise expressly provided herein.
  - 13.6.2. **Termination for Pfizer's Convenience**. Upon Pfizer's termination pursuant to Section 13.4 (a) [\*\*\*]; and (b) [\*\*\*].
- 13.6.3. **No Effect on Related Agreements.** Unless explicitly agreed otherwise, termination or expiration of this Agreement shall not affect any other agreements concluded hereunder, including the Commercialization Agreement or any Manufacturing agreements pursuant to Article 8.
- 13.6.4. **Continuation of Pfizer Licenses.** Except in the event of Pfizer's termination pursuant to Section 13.3 or 13.7.1, (a) [\*\*\*], (b) [\*\*\*], (c) [\*\*\*], and (d) [\*\*\*].

13.6.5. **Exclusivity.** In the event of Pfizer's termination pursuant to Section 13.7, the Parties' obligations pursuant to Section 3.10.3 shall survive the termination or expiration of this Agreement for a period of [\*\*\*] years provided that BioNTech shall not be prevented from using the Product within the Field. In the event of Pfizer's termination pursuant to Section 13.4 or 13.5, Pfizer shall not be entitled to enter into any collaboration or license agreement with any Third Party to Develop or Commercialize in the Territory an immunogenic composition comprising mRNA in the Field for a period of [\*\*\*] months commencing on the date of the termination notice served by Pfizer, provided that such obligation shall not (i) restrict Pfizer's or its Affiliates' right to work as contract manufacturer for a Third Party, (ii) prohibit Pfizer or its Affiliate from acquiring any Third Party, or being acquired by any Third Party, that at the time of acquisition is active in the Development or Commercialization of an immunogenic composition comprising mRNA in the Field, or (iii) prohibit Pfizer or its Affiliate from undertaking non-clinical research work.

13.6.6. **Accrued Rights.** 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.

13.6.7. **Survival Period**. The following sections, together with any sections that expressly survive, will survive expiration or termination of this Agreement for any reason: Sections 1 (Definitions), 3.5 (additional licenses), 5.4.2(a) through (d) only (Repayment of BioNTech Deferred Development Costs) (except in the event of a termination by Pfizer pursuant to Section 13.4), 5.6 (Records and Accounting Principles), 5.7.1 (Withholding Taxes), 5.10 (Audits), 5.10.1 (Underpayments/Overpayments), 5.10.2 (Confidentiality), 7.4.2 (Title to Pfizer Materials and BioNTech Materials), 7.4.4 (Return of Proprietary Materials), 9.2.5, first sentence only (Ownership of Regulatory Filings), 9.7 (Liability), 10.2 (Ownership of Intellectual Property), 10.3.1.2, 10.3.1.3 and 10.3.2 (Filing, Prosecution and Maintenance of Patent Rights), 11 (Confidentiality), 13.6 (Effects of Termination), 13.7 (Provision for Insolvency), 15.1 (No Consequential Damages), 15.2 (Indemnification by Pfizer), 15.3 (Indemnification by BioNTech), 15.4 (Procedure), 16 (Miscellaneous) and, to the extent an Enforcement Action or Infringement Claim is active, live or pending at the time of expiry or termination, Sections 10.4 or 10.8, as applicable.

# 13.7. Provision for Insolvency.

13.7.1. **Termination Right**. BioNTech will be deemed a "<u>Debtor</u>" 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 13.7.1, 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 13.6.7 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 13.7.1 will limit any other remedy Pfizer may have for any breach by BioNTech of this Agreement.

13.7.2. 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 3.1.1, 3.2.1, 3.3, 3.4.1 and 3.5.1 and Section 10 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 5 and all other payments by Pfizer to BioNTech hereunder or under the Commercialization Agreement 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 Rights 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, Product Technology, and RNA Technology, (v) laboratory notes and notebooks; (vi) Candidate and Product data or filings, and (vii) rights of reference in respect of filings for and Regulatory 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 Rights 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 Rights 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.

13.7.3. **No Limitation of Rights**. All rights, powers and remedies of Pfizer provided in this Section 13.7 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 to 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.

# 14. CHANGE OF CONTROL

- 14.1. <u>Change of Control</u>. If a Change of Control occurs with respect to a Party and a Third Party during the Term, or if a Party or any of its Affiliates acquires or merges with a Third Party during the Term, (in either case such Party being the "<u>Affected Party</u>"):
  - 14.1.1. if such Third Party is, at the time of such Change of Control or acquisition or merger, conducting activities that would cause the Affected Party or one of its Affiliates to violate Section 3.10.1 (such activities, a "<u>Acquisition Program</u>"), then such Affected Party or such Third Party shall be permitted to continue such Acquisition Program and such continuation will not constitute a violation of Section 3.10.1;
  - 14.1.2. the provisions of Section 11.7 shall apply and no Confidential Information of the other Party or its Affiliates may be disclosed to the Third Party and shall not be used in any Acquisition Program (if any) and the Affected Party shall implement and maintain, in accordance with such Affected Party's internal commercially reasonable practices, an information and personnel barrier between the working teams involved in the day to day conduct of such Affected Party's internal program of Development and Manufacture of Candidates and Products under this Agreement, and any activities of the Third Party, including under any Acquisition Program; and
    - 14.1.3. if BioNTech is the Affected Party then:

14.1.3.1.[\*\*\*]; 14.1.3.2.[\*\*\*]; 14.1.3.3.[\*\*\*]; 14.1.3.4.[\*\*\*]; and 14.1.3.5.[\*\*\*].

- 14.2. <u>Effects of Change of Control</u>. In the event of a Change of Control of BioNTech by during the Term, the following provisions of this Section 14 shall also apply:
  - 14.2.1. **BioNTech Intellectual Property.** All BioNTech Technology and Research and Development Program Technology, Controlled by BioNTech immediately prior to such BioNTech Change of Control shall continue to be BioNTech Technology and Research and Development Program Technology licensed to Pfizer for purposes of this Agreement.
  - 14.2.2. **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 "<u>Acquirer</u>") shall not be included within the licenses granted to Pfizer hereunder.
  - 14.2.3. **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 and Development Plan or the Manufacturing Plan and without use of Pfizer's Technology, Pfizer's Confidential Information, Research and Development Program Technology, BioNTech Improvements or BioNTech Technology shall not be included within the Research and Development Program Technology or BioNTech Technology or BioNTech Third Party Agreements (it being understood, however, for the avoidance of doubt, that all BioNTech Technology, Research and Development 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 and Development 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).
  - 14.2.4. **Research and Development Program Technology.** No Research and Development Program Technology Controlled by Pfizer including 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.
  - 14.2.5. **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 3.10 using any Research and Development Program Technology, Pfizer Technology, Pfizer Improvements or Confidential Information of Pfizer.

# 15. LIMITATION ON LIABILITY, INDEMNIFICATION AND INSURANCE

15.1. <u>No Consequential Damages</u>. Except with respect to liability arising from a breach of Sections 10 or 10.1, 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 15, 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, regulatory, launch or sales threshold milestone payments due or any other unearned, speculative or otherwise contingent payments provided for in this Agreement.

- 15.2. <u>Indemnification by Pfizer</u>. 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 "<u>BioNTech Indemnified Party</u>") 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, "<u>Liabilities</u>") that the BioNTech Indemnified Party may be required to pay to one or more Third Parties resulting from or arising out of (a) use of the Pfizer Technology, Pfizer Materials, and/or Pfizer Know-How disclosed by or on behalf of Pfizer in accordance with the rights licensed under this Agreement or (c) the material breach by Pfizer of any of its representations, warranties or covenants set forth in Section 7.4.1, Section 12.1 or Section 12.2 or Section 12.6; except, in each case, to the extent caused by the negligence, recklessness or intentional acts of BioNTech or any BioNTech Indemnified Party.
- 15.3. <u>Indemnification by BioNTech</u>. 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 "<u>Pfizer Indemnified Party</u>") 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 (a) use of the BioNTech Technology [\*\*\*], BioNTech Materials, and/or BioNTech Know-How disclosed by or on behalf of BioNTech in accordance with the rights licensed under this Agreement, (b) the Candidates or Products in accordance with the rights licensed under this Agreement, save to the extent the Liabilities are in respect of (i) the exploitation of Pfizer Technology infringing a Third Party Patent Right or (ii) [\*\*\*]; (c) use of the BioNTech name or logo in accordance with the rights licensed under this Agreement, (d) 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 and Development Program Technology used in any Candidate or Product; or (e) the material breach by BioNTech or any of its Representatives of any of its representations, warranties or covenants set forth in Section 9, Section 12.1, Section 12.2, Section 12.3, or Section 12.5 except to the extent caused by the negligence, recklessness or intentional acts of Pfizer or any Pfizer Indemnified Party.

# 15.4. Procedure.

15.4.1. **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 "<u>Indemnified Party</u>.") is entitled to indemnification hereunder (a "<u>Third Party Claim</u>"), then the Indemnified Party will promptly notify the Party obligated to indemnify the Indemnified Party (the "<u>Indemnifying Party</u>") 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.

15.4.2. Control. Subject to either Party's right to control any actions described in Section 10 (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.

15.4.3. **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.

15.5. 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 15.2 or Section 15.3, as applicable, in each case with limits of not less than \$[\*\*\*] ([\*\*\*] 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 (a) Pfizer Inc. and its Affiliates will be indemnified as principal on BioNTech's commercial general liability and products liability and (b) 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 15.5 to the contrary, Pfizer may meet its obligations under this Section 15.5 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 15.

#### 16. MISCELLANEOUS

- 16.1. <u>Assignment.</u> 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 16.1. This Agreement will be binding upon the successors and permitted assigns to the extent necessary to carry out the intent of this Agreement. Any assignment not in accordance with this Section 16.1 will be void.
- 16.2. <u>Further Actions</u>. 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.
- 16.3. 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.

16.4. 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 replacem

16.5. 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: [\*\*\*]
with a copy to:
Pfizer Inc.
Notices: Pfizer Legal Division
[\*\*\*]

[\*\*\*]

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 SE
[\*\*\*]

- 16.6. <u>Amendment</u>. 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.
- 16.7. <u>Waiver</u>. 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.
- 16.8. 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 of 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.
- 16.9. <u>Descriptive Headings</u>. 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.
- 16.10. <u>Global Trade Control Laws</u>. 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 ("<u>Global Trade Control Laws</u>"). 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:
  - 16.10.1. Each Party will not, for activities under this Agreement, (a) engage in any such activities in a Restricted Market; (b) involve individuals ordinarily resident in a Restricted Market; or (c) 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.

16.10.2. 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.

- 16.10.3. Neither Party will knowingly transfer to the other Party any goods, software, technology or services that are (a) 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 (b) specifically identified as an E.U. Dual Use Item or on an applicable export control list of another country.
- 16.11. <u>Dispute Resolution</u>. 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:
  - 16.11.1. 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.
  - 16.11.2. Within 30 days of receipt of a Notice of Dispute and in advance of any meeting pursuant to Section 16.11.3, the receiving Party will provide a written response to the other Party's claims regarding the dispute.
  - 16.11.3. 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 16.11 will survive for five years from the date of termination or expiration of this Agreement.

16.12. <u>Governing Law</u>. 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.

- 16.13. <u>Consent to Jurisdiction and Venue</u>. 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).
- 16.14. 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 (a) that certain [\*\*\*] (which is hereby terminated effective as of the Effective Date, *provided that* such Confidential Disclosure Agreement will continue to govern the treatment of Confidential Information disclosed by the Parties prior to the Effective Date in accordance with its terms), (b) that certain [\*\*\*] (which is hereby terminated effective as of the Effective Date, *provided that* the terms of this Agreement shall also apply to all activities made under the [\*\*\*] (which is hereby terminated effective as of the Effective Date).
- 16.15. <u>Flu Collaboration</u>. Except as provided in Section 8.2, nothing in this Agreement varies, amends or otherwise supersedes or replaces the provisions and rights under the Flu Collaboration License, and the Flu Collaboration License and this Agreement shall be treated as separate arm's length transactions.
- 16.16. <u>Independent Contractors</u>. 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.
- 16.17. <u>Counterparts</u>. 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.
- 16.18. 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)

PFIZER INC.

By
By
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By
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[Signature page to Collaboration Agreement]

IN WITNESS WHEREOF, authorized representatives of the Parties have duly executed this Agreement as of the Effective Date to be effective as

of the Effective Date.

# Exhibit A

# **Research and Development Plan**

To be agreed by the Parties in accordance with Section 2.2 and added after the Signing Date.

#### 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.

#### Exhibit C

#### 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.

## Candidates

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## **Current Licenses**

## **Developing Countries List**

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## **Initial Development Budget**

To be agreed by the Parties in accordance with Section 2.2 and added after the Signing Date.

## **Initial Manufacturing Plan**

To be agreed by the Parties in accordance with Section 2.2 and added after the Signing Date.

## **Commercialization Agreement Term Sheet**

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## ANNEX A ABAC Compliance Certification

[I/I on behalf of Party] hereby certify:

- 1. [I have/Party has] communicated our *International Anti-Bribery and Anti-Corruption Principles* to all persons acting on [my/its] behalf in connection with work under this Agreement, including any agents, contractors, or subcontractors;
- 2. With respect to any [Products], payments, or [Services] provided under this Agreement, [Party] has not taken any action directly or indirectly to (i) offer, promise, provide, or authorize the offer or provision of money or anything of value, in order to improperly or corruptly seek to influence any Government Official or any other person in order to obtain or retain business or any other improper business advantage; (ii) request or accept any such improper payment; or (iii) cause a violation of any applicable Anti-Corruption Law. For example, this includes providing any inducement for such Government Official or person to approve, reimburse, prescribe, or purchase a [Product], to influence the outcome of a clinical trial, or otherwise to benefit [Counterparty]'s business activities improperly;
- 3. [Party] has ensured that it and every agent, contractor, or subcontractor performing [Services] in connection with the Agreement has agreed to comply with and be bound by the provisions of the Agreement;
- 4. [Party has] met all relevant disclosure obligations required under the Agreement; and
- 5. To the extent requested by Pfizer, any persons acting on behalf of [me/Party] in connection with the Agreement, have completed anti-corruption compliance training provided by Pfizer.

COMPANY NAME:	
NAME:	
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## <u>Schedule 5.5</u> Potential Third Party Funders

# Schedule 7.3.5 Decision-Making Rights

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## Responsibilities delegated to Pfizer in the USA or other countries in the Territory where it is the Lead Development Party

Subject to the Agreement, the activities delegated to Pfizer will be managed within Pfizer's quality systems including:

## Schedule 9.2.7

## Pharmacovigilance Agreement Term Sheet

		Schedule 12.	.3		
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**Schedule 12.3.4** 

**BioNTech Patent Rights existing as of the Effective Date** 

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## Schedule 12.9

## **BioNTech Management with Knowledge**

[\*\*\*]

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

Contract number (FI No): [\*\*\*] Contract number (FI No): [\*\*\*] Serapis No: [\*\*\*]

# ANTIVIRAL VACCINE RDI

Finance Contract

between the

European Investment Bank

and

BioNTech SE

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## THIS CONTRACT IS MADE ON 10 JUNE 2020 BETWEEN:

The European Investment Bank having its seat at 100 blvd Konrad Adenauer, Luxembourg, L-2950 Luxembourg, represented by Donald Fitzpatrick, Head of Divission and Emma Milne, Legal Counsel

and

BioNTech SE a European public limited liability company ( $Europ\ddot{a}ische$  Gesellschaft)

incorporated in Germany, having its registered office at An der Goldgrube 12, D- 55131 Mainz, Germany, registered with the commercial register (*Handelsregister*) of the local court (*Amtsgericht*) of Mainz under HRB 48720, represented by Dr. Sierk Poetting, CFO & COO (*Vorstand*) and Dr. James Timothy Patrick Ryan (*Prokurist*)

(the "Bank")

(the "Borrower")

\_

#### WHEREAS:

- (A) The Borrower has stated that it is implementing an investment programme relating to research and development and related expenses for the development of a prophylactic vaccine against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) as more particularly described in the technical description (the "**Technical Description**") set out in Schedule A (*Investment Specification and Reporting*) (the "**Investment**"). The total cost of the Investment, as estimated by the Bank, is EUR [\*\*\*] euro).
- (B) The Bank, considering that the financing of the Investment falls within the scope of its functions, agreed to provide the Borrower with a credit (including a profit participation credit (*partiarisches Darlehen*)) in an amount of EUR 100,000,000 (one hundred million euro) under this finance contract (the "Contract") to partially finance the Investment; **provided that** the amount of the loan hereunder shall not, in any case, exceed 50% (fifty per cent.) of the cost of the Investment. The Parties being aware of the differences between a profit participation credit (*partiarisches Darlehen*) and a silent partnership (*stille Gesellschaft*), have consciously decided to enter into this Contract.
- (C) This operation benefits from a guarantee from the European Union under the European Fund for Strategic Investments ("EFSI").
- (D) The Credit falls under a joint initiative between the Bank and the European Commission, which is intended as a new Bank financing instrument, to finance *inter alia* research projects and research infrastructure under the Horizon 2020 framework programme of the European Union for Research and Technological Development (2014-2020) (the "Horizon 2020 Framework EU Programme") and, in particular, under the programme called "Risk Sharing for Corporate Research and Innovation Facility".
- (E) The statute of the Bank provides that the Bank shall ensure that its funds are used as rationally as possible in the interests of the European Union; and, accordingly, the terms and conditions of the Bank's loan operations must be consistent with relevant policies of the European Union.
- (F) The financing of the Investment includes certain state subsidies or grants and the provision of such funds has been duly authorised and will be provided in compliance with all relevant legislation of the European Union.
- (G) The Bank considers that access to information plays an essential role in the reduction of environmental and social risks, including human rights violations, linked to the projects it finances and has therefore established its transparency policy, the purpose of which is to enhance the accountability of the Bank's group towards its stakeholders and the citizens of the European Union in general.
- (H) The processing of personal data shall be carried out by the Bank in accordance with applicable European Union legislation on the protection of individuals with regard to the processing of personal data by the European Union institutions and bodies and on the free movement of such data.
- (I) The Bank supports the implementation of international and EU standards in the field of anti-money laundering and countering the financing of terrorism and promotes tax good governance standards. It has established policies and procedures to avoid the risk of misuse of its funds for purposes which are illegal or abusive in relation to applicable laws. The Bank's group statement on tax fraud, tax evasion, tax avoidance, aggressive tax planning, money laundering and financing of terrorism is available on the Bank's website and offers further guidance to the Bank's contracting counterparties.

## **ARTICLE 1**

#### **Interpretation and definitions**

## 1.1 Interpretation

In this Contract:

- (a) references to Articles, Recitals, Schedules and (Sub-)Paragraphs are, save if explicitly stipulated otherwise, references respectively to articles of, and recitals, schedules and (sub-)paragraphs of schedules to, this Contract. All Recitals and Schedules form part of this Contract;
- (b) references to "law" or "laws" mean (i) any applicable law and any applicable treaty, constitution, statute, legislation, decree, normative act, rule, regulation, judgement, order, writ, injunction, determination, award or other legislative or administrative measure or judicial or arbitral decision in any jurisdiction which is binding or applicable case law, and (ii) EU Law;
- (c) references to applicable law, applicable laws or applicable jurisdiction means (i) a law or jurisdiction applicable to the Borrower or any other Obligor (as the context requires), its respective rights and/or obligations (in each case arising out of or in connection with the Finance Documents), its capacity and/or assets and/or the Investment; and/or, as applicable, (ii) a law or jurisdiction (including in each case the Bank's Statute) applicable to the Bank, its rights, obligations, capacity and/or assets;
- (d) references to a provision of law are references to that provision as amended or re-enacted;
- (e) references to any Finance Document or other agreement or instrument are references to that Finance Document or other agreement or instrument as amended, novated, supplemented, extended or restated;
- (f) words and expressions in plural shall include singular and vice versa;
- (g) "promptly" is to be construed as *unverzüglich* (without undue delay) within the meaning of Section 121 para. 1 sentence 1 of the BGB;
- (h) a Default (other than an Event of Default) is "continuing" if it has not been remedied or waived and an Event of Default is "continuing" if it has not been waived; and
- (i) terms defined in the GDPR (as defined below), including the terms "data subject", "personal data" and "processing" have the same meanings when used in Paragraph 25 (*Data Protection*) of Schedule H (*General Undertakings*) of, this Contract.
  - This Contract is made in the English language. For the avoidance of doubt, the English language version of this Contract shall prevail over any translation of this Contract. However, where a German translation of a word or phrase appears in the text of this Contract, the German translation of such word or phrase shall prevail.

## 1.2 **Definitions**

In this Contract:

"Accepted Tranche" means a Tranche in respect of a Disbursement Offer which has been duly accepted by the Borrower in accordance with its terms on or before the Disbursement Acceptance Deadline.

"acting in concert" means acting together pursuant to an agreement or understanding (whether formal or informal).

"AktG" means the German stock corporation act (Aktiengesetz).

"Auditor" means an independent, international and leading firm of accounts (which has at least offices in Luxembourg and Frankfurt am Main) appointed by the Bank and accepted by the Borrower. If the Bank and the Borrower have not agreed on an Auditor within 60 (sixty) days of any such request, the Bank will have sole discretion to appoint an Auditor.

- "Authorisation" means an authorisation, permit, consent, approval, resolution, licence, exemption, filing, notarisation or registration.
- "Authorised Signatory" means a person authorised to sign individually or jointly (as the case may be) Disbursement Acceptances on behalf of the Borrower and named in the most recent List of Authorised Signatories and Accounts received by the Bank prior to the receipt of the relevant Disbursement Acceptance.
- "BGB" means the German Civil Code (Bürgerliches Gesetzbuch).
- "Budget" has the meaning given to that term in Sub-Paragraph (b) of Paragraph 2 (Information concerning the Borrower) of Schedule I (Information and Visits).
- "Business Day" means a day (other than a Saturday or Sunday) on which the Bank and commercial banks are open for general business in Luxembourg and Mainz, Germany.
- "Cancellation Fee" has the meaning given to such term in Article 1.2 (*Definitions*) of the Finance Fee Letter.
- "Cash Interest Fixed Rate" means a fixed rate of [\*\*\*]% ([\*\*\*] basis points) per annum.
- "Change in the Beneficial Ownership" means a change in the ultimate ownership or control of the Borrower according to the definition of "beneficial owner" set out in article 3(6) of Directive 2015/849 of the European Parliament and of the Council of 20 May 2015 on the prevention of the use of the financial system for the purposes of money laundering or terrorist financing, as amended, supplemented or restated.

## "Change-of-Control Event" means:

- (a) any person or group of persons acting in concert gains Control of the Borrower or of any entity directly or indirectly Controlling the Borrower; or
- (b) the Borrower ceases to Control any Guarantor; or
- (c) a Delisting of the Borrower.
- "Change-of-Law Event" means the enactment, promulgation, execution or ratification of or any change in or amendment to any law, rule or regulation (or in the application or official interpretation of any law, rule or regulation) that occurs after the date of this Contract and which, in the opinion of the Bank, would materially impair an Obligor's ability to perform its obligations under the Finance Documents.
- "Clinical Study" means each of the ongoing clinical studies with references NCT04380701 and NCT04368728.
- "Compliance Certificate" means a certificate substantially in the form set out in Schedule E (Form of Compliance Certificate).
- "Contract Number" shall mean each Bank generated number identifying this Contract and indicated on the cover page of this Contract after the letters "FI N°".
- "Control" means (i) owning (directly or indirectly) more than 50% (fifty per cent) of the shares in an entity, (ii) the power to cast, or to control the casting of, more than 50% (fifty per cent) of the maximum number of votes that might be cast at a shareholder or general meeting of an entity, (iii) the power to appoint or remove all, or the majority, of the directors of an entity, and/or (iv) the power to direct the management and policies of an entity, whether through the ownership of voting capital, by contract or otherwise, and "Controlling" and "Controlled" has the corresponding meaning.
- "COVID-19 Syndrome" means severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).
- "COVID-19 Vaccine" means a vaccine against COVID-19 Syndrome developed by the Borrower.
- "COVID-19 Vaccine Gross Profit" means the Group's share of the aggregate amount of:

- (a) [\*\*\*]; and
- (b) [\*\*\*],

less such amounts applied towards reimbursement of the 'BioNTech Deferred Development Costs' under and as defined in section 5.4.2 of the Pfizer Agreement as at 17 March 2020.

"Credit" has the meaning given to it in Article 2.1 (Amount of Credit).

"**Default**" means an Event of Default or any event or circumstance specified in Article 9 (*Events of Default*) which would (with the expiry of a grace period, the giving of notice, the making of any determination under this Contract or any combination of any of the foregoing) be an Event of Default.

"Deferred Interest Fixed Rate" means a fixed rate of [\*\*\*]% ([\*\*\*] basis points) per annum [\*\*\*].

"Delisting" means voluntary or involuntary removal of listed shares from a regulated market or revocation of admission to trading of shares on a regulated market.

"Disbursement Acceptance" means a copy of the Disbursement Offer duly countersigned by the Borrower.

"Disbursement Acceptance Deadline" means the date and time of expiry of a Disbursement Offer as specified therein.

"Disbursement Account" means, in respect of each Tranche, the bank account set out in the most recent List of Authorised Signatories and Accounts.

"Disbursement Date" means the date on which disbursement of a Tranche is made by the Bank.

"Disbursement Offer" means a letter substantially in the form set out in Schedule C (Form of Disbursement Offer/Acceptance).

"Dispute" has the meaning given to it in Article 10.2 (Jurisdiction).

"Disruption Event" means either or both of:

- (a) a material disruption to those payment or communications systems or to those financial markets which are, in each case, required to operate in order for payments to be made in connection with this Contract; or
- (b) the occurrence of any other event which results in a disruption (of a technical or systems-related nature) to the treasury or payments operations of either the Bank or the Borrower, preventing that party from:
  - (i) performing its payment obligations under this Contract; or
  - (ii) communicating with other parties in accordance with the terms of this Contract,

and which disruption (in either such case as per Paragraph (a) or (b) above) is not caused by, and is beyond the control of, the party whose operations are disrupted.

"EBITDA" means, in respect of any Relevant Period, the consolidated operating profit of the Group before taxation (excluding the results from discontinued operations):

- (a) after deducting own work capitalised;
- (b) before deducting any interest, commission, fees, discounts, prepayment fees, premiums or charges and other finance payments whether paid, payable or capitalised by any Group Company (calculated on a consolidated basis) in respect of that Relevant Period;
- (c) not including any accrued interest owing to any Group Company;
- (d) after adding back any amount attributable to the amortisation or depreciation of assets of members of the Group;
- (e) before taking into account any Exceptional Items;

- (f) after deducting the amount of any profit (or adding back the amount of any loss) of any Group Company which is attributable to minority interests;
- (g) plus or minus the Group's share of the profits or losses (after finance costs and tax) of entities which are not Group Companies;
- (h) before taking into account any unrealised gains or losses on any financial instrument (other than any derivative instrument which is accounted for on a hedge accounting basis); and
- (i) before taking into account any gain arising from an upward revaluation of any other asset, in each case, to the extent added, deducted or taken into account, as the case may be, for the purposes of determining operating profits of the Group before taxation.
- "EIB Fee Letter" means the letter from the Bank to the Borrower dated 17 April 2020.
- "EFSI" has the meaning given in Recital (C).
- "EFSI Regulation" means the Regulation 2015/1017 of the European Parliament and of the Council of 25 June 2015 on the European Fund for Strategic Investments, as amended, supplemented or restated.
- "Environment" means the following, in so far as they affect human health or social well-being:
- (a) fauna and flora;
- (b) soil, water, air, climate and the landscape; and
- (c) cultural heritage and the built environment,

and includes, without limitation, occupational and community health and safety.

- "Environmental Approval" means any Authorisation required by Environmental Law.
- "Environmental Claim" means any claim, proceeding, formal notice or investigation by any person in respect of any Environmental Law.
- "Environmental Law" means EU Law including principles and standards, and national laws and regulations, of which a principal objective is the preservation, protection or improvement of the Environment.

## "Equity Investments" mean:

- (a) the investment of USD 113,000,000 (one hundred and thirteen million dollars) by Pfizer; and
- (b) the investment of USD 50,000,000 (fifty million dollars) by Fosun,

for subscribed shares in the Borrower.

- "EU Directives" means the directives of the European Union.
- **"EU Law"** means the acquis communautaire of the European Union as expressed through the Treaties of the European Union, the regulations, the EU Directives, delegated acts, implementing acts, and the case law of the Court of Justice of the European Union.
- "EUR" or "euro" means the lawful currency of the Member States of the European Union which adopt or have adopted it as their currency in accordance with the relevant provisions of the Treaty on European Union and the Treaty on the Functioning of the European Union or their succeeding treaties.
- "EURIBOR" has the meaning given to it in Schedule B (Definition of EURIBOR).
- "Event of Default" means any of the circumstances, events or occurrences specified in Article 9 (Events of Default).
- "Exceptional Items" means any material items of an unusual or non-recurring nature which represent gains or losses including those arising on:
- (a) the restructuring of the activities of an entity and reversals of any provisions for the cost of restructuring;

- (b) disposals, revaluations, write downs or impairment of non-current assets or any reversal of any write down or impairment;
- (c) disposals of assets associated with discontinued operations; and
- (d) any other examples of "exceptional items" (as such term has the meaning attributed to it in IFRS).

"Existing EIB Finance Contract" means the finance contract entered into by the Bank and the Borrower on 12 December 2019.

"Existing Indebtedness" means any Indebtedness of members of the Group arising under any arrangement listed in Schedule J (Existing Indebtedness).

"Existing Security" means any Security granted by members of the Group which is listed in Schedule K (Existing Security).

"Fee Letters" means the EIB Finance Letter and the Finance Fee Letter.

"Finance Fee Letter" means the Luxembourg law governed finance fee letter from the Bank to the Borrower dated on or about the date hereof.

"Final Availability Date" means the day falling [\*\*\*] ([\*\*\*]) months after the date of this Contract.

"Finance Documents" means this Contract, any Guarantee Agreement, the Fee Letters and any other document designated a "Finance Document" by the Borrower and the Bank.

"Finance Lease" means any lease or hire purchase contract which would, in accordance with IFRS in force prior to 1 January 2019, be treated as a finance or capital lease; it is understood between the parties to this Contract that the definition of "Finance Lease" does not include operational lease.

"Fosun" means Shanghai Fosun Pharmaceutical Industrial Development, Co., Ltd, a company incorporated in the People's Republic of China, and having a place of business at No. 1289 Yishan Road, Shanghai, People's Republic of China.

"Fosun Agreement" means the development and license agreement between Fosun and the Borrower dated 13 March 2020.

"GAAP" means generally accepted accounting principles (Grundsätze ordnungsgemäßer Buchführung) in Germany, including IFRS.

"GDPR" means General Data Protection Regulation (EU) 2016/679.

[\*\*\*

[\*\*\*]

[\*\*\*]

"Germany" means the Federal Republic of Germany.

"Group" means the Group Companies, taken together as a whole.

"Group Company" means the Borrower and its Subsidiaries.

"Guarantee Agreement" means a guarantee and indemnity agreement in form and substance satisfactory to the Bank to be entered into by a Guarantor as guarantor and the Bank as beneficiary.

## "Guarantor" means:

- (a) BioNTech RNA Pharmaceuticals GmbH;
- (b) BioNTech Innovative Manufacturing Services GmbH;
- (c) JPT Peptide Technologies GmbH;
- (d) BioNTech Cell & Gene Therapies GmbH; and

- (e) each Material Subsidiary which enters into a Guarantee Agreement in accordance with Sub-Paragraph (b) of Paragraph 16 (*Guarantees*) of Schedule H (*General Undertakings*).
- "Horizon 2020 Framework EU Programme" has the meaning given in Recital (D).
- "Horizon 2020 Legal Basis" means the Regulation 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 and Council Decision of 3 December 2013 establishing the specific programme implementing Horizon 2020.
- "IFRS" means international accounting standards within the meaning of IAS Regulation 1606/2002 to the extent applicable to the relevant financial statements.
- "Illegal Activities" means any of the following illegal activities or activities carried out for illegal purposes: tax crimes (as referred to in the directive (EU) 2015/849 of 20 May 2015), fraud, corruption, coercion, collusion, obstruction, money laundering, financing of terrorism or any illegal activity that may affect the financial interests of the EU, according to applicable laws.

## "Indebtedness" means any:

- (a) obligations for borrowed money;
- (b) indebtedness under any acceptance credit;
- (c) indebtedness under any bond, debenture, note or similar instrument;
- (d) instrument under any bill of exchange;
- (e) indebtedness in respect of any interest rate or currency swap or forward currency sale or purchase or other form of interest or currency hedging transaction (including without limit caps, collars and floors);
- (f) indebtedness under any Finance Lease;
- (g) indebtedness (actual or contingent) under any guarantee, bond security, indemnity or other agreement;
- (h) indebtedness (actual or contingent) under any instrument entered into for the purpose of raising finance;
- (i) indebtedness in respect of a liability to reimburse a purchaser of any receivables sold or discounted in the event that any amount of those receivables is not paid;
- (j) indebtedness arising under a securitisation; or
- (k) other transaction which has the commercial effect of borrowing.
- "Independent Expert" means an investment bank or consultancy firm of international standing and repute, appointed by the Borrower and accepted by the Bank. If the Bank and the Borrower have not agreed on an Independent Expert within 60 (sixty) days of any such request, the Independent Expert shall be appointed by the President of the Chamber of Industry and Commerce Frankfurt am Main (*Industrie- und Handelskammer Frankfurt am Main*) upon application by either the Bank or the Borrower.
- "Initial Ownership Stake" has the meaning given to that term in Sub-Paragraph (b)(i) of Paragraph 13 (*Ownership*) of Schedule H (*General Undertakings*).
- "InsO" means the German Insolvency Code (Insolvenzordnung).
- "Intellectual Property Rights" means intellectual property rights (*gewerbliche Schutzrechte*; *Immaterialgüterrechte*) of every designation (including, without limitation, patents, utility patents, copyrights, design rights, trademarks, software, service marks and know how) whether capable of registration or not.
- "Investment" has the meaning given to that term in Recital (A).
- "Key Contracts" means [\*\*\*] and any other document designated a "Key Contract" by the Borrower and the Bank.

- "Lead Organisation" means the European Union, the United Nations and international standard setting organisations including the International Monetary Fund, the Financial Stability Board, the Financial Action Task Force, the Organisation for Economic Cooperation and Development and the Global Forum on Transparency and Exchange of Information for Tax Purposes and any successor organisations.
- "List of Authorised Signatories and Accounts" means a list (signed by Authorised Signatories), in form and substance satisfactory to the Bank, setting out: (i) the Authorised Signatories, accompanied by evidence of signing authority of the persons named on the list and specifying if they have individual or joint signing authority, (ii) the specimen signatures of such persons, and (iii) the bank account(s) to which disbursements may be made under this Contract (specified by IBAN code if the country is included in the IBAN Registry published by SWIFT, or in the appropriate account format in line with the local banking practice), BIC/SWIFT code of the bank and the name of the bank account(s) beneficiary.
- "Loan" means the aggregate of the amounts disbursed from time to time by the Bank under this Contract.
- "Loan Outstanding" means the aggregate of the amounts disbursed from time to time by the Bank under this Contract that remains outstanding.
- "Material Adverse Change" means, any event or change of condition, which, in the reasonable opinion of the Bank has a material adverse effect on:
- (a) the ability of any Obligor to perform its respective obligations under the Finance Documents;
- (b) the business, operations, property or condition (financial or otherwise) of any Obligor or the Group as a whole; or
- (c) the legality, validity or enforceability of, or the effectiveness or ranking of, the rights or remedies of the Bank under the Finance Documents.
- "Material Subsidiary" means BioNTech RNA Pharmaceuticals GmbH, BioNTech Innovative Manufacturing Services GmbH, JPT Peptide Technologies GmbH, BioNTech Cell & Gene Therapies GmbH and any Subsidiary from time to time, whose gross revenues, Total Assets or EBITDA represents more than 5% (five per cent.) of (i) the consolidated gross revenues of the Group or, (ii) the Total Assets, or, (iii) as the case may be, the consolidated EBITDA of the Group, as calculated based on the then latest consolidated audited accounts of the Group.
- "Maturity Date" means, for each Tranche, the last Repayment Date of that Tranche as specified in the relevant Disbursement Offer, being the date falling 6 (six) years from the respective Disbursement Date of the relevant Tranche.
- "Milestone Events" means collectively the Tranche A Milestone Events and the Tranche B Milestone Events.
- "Non-EIB Financing" includes any loan (save for the Loan and any other direct loans from the Bank to the Borrower (or any other Group Company or a Guarantor)), credit bond or other form of financial indebtedness or any obligation for the payment or repayment of money originally granted to the Borrower (or any other Group Company or a Guarantor)) for a term of more than 3 (three) years.
- "Obligor" means the Borrower and each Guarantor.
- "Payment Date" means the quarterly dates specified in the Disbursement Offer until and including the Maturity Date, save that, in case any such date is not a Relevant Business Day, it means the following Relevant Business Day, without adjustment to the interest due under Article 4 (*Interest*), except for those cases where a payment is made as a single instalment in accordance with Article 5.1 (*Normal Repayment*), and to the final interest payment only, when it shall mean the preceding Relevant Business Day, with adjustment to the interest due under Article 4 (*Interest*).
- "Permitted Disposal" means each disposal permitted in accordance with Sub-Paragraph (b) of Paragraph 7 (*Disposal of assets*) of Schedule H (*General Undertakings*).
- "Permitted Guarantees" means each and every guarantee permitted in accordance with Paragraph 16 (*Guarantees*) of Schedule H (*General Undertakings*).

- "Permitted Hedging" has the meaning given to such term in Paragraph 17 (Hedging) of Schedule H (General Undertakings).
- "Permitted Indebtedness" means Indebtedness of the Borrower and/or any Group Company which is permitted in accordance with Paragraph 15 (*Indebtedness*) of Schedule H (*General Undertakings*).
- "**Permitted Security**" means Security of the Borrower and/or any Group Company which is permitted in accordance with Sub-Paragraph (c) Paragraph 23 (*Negative pledge*) of Schedule H (*General Undertakings*).
- "**Pfizer**" means 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 Agreement" means the collaboration agreement between the Borrower and Pfizer dated 17 March 2020.
- **"Pfizer Commercialisation Agreement"** means the definitive agreement pursuant to which Pfizer shall be licensed to commercialise the COVID-19 Vaccine in accordance with the provisions of the Pfizer Agreement.
- "**Prepayment Amount**" means the amount of a Tranche to be prepaid by the Borrower in accordance with Articles 5.2 (*Voluntary prepayment*), 5.3 (*Compulsory prepayment*) or 9.1 (*Right to demand repayment*).
- "**Prepayment Date**" means the date on which the Borrower proposes or is requested by the Bank, as applicable, to effect prepayment of a Prepayment Amount.
- "Prepayment Event" means any of the events described in Article 5.3 (Compulsory Prepayment).
- "Prepayment Fee" means, in relation to a Prepayment Amount in respect of a Tranche, a fee as follows:
- (a) a fee of 4% (four hundred basis points) of the Prepayment Amount if the Prepayment Date is after the relevant Disbursement Date but before or on the first anniversary of such Disbursement Date;
- (b) a fee of 3% (three hundred basis points) of the Prepayment Amount if the Prepayment Date is after the first anniversary of the relevant Disbursement Date but before or on the second anniversary of such Disbursement Date;
- (c) a fee of 2% (two hundred basis points) of the Prepayment Amount if the Prepayment Date is after the second anniversary of the relevant Disbursement Date but before or on the third anniversary of such Disbursement Date;
- (d) a fee of 1% (one hundred basis points) of the Prepayment Amount if the Prepayment Date is after the third anniversary of the relevant Disbursement Date but before or on the fourth anniversary of such Disbursement Date; or
- (e) a fee of 0.5% (fifty basis points) of the Prepayment Amount if the Prepayment Date is after the fourth anniversary of the relevant Disbursement Date but before the Maturity Date,

with such fee being payable on the applicable Prepayment Date.

- "Prepayment Notice" means a written notice from the Bank to the Borrower in accordance with Article 5.2.3 (Prepayment mechanics).
- "**Prepayment Request**" means a written request from the Borrower to the Bank to prepay all or part of the Loan Outstanding, in accordance with Article 5.2.1 (*Prepayment option*).
- "**Profit Participation Cap**" means, at any time, an amount of EUR 25,000,000 (twenty five million euro) or any other amount agreed between the Bank and the Borrower in writing.
- "Profit Participation Payments" has the meaning given to it in Paragraph (a) of Article 4.3 (Profit Participation).

- "**Profit Participation Period**" means the 6 (six) year period starting with the date on which the first sale of the COVID-19 Vaccine has occurred after regulatory approval for commercial sale has been obtained by the US Food and Drug Administration or the European Medicines Agency, which may include a conditional or emergency approval.
- "Relevant Business Day" means a day on which the Trans-European Automated Real-time Gross Settlement Express Transfer payment system which utilises a single shared platform and which was launched on 19 November 2007 (TARGET2) is open for the settlement of payments in EUR.
- "Relevant Period" means each period of 12 (twelve) months ending on or about the last day of the financial year.
- "Repayment Date" shall mean the sole Payment Date specified in the Disbursement Offer for the repayment of a Tranche in accordance with Article 5.1 (*Normal repayment*).
- "Repeating Representations" means each of the representations set out in Schedule G (*Representations and Warranties*) other than those Paragraphs thereof which are identified with the words "(*Non-repeating*)" at the end of the Paragraphs.
- "Replacement Conditions" has the meaning given to that term in Sub-Paragraph (e) of Paragraph 14 (*Acquisitions*) of Schedule H (*General Undertakings*).
- "Sales Milestone Payments" means [\*\*\*].
- "Security" means any mortgage, land charge (*Grundschuld*), pledge, lien, charge, assignment, security transfer (*Sicherungsübereignung*), retention of title arrangements, hypothecation, or other security interest securing any obligation of any person or any other agreement or arrangement having a similar effect.
- "Semi-Annual Date" means each of 30 June and 31 December.
- "Standby Fee" has the meaning given to such term in Article 2. (Standby fee) of the Finance

Fee Letter.

- "Subsidiary" means a subsidiary within the meaning of Sections 15 to 17 AktG and an entity of which the Borrower has direct or indirect Control.
- "Tax" means any tax, levy, impost, duty or other charge or withholding of a similar nature (including any penalty or interest payable in connection with any failure to pay or any delay in paying any of the same).
- "Technical Description" has the meaning given to it in Recital (A).
- "Total Assets" means the total consolidated assets of the Group, as shown in the Borrower's latest consolidated financial statements, as at the end of any Relevant Period.
- "Tranche" means each disbursement made or to be made under this Contract consisting of Tranche A and Tranche B. In the event that no Disbursement Acceptance has been received, Tranche shall mean a Tranche as offered under Article 2.2.2 (*Disbursement Offer*).
- "**Tranche A**" means the first Tranche in the amount set out in Paragraph (a) of Article 2.2.1 (*Tranches*), in relation to which a [\*\*\*] shall be paid in accordance with Article [\*\*\*] and [\*\*\*] shall be paid in accordance with Article [\*\*\*].
- "Tranche A Milestone Events" has the meaning given to such term in Part A of Schedule F (Conditions Precedent).

"**Tranche B**" means the second Tranche in the amount set out in Paragraph (b) of Article 2.2.1 (*Tranches*), in relation to which a [\*\*\*] shall be paid in accordance with Article [\*\*\*] and furthermore [\*\*\*] to the Bank in accordance with Article [\*\*\*].

"Tranche B Milestone Events" has the meaning given to such term in Part B of Schedule F (Conditions Precedent).

#### "Upfront Payments" mean:

- (a) [\*\*\*]; and
- (b) [\*\*\*].

"Voluntary Non EIB Prepayment" means a voluntary prepayment by any Group Company or any Guarantor (for the avoidance of doubt, prepayment shall include a repurchase, redemption or cancellation where applicable) of a part or the whole of any Non-EIB Financing where:

- (a) such prepayment is not made within a revolving credit facility (save for the cancellation of a revolving credit facility); or
- (b) such prepayment is not made out of the proceeds of a loan or other indebtedness having a term at least equal to the unexpired term of the Non-EIB Financing prepaid.

#### **ARTICLE 2**

#### **Credit and Disbursements**

## 2.1 Amount of Credit

By this Contract, the Bank establishes in favour of the Borrower, and the Borrower accepts, a credit (including a profit participation credit (*partiarisches Darlehen*)) in an aggregate amount of up to EUR 100,000,000 (one hundred million euro) for the financing of the Investment (the "Credit").

## 2.2 <u>Disbursement procedure</u>

## 2.2.1 Tranches

The Bank shall disburse the Credit in Euros in 2 (two) Tranches, as set out below:

- (a) Tranche A, in an amount of EUR 50,000,000 (fifty million euro); and
- (b) Tranche B, in an amount of EUR 50,000,000 (fifty million euro).

#### 2.2.2 Disbursement Offer

Upon request by the Borrower and subject to Article 2.5 (*Conditions of Disbursement*), provided that no event mentioned in Sub-Paragraph (b) of Article 2.6 (*Cancellation*) has occurred and is continuing, the Bank shall send to the Borrower a Disbursement Offer for the disbursement of a Tranche. The latest time for receipt by the Borrower of a Disbursement Offer is [\*\*\*] ([\*\*\*]) days before the Final Availability Date. The Disbursement Offer shall specify:

- (a) the amount of the Tranche;
- (b) the Disbursement Date, which shall be a Relevant Business Day, falling at least [\*\*\*] ([\*\*\*]) days after the date of the Disbursement Offer and on or before the Final Availability Date;
- (c) the interest rate basis of the Tranche, namely:
  - (i) the Cash Interest Fixed Rate;
  - (ii) if relevant, the Deferred Interest Fixed Rate;

- (iii) the Payment Dates;
- (d) the terms and frequency for repayment of principal (bullet);
- (e) the Maturity Date; and
- (f) the Disbursement Acceptance Deadline.

## 2.2.3 Disbursement Acceptance

- (a) The Borrower may accept a Disbursement Offer by delivering a Disbursement Acceptance to the Bank no later than the Disbursement Acceptance Deadline. The Disbursement Acceptance shall be signed by an Authorised Signatory with individual representation rights or 2 (two) or more Authorised Signatories with joint representation rights and shall specify the Disbursement Account to which disbursement of the Tranche should be made in accordance with Article 2.3 (*Disbursement Account*).
- (b) If a Disbursement Offer is duly accepted by the Borrower in accordance with its terms on or before the Disbursement Acceptance Deadline, and provided the conditions in Article 2.5.4 (*All Tranches Other Conditions*) are met, the Bank shall make the Accepted Tranche available to the Borrower in accordance with the relevant Disbursement Offer and subject to the terms and conditions of this Contract.
- (c) The Borrower shall be deemed to have refused any Disbursement Offer which has not been duly accepted in accordance with its terms on or before the Disbursement Acceptance Deadline, in which case the Tranche shall not be made available to the Borrower by the Bank, and the Credit shall not be affected.

## 2.3 <u>Disbursement Account</u>

- (a) Disbursement shall be made to the Disbursement Account specified in the relevant Disbursement Acceptance, provided that such Disbursement Account is acceptable to the Bank in accordance with paragraph (d) of Article 6.2 (*Time and place of payment*).
- (b) Only one Disbursement Account may be specified for each Tranche.

#### 2.4 Currency of disbursement

The Bank shall disburse each Tranche in EUR.

#### 2.5 Conditions of Disbursement

#### 2.5.1 Initial Documentary Conditions Precedent

Without prejudice to Articles 2.5.2 (*Tranche B – Additional Conditions Precedent*) to 2.5.4 (*All Tranches – Other Conditions*), no Disbursement Offer will be provided by the Bank under this Contract unless the Bank has received all of the documents and other evidence listed in Part A of Schedule F (*Conditions Precedent*) in agreed form or otherwise in form and substance satisfactory to the Bank.

#### 2.5.2 Tranche B - Additional Conditions Precedent

Without prejudice to the generality of Articles 2.5.1 (*Initial Documentary Conditions Precedent*) to 2.5.4 (*All Tranches – Other Conditions*), no Disbursement Offer will be provided by the Bank under this Contract in respect of Tranche B unless the Bank has received all of the additional documents and other evidence listed in Part B of Schedule F (*Conditions Precedent*) in agreed form or otherwise in form and substance satisfactory to the Bank, including the Tranche B Milestone Events.

## 2.5.3 All Tranches—Documentary Conditions Precedent

No Disbursement Offer, including the first Disbursement Offer, will be provided by the Bank under this Contract unless the Bank has confirmed that it has received, in form and substance satisfactory to it:

- (a) a certificate from the Borrower in the form of Schedule D (*Form of Drawdown Certificate*), signed by an Authorised Signatory of the Borrower and dated no earlier than the date falling 14 (fourteen) days before the respective Disbursement Date; and
- (b) a certificate (signed by one or more Authorised Signatories of the Borrower as appropriate) from the Borrower which confirms that the Borrower has sufficient resources to pay its debts as they fall due for at least [\*\*\*] ([\*\*\*]) months from the Disbursement Date not taking into account the disbursement of the proposed Tranche with a current extract from the commercial register (*Handelsregisterauszug*) of the Borrower and an up-to-date search on www.insolvenzbekanntmachungen.de in relation to the Borrower attached.

#### 2.5.4 All Tranches - Other Conditions

The Bank will only be obliged to make any Accepted Tranche available to the Borrower if on the Disbursement Date for the proposed Tranche:

- (a) the Repeating Representations made by the Borrower (in respect of itself and, where applicable, the other Obligors) are correct in all respects;
- (b) no event or circumstance has occurred and is continuing which constitutes or would with the expiry of a grace period and/or the giving of notice under this Contract constitute a Prepayment Event other than pursuant to Article 5.3.1 (*Cost Reduction*) or would, in each case, result from the disbursement of the proposed Tranche;
- (c) no event or circumstance has occurred and is continuing which constitutes a Default or an Event of Default or would, in each case, result from the disbursement of the proposed Tranche; and
- (d) the Borrower complies with all preceding and already achieved Milestone Events.

#### 2.6 Cancellation

- (a) The Borrower may send a written notice to the Bank requesting the cancellation of the undisbursed portion of the Credit. The written notice:
  - (i) must specify whether the Borrower would like to cancel the undisbursed portion of the Credit in whole or in part and, if in part, the amount of the Credit the Borrower would like to cancel; and
  - (ii) must not relate to an Accepted Tranche which has a Disbursement Date falling within [\*\*\*] ([\*\*\*]) Business Days of the date of the written notice.

Upon receipt of such written notice, the Bank shall cancel the requested undisbursed portion of the Credit with immediate effect.

- (b) At any time upon the occurrence of the following events, the Bank may notify the Borrower in writing that the undisbursed portion of the Credit shall be cancelled in whole or in part:
  - (i) a Prepayment Event, which in case cancellation pursuant to Article 5.3.1 (*Cost Reduction*) only shall be in respect of an amount equal to the amount by which it is entitled to cancel the Credit under such Article 5.3.1 (*Cost Reduction*);
  - (ii) an Event of Default; or
  - (iii) an event or circumstance which would with the passage of time or giving of notice under this Contract constitute a Prepayment Event other than pursuant to Article 5.3.1 (*Cost Reduction*) or an Event of Default.

On the date of such written notification the relevant undisbursed portion of the Credit shall be cancelled with immediate effect.

## 2.7 Fee for cancellation of an Accepted Tranche

- (a) If pursuant to Sub-Paragraph (a) of Article 2.6 (*Cancellation*) the Borrower cancels an Accepted Tranche, the Borrower shall pay to the Bank the Cancellation Fee in accordance with the terms of the Finance Fee Letter.
- (b) If pursuant to Sub-Paragraph (b) of Article 2.6 (*Cancellation*) the Bank cancels all or part of an Accepted Tranche, the Borrower shall pay to the Bank the Cancellation Fee in accordance with the terms of the Finance Fee Letter.
- (c) If an Accepted Tranche is not disbursed on the Disbursement Date because the conditions precedent set out in Article 2.5.4 (*All Tranches Other Conditions*) are not satisfied on such date, such Tranche shall be cancelled and the Borrower shall pay to the Bank the relevant Cancellation Fee in accordance with the terms of the Finance Fee Letter.

## 2.8 Cancellation after expiry of the Credit

On the day following the Final Availability Date, and unless otherwise specifically agreed to in writing by the Bank, any part of the Credit in respect of which no Disbursement Acceptance has been received in accordance with Article 2.2.3 (*Disbursement Acceptance*) shall be automatically cancelled, without any notice being served by the Bank to the Borrower.

## 2.9 Standby fee

- (a) The Borrower shall pay to the Bank the Standby Fee in accordance with the terms of the Finance Fee Letter.
- (b) For the avoidance of doubt, the Standby Fee payable under this Article 2.9 (*Standby fee*) is independent of any other fees stipulated in this Contract.

## 2.10 Sums due under Article 2

Sums due under this Article 2 shall be payable in EUR. Sums due under this Article 2 shall be payable within [\*\*\*] ([\*\*\*]) days of the Borrower's receipt of the Bank's demand or within any longer period specified in the Bank's demand.

## **ARTICLE 3**

#### The Loan

#### 3.1 Amount of Loan

The Loan shall comprise the aggregate amount of Tranches disbursed by the Bank under the Credit.

## 3.2 Currency of repayment, interest and other charges

- (a) Interest, Participation Payments, repayments and other charges payable in respect of each Tranche shall be made by the Borrower in EUR.
- (b) Any other payment shall be made in the currency specified by the Bank having regard to the currency of the expenditure to be reimbursed by means of that payment.

## **ARTICLE 4**

## <u>Interest</u>

## 4.1 Cash Interest Fixed Rate

The Borrower shall pay interest on the outstanding balance of each Tranche at the Cash Interest Fixed Rate quarterly in arrear on the relevant Payment Dates specified in the

Disbursement Offer, and calculated on the basis of Article 6.1 (*Day count convention*). If the period from the Disbursement Date to the first Payment Date is [\*\*\*] ([\*\*\*]) days or less then the payment of interest accrued during such period shall be postponed to the following Payment Date

#### 4.2 Deferred Interest Fixed Rate

In addition to the interest payable pursuant to Article 4.1 (*Cash Interest Fixed Rate*), interest shall accrue on the outstanding balance of Tranche A at the Deferred Interest Fixed Rate, and calculated on the basis of Article 6.1 (*Day count convention*), and such interest shall be due and payable on the Maturity Date of such Tranche or, where such Tranche is cancelled or prepaid, on the date of cancellation or Prepayment Date. For the avoidance of doubt, any such interest shall not be capitalised and shall not bear interest.

#### 4.3 Profit Participation

- (a) Subject to Paragraph (b) below and in addition to the interest payable pursuant to Article 4.1 (*Cash Interest Fixed Rate*) and in consideration of the Bank making the Credit available to the Borrower in accordance with this Contract, the Borrower hereby grants and reserves for the benefit of the Bank if Tranche [\*\*\*] is disbursed, the aggregate amount of:
  - (i) a participation in the annual COVID-19 Vaccine Gross Profit during the Profit Participation Period equal to:
    - (A) [\*\*\*]% ([\*\*\*]) of the annual COVID-19 Vaccine Gross Profit below USD 55,000,000 (fifty five million dollars);
    - (B) [\*\*\*]% ([\*\*\*]) of the annual COVID-19 Vaccine Gross Profit between USD 55,000,000 (fifty five million dollars) and USD 165,000,000 (one hundred and sixty five million dollars); and
    - (C) [\*\*\*]% ([\*\*\*]) of the annual COVID-19 Vaccine Gross Profit above USD 165,000,000 (one hundred and sixty five million dollars); and
  - (ii) [\*\*\*]% (four per cent.) of the annual Sales Milestone Payments during the Profit Participation Period,

the "**Profit Participation Payments**", and hereby undertakes to pay the respective Profit Participation Payments to the Bank subject to the terms of this Contract. For the avoidance of doubt and by way of distinction from a silent partnership (*stille Beteiligung*), the Bank does not participate in any loss of the Borrower or any other Group Company.

- (b) The obligation of the Borrower to make Profit Participation Payments pursuant to Paragraph (a) above shall exist only for so long as and to the extent that a due Profit Participation Payment together with the aggregate amount of all preceding Profit Participation Payments does not exceed the Profit Participation Cap.
- (c) Each Profit Participation Payment shall become due and payable on the Payment Date immediately following the date falling [\*\*\*] ([\*\*\*]) months after the end of each financial year within the Profit Participation Period.
- (d) The Borrower shall permit an Auditor, at reasonable times and at reasonable notice, to audit the books and records maintained by the Borrower to ensure the accuracy of the Profit Participation Payments. The cost of this audit shall be borne by the Borrower. If any such audit concludes that additional amounts are owed to the Bank, subject to the Profit Participation Cap the Borrower shall pay the Bank such additional amounts with interest in accordance with Article 4.4 (*Interest on overdue sums*) within [\*\*\*] ([\*\*\*]) days of the date of the completion of such audit.

- (e) Upon the Bank's written request, the Borrower shall promptly exercise its rights under clause 8.9 (*Audit*) (or a corresponding amended provision or replacement provision) of the Fosun Agreement or clause 5.10 (*Audits*) (or a corresponding amended provision or replacement provision) of the Pfizer Agreement. If any such audit concludes that additional amounts are owed to the Borrower, Sub-Paragraph (a) above shall be re-calculated based on the figures ascertained from the audit and any additional amounts with interest in accordance with Article 4.4. (*Interest on overdue* sums) shall be paid by the Borrower to the Bank within [\*\*\*] ([\*\*\*]) days of the date of such audit. For the avoidance of doubt, any information or document concerning any audit under a Key Contract must be shared with the Bank in accordance with Sub-Paragraph (a)(vi) of Paragraph 2 (*Information concerning the Borrower*) of Schedule I (*Information and Visits*).
- (f) In case a Tranche is cancelled or prepaid pursuant to Articles 5.2 (*Voluntary prepayment*) or 5.3 (*Compulsory prepayment*) within the Profit Participation Period, the Bank shall have the right (but not the obligation) to demand from the Borrower the payment of the present value of all future Profit Participation Payments (up to the Profit Participation Cap), as determined by an Independent Expert (the "Expert Determination"). The costs related to the Expert's Determination shall be borne by the Borrower and the Expert's Determination shall, in the absence of manifest error, be conclusive and binding on all parties to this Contract as to the matters to which it relates. The Borrower shall, within [\*\*\*] ([\*\*\*]) Business Days of delivery of the Expert's Determination and upon the Bank's demand, pay to the Bank the amount determined by the Expert Determination.
- (g) For the avoidance of doubt, if Tranche [\*\*\*] is disbursed then the Borrower's obligation under this Article 4.3 (*Profit Participation*) to make Profit Participation Payments shall continue regardless of:
  - (i) any cancellation or prepayment in respect of Tranche B within the Profit Participation Period pursuant to Articles 5.2 (*Voluntary prepayment*) or 5.3 (*Compulsory prepayment*), or
  - (ii) any repayment of Tranche B in accordance with Article 5.1 (*Normal repayment*),
  - unless the Bank has exercised its rights under Paragraph (f) of this Article 4.3 (*Profit Participation*) and the Borrower has made the payment required under such Paragraph.
- (h) The Borrower shall withhold any statutory withholding tax (*Kapitalertragssteuer*) from the Profit Participation Payments and shall pay it to the competent tax office.
- (i) Sums due under this Article 4.3 (*Profit Participation*) shall be payable in EUR. For the calculation of the Profit Participation Payment, where amounts relating to such calculation are received by the Borrower in currencies other than EUR, the applicable rate published by the European Central Bank in Frankfurt on the Business Day preceding the relevant Payment Date shall apply to determine such amounts equivalent in EUR.

#### 4.4 Interest on overdue sums

- (a) Without prejudice to Article 9 (*Events of default*) and by way of exception to Article 4.1 (*Cash Interest Fixed Rate*) and Article 4.2 (*Deferred Interest Fixed Rate*), if the Borrower fails to pay any amount (other than any interest amount) payable by it under the Contract on its due date (including any amount due in respect of a Profit Participation Payment), interest shall accrue on any such overdue amount (other than any interest amount) from the due date to the date of actual payment at an annual rate equal to:
  - (i) for overdue sums related to a Tranche, the higher of (A) the Cash Interest Fixed Rate and, if applicable, the Deferred Interest Fixed Rate plus [\*\*\*]% ([\*\*\*] basis points) or (B) EURIBOR plus [\*\*\*]% ([\*\*\*] basis points);
  - (ii) for overdue sums other than under Sub-Paragraph (a) of Article 4.4 (*Interest on overdue sums*) above, EURIBOR plus [\*\*\*]% ([\*\*\*] basis points).

and shall be payable in accordance with the demand of the Bank.

(b) If the Borrower fails to pay any interest amount payable by it under this Contract on its due date, it shall make a liquidated damages payment (pauschalierter Schadensersatz) from the due date up to the date of actual payment at an annual rate equal to the higher of (i) the applicable Fixed Rate plus [\*\*\*]% ([\*\*\*] basis points) or (ii) EURIBOR plus [\*\*\*]% ([\*\*\*] basis points), provided that the Borrower shall have the right to prove that no damages have arisen, or that damages have not arisen in the asserted amount. The amount determined in accordance with this Sub-Paragraph (b) of Article 4.4 (Interest on overdue sums) shall be payable in accordance with the demand of the Bank.

For the purpose of determining EURIBOR in relation to this Article 4.4 (*Interest on overdue sums*), the relevant periods within the meaning of Schedule B (*Definition of EURIBOR*) shall be successive periods of one month commencing on the due date.

If the overdue sum is in a currency other than the currency of the Loan, the relevant interbank rate that is generally retained by the Bank for transactions in that currency plus [\*\*\*]% ([\*\*\*] basis points) shall apply, calculated in accordance with the market practice for such rate.

#### **ARTICLE 5**

## Repayment

## 5.1 Normal repayment

The Borrower shall repay each Tranche, together with all other amounts outstanding under this Contract in relation to that Tranche, in a single instalment on the Maturity Date of that Tranche.

#### 5.2 Voluntary prepayment

## 5.2.1 Prepayment option

- (a) Subject to Articles 5.2.2 (*Prepayment Fee*), 5.2.3 (*Prepayment mechanics*) and 5.4 (*General*), the Borrower may prepay all or part of any Tranche, together with any accrued interest under Article 4.1 (*Cash Interest Fixed Rate*), Article 4.2 (*Deferred Interest Fixed Rate*), any Profit Participation Payment (up to the Profit Participation Cap) specified under Article 4.3 (*Profit Participation*), any Prepayment Fee and indemnities if any, upon giving a Prepayment Request with at least [\*\*\*] ([\*\*\*]) calendar days prior notice specifying:
  - (i) the Prepayment Amount;
  - (ii) the Prepayment Date; and
  - (iii) each Contract Number.
- (b) The Prepayment Request shall be irrevocable.

#### 5.2.2 Prepayment Fee

If the Borrower prepays a Tranche, the Borrower shall pay the relevant Prepayment Fee on the Prepayment Date.

## 5.2.3 Prepayment mechanics

Upon presentation by the Borrower to the Bank of a Prepayment Request, the Bank shall issue a Prepayment Notice to the Borrower, not later than [\*\*\*] ([\*\*\*]) days prior to the Prepayment Date. If the Borrower evidences to the Bank that – taking into account the time for procuring of the Expert Determination—takes longer than [\*\*\*] ([\*\*\*]) days, the Borrower and the Bank will agree on a longer deadline. The Prepayment Notice shall specify the Prepayment Amount, the accrued interest due thereon, the Prepayment Fee. If the Prepayment Notice specifies Prepayment Fee, it shall also specify the deadline by which the Borrower may accept the Prepayment Notice, and the Borrower must accept the Prepayment Notice no later than such deadline as a condition to prepayment.

The Borrower shall make a prepayment in accordance with the Prepayment Notice and shall accompany the prepayment by the payment of accrued interest (including any interest under Article 4.2 (*Deferred Interest Fixed Rate*) and any Profit Participation Payment specified under Sub-Paragraph (c) of Article 4.3 (*Profit Participation*) and Prepayment Fee or indemnity, if any, due on the Prepayment Amount, as specified in the Prepayment Notice, and shall identify each Contract Number in the prepayment transfer.

## 5.3 Compulsory prepayment

#### 5.3.1 Cost Reduction

If the total cost of the Investment at completion by the final date specified in the Technical Description falls below the figure stated in Recital (A) so that the amount of the Credit exceeds 50% (fifty per cent.) of such total cost, the Bank may forthwith, by notice to the Borrower, cancel the undisbursed portion of the Credit and/or demand prepayment of the Loan Outstanding up to the amount by which the Credit exceeds 50% (fifty per cent.) of the total cost of the Investment.

## 5.3.2 Change Events

The Borrower shall promptly inform the Bank if:

- (a) a Change-of-Control Event has occurred or is likely to occur in respect of itself or a Guarantor; or
- (b) there is or is likely to be an enactment, promulgation, execution or ratification of or any change in or amendment to any law, rule or regulation (or in the application or official interpretation of any law, rule or regulation) that occurs or is likely to occur after the date of this Contract and which, in the opinion of the Borrower, would impair an Obligor's ability to perform its obligations under the Finance Documents.

In such case, or if the Bank has reasonable cause to believe that a Change-of-Control Event or a Change-of-Law Event has occurred or is likely to occur, the Borrower shall, on request of the Bank, consult with the Bank as to the impact of such event. If [\*\*\*] ([\*\*\*]) days have passed since the date of such request and the Bank is of the reasonable opinion that the effects of such event cannot be mitigated to its satisfaction, or in any event if a Change-of-Control Event or Change-of-Law Event has actually occurred, the Bank may by notice to the Borrower, cancel the undisbursed portion of the Credit and/or demand prepayment of the Loan Outstanding, together with accrued interest (if any) and all other amounts accrued or outstanding under this Contract.

## 5.3.3 Illegality

If it becomes unlawful in any applicable jurisdiction for the Bank to perform any of its obligations as contemplated in this Contract or to fund or maintain the Loan, the Bank shall promptly notify the Borrower and may immediately cancel the undisbursed portion of the Credit and/or demand prepayment of the Loan Outstanding, together with accrued interest (if any) and all other amounts accrued or outstanding under this Contract.

#### 5.3.4 Disposals

If the Borrower disposes of assets forming part of the Investment or shares in subsidiaries holding assets forming part of the Investment, neither with the approval of the Bank nor in accordance with Sub-Paragraph (c) of Paragraph 7 (*Disposal of assets*) of Schedule H (*General Undertakings*), the Borrower shall apply all proceeds of such disposal to prepay the Loan Outstanding (in part or in whole), together with accrued interest (if any), promptly following receipt of such proceeds.

#### 5.3.5 Expiry of Guarantee Agreement

If (a) a Guarantee Agreement has a shorter duration than this Contract (as modified, extended and/or prolonged from time to time) and (ii) on the date falling [\*\*\*] ([\*\*\*]) days prior to the initial expiry date or, as the case may be, to any subsequent expiry date agreed under the Guarantee Agreement, the Borrower has failed to procure extension of the duration of the obligations of the Guarantor under the Guarantee Agreement or, as the case may be, to

replace the Guarantor by another guarantor on terms acceptable to the Bank or provide additional security for the Loan in manner, form and substance satisfactory to the Bank, the Bank may, without prejudice to its other rights, require the Borrower to prepay the Loan Outstanding (in part or in whole), together with accrued interest (if any) and all other amounts accrued or outstanding under this Contract.

## 5.3.6 Pari Passu to Non-EIB Financing

- (a) If a Voluntary Non EIB Prepayment has occurred the Bank may, by notice to the Borrower, cancel the undisbursed portion of the Credit and demand prepayment of the Loan; or
- (b) If (i) a Voluntary Non EIB Prepayment is likely to occur, (ii) the Bank has requested a consultation in respect of such Voluntary Non EIB Prepayment, (iii) the Borrower has complied with such request (to the satisfaction of the Bank) and (iv) at least [\*\*\*] ([\*\*\*]) days have passed since the date of such request, the Bank may, by notice to the Borrower, cancel the undisbursed portion of the Credit and demand prepayment of the Loan.
- (c) If (i) a Voluntary Non EIB Prepayment is likely to occur, (ii) the Bank has requested a consultation in respect of such Voluntary Non EIB Prepayment, (iii) the Borrower has not complied with such request within a reasonable period set by the Bank and (iv) at least [\*\*\*] ([\*\*\*]) days have passed since the date of such request, the Bank may, by notice to the Borrower, cancel the undisbursed portion of the Credit and demand prepayment of the Loan.

The proportion of the Loan that the Bank may require to be prepaid shall in each case of Paragraphs (a) to (c) above be the same as the proportion that the prepaid amount of the Non-EIB Financing bears to the aggregate outstanding amount of all Non-EIB Financing.

## 5.3.7 Prepayment Fee

In the case of a Prepayment Event in relation to a Tranche, the Borrower shall pay the relevant Prepayment Fee.

## 5.3.8 Prepayment mechanics

Any sum demanded by the Bank pursuant to Articles 5.3.1 (*Cost Reduction*) to 5.3.6 (*Pari Passu to Non-EIB Financing*) shall be paid on the date indicated by the Bank in its notice of demand, such date being a date falling not less than [\*\*\*] ([\*\*\*]) days from the date of the demand (or, if earlier, the last day of any applicable grace period permitted by law in respect of the event in Article 5.3.3 (*Illegality*)).

#### 5.4 General

- (a) A repaid or prepaid amount may not be reborrowed.
- (b) If the Borrower prepays a Tranche on a date other than a relevant Payment Date, or if the Bank exceptionally accepts, solely upon the Bank's discretion, a Prepayment Request with prior notice of less than [\*\*\*] ([\*\*\*]) calendar days, the Borrower shall pay to the Bank an administrative fee in such an amount as the Bank shall notify to the Borrower.

## **ARTICLE 6**

## **Payments**

## 6.1 Day count convention

Any amount due under this Contract and calculated in respect of a fraction of a year shall be determined based on a year of 360 (three hundred and sixty) days and a month of 30 (thirty) days.

## 6.2 Time and place of payment

- (a) If neither this Contract nor the Bank's demand specifies a due date, all sums other than sums of interest, indemnity and principal are payable within [\*\*\*] ([\*\*\*]) days of the Borrower's receipt of the Bank's demand.
- (b) Each sum payable by the Borrower under this Contract shall be paid to the following account:

Bank: [\*\*\*]
City: [\*\*\*]
Account number: [\*\*\*]
SWIFT Code/BIC: [\*\*\*]
Remark: [\*\*\*]

or such other account notified by the Bank to the Borrower.

- (c) The Borrower shall provide each Contract Number as a reference for each payment made under this Contract.
- (d) Any disbursements by and payments to the Bank under this Contract shall be made using account(s) acceptable to the Bank. Any duly authorised financial institution in the jurisdiction where the Borrower is incorporated or where the Investment is undertaken is deemed an acceptable account bank and any account in the name of the Borrower with such account bank is deemed acceptable to the Bank.

#### 6.3 No set-off by the Borrower

All payments to be made by the Borrower under this Contract shall be calculated and be made without (and free and clear of any deduction for) set-off or counterclaim, unless the counterclaim is undisputed (*unbestritten*) or has been confirmed in a final non-appealable judgement (*rechtskräftig festgestellt*).

#### 6.4 Disruption to Payment Systems

If either the Bank determines (in its discretion) that a Disruption Event has occurred or the Bank is notified by the Borrower that a Disruption Event has occurred:

- (a) the Bank may, and shall if requested to do so by the Borrower, consult with the Borrower with a view to agreeing with the Borrower such changes to the operation or administration of the Contract as the Bank may deem necessary in the circumstances;
- (b) the Bank shall not be obliged to consult with the Borrower in relation to any changes mentioned in Sub-Paragraph (a) of Article 6.4 (*Disruption to Payment* Systems) above if, in its opinion, it is not practicable to do so in the circumstances and, in any event, shall have no obligation to agree to such changes; and
- (c) the Bank shall not be liable for any damages, costs or losses whatsoever arising as a result of a Disruption Event or for taking or not taking any action pursuant to or in connection with this Article 6.4 (*Disruption to Payment Systems*).

## 6.5 Application of sums received

## 6.5.1 General

Sums received from the Borrower shall only discharge its payment obligations if and when received in accordance with the terms of this Contract.

## 6.5.2 Partial payments

If the Bank receives a payment that is insufficient to discharge all the amounts then due and payable by the Borrower under this Contract, the Bank shall apply that payment in or towards payment of:

- (a) first, any unpaid fees, costs, indemnities and expenses due under this Contract;
- (b) secondly, any accrued interest due but unpaid under this Contract;
- (c) thirdly, any principal due but unpaid under this Contract;
- (d) fourthly, any Profit Participation Payments due but unpaid under this Contract; and
- (e) lastly, any other sum due but unpaid under this Contract.

## 6.5.3 Allocation of sums related to Tranches

In case of receipt of sums which cannot be identified as applicable to a specific Tranche, and on which there is no agreement between the Bank and the Borrower on their application, the Bank may apply these between Tranches at its discretion.

## **ARTICLE 7**

## **Borrower undertakings and representations**

- (a) The Borrower makes the representations and warranties set out in Schedule G (*Representations and Warranties*) to the Bank on the date of this Contract in respect of itself and, where applicable, the other Obligors.
- (b) The Repeating Representations are deemed to be made by the Borrower (in respect of itself and, where applicable, the other Obligors) on the date of each Disbursement Acceptance, each Disbursement Date and each Payment Date by reference to the facts and circumstances then existing.
- (c) The undertakings in Schedule H (*General Undertakings*) and Schedule I (*Information and Visits*) remain in force from the date of this Contract for so long as any amount is outstanding under this Contract or the Credit is available.

## **ARTICLE 8**

#### **Charges and expenses**

#### 8.1 Taxes, duties and fees

- (a) The Borrower shall pay all Taxes, duties, fees (including any notarial and pre-agreed legal fees) and other impositions of whatsoever nature, including stamp duty and registration fees, arising out of the execution or implementation of each Finance Document or any related document and the creation, perfection or registration of any security for the Loan.
- (b) The Borrower shall pay all Taxes, duties fees (including any notarial and legal fees) and other impositions whatsoever nature, including stamp duty and registration fees, arising out of the amendment, preservation of any rights under or enforcement of any Finance Document and any security for the Loan to the extent applicable.
- (c) The Borrower shall pay all principal, interest, Profit Participation Payments, indemnities and other amounts due under this Contract gross without any withholding or deduction of any national or local impositions whatsoever, provided that if the Borrower is required by law or an agreement with a governmental authority or otherwise to make any such withholding or deduction, it will gross up the payment to the Bank so that after withholding or deduction, the net amount received by the Bank is equivalent to the sum due.

## 8.2 <u>Other charges</u>

The Borrower shall bear all charges and expenses, including any notarial and legal fees, professional, banking or exchange charges incurred in connection with the preparation, execution, implementation, enforcement and termination of the Finance Documents (including, but not limited to, any Guarantee Agreement entered into pursuant to Paragraph 16

(*Guarantees*) of Schedule H (*General Undertakings*)) or any related document, any amendment, supplement or waiver in respect of the Finance Documents or any related document, and in the amendment, creation, management, enforcement and realisation of any security for the Loan.

The Bank shall provide documentary support for any such charges or expenses upon the Borrower's request.

## 8.3 Increased costs, indemnity and set-off

- (a) The Borrower shall pay to the Bank any costs or expenses incurred or suffered by the Bank as a consequence of the introduction of or any change in (or in the interpretation, administration or application of) any law or regulation or compliance with any law or regulation which occurs after the date of this Contract, in accordance with or as a result of which (i) the Bank is obliged to incur additional costs in order to fund or perform its obligations under this Contract, or (ii) any amount owed to the Bank under this Contract or the financial income resulting from the granting of the Credit or the Loan by the Bank to the Borrower is reduced or eliminated. This Paragraph (a) does not apply to the extent any such costs or expenses are attributable to the wilful breach by the Bank of any law or regulation.
- (b) Without prejudice to any other rights of the Bank under this Contract or under any applicable law, the Borrower shall indemnify and hold the Bank harmless from and against any loss incurred as a result of any full or partial discharge that takes place in a manner other than as expressly set out in this Contract.
- (c) The Bank may set off any matured obligation due from the Borrower under any Finance Document (to the extent beneficially owned by the Bank) against any satisfiable (*erfüllbar*) obligation (within the meaning of Section 387 BGB) owed by the Bank to the Borrower regardless of the place of payment, booking branch or currency of either obligation. If the obligations are in different currencies, the Bank may convert either obligation at a market rate of exchange in its usual course of business for the purpose of the set-off. If either obligation is unliquidated or unascertained, the Bank may set off in an amount estimated by it in good faith to be the amount of that obligation.

#### **ARTICLE 9**

#### **Events of default**

## 9.1 Right to demand repayment

The Bank may demand (in writing) without prior notice or any judicial or extra judicial step immediate repayment by the Borrower of all or part of the Loan Outstanding (as requested by the Bank), together with accrued interest, any Profit Participation Payment, any Prepayment Fee and all other accrued or outstanding amounts under this Contract, if:

- (a) any amount payable pursuant to any Finance Document is not paid on the due date at the place and in the currency in which it is expressed to be payable, unless (i) its failure to pay is caused by an administrative or technical error or a Disruption Event and (ii) payment is made within [\*\*\*] ([\*\*\*]) Business Days of its due date;
- (b) any information or document given to the Bank by or on behalf of any Obligor or any representation, warranty or statement made or deemed to be made by the Borrower in, pursuant to or for the purpose of entering into any Finance Document is or proves to have been incorrect, incomplete or misleading in any material respect;
- (c) following any default of any Obligor in relation to any loan, or any obligation arising out of any financial transaction, other than the Loan,
  - (i) such Obligor is required or is capable of being required or will, following expiry of any applicable contractual grace period, be required or be capable of being required to prepay, discharge, close out or terminate ahead of maturity such other loan or obligation; or

- (ii) any financial commitment for such other loan or obligation is cancelled or suspended; and
- (iii) such other loans or obligations or commitments falling under Sub-Paragraphs (i) and/or (ii) above are in an aggregate principal amount in excess of EUR [\*\*\*] ([\*\*\*] euro) or its equivalent in any other currency or currencies;
- (d) any Obligor is unable or admits inability to pay its debts as they fall due, or suspends any of its debts, or makes or seeks to make a composition with its creditors including a moratorium, or commences negotiations with one or more of its creditors with a view to rescheduling any of its financial indebtedness;
- (e) any corporate action, legal proceedings or other procedure or step is taken in relation to the suspension of payments, a moratorium of any indebtedness, dissolution, administration or reorganisation (by way of voluntary arrangement, scheme of arrangement or otherwise) or an order is made or an effective resolution is passed for the winding up of any Obligor, or if any Obligor takes steps towards a substantial reduction in its capital, is declared insolvent or ceases or resolves to cease to carry on the whole or any substantial part of its business or activities or any situation similar to any of the above occurs under any applicable law;
- (f) any Obligor incorporated in Germany is unable to pay its debts as they fall due (*zahlungsunfähig*) within the meaning of Section 17 InsO or is overindebted (*überschuldet*) within the meaning of Section 19 InsO;
- (g) an encumbrancer takes possession of, or a receiver, liquidator, administrator, administrative receiver or similar officer is appointed, whether by a court of competent jurisdiction or by any competent administrative authority or by any person, of or over, any part of the business or assets of any Obligor or any property forming part of the Investment;
- (h) any Obligor defaults in the performance of any obligation in respect of any other loan granted by the Bank or financial instrument entered into with the Bank;
- (i) any Obligor defaults in the performance of any obligation in respect of any other loan made to it from the resources of the Bank or the European Union;
- (j) any distress, execution, sequestration or other process is levied or enforced upon the property of any Obligor or any property forming part of the Investment and is not discharged or stayed within [\*\*\*] ([\*\*\*]) days;
- (k) a Material Adverse Change occurs, as compared with the position at the date of this Contract;
- (l) it is or becomes unlawful for any Obligor to perform any of its obligations under the Finance Documents, or the Finance Documents are not effective in accordance with its terms or is alleged by any Obligor to be ineffective in accordance with its terms; or
- (m) any Obligor fails to comply with any other provision under the Finance Documents (including, without limitation, each of the undertakings in Schedule H (*General Undertakings*) and Schedule I (*Information and Visits*)), unless the non-compliance or circumstance giving rise to the non-compliance is capable of remedy and is remedied within [\*\*\*] ([\*\*\*]) Business Days from the earlier of the Borrower becoming aware of the non-compliance and a notice served by the Bank on the Borrower.

## 9.2 Other rights at law

Article 9.1 (*Right to demand repayment*) shall not restrict any other right of the Bank at law (e.g. pursuant to Sections 314 or 490 BGB) to require prepayment of the Loan Outstanding together with any sum, interest, fee or accrued amount, irrespectively of the fact that the Contract might convert into a so called settlement contractual relationship (*Abwicklungsschuldverhältnis*).

## 9.3 Prepayment Fee

In case of demand under Article 9.1 (*Right to demand repayment*), the Borrower shall pay the Bank the amount demanded together with the relevant Prepayment Fee.

#### 9.4 Non-Waiver

No failure or delay or single or partial exercise by the Bank in exercising any of its rights or remedies under this Contract shall be construed as a waiver of such right or remedy. The rights and remedies provided in this Contract are cumulative and not exclusive of any rights or remedies provided by law.

#### **ARTICLE 10**

## Law and jurisdiction, miscellaneous

## 10.1 Governing Law

This Contract and any non-contractual obligations arising out of or in connection with it shall be governed by the laws of Germany.

## 10.2 Jurisdiction

- (a) The courts of Frankfurt am Main, Germany, have exclusive jurisdiction to settle any dispute (a "**Dispute**") arising out of or in connection with this Contract (including a dispute regarding the existence, validity or termination of this Contract or the consequences of its nullity) or any non-contractual obligation arising out of or in connection with this Contract.
- (b) The parties agree that the courts of Frankfurt am Main, Germany, are the most appropriate and convenient courts to settle Disputes between them and, accordingly, that they will not argue to the contrary.
- (c) This Article 10.2 (*Jurisdiction*) is for the benefit of the Bank only. As a result and notwithstanding Sub-Paragraph (a) above, it does not prevent the Bank from taking proceedings relating to a Dispute in any other courts with jurisdiction. To the extent allowed by law, the Bank may take concurrent proceedings in any number of jurisdictions.

## 10.3 Place of performance

Unless otherwise specifically agreed by the Bank in writing, the place of performance under this Contract, shall be the seat of the Bank.

## 10.4 Evidence of sums due

In any legal action arising out of this Contract the certificate of the Bank as to any amount or rate due to the Bank under this Contract shall, in the absence of manifest error, be *prima facie* evidence of such amount or rate.

## 10.5 Third party rights

A person who is not a party to this Contract has no right to enforce or to enjoy the benefit of any term of this Contract (no *echter Vertrag zugunsten Dritter* within the meaning of Section 328 para. 1 BGB).

## 10.6 Entire Agreement

This Contract (together with the other Finance Documents) constitutes the entire agreement between the Bank and the Borrower in relation to the provision of the Credit hereunder, and supersedes any previous agreement, whether express or implied, on the same matter.

#### 10.7 Invalidity

If at any time any term of this Contract is or becomes illegal (*nichtig*), invalid or unenforceable in any respect, or this Contract is or becomes ineffective (*unwirksam*) in any respect, under the laws of any jurisdiction, such illegality (*Nichtigkeit*), invalidity, unenforceability or ineffectiveness (*Unwirksamkeit*) shall indisputably (*unwiderlegbar*) not affect:

- (a) the legality, validity or enforceability in that jurisdiction of any other term of this Contract or the effectiveness in any other respect of this Contract in that jurisdiction; or
- (b) the legality, validity or enforceability in other jurisdictions of that or any other term of this Contract or the effectiveness of this Contract under the laws of such other jurisdictions,

without any party to this Contract having to argue (*darlegen*) and prove (*beweisen*) such parties' intent to uphold this Contract even without the void, invalid or ineffective provisions.

The illegal, invalid, unenforceable or ineffective provision shall be deemed replaced by such legal, valid, enforceable and effective provision that in legal and economic terms comes closest to what the Parties intended or would have intended in accordance with the purpose of this Contract if they had considered the point at the time of conclusion of this Contract. The same applies in the event that this Contract or any other Finance Document does not contain a provision which it needs to contain in order to achieve the economic purpose as expressed herein (*Regelungslücke*).

#### 10.8 Amendments

Any amendment to this Contract (including this Article 10.8) or any other Finance Document shall be made in writing (or in notarial form, if required) and shall be signed by the parties thereto.

## 10.9 Counterparts

This Contract may be executed in any number of counterparts, all of which taken together shall constitute one and the same instrument. Each counterpart is an original, but all counterparts shall together constitute one and the same instrument.

#### 10.10 Assignment and transfer by the Bank

- (a) Subject to Sub-Paragraph (b) of this Article 10.10 (*Assignment and transfer by the* Bank), the consent of the Borrower is required for an assignment or transfer (by way of assumption of contract (*Vertragsübernahme*), sub-participation or otherwise) by the Bank of all or part of its rights, benefits or obligations under the Finance Documents, unless the assignment or transfer:
  - (i) is to a Bank Affiliate; or
  - (ii) is made at a time when an Event of Default has occurred and is continuing; or
  - (iii) is made in respect of a sub-participation or securitisation (or similar transaction of broadly equivalent economic effect) where the Bank remains the lender of record of the Loan.
- (b) The consent of the Borrower to an assignment or transfer must not be unreasonably withheld or delayed. The Borrower will be deemed to have given its consent [\*\*\*] ([\*\*\*]) Business Days after the Bank has requested it unless consent is expressly refused by the Borrower within that time.
- (c) The Bank shall have the right to disclose all information relating to or concerning the Borrower, the Group, the Finance Documents and the Loan in connection with or in contemplation of any such assignment or transfer.

For the purpose of this Article 10.10 (Assignment and transfer by the Bank):

"Affiliate" means any entity directly or indirectly Controlling, Controlled by or under common Control with the Bank,

"Bank Affiliate" means an Affiliate of the Bank and any other entity or platform initiated, managed or advised by the Bank.

#### **ARTICLE 11**

## **Final Articles**

#### 11.1 Notices

#### 11.1.1 Form of notice

- (a) Any notice or other communication given under this Contract must be in writing and, unless otherwise stated, may be made by letter and electronic mail.
- (b) Notices and other communications for which fixed periods are laid down in this Contract or which themselves fix periods binding on the addressee, may be made by hand delivery, registered letter or by electronic mail. Such notices and communications shall be deemed to have been received by the other party:
  - (i) on the date of delivery in relation to a hand-delivered or registered letter; or
  - (ii) in the case of any electronic mail, when the electronic mail is received in readable form,
- (c) Any notice provided by the Borrower or a Guarantor to the Bank by electronic mail shall:
  - (i) mention each Contract Number in the subject line; and
  - (ii) be in the form of a non-editable electronic image (pdf, tif or other common non-editable file format agreed between the parties) of the notice signed by one or more Authorised Signatories of the Borrower as appropriate, attached to the electronic mail.
- (d) Notices issued by the Borrower pursuant to any provision of this Contract shall, where required by the Bank, be delivered to the Bank together with satisfactory evidence of the authority of the person or persons authorised to sign such notice on behalf of the Borrower and the authenticated specimen signature of such person or persons, unless such person is listed in the then current List of Authorised Signatories and Accounts.
- (e) Without affecting the validity of electronic mail or communication made in accordance with this Article 11.1 (*Notices*), the following notices, communications and documents shall also be sent by registered letter to the relevant party at the latest on the immediately following Business Day:
  - (i) Disbursement Acceptance;
  - (ii) any notices and communication in respect of the cancellation of a disbursement of any Tranche, Prepayment Request, Prepayment Notice, Event of Default, any demand for prepayment, and
  - (iii) any other notice, communication or document required by the Bank.
- (f) The parties agree that any above communication (including via electronic mail) is an accepted form of communication, shall constitute admissible evidence in court and shall have the same evidential value as an agreement under hand.
- (g) Any communication or document made or delivered to the Borrower in accordance with this Article 11.1 (*Notices*) will be deemed to have been made or delivered to each of the Obligors or any other member of the Group party to a Finance Document. Each Obligor incorporated in Germany, for this purpose, appoints the Borrower as its receipt agent (*Empfangsboten*).

## 11.1.2 Addresses

The address and electronic mail address (and the department or officer, if any, for whose attention the communication is to be made) of each party for any communication to be made or document to be delivered under or in connection with this Contract is:

For the Bank Attention: OPS/ENPST/3-GC&IF

100 boulevard Konrad Adenauer

L-2950 Luxembourg Email address: [\*\*\*]

For the Borrower Attention: Chief Financial Officer (CFO)

Germany

An der Goldgrube 12 D-55131 Mainz

Email address: [\*\*\*]

## 11.1.3 Demand after notice to remedy

The Bank and the Borrower shall promptly notify the other party in writing of any change in their respective communication details.

## 11.2 English language

- (a) Any notice or communication given under or in connection with this Contract must be in English.
- (b) All other documents provided under or in connection with this Contract must be:
  - (i) in English; or
  - (ii) if not in English, and if so required by the Bank, accompanied by a certified English translation and, in this case, the English translation will prevail.

## 11.3 Conclusion of this Contract (Vertragsschluss)

- (a) The parties to this Contract may choose to conclude this Contract by an exchange of signed signature page(s), transmitted by any means of telecommunication (*telekommunikative Übermittlung*) such as by way of fax or attached as an electronic photocopy (.pdf, .tif, etc) to electronic mail.
- (b) If the parties to this Contract choose to conclude this Contract pursuant to this Article 11.3 (*Conclusion of this Contract (Vertragsschluss*)), they will transmit the signed signature page(s) of this Contract to [\*\*\*](each a "**Recipient**"). The Contract will be considered concluded once a Recipient has actually received the signed signature page(s) (*Zugang der Unterschriftsseite(n)*) from all Parties (whether electronic photocopy or other means of telecommunication and at the time of the receipt of the last outstanding signature page(s) by such one Recipient).
- (c) For the purposes of this Article 11.3 (*Conclusion of this Contract (Vertragsschluss*)) only, the parties to this Contract appoint each Recipient as their attorney (*Empfangsvertreter*) and expressly allow (*gestatten*) each Recipient to collect the signed signature page(s) from all and for all parties to this Contract. For the avoidance of doubt, each Recipient will have no further duties connected with its position as Recipient. In particular, each Recipient may assume the conformity to the authentic original(s) of the signature page(s) transmitted to it by means of telecommunication, the genuineness of all signatures on the original signature page(s) and the signing authority of the signatories.
- (d) For the purposes of proof and confirmation, each party to this Contract has to provide the Recipients with original signature page(s) promptly, but no later than [\*\*\*] ([\*\*\*]) Business Days, after signing this Contract in accordance with this Article 11.3 (*Conclusion of this Contract (Vertragsschluss*)). The Bank may demand that the Borrower subsequently sign one or more copies of this Contract.

**IN WITNESS WHEREOF** the parties hereto have caused this Contract to be executed in three (3) originals (two (2) originals for the Bank and one (1) original for the Borrower) in the English language.

# Signed for and on behalf of EUROPEAN INVESTMENT BANK

# Signed for and on behalf of BIONTECH SE

By:		By:	
Name:		Name:	Dr. Sierk Poetting
Title:		Title:	CFO & COO (Vorstand)
		By:	
		Name:	Dr. James Timothy Patrick Ryan
		Title:	Authorised Representative ( <i>Prokurist</i> )
By:			
Name:	-		
Title:			

# **Investment Specification and Reporting**

## A.1 Technical Description

[\*\*\*]

## A.2 Information Duties

## 1. Dispatch of information: designation of the person responsible

The information below has to be sent to the Bank under the responsibility of:

	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

The above-mentioned contact person(s) is (are) the responsible contact(s) for the time being. The Borrower shall inform the Bank immediately in case of any change.

## 2. Information on the project's implementation

The Borrower shall deliver to the Bank the following information on project progress during implementation at the latest:

	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

# 3. Information on the end of works and first year of operation

The Borrower shall deliver to the Bank the following information on project completion and initial operation at the latest by the deadline indicated below.

[***]	[***]
[***]	[***]
[***]	[***]

# **Definition of EURIBOR**

"EURIBOR" means:

[\*\*\*]

# Form of Disbursement Offer/Acceptance

To: BioNTech SE

From: European Investment Bank

Date:

Subject: Disbursement Offer/Acceptance for the Finance Contract between European Investment Bank and BioNTech SE dated [ \*\*\* ]

June 2020 (the "Finance Contract")

Contract Number [\*\*\*] and [\*\*\*] Serapis Number [\*\*\*]

Dear Sirs.

We refer to the Finance Contract. Terms defined in the Finance Contract have the same meaning when used in this letter.

Following your request for a Disbursement Offer from the Bank, in accordance with Article 2.2.2 (*Disbursement Offer*) of the Finance Contract, we hereby offer to make available to you the following Tranche:

- (a) Tranche [A/B]
- (b) Amount to be disbursed:
- (c) Disbursement Date:
- (d) Cash Interest Fixed Rate:
- (e) Deferred Interest Fixed Rate (if applicable):
- (f) Payment Dates and interest periods: [●] / quarterly
- (g) Terms and frequency for repayment of principal:
- (h) Maturity Date:

To make the Tranche available subject to the terms and conditions of the Finance Contract, the Bank must receive a Disbursement Acceptance in the form of a copy of this Disbursement Offer duly signed on your behalf, to the following electronic mail [●] no later than the Disbursement Acceptance Deadline of [time], Luxembourg time, on [date].

The Disbursement Acceptance below must be signed by an Authorised Signatory and must be fully completed as indicated, to include the details of the Disbursement Account.

If not duly accepted by the above stated time, the offer contained in this document shall be deemed to have been refused and shall automatically lapse.

If you do accept the Tranche as described in this Disbursement Offer, all the related terms and conditions of the Finance Contract shall apply, in particular, the provisions of Article 2.5 (*Conditions of Disbursement*).

Yours faithfully,

# EUROPEAN INVESTMENT BANK

SONOT EARLY INVESTMENT BANK
We hereby accept the above Disbursement Offer for and on behalf of the Borrower:
Date:

Account to be credited1:

Account No:

Account Holder/Beneficiary:

(please, provide IBAN format if the country is included in IBAN Registry published by SWIFT, otherwise an appropriate format in line with the local banking practice should be provided)

Bank name, identification code (BIC) and address:

Payment details to be provided:

Please transmit information relevant to:

Name(s) of the Borrower's Authorised Signatory(ies):

Signature(s) of the Borrower's Authorised Signatory(ies): Name(s)/Title(s):

## IMPORTANT NOTICE TO THE BORROWER:

BY COUNTERSIGNING ABOVE YOU CONFIRM THAT THE LIST OF AUTHORISED SIGNATORIES AND ACCOUNTS PROVIDED TO THE BANK WAS DULY UPDATED PRIOR TO THE PRESENTATION OF THE ABOVE DISBURSEMENT OFFER BY THE BANK.

IN THE EVENT THAT ANY SIGNATORIES OR ACCOUNTS APPEARING IN THIS DISBURSEMENT ACCEPTANCE ARE NOT INCLUDED IN THE LATEST LIST OF AUTHORISED SIGNATORIES AND ACCOUNTS RECEIVED BY THE BANK, THE ABOVE DISBURSEMENT OFFER SHALL BE DEEMED AS NOT HAVING BEEN MADE.

<sup>1</sup> The details concerning banking intermediary are also to be provided if such intermediary has to be used to make the transfer to the Beneficiary's Account.

# Form of Drawdown Certificate

To: European Investment Bank

From:

BioNTech SE

Date: Subject:

Finance Contract between European Investment Bank and BioNTech SE dated [ \*\*\* ] June 2020 (the "Finance Contract")

Contract Number [\*\*\*] and [\*\*\*] Serapis Number [\*\*\*]

Dear Sirs,

Terms defined in the Finance Contract have the same meaning when used in this letter.

For the purposes of Article 2.5 (Conditions of Disbursement) of the Finance Contract we hereby certify to you as follows:

- (a) no Prepayment Event has occurred and is continuing;
- (b) no security of the type prohibited under Paragraph 23 (*Negative pledge*) of Schedule H (*General Undertakings*) has been created or is in existence;
- (c) there has been no material change to any aspect of the Investment or in respect of which we are obliged to report under the Finance Contract, save as previously communicated by us;
- (d) no Default, Event of Default or a Prepayment Event other than pursuant to Article 5.3.1 (*Cost Reduction*) of the Finance Contract has occurred or is continuing, or would, in each case, result from the disbursement of the proposed Tranche;
- (e) no litigation, arbitration administrative proceedings or investigation is current or to our knowledge and belief (having made due and careful enquiry) is threatened or pending before any court, arbitral body or agency which has resulted or if adversely determined is reasonably likely to result in a Material Adverse Change, nor is there subsisting against us or any of our subsidiaries any unsatisfied judgement or award;
- (f) the Repeating Representations are correct in all respects;
- (g) no Material Adverse Change has occurred, as compared with the situation at the date of the Finance Contract; and
- (h) the borrowing of the Credit, or any part thereof, by the Borrower is within the corporate powers of the Borrower.

Yours faithfully,

For and on behalf of BioNTech SE

Date:

Name(s)/Title(s):

# **Form of Compliance Certificate**

To: European Investment Bank

From: BioNTech SE

Date:

Subject: Finance Contract between European Investment Bank and BioNTech SE dated [ \*\*\* ] June 2020 (the "Finance Contract")

Contract Number [\*\*\*] and [\*\*\*] Serapis Number [\*\*\*]

Dear Sirs,

We refer to the Finance Contract. This is a Compliance Certificate. Terms defined in the Finance Contract have the same meaning when used in this Compliance Certificate.

# Part A – General Confirmations

We hereby confirm:

- (a) [insert information regarding asset disposal];
- (b) [no security of the type prohibited under Paragraph 23 (*Negative pledge*) of Schedule H (*General Undertakings*) has been created or is in existence; and]
- (c) [no Default, Event of Default or a Prepayment Event other than pursuant to Article 5.3.1 (*Cost Reduction*) of the Finance Contract has occurred or is continuing.] [*If this statement cannot be made, this certificate should identify any potential event of default that is continuing and the steps, if any, being taken to remedy it*].

# [Part B – Profit Participation Information5

We hereby:

- (a) attach all reports or other documents received by the Borrower pursuant to any Key Contract which relates to the calculation of Gross Profits or Sales Milestone Payments; and
- (b) confirm that for the financial year [ \*\*\* ] the COVID-19 Vaccine Gross Profit is [ \*\*\* ] and the Sales Milestone Payments are [ \*\*\* ] and therefore the Profit Participation Payment is [ \*\*\* ] and we set out in the annex to this Compliance Certificate in reasonable detail the calculations used to determine such amounts.]

Yours faithfully,

For and on behalf of BioNTech SE

Date:

Name(s)/Title(s):

<sup>5</sup> To be completed for financial years covered by the Profit Participation Period, if [\*\*\*] is disbursed.

#### **Conditions Precedent**

# Part A—Initial Documentary Conditions Precedent and Tranche A Conditions Precedent

- (a) The following, duly executed Finance Documents:
  - (i) originals of this Contract;
  - (ii) originals of the Guarantee Agreements; and
  - (iii) original of the Fee Letters.
- (b) The constitutional documents of each Obligor, being in relation to an Obligor incorporated in Germany electronic copies of (i) an up-to-date (dated no earlier than the date falling [\*\*\*] ([\*\*\*]) days before the Disbursement Date) electronic extract from the commercial register (*Handelsregisterauszug*), (ii) its articles of association (*Gesellschaftsvertrag*) and copies of any by-laws and rules of procedures (*Geschäftsordnungen*) and (iii) its list of shareholders (*Gesellschafterliste*) or list of supervisory board members (if applicable).
- (c) A copy of the resolution of the competent body (board of directors (*Vorstand*), supervisory board (*Aufsichtsrat*), administrative board (*Verwaltungsrat*) or general meeting of shareholders (*Gesellschafterversammlung*) of each Obligor:
  - (i) approving the terms of, and the transactions contemplated by, the Finance Documents to which it is a party as and duly authorising the execution of the Finance Documents to which it is a party;
  - (ii) duly authorising the relevant signatories to execute the Finance Documents to which it is a party on its behalf; and
  - (iii) authorising a signatory or signatories, on its behalf, to sign and/or despatch all documents and notices to be signed and/or despatched by it under or in connection with the Finance Documents to which it is a party.
- (d) An up-to-date (dated no earlier than the date falling [\*\*\*] ([\*\*\*]) days before the Disbursement Date) structure chart showing the Group certified as being complete and correct by an Authorised Signatory of the Borrower (to be attached to and certified by way of the certificate of an Authorised Signatory of the Borrower as required pursuant to Paragraph (e) below).
- (e) A certificate of an Authorised Signatory of each Obligor certifying that each copy document relating to it specified in Paragraph (b) and (c) of this Part A of Schedule F (*Initial Documentary Conditions Precedent and Tranche A Conditions Precedents*) is correct, complete and in full force and effect as at a date no earlier than the date falling [\*\*\*] ([\*\*\*]) days before the first Disbursement Date.
- (f) The List of Authorised Signatories and Accounts.
- (g) A legal enforceability opinion of Noerr LLP, addressed to the Bank on the legality, validity and enforceability of the Finance Documents and including statements as to no consents, registrations or filings are required and no stamp duty is to be paid in respect of the Finance Documents, choice of law and enforceability of judgments.
- (h) A legal enforceability opinion of Arendt & Medernach, addressed to the Bank on the legality, validity and enforceability of the Finance Fee Letter under Luxembourg law;
- (i) A legal opinion of Osborne Clarke Rechtsanwälte Steuerberater Partnerschaft mbB, legal adviser to the Borrower, addressed to the Bank, and dated no earlier than the date falling [\*\*\*] ([\*\*\*]) days before the Disbursement Date:
  - (i) which includes an insolvency search on www.insolvenzbekanntmachungen.de on the relevant Obligor conducted on the date of such legal opinion; and
  - (ii) on the valid existence of each Obligor, the authority and capacity of each Obligor to enter into the Finance Documents and perform its obligations thereunder, non-conflict with constitutional documents and on laws applicable to companies generally in Germany, all corporate and other action required to be taken has indeed been taken, the due execution of the Finance Documents and that the Obligor is not entitled to claim immunity.

- (j) The latest audited financial statements of the Obligors.
- (k) Evidence of payment of all the fees (including lawyer fees) and expenses as required under the Finance Documents.
- (l) Evidence satisfactory to the Bank of the fulfilment of the following milestones (the "Tranche A Milestone Events"):
  - (i) completion of the Equity Investments;
  - (ii) receipt of the Upfront Payments; and
  - (iii) [\*\*\*]
- (m) A copy of any other document, authorisation, opinion or assurance which the Bank has notified the Borrower is necessary or desirable in connection with the entry into and performance of, and the transactions contemplated by, the Finance Documents or the validity and enforceability of the same.

# Part B—Tranche B Conditions Precedent

- (a) Tranche A has been fully drawn.
- (b) Evidence satisfactory to the Bank of the fulfilment of the following milestones (the "Tranche B Milestone Events"):
  - (i) [\*\*\*]; and
  - (ii) [\*\*\*].

# **Part C—Guarantor Conditions Precedent**

- (a) The duly executed Guarantee Agreement or, as applicable, accession letter to the Guarantee Agreement.
- (b) The constitutional documents of such Guarantor(s).
- (c) If applicable, an original of a certificate of incorporation and an encumbrance certificate of the Guarantor(s) not incorporated or established in Germany ("Non-German Guarantor") dated no more than [\*\*\*] ([\*\*\*]) Business Days from the date of execution of the Guarantee Agreement or accession letter to the Guarantee Agreement (as applicable) (or any equivalent document in the jurisdiction of incorporation of such Non-German Guarantor(s)).
- (d) A copy of the resolution of the competent body (board of directors, supervisory board (*Aufsichtsrat*), administrative body (*Verwaltungsrat*), advisory board (*Beirat*) or general meeting of shareholders (*Gesellschafterversammlung*)) of each Obligor:

- (i) approving the terms of, and the transactions contemplated by, the Finance Documents to which it is a party as and duly authorising the execution of the Finance Documents to which it is a party;
- (ii) duly authorising the relevant signatories to execute the Finance Documents to which it is a party on its behalf; and
- (iii) authorising a signatory or signatories, on its behalf, to sign and/or despatch all documents and notices to be signed and/or despatched by it under or in connection with the Finance Documents to which it is a party.
- (e) A certificate of an authorised signatory of the respective Guarantor(s) certifying that each copy document relating to it specified in Paragraphs (b) to (d) of this Part C of Schedule F (*Conditions Precedent*) is correct, complete and in full force and effect as at a date no earlier than the date of their/its entry into or accession to the Guarantee Agreement, including a specimen of the signature of each person authorised by the resolution in Paragraph (d) above and, if applicable, confirming that guaranteeing or securing, as appropriate, the Loan would not cause any guarantee, security or similar limit or restriction binding on it to be exceeded.
- (f) A legal opinion of a reputable law firm, addressed to the Bank, on the valid existence of the Guarantor(s), the authority and capacity of the Guarantor(s) to enter into or accede to the Guarantee Agreement (and execute its/their obligations therein) and on the due execution of the Guarantee Agreement (or the accession letter).
- (g) Copies of such documentation and other evidence as the Bank may request to carry out and be satisfied with the results of all necessary "know your customer" requirements or other checks in relation to the identity of any person that it is required (in order to comply with applicable money laundering laws and regulations) to carry out in relation to the concerned Guarantor(s).
- (h) A copy of any other document, authorisation, opinion or assurance which the Bank has notified the Borrower or the respective Guarantor is necessary or desirable in connection with the entry into and performance of, and the transactions contemplated by, the Guarantee Agreement or the validity and enforceability of the same.

## **Representations and Warranties**

## 1. Authorisations and Binding Obligations

- (a) Each Obligor is duly incorporated and validly existing as a corporation or company with limited liability under the laws of its jurisdiction of incorporation.
- (b) Each Obligor has the power to carry on its business as it is now being conducted and to own its property and other assets, and to execute, deliver and perform its obligations under the Finance Documents.
- (c) Each Obligor has obtained all necessary Authorisations in connection with the execution, delivery and performance of the Finance Documents and in order to lawfully comply with its obligations thereunder, and in respect of the Investment, and all such Authorisations are in full force and effect and admissible in evidence.
- (d) The execution and delivery of, the performance of each Obligor's obligations under and compliance with the provisions of the Finance Documents do not and will not contravene or conflict with:
  - (i) any applicable law, statute, rule or regulation, or any judgement, decree or permit to which it is subject;
  - (ii) any agreement or other instrument binding upon it which might reasonably be expected to have a material adverse effect on its ability to perform its obligations under the Finance Documents; or
  - (iii) any provision of its constitutional documents.
- (e) The obligations expressed to be assumed by each Obligor in each Finance Document to which it is a party are legal, valid, binding and enforceable obligations.

#### 2. No default or other adverse event

- (a) There has been no Material Adverse Change since [\*\*\*]. (Non-repeating)
- (b) No event or circumstance which constitutes an Event of Default has occurred and is continuing unremedied or unwaived.

# 3. No proceedings

- (a) No litigation, arbitration, administrative proceedings or investigation is current or to the best of its knowledge and belief (having made due and careful enquiry) is threatened or pending before any court, arbitral body or agency which has resulted or if adversely determined is reasonably likely to result in a Material Adverse Change, nor is there subsisting against it or any of its Subsidiaries any unsatisfied judgement or award. (Non-repeating)
- (b) To the best of its knowledge and belief (having made due and careful enquiry) no material Environmental Claim has been commenced or is threatened against any Obligor.
- (c) As at the date of this Contract, no Obligor has taken any action to commence proceedings for, nor have any other steps been taken or legal proceedings commenced or, so far as the Borrower is aware, threatened against any Obligor for its insolvency, winding up or dissolution, or for any Obligor to enter into any arrangement or compositions for the benefit of creditors, or for the appointment of an administrator, receiver, administrative receiver, examiner, trustee or similar officer.

## 4. Security

At the date of this Contract, no Security exists over the assets of any Group Company other than Permitted Security.

## 5. Ranking

- (a) Its payment obligations under this Contract rank not less than *pari passu* in right of payment with all other present and future unsecured and unsubordinated obligations under any of its debt instruments except for obligations mandatorily preferred by law applying to companies generally.
- (b) No financial covenants have been concluded with any other creditor of any Obligor.
- (c) No Voluntary Non EIB Prepayment has occurred.

### 6. Anti-Corruption

- (a) Each Obligor is in compliance with all applicable European Union and national legislation, including any applicable anti-corruption legislation.
- (b) To the best of its knowledge, no funds invested in the Investment by any Obligor or any other Group Company are of illicit origin, including products of money laundering or linked to the financing of terrorism.
- (c) No Obligor is engaged in any Illegal Activities and to the best of the Borrower's knowledge no Illegal Activities have occurred in connection with the Investment. (*Non-repeating*)

## 7. Accounting and Tax

- (a) The latest available consolidated and unconsolidated audited accounts of the Borrower and the other Obligors have been prepared on a basis consistent with previous years and have been approved by its auditors as representing a true and fair view of the results of its operations for that year and accurately disclose or reserve against all the liabilities (actual or contingent) of the Borrower and the other Obligors, as relevant.
- (b) The accounting reference date of the Borrower and each Obligor is 31 December.
- (c) No Obligor is required to make any deduction for or on account of any Tax from any payment it may make under the Finance Documents, except for withholding tax (*Kapitalertragssteuer*) which have to be deducted pursuant to Sub-Paragraph (e) of Article 4.3 (*Profit Participation*).(*Non-repeating*)
- (d) All Tax returns required to have been filed by each Obligor or on its behalf under any applicable law have been filed when due and contain the information required by applicable law to be contained in them.
- (e) Each Obligor has paid when due all Taxes payable by it under applicable law except to the extent that it is contesting payment in good faith and by appropriate means.
- (f) With respect to Taxes which have not fallen due or which it is contesting, each Obligor is maintaining reserves adequate for their payment and in accordance, where applicable, with GAAP.
- (g) Under the laws of the jurisdiction of incorporation of each Obligor, it is not necessary that the Finance Documents be filed, recorded or enrolled with any court or other authority or that any stamp, registration or similar tax be paid on or in relation to the Finance Documents, or the transactions contemplated by the Finance Documents. (*Non-repeating*)

# 8. Information provided

(a) Any factual information provided by any Group Company for the purposes of entering into this Contract and any related documentation was true and accurate in all material respects as at the date it was provided or as at the date (if any) at which it is stated and continues to be true and accurate in all material respect as at the date of this Contract. (*Non-repeating*)

(b) The Group structure chart is true, complete and accurate in all material respects and represents the complete corporate structure of the Group as at the date of this Contract, and other than as set out therein the Borrower owns no other equity and/or shares in any other business entity. (*Non-repeating*)

# 9. No indebtedness

No Obligor has Indebtedness outstanding other than Permitted Indebtedness. (Non-repeating).

# 10. No Immunity

No Obligor, nor any of its assets, is entitled to immunity from suit, execution, attachment or other legal process.

# 11. Pensions

The pension schemes for the time being operated by the Obligors (if any) are funded in accordance with their rules and to the extent required by law or otherwise comply with the requirements of any law applicable in the jurisdiction in which the relevant pension scheme is maintained.

# **General Undertakings**

#### 1. Use of Loan

The Borrower shall use all amounts borrowed by it under the Loan to carry out the Investment.

## 2. Completion of Investment

The Borrower shall or shall procure that the Investment is carried out in accordance with the Technical Description as may be modified from time to time with the approval of the Bank, and complete it by the final date specified therein.

## 3. Procurement procedure

The Borrower shall secure goods and services for the Investment (a) in so far as they apply to it or to the Investment, in accordance with EU Law in general and in particular with the relevant EU Directives, and (b) in so far as EU Directives do not apply, by procurement procedures which conform to the relevant requirements set out in the Bank's "Guide to Procurement for projects financed by the EIB (2018)".

# 4. Compliance with laws

Each Obligor shall comply in all respects with all laws and regulations to which it or the Investment is subject.

#### 5. Environment

The Borrower shall:

- (a) implement and operate the Investment in compliance with Environmental Law;
- $(b) \qquad \text{obtain, maintain and comply with requisite Environmental Approvals for the Investment,} \\$

and upon becoming aware of any breach of this Paragraph 5 (*Environment*):

- (i) the Borrower shall promptly notify the Bank;
- (ii) the Borrower and the Bank will consult for up to [\*\*\*] ( [\*\*\*]) Business Days from the date of notification with a view to agreeing the manner in which the breach should be rectified; and
- (iii) the Borrower shall remedy the breach within [\*\*\*] ( [\*\*\*]) Business Days of the end of the consultation period.

## 6. Integrity

The Borrower shall take, within a reasonable timeframe, appropriate and legally permissible measures in respect of any member of its management bodies who has been convicted by a final and irrevocable court ruling of an Illegal Activity perpetrated in the course of the exercise of his/her professional duties, in order to ensure that such member is excluded from any Borrower's activity in relation to the Loan or the Investment.

## 7. Disposal of assets

(a) Except as provided under Sub-Paragraph (b) below, the Borrower shall not, and shall procure that no Group Company shall, either in a single transaction or in a series of transactions whether related or not and whether voluntarily or involuntarily dispose of all or any part of any Group Company's business, undertaking or assets (including any shares, real estate or security of any entity or a business or undertaking, or any interest in any of them).

- (b) Sub-Paragraph (a) above does not apply to any such disposal ("**Permitted Disposal**"):
  - (i) made with the prior written consent of the Bank;
  - (ii) made on arm's length terms in the ordinary course of business of a Group Company;
  - (iii) made on arm's length terms and at fair market value for cash, which is reinvested in assets of comparable or superior type, value and quality;
  - (iv) made on arm's length terms in exchange for other assets (other than shares, businesses and real estate) comparable or superior as to type, value and quality;
  - (v) by (A) one Obligor to another Obligor, or (B) a group Company which is not an Obligor to another Group Company which is not an Obligor;
  - (vi) constituted by a licence of Intellectual Property Rights on arm's length terms in the ordinary course of business of a Group Company;
  - (vii) made in relation to non-material assets which have depreciated to less than [\*\*\*] % ([\*\*\*] per cent.) of their initial value or which are obsolete;
  - (viii) excluding any disposal otherwise permitted under (ii) to (vii) above, disposals where the higher of the market value or consideration receivable for such disposals does not exceed EUR [\*\*\*] ([\*\*\*] euro) over the lifetime of this Contract; or
  - (ix) arising as a result of Permitted Security.
- (c) A disposal shall in each case only qualify as Permitted Disposal within the meaning of paragraph (b) above, if the relevant disposal is not of assets forming part of the Investment or shares in subsidiaries holding assets forming part of the Investment, which may not be disposed of unless either (i) such disposal is made in accordance with Paragraph (b)(vi) above, (ii) the Borrower consults the Bank in relation to such disposal, and the Bank approves such disposal (such approval not to be unreasonably withheld), or (iii) the proceeds of such disposal are applied to prepay the Bank in accordance with Article 5.3.4 (*Disposals*).

For the purposes of this Paragraph 7 (*Disposal of assets*), "dispose" and "disposal" includes any act effecting sale, transfer, lease or other disposal (*Verfügung*).

## 8. Maintenance of assets

The Borrower shall maintain, repair, overhaul and renew all assets required in relation to the Investment as required to keep such assets in good working order (ordinary wear and tear excepted).

# 9. Insurances

The Borrower shall, and shall procure that each Group Company shall, maintain insurances on and in relation to its business and assets with reputable underwriters or insurance companies against those risks and to the extent as is usual for companies carrying on the same or substantially similar business.

# 10. Change in business

The Borrower shall procure that no substantial change is made to the general nature business of the Borrower or the Group as a whole from that carried on at the date of this Contract.

# 11. Merger

The Borrower shall not, and shall procure that no Group Company shall, enter into any amalgamation, demerger, merger or corporate reconstruction (including the conclusion of any domination and/or profit and loss transfer agreements (*Beherrschungs- und/oder* 

Gewinnabführungsverträge) or any other enterprise agreements (Unternehmensverträge) with the meaning of section 291 AktG) unless:

- (a) with the prior written consent of the Bank; or
- (b) such amalgamation, demerger, merger or corporate reconstruction does not result in a Material Adverse Change and is on a solvent basis, and provided that:
  - (i) only Group Companies are involved and if a Guarantor is involved, the surviving entity will also be or become a Guarantor;
  - (ii) the resulting entity will not be incorporated or located in a country which is in a jurisdiction that is blacklisted by any Lead Organisation in connection with activities such as money laundering, financing of terrorism, tax fraud and tax evasion or harmful tax practices as such blacklist may be amended from time to time; and
  - (iii) if the Borrower is involved, (A) the rights and obligations of the Borrower under this Contract will remain with the Borrower, (B) the surviving entity will be the Borrower and the statutory seat of the Borrower would not as a result of such merger be transferred to a different jurisdiction, (C) the merger will not have an effect on the validity, legality or enforceability of the Borrower's obligations under this Contract; and (D) all of the business and assets of the Borrower are retained by it; or
- (c) the enterprise value of the company (including any Indebtedness remaining in such company) involved in an amalgamation, demerger, merger or corporate reconstruction not already permitted under Paragraph (b) above (i) does not exceed an amount of EUR [\*\*\*] ( [\*\*\*] euro) in a single transaction and EUR [\*\*\*] ( [\*\*\*] euro) during the Term of the Credit and (ii) provided Paragraphs (b)(ii) and (iii) above are fulfilled.

## 12. Books and records

Each Obligor shall ensure that it has kept and will continue to keep proper books and records of account, in which full and correct entries shall be made of all financial transactions and its assets and business, including expenditures in connection with the Investment, in accordance with GAAP as in effect from time to time for a period of five (5) years following the last repayment of the Credit under this Contract.

## 13. Ownership

- (a) The Borrower shall maintain more than 50% (fifty per cent.) of the share capital, directly or indirectly, of each of its Material Subsidiaries, unless a prior written consent of the Bank is received by the Borrower.
- (b) The Borrower shall in aggregate maintain not less than 100% (one hundred per cent.) of the share capital, directly or indirectly, of each Guarantor and each Material Subsidiary, unless:
  - (i) the percentage of the share capital in the relevant Guarantor or Material Subsidiary at the date of this Contract is lower than 100% (one hundred per cent.) ("Initial Ownership Stake"), in which case the Borrower shall maintain such Initial Ownership Stake; or
  - (ii) prior written consent of the Bank is received by the Borrower.
- (c) The Borrower shall immediately notify the Bank in the event of a new entity becoming a Subsidiary of the Borrower through any means, including but not limited to acquisition, creation and spin-off.
- (d) The undertakings in Sub-Paragraphs (a), (b) and (c) above shall be calculated in accordance with GAAP as applied by the Borrower on the date of this Contract and as GAAP is amended from time to time and tested annually.

## 14. Acquisitions

The Borrower shall not, and shall procure that no Group Company shall, invest in (including by way of payment into the capital reserve (*Kapitalrücklage*)) or acquire any entity or a business going concern or an undertaking (whether whole or substantially the whole of the assets or business), or any division or operating unit thereof, or any shares or securities of any entity or a business or undertaking (or in each case, any interest in any of them) (or agree to any of the foregoing), save for an acquisition or investment:

- (a) [\*\*\*]
- (b) with the prior written consent of the Bank;
- (c) by one Obligor of an asset sold, leased, transferred or otherwise disposed of by another Obligor;
- (d) by a Group Company of all the shares or other ownership interests in any limited liability company or corporation, limited liability partnership or any equivalent company, provided that:
  - (i) such entity has not yet commenced commercial operations;
  - (ii) such entity is incorporated in a country that is a member of either or both of the European Union or the Organisation of Economic Co-Operation and Development; and
  - (iii) no Event of Default is continuing on the date the relevant acquisition agreement is entered into or would occur as a result of the acquisition; or
- (e) of shares or other ownership interests in any limited liability company or corporation, limited liability partnership or any equivalent company, the consideration for which does not exceed an aggregate amount of:
  - (X) EUR [\*\*\*] ([\*\*\*] euro) during any financial year, and
  - (Y) EUR [\*\*\*] ([\*\*\*] euro) during the term of the Credit,

provided that:

- (i) no Event of Default is continuing on the date the relevant acquisition agreement is entered into or would occur as a result of the acquisition;
- (ii) the acquired entity is engaged in a business similar or complementary to the business carried on by the Group as at the date of this Contract:
- (iii) the acquired entity is not incorporated or located in a jurisdiction that is blacklisted by any Lead Organisation in connection with activities such as money laundering, financing of terrorism, tax fraud and tax evasion or harmful tax practices as such blacklist may be amended from time to time; and
- (iv) the Borrower provides a Compliance Certificate for the [\*\*\*] ([\*\*\*]) [\*\*\*] ([\*\*\*]) month financial periods immediately following the acquisition, updated on a pro forma basis as if the acquisition has occurred.
- (f) In relation to Paragraph (e) above the Parties agree, that if:
  - the EBITDA of the Borrower is positive for the Relevant Period ending on the most recent Semi-Annual Date prior to that acquisition or investment; and
  - (ii) the revenues of the Borrower exceed EUR [\*\*\*] ([\*\*\*] euro),

(together the "Replacement Conditions"), the threshold included:

- (A) in Sub-Paragraph (X) of Paragraph (e) above will be replaced by a threshold of "[\*\*\*]% of the Total Assets during any financial year"; and
- (B) in Sub-Paragraph (Y) of Paragraph (e) above will be replaced by a threshold of "[\*\*\*]% of the Total Assets during the term of the Credit ",

(together the "**Replaced Thresholds**"), whereby (x) the amounts of already done acquisitions or investments permitted under Paragraphs (a) to (e) above shall count towards the Replaced Thresholds and (y) to the extent and for so long as the Borrower complies with the Replacement Conditions. In case the Borrower does not further comply with any of the Replacement Conditions, the thresholds included in Sub-Paragraphs (X) and (Y) of Paragraph (e) above shall apply again and the Borrower shall use its reasonable best efforts to comply with such thresholds within a reasonable timeframe. The Borrower shall provide evidence satisfactory to the Bank of the fulfilment of the Replacement Conditions and compliance with the Replacement Conditions upon reasonable demand of the Bank.

## 15. Indebtedness

The Borrower shall not, and shall procure that no other Group Company shall, incur any Indebtedness, save for any Existing Indebtedness and Indebtedness ("**Permitted Indebtedness**"):

- (a) incurred with the prior written consent of the Bank;
- (b) incurred under this Contract;
- (c) incurred under the Existing EIB Finance Contract;
- (d) under Permitted Hedging;
- (e) in respect of a Permitted Guarantee;
- (f) owing by an Obligor to another Obligor;
- (g) unsecured Indebtedness to trade creditors and, in respect of the German trade creditors, Indebtedness secured by customary retention of title arrangements (*Eigentumsvorbehalte*) incurred in the ordinary course of day-to-day business; or
- (h) not permitted by the preceding Sub-Paragraphs and the outstanding amount of Indebtedness (including drawn down debt provided by the Bank and other existing outstanding interest-bearing liabilities) which does not exceed twice the last 12 (twelve) months EBITDA.

#### 16. Guarantees

- (a) The Borrower shall not, and shall procure that no other Group Company shall, issue or allow to remain outstanding any guarantees or sureties (*Bürgschaften*) in respect of any liability or obligation of any person save for:
  - (i) any guarantee or surety (Bürgschaft) under any Guarantee Agreement or with the prior written consent of the Bank; or
  - (ii) guarantees or sureties (Bürgschaften) issued by any Group Company under or in connection with:
    - (1) under any negotiable instruments in the ordinary course of trade;
    - (2) in connection with any performance bond in the ordinary course of trade;
    - (3) in connection with any Permitted Indebtedness;
    - (4) issued by one Obligor to another Obligor;
    - (5) any bank guarantee issued the benefit of a contractor in connection with construction work to secure such contractor's claims (*Bauhandwerkersicherung*);
    - (6) any guarantee created or subsisting in order to comply with Section 8a of the German Altersteilzeitgesetz (*AltTZG*) or pursuant to Section 7e of the German Social Law Act No. 4 (*Sozialgesetzbuch IV*); or

- (7) any guarantees or sureties (*Bürgschaften*) not permitted by the preceding Sub-Paragraphs and the outstanding amount of which does not exceed EUR [\*\*\*] ([\*\*\*] euro) (or its equivalent) in aggregate for the Group at any time. If and for so long as the Borrower fulfils the Replacement Conditions prior to issuing the guarantee or surety (*Bürgschaft*), the threshold amount of EUR [\*\*\*] ([\*\*\*] euro) increases to EUR [\*\*\*] ([\*\*\*] euro). In case the Borrower does not further comply with any of the Replacement Conditions, the threshold of EUR [\*\*\*] ([\*\*\*] euro) shall apply again and the Borrower shall use its reasonable best efforts to comply with such threshold within a reasonable timeframe.
- (b) The Borrower shall procure that, as soon as any Group Company becomes a Material Subsidiary (as identified in any accounts delivered to the Bank from time to time pursuant to Paragraph 2 (*Information concerning the Borrower*) of Schedule I (*Information and Visits*), that Group Company shall promptly notify the Bank and on the Bank's request enter into a Guarantee Agreement and provide the Bank with the documentary conditions precedent (each in form and substance satisfactory to the Bank) listed in Part C of Schedule F (*Guarantor Conditions Precedent*) within [\*\*\*] ([\*\*\*]) Business Days following the date on which such Group Company qualifies as a Material Subsidiary.

## 17. Hedging

The Borrower shall not, and shall procure that no other Group Company shall, enter into any derivative transaction other than Permitted Hedging, where "Permitted Hedging" means:

- (a) any derivative transaction entered into by a Group Company with the prior written consent of the Bank;
- (b) any derivative transaction by a Group Company to hedge actual or projected exposure arising in the ordinary course of trading and not for speculative purposes; and
- (c) any derivative instrument of a Group Company which is accounted for on a hedge accounting basis but is not entered into for speculative purposes.

## 18. Restrictions on distributions

The Borrower shall not, and shall procure that no other Group Company shall, declare or distribute dividends, or return or purchase shares, save for:

- (a) with the prior written consent of the Bank;
- (b) payments to a Group Company as a result of a solvent liquidation or reorganisation of a Group Company which is not an Obligor; and
- (c) any dividend payments made by any Subsidiary.

## 19. Restrictions on loans

The Borrower shall not, and shall ensure that no other member of the Group will, be a creditor in respect of any Indebtedness, save for:

- (a) with the prior written consent of the Bank;
- (b) any trade credit extended by any member of the Group to its customers on normal commercial terms and in the ordinary course of its trading activities;
- (c) any loan made by one member of the Group (other than an Obligor) to another member of the Group;
- (d) a loan made by one Obligor to another Obligor;

- (e) a loan made by one Obligor to a member of the Group (other than an Obligor) not exceeding an amount of EUR [\*\*\*] ([\*\*\*] euro) during the Term of the Credit; or
- (f) any other Indebtedness or loan advanced to or made available by any member of the Group with the prior written consent of the Bank.

#### 20. Restrictions on intercompany loans

The Borrower shall not, and shall procure that no other Group Company shall, make any payment in respect of any intercompany loan, save for:

- (a) with the prior written consent of the Bank;
- (b) where the lender of the intercompany loan is the Borrower or an Obligor; or
- (c) the payments to a Group Company as a result of a solvent liquidation or reorganisation of a Group Company which is not an Obligor.

# 21. Intellectual Property Rights

The Borrower shall, and shall procure that each other Group Company shall, (i) obtain, safeguard and maintain its rights with respect to the Intellectual Property Rights required for the implementation of the Investment in accordance with this Contract, including complying with all material contractual provisions and that the implementation of the Investment in accordance with this Contract will not result in the infringement of the rights of any person with regard to the Intellectual Property Rights and (ii) ensure that any Intellectual Property Rights required for the implementation of the Investment will be owned by or licensed to the Borrower, and where such Intellectual Property Rights which are owned by a Group Company are capable of registration, are registered to such party.

## 22. Maintenance of Status

The Borrower shall, and shall procure that each other Group Company shall, remain duly incorporated and validly existing as a corporate entity with limited liability under the jurisdiction in which it is incorporated and that it will have no centre of main interests, permanent establishment or place of business outside the jurisdiction in which it is incorporated, and that it will continue to have the power to carry on its business as it is now being conducted and continue to own its property and other assets.

# 23. Negative pledge

- (a) The Borrower shall not (and shall procure that no other Group Company shall) create or permit to subsist any Security over any of its assets.
- (b) For the purposes of this Paragraph 23 (*Negative pledge*), the term Security shall also include any arrangement or transaction on assets or receivables or money (such as the sale, transfer or other disposal of assets on terms whereby they are or may be leased to or re-acquired by any Group Company, the sale, transfer or other disposal of any receivables on recourse terms or any arrangement under which money or the benefit of a bank account or other account may be applied or set off or any preferential arrangement having a similar effect) in circumstances where the arrangement or transaction is entered into primarily as a method of raising credit or of financing the acquisition of an asset.
- (c) Sub-Paragraph (a) above does not apply to any Existing Security and any Security listed below ("Permitted Security"):
  - (i) any netting or set-off arrangement entered into by any Group Company in the ordinary course of its banking arrangements for the purpose of netting debit and credit balances and any Security arising under general business conditions (*Allgemeine Geschäftsbedingungen*) of banks or financial institutions;

- (ii) any payment or close out netting or set-off arrangement pursuant to any Permitted Hedging, but excluding any Security under a credit support arrangement in relation to a hedging transaction;
- (iii) any Security arising by operation of law and in the ordinary course of trading;
- (iv) any Security over or affecting any asset acquired by Group Company after the date of this Contract if:
  - (1) the Security was not created in contemplation of the acquisition of that asset by a Group Company;
  - (2) the principal amount secured has not been increased in contemplation of or since the acquisition of that asset by a Group Company; and
  - (3) the Security is removed or discharged within [\*\*\*] ([\*\*\*]) months of the date of acquisition of such asset;
- (v) any Security over or affecting any asset of any company which becomes a Group Company after the date of this Contract, where the Security is created prior to the date on which that company becomes a Group Company, if:
  - (1) the Security was not created in contemplation of the acquisition of that company;
  - (2) the principal amount secured has not increased in contemplation of or since the acquisition of that company; and
  - (3) the Security is removed or discharged within [\*\*\*] ([\*\*\*]) months of that company becoming a Group Company;
- (vi) any Security arising under any retention of title including extended retention of title (*verlängerter Eigentumsvorbehalt*)), hire purchase or conditional sale arrangement or arrangements having similar effect in respect of goods supplied to a Group Company in the ordinary course of trading and on the supplier's standard or usual terms and not arising as a result of any default or omission by any Group Company;
- (vii) any Security created or subsisting in order to comply with Section 8a of the German Altersteilzeitgesetz (*AltTZG*) or pursuant to Section 7e of the German Social Law Act No. 4 (*Sozialgesetzbuch IV*);
- (viii) any contractor's lien arising by operation of law (*Werkunternehmerpfandrecht*) in connection with repairs and maintenance work and any landlord's pledge (*Vermieterpfandrecht*) arising by operation of law under a lease in favour of the relevant third party landlord; or
- (ix) any Security securing indebtedness the principal amount of which (when aggregated with the principal amount of any other indebtedness which has the benefit of Security given by a Group Company other than any permitted under Sub-Paragraphs (i) to (viii) above) does not exceed EUR [\*\*\*] ([\*\*\*] euro) during the term of this Credit. In relation to this Paragraph (xi) the Parties agree, that if and for so long as the Borrower fulfils the Replacement Conditions prior to providing the security, the threshold in this Paragraph (ix) will be replaced by a threshold constituting the lesser of (A) [\*\*\*] % ([\*\*\*] cent.) of the Total Assets during any financial year, and (B) EUR [\*\*\*] ([\*\*\*] euro).

## 24. Other Undertakings

The Borrower shall take note of the Bank's group statement on tax fraud, tax evasion, tax avoidance, aggressive tax planning, money laundering and financing of terrorism (as published on the Bank's website and as may be amended from time to time).

## 25. Data Protection

Before disclosing any personal data (other than mere contact information relating to the Borrower's personnel involved in the management of this Contract) to the Bank in connection with this Contract, the Borrower shall ensure that each data subject of those personal data:

- (a) has been informed of the disclosure (including the categories of personal data to be disclosed); and
- (b) has the information in (or has been provided with an appropriate link to) the Bank's privacy statement in relation to its lending and investment activities set out at the relevant time at <a href="https://www.eib.org/en/privacy/lending">https://www.eib.org/en/privacy/lending</a> (or such other address as the Bank may notify to the Borrower in writing from time to time).

## 26. Sanctions

The Borrower shall ensure that all amounts borrowed by it under this Contract are not made available to, or for the benefit of, persons or entities designated by restrictive measures adopted pursuant to Article 215 of the Treaty on the Functioning of the European Union insofar as the giving of and compliance with such undertaking does not and will not result in a violation of or conflict with or liability under section 7 of the German Foreign Trade Regulation (*Außenwirtschaftsverordnung*, *AWV*) (in conjunction with sections 4, 19 paragraph 3 no. 1a) of the German Foreign Trade Act (*Außenwirtschaftsgesetz*, *AWG*) and section 81 paragraph 1 no. 1 AWV) where the Borrower need not comply but only to the extent of the breach.

[\*\*\*]

# 29. Clauses by inclusion

If the Borrower or any Group Company concludes with any other secured and unsubordinated creditor a financing agreement that includes a loss-of-rating clause or a covenant or other provision regarding its financial ratios, if applicable, that is not provided

for in this Contract or is more favourable to the relevant creditor than any equivalent provision of this Contract is to the Bank, the Borrower shall promptly inform the Bank and shall provide a copy of the more favourable provision to the Bank. The Bank may request that the Borrower promptly executes an agreement to amend this Contract so as to provide for an equivalent provision in favour of the Bank.

#### **Information and Visits**

## 1. Information concerning the Investment

Subject to Paragraph 5 (Confidential information) below:

- (a) The Borrower shall deliver to the Bank:
  - (i) the information in content and in form, and at the times, specified in Part 2 (*Information Duties*) of Schedule A (*Investment Specification and Reporting*) or otherwise as agreed from time to time by the parties to this Contract;
  - (ii) any such information or further document concerning the Investment as the Bank may require to comply with its obligations under the EFSI Regulation or the Horizon 2020 Legal Basis; and
  - (iii) any such information or further document concerning the financing, procurement, implementation, operation and environmental matters of or for the Investment as the Bank may reasonably require within a reasonable time;

**provided always that** if such information or document is not delivered to the Bank on time, and the Borrower does not rectify the omission within a reasonable time set by the Bank in writing, the Bank may remedy the deficiency, to the extent feasible, by employing its own staff or a consultant or any other third party, at the Borrower's expense and the Borrower shall provide such persons with all assistance necessary for the purpose.

- (b) The Borrower shall submit for the approval of the Bank without delay any material changes to the Investment, also taking into account the disclosures made to the Bank in connection with the Investment prior to the signing of this Contract, in respect of, inter alia, the total cost, plans, timetable or to the expenditure programme or financing plan for the Investment.
- (c) The Borrower shall promptly inform the Bank of:
  - (i) any action initiated or any objection raised by any third party or any genuine complaint received by the Borrower or any Environmental Claim that is to its knowledge commenced, pending or threatened against it with regard to environmental or other matters affecting the Investment; and
  - (ii) any fact or event known to the Borrower, which may substantially prejudice or affect the Borrower's ability to execute the Investment;
  - (iii) a genuine allegation, complaint or information with regard to Illegal Activities related to the Loan and/or the Investment;
  - (iv) any non-compliance by it with any applicable Environmental Law; and
  - (v) any suspension, revocation or modification of any Environmental Approval,

and set out the action to be taken with respect to such matters;

- (d) If the total cost of the Investment exceeds the estimated figure set out in Recital (A), the Borrower shall notify the Bank without delay and shall inform the Bank of its plans to fund the increased costs.
- (e) The Borrower shall, and shall procure that each other Group Company shall, promptly inform the Bank if at any time it becomes aware of the illicit origin (including products of money laundering or linked to the financing of terrorism) of any funds invested in the Investment by the Borrower or another Group Company.
- (f) The Borrower shall provide to the Bank, if so requested:
  - (i) a certificate of its insurers showing that all assets required in order to carry out the Investment are insured with reputable underwriters or insurance companies against those risks and to the extent as is usual for companies carrying on the same or substantially similar business; and

(ii) annually, a list of policies in force covering any aspect of the Investment, together with confirmation of payment of the current premiums.

## 2. Information concerning the Borrower

Subject to Paragraph 5 (Confidential information):

- (a) The Borrower shall deliver to the Bank:
  - (i) as soon as they become available but in any event within [\*\*\*] ([\*\*\*]) months after the end of each of its financial years:
    - (A) its audited consolidated and unconsolidated annual report, balance sheet, cash flow statement, profit and loss account and auditors report for that financial year;
    - (B) a Compliance Certificate signed by [\*\*\*] ([\*\*\*]) directors (*Vorstände*) which, during the Profit Participation Period and if Tranche B has been disbursed, should have Part B (*Profit Participation*) of the Compliance Certificate fully completed;
    - (C) the unconsolidated financial statements (audited, if available) of each Obligor for such financial year.
  - (ii) as soon as they become available but in any event within [\*\*\*] ([\*\*\*]) months after the end of each of the relevant accounting periods its interim consolidated and unconsolidated semi-annual report, balance sheet, profit and loss account and cash flow statement for the first half-year of each of its financial years together with a Compliance Certificate signed by [\*\*\*] ([\*\*\*]) directors (Vorstände):
  - (iii) such further information, evidence or document concerning its general financial situation or such certificates of compliance with the undertakings of Article 7 (*Borrower undertakings and representations*) as the Bank may deem necessary or may reasonably require to be provided within a reasonable time;
  - (iv) any such further information, evidence or document concerning the compliance with the due diligence requirements of the Bank, including, but not limited to "know your customer" (KYC) or similar identification procedures, when requested and within a reasonable time;
  - (v) such further information, evidence or document concerning the factual information or documents provided to the Bank for the purposes of entering into this Contract, as the Bank may deem necessary or may require to be provided within a reasonable time;
  - (vi) any information, report or other document received by the Borrower in respect of an audit undertaken pursuant to a Key Contract subject to a non-disclosure agreement signed by the Bank and the Borrower.
- (b) The Borrower shall deliver to the Bank as soon as possible but in any event within [\*\*\*] ([\*\*\*]) days after the start of each half-year a budget for that half-year ("**Budget**"). The Borrower shall ensure that each Budget:
  - (i) includes [\*\*\*];
  - (ii) is prepared in all material respects in accordance with GAAP and the accounting practices and financial reference periods applied to the consolidated financial statements of the Group; and
  - (iii) has been approved by Authorised Signatories of the Borrower.
- (c) The Borrower shall inform the Bank immediately of:

- (i) any Default or Event of Default having occurred or being threatened or anticipated;
- (ii) to the extent permitted by law, any material litigation, arbitration, administrative proceedings or investigation carried out by a court, administration or similar public authority, which, to the best of its knowledge and belief is current, threatened or pending:
  - against any Obligor or its controlling entities or members of the Borrower's management bodies in connection with Illegal Activities related to the Loan or the Investment; or
  - (2) which would if adversely determined result in a Material Adverse Change;
- (iii) to the extent permitted by any law applicable to the Borrower, any measure taken by the Borrower pursuant to Paragraph 6 (*Integrity*) of Schedule H (*General Undertakings*);
- (iv) any Change in the Beneficial Ownership of the Borrower and any material update of or change to the Budget; and
- (v) any Voluntary Non EIB Prepayment that has occurred or is likely to occur.

# 3. Visits by the Bank

- (a) Each Obligor shall allow the Bank and, when either required by the relevant mandatory provisions of EU law or pursuant to the EFSI Regulation or the Horizon 2020 Legal Basis, the competent EU institutions including the European Court of Auditors, the Commission, the European Anti-Fraud Office, the European Public Prosecutor's Office as well as persons designated by the foregoing:
  - (i) to visit during normal business hours with prior notice, except in cases of emergency, the sites, installations and works comprising the Investment;
  - (ii) to interview representatives of each Obligor, and not obstruct contacts with any other person involved in or affected by the Investment; and
  - (iii) to conduct such investigations, inspections, on the spot audits and checks as they may wish and review the Obligors' books and records in relation to the execution of the Investment and to be able to take copies of related documents to the extent not prohibited by the law.
- (b) Each Obligor shall provide the Bank, or ensure that the Bank is provided, with all necessary assistance for the purposes described in this Paragraph 3 (*Visits by the Bank*).
- (c) In the case of a genuine allegation, complaint or information with regard to Illegal Activities related to the Loan and/or the Investment, the Borrower shall consult with the Bank in good faith regarding appropriate actions. In particular, if it is proven that a third party committed Illegal Activities in connection with the Loan and/or the Investment with the result that the Loan or the EFSI financing or financing under the Horizon 2020 Framework EU Programme were misapplied, the Bank may, without prejudice to the other provisions of this Contract, inform the Borrower if, in its view, the Borrower should take appropriate recovery measures against such third party. In any such case, the Borrower shall in good faith consider the Bank's views and keep the Bank informed.

# 4. Disclosure and publication

- (a) The Bank acknowledges and agrees that the Borrower may be obliged to disclose the terms of this Contract and make any other public written disclosure regarding the existence of, or performance under, this Contract, to the extent required, in the reasonable opinion of BioNTech's legal counsel, to comply with (i) law, statute or regulation applicable to the Borrower, including the rules and regulations promulgated by the United States Securities and Exchange Commission or (ii) any equivalent governmental authority, securities exchange or securities regulator in any country shares of the Borrower are listed. Before disclosing this Contract or any of the terms hereof pursuant to this Sub-Paragraph (a) of Paragraph 4 (*Disclosure and publication*), the Borrower will inform the Bank with at least [\*\*\*] ([\*\*\*]) Business Days prior notice of the intended disclosure and will consult with the Bank in making any such disclosure acceptable to the Bank. Further, if the Borrower discloses this Contract or any of the terms hereof in accordance with this Sub-Paragraph (a) of Paragraph 4 (*Disclosure and publication*), the Borrower will, at its own expense, seek such confidential treatment of confidential portions of this Contract and limit its disclosure of such terms to that the extent required to comply with law, statute or regulation applicable to the Borrower.
- (b) The Borrower acknowledges and agrees that:
  - (i) the Bank may be obliged to communicate information relating to any Obligor and the Investment to any competent institution or body of the European Union in accordance with the relevant mandatory provisions of European Union law or pursuant to the Horizon 2020 Legal Basis or the EFSI Regulation; and
  - (ii) the Bank may publish in its website or produce press releases containing information related to the financing provided pursuant to this Contract with support of the EFSI and the Horizon 2020 Framework EU Programme, including the name, address and country of establishment of the Borrower, the purpose of the financing, and the type and amount of financial support received under this Contract.
- (c) To the extent legally and practically possible, the Bank shall communicate and/or publish such information only upon prior coordination with the Borrower. To the extent the Bank has coordinated such communication/publication with the Borrower, the Borrower will ensure that to the same extent and at the same time such information is made available to the United States Securities and Exchange Commission. The Borrower agrees to cooperate with the Bank to ensure that any press releases or publications made by the Borrower regarding the financing and the Investment include an appropriate acknowledgement of the financial support provided by the Bank with the backing of the European Union through EFSI and Horizon 2020 Framework EU Programme.
- (d) The Obligors are entitled and, if requested by the Bank, each Obligor undertakes to refer to this financing and other Bank financings in its public communications, if appropriate, during the availability period, and in connection with any drawdowns, and communications on major corporate events.

## 5. Confidential information

Where the Borrower provides information to the Bank in connection with this Contract, it shall clearly indicate whether such information is already public or being maintained by the Borrower as confidential information. If regulated or prohibited by applicable legislation including the rules and regulations promulgated by the United States Securities and Exchange Commission and securities law relating to insider dealing and market abuse, the Borrower will not share (and is not obliged to do so) any inside information with the Bank before it is published to the market. For the avoidance of doubt the Parties agree that the Borrower shall only be required to provide information to the Bank to the extent legally permissible and in particular in compliance with applicable laws on inside information. The Bank is not responsible or liable for any determination as to whether any information provided or to be provided to it is non-public information the use of which may be regulated or prohibited by applicable law or regulation relating to insider dealing or otherwise.

# **Existing Indebtedness**

- 1. Indebtedness in connection with a secured EUR 10,000,000 loan agreement dated 21 November 2017 and entered into by BioNTech Innovative Manufacturing Services GmbH as borrower and Deutsche Bank AG as lender.
- 2. Indebtedness in connection with a secured EUR 9,450,000 loan agreement dated 18 July 2018 and entered into by JPT Peptide Technologies GmbH as borrower and Deutsche Bank AG as lender.
- 3. Indebtedness in connection with Existing EIB Financing Contract.

# **Existing Security**

- 1. EUR 10,000,000.00 loan agreement dated 21 November 2017 with BioNTech Innovative Manufacturing Services GmbH as borrower and Deutsche Bank AG as lender.
  - First-priority land charges (*Grundschulden*) of EUR 10,000,000 on commercial property (*Betriebsimmobilie*) in 55743 Idar-Oberstein, Germany, Idar-Oberstein [\*\*\*], granted by BioNTech Innovative Manufacturing Services GmbH;
  - [\*\*\*]
  - [\*\*\*]
- 2. EUR 9,450,000 loan agreement dated 18 July 2018 with JPT Peptide Technologies GmbH as borrower and Deutsche Bank AG as lender.
  - First-priority land charges (Grundschulden) of EUR 9,450,000 on commercial property (Betriebsimmobilie) Berlin-Adlershof; Germany, [\*\*\*] granted by JPT Peptide Technologies GmbH;
  - [\*\*\*]
  - [\*\*\*]
- 3. Security granted or to be granted under and in connection with the Existing EIB Finance Contract.

# 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

## FINANCE FEE LETTER

From: European Investment Bank

100 boulevard Konrad Adenauer

L-2950 Luxembourg

Grand Duchy of Luxembourg

(the "Bank")

To: BioNTech SE

An der Goldgrube 12 55131 Mainz Germany (the "**Borrower**")

Date: 10 June 2020

Subject: Finance Contract between European Investment Bank and BioNTech SE dated 10 June 2020

Contract numbers (FI No) [\*\*\*] and [\*\*\*]; Serapis No.: [\*\*\*]

Dear Sirs

We refer to the EUR 100,000,000 finance contract dated 10 June 2020 between the Bank as lender and the Borrower (the "Finance Contract").

This Finance Fee Letter is a Fee Letter as referred to in the Finance Contract.

#### 1. **DEFINITIONS**

- 1.1 Terms defined in the Finance Contract shall have the same meaning when used in this Fee Letter, unless a contrary indication appears. This Fee Letter is a Finance Document.
- 1.2 In this Fee Letter:

"Cancellation Fee" means, in relation to the cancellation of an Accepted Tranche by the Borrower under Sub-Paragraph (a) of Article 2.6 (*Cancellation*) of the Finance Contract, or in relation to an amount cancelled by the Bank under Sub-Paragraphs (b) of Article 2.6 (*Cancellation*) of the Finance Contract, a fee of 2% (200 basis points) of the cancelled amount.

## 2. STANDBY FEE

2.1 If no Disbursement Offer is made by the Bank within [\*\*\*] ([\*\*\*]) months from the date of the Finance Contract or in case the Credit is cancelled in full under Article 2.6 (*Cancellation*) of the Finance Contract prior to the expiry of this term, the Borrower shall pay to the Bank a one-off contractual fee equal to 1% (100 basis points) of the Credit (the "**Standby Fee**").

2.2 The Standby Fee shall be payable by the Borrower to the Bank within [\*\*\*] ([\*\*\*]) days of the Borrower's receipt of the Bank's demand or within any longer period specified in the Bank's demand.

# 3. CANCELLATION FEE

If the Borrower pursuant to Article 2.7(a) (*Fee for cancellation of an Accepted Tranche*) or the Bank pursuant to Article 2.7(b) (*Fee for cancellation of an Accepted Tranche*) or Article 2.7(c) (*Fee for cancellation of an Accepted Tranche*) of the Finance Contract cancels an Accepted Tranche, the Borrower shall pay to the Bank the relevant Cancellation Fee.

# 4. MISCELLANEOUS

- 4.1 The provisions of Article 2.10 (*Sums due under Article 2*) and Article 8.1 (*Taxes, duties and fees*) of the Finance Contract shall apply to all payments made or to be made under this Fee Letter.
- 4.2 If the date on which a fee under this Fee Letter is due to be paid is not a Relevant Business Day, payment shall be made on the next Relevant Business Day.

## 5. COUNTERPARTS

This Fee Letter may be executed in any number of counterparts, and this has the same effect as if the signatures on the counterparts were on a single copy of this Fee Letter.

# 6. **GOVERNING LAW**

This Fee Letter and any non-contractual obligations arising out of or in connection with it are governed by Luxembourg law. The parties submit to the exclusive jurisdiction of the Luxembourg courts.

If you agree to the above, please sign, date and return to the Bank the enclosed copy of this Fee Letter.

Yours faithfully	
Name: Roger Stuart	Name: Diana Danciulescu
Title: Head of Division	Title: Senior Counsel
For and on behalf of	

**European Investment Bank** 

We acknowledge and agree to the above:	
For and on behalf of <b>BioNTech SE</b>	
Name: Dr. Sierk Poetting	Name: Dr. James Timothy Patrick Ryan
Title: CFO & COO (Vorstand)	Title: Authorised Representative ( <i>Prokurist</i> )

License Agreement

by and between

The Broad Institute, Inc. and

Neon Therapeutics, Inc.

**November 13, 2015** 

# **EXECUTION VERSION**

CONFIDENTIAL TREATMENT REQUESTED. INFORMATION FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED IS OMITTED AND MARKED WITH "[\*\*\*]". AN UNREDACTED VERSION OF THE DOCUMENT HAS ALSO BEEN FURNISHED SEPARATELY TO THE SECURITIES AND EXCHANGE COMMISSION AS REQUIRED BY RULE 406 UNDER THE SECURITIES ACT OF 1933, AS AMENDED.

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# **Schedules and Exhibits**

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Schedule 1.85 Neoantigen Vaccine Product

Schedule 1.86 NeoVax Product

## LICENSE AGREEMENT

This License Agreement (this "**Agreement**") is entered into as of this 13th day of November, 2015 (the "**Effective Date**"), by and between the Broad Institute, Inc., a non-profit Massachusetts corporation, with a principal office at 415 Main Street, Cambridge, MA 02142 ("**Broad**"), and Neon Therapeutics, Inc., a Delaware corporation with a principal office at 215 First Street, Cambridge, MA 02142 ("**Company**"). Company and Broad are each referred to herein as a "**Party**" and collectively as the "**Parties**".

**WHEREAS**, the technology taught in the Licensed Patent Rights (as defined below) was discovered by researchers at Broad, individually or collectively with researchers at Dana Farber Cancer Institute, a not-for-profit Massachusetts corporation with a principal office at 44 Binney Street, Boston, MA 02115 ("**DFCI**") or The General Hospital Corporation d/b/a Massachusetts General Hospital, a not-for-profit Massachusetts corporation with a principal office at 55 Fruit Street, Boston, MA 02114 ("**MGH**," together with Broad and DFCI, the "**Institutions**" and individually, an "**Institution**");

WHEREAS, Broad, DFCI or MGH is either the sole owner or a co-owner of each of the Licensed Patent Rights;

**WHEREAS**, pursuant to the Operating Agreement (as defined below), Broad has the right to control the licensing of DFCI's and MGH's respective interest in the Licensed Patent Rights, Broad has negotiated this Agreement on behalf of each of Broad, DCFI and MGH, and DFCI and MGH have authorized Broad to enter into this Agreement on their behalf with respect to such Licensed Patent Rights;

**WHEREAS**, Company is interested in developing and commercializing one or more oncology therapeutics that are covered by the Licensed Patent Rights;

WHEREAS, Company wishes to obtain certain licenses under the Licensed Patent Rights to develop and commercialize Licensed Products;

WHEREAS, Institutions desire to have Licensed Products developed and commercialized to benefit the public and are willing to grant licenses hereunder; and

**WHEREAS**, Company has represented to Broad, in order to induce Broad to enter into this Agreement, that Company shall commit itself to the development and commercialization of Licensed Products, as set forth herein, so that public utilization shall result therefrom;

**NOW, THEREFORE,** the Parties hereto, intending to be legally bound, hereby agree as follows:

## 1. DEFINITIONS.

Whenever used in this Agreement with an initial capital letter, the terms defined in this <u>Article 1</u>, whether used in the singular or the plural, shall have the meanings specified below.

- **1.1** "Abandoned Patent Rights" has the meaning set forth in Section 6.4.1.
- **1.2** "Achieved Milestone" has the meaning set forth in Section 4.3.1.1.
- **1.3** "Additional Family 3 Licensee" has the meaning set forth in Section 6.3.
- **1.4** "Additional National Stage Filings" has the meaning set forth in Section 6.1.4.
- **1.5** "Affiliate" means, as to any Person, any other Person that controls, is controlled by, or is under common control with, such Person. For purposes of this definition only, "control" and, with correlative meanings, the terms "controlled by" and "under common control with" means the possession, directly or indirectly, of the power to direct the management or policies of an organization or entity, whether through the ownership of voting securities or by contract relating to voting rights or corporate governance, or otherwise. Without limiting the foregoing, control shall be presumed to exist when a Person (a) owns or directly controls more than fifty percent (50%) of the voting securities or other ownership interest of another Person or (b) possesses, directly or indirectly, the power to elect or appoint more than fifty percent (50%) of the members of the governing body of the other Person.
  - **1.6** "**Agreement**" has the meaning set forth in the Preamble.
- **1.7 "Arbitration Dispute"** means a dispute by the Broad under <u>Section 4.4.2</u> regarding Company's credit of amounts actually paid by Company to a Third Party against the Royalties due to Broad for Licensed Products or under <u>Section 4.5</u> of the relative value to be attributed to a Sublicense of the Licensed Patent Rights as part of an overall sublicense agreement.
  - **1.8 "Arbitrators"** has the meaning set forth in Section 11.7.2.
  - **1.9** "Bankruptcy Event" means, with respect to any Person, any of the following:
- (a) such Person shall commence a voluntary case or other proceeding seeking liquidation, reorganization or other relief with respect to itself or its debts under any bankruptcy, insolvency or other similar law now or hereafter in effect or seeking the appointment of a trustee, receiver, liquidator, custodian or other similar official of it or any substantial part of its property, or shall consent to any such relief or to the appointment of or taking possession by any such official in an involuntary case or other proceeding commenced against it, or shall make a general assignment for the benefit of creditors, or shall fail generally to pay its debts as they become due, or shall take any corporate action to authorize any of the foregoing;
- (b) an involuntary case or other proceeding shall be commenced against such Person seeking liquidation, reorganization or other relief with respect to it or its debts under any bankruptcy, insolvency or other similar law now or hereafter in effect or seeking the appointment of a trustee, receiver, liquidator, custodian or other similar official of it or any substantial part of its property, and such involuntary case or other proceeding shall remain undismissed and unstayed for a period of ninety (90) days; or

- (c) an order for relief shall be entered against such Person under the federal bankruptcy laws as now or hereafter in effect; or a receiver or trustee shall be appointed with respect to such Person or all or substantially all of the assets of such Person.
  - **1.10** "Broad" has the meaning set forth in the Preamble.
  - **1.11** "Broad Confidential Information" has the meaning set forth in Section 11.1.1.
  - **1.12** "Broad Response Period" has the meaning set forth in Section 3.4.
- **1.13** "Calendar Quarter" means each of the periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31 during the Term; <u>provided</u> that, the first Calendar Quarter of the Term shall begin on the Effective Date and end on the first to occur of March 31, June 30, September 30 or December 31 thereafter and the last Calendar Quarter of the Term shall end on the last day of the Term.
- **1.14** "Calendar Year" means each successive period of twelve (12) months commencing on January 1 and ending on December 31; <u>provided</u> that, the first Calendar Year of the Term shall begin on the Effective Date and end on the first December 31 thereafter and the last Calendar Year of the Term shall end on the last day of the Term.
- **1.15** "Challenging Party" means any Person that brings, assumes or participates in, or that knowingly or willfully assists in bringing, a Patent Challenge.
- **1.16** "Change of Control" means, with respect to Company, (a) a merger or consolidation of Company with a third party which results in the voting securities of Company outstanding immediately prior thereto ceasing to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger or consolidation, (b) a transaction or series of related transactions in which a third party, together with its Affiliates, becomes the owner of more than fifty percent (50%) of the combined voting power of Company's outstanding securities other than through issuances by Company of securities of Company in a bona fide financing transaction or series of related bona fide financing transactions, or (c) the sale or other transfer to a third party of all or substantially all of Company's assets or business to which this Agreement relates.
  - **1.17** "Claims" has the meaning set forth in Section 9.1.1.
- **1.18** "Combination Product" means (a) a product containing a Licensed Product together with one or more active ingredients not Covered by the Licensed Patent Rights, whether co-formulated or co-packaged, or (b) a Licensed Product sold in combination with one or more other products or services not Covered by the Licensed Patent Rights for a single invoice price (such other active ingredients described in clause (a) and such other products or services described in this clause (b), "Other Components").
  - 1.19 "Company" has the meaning set forth in the Preamble.

- **1.20** "Company Confidential Information" has the meaning set forth in Section 11.1.1.
- **1.21 "Company Exclusive License"** has the meaning set forth in Section 2.1.1.
- **1.22** "Company Non-Exclusive License" has the meaning set forth in Section 2.1.3.
- **1.23 "Company Patent Rights"** mean any Patent Rights that are Controlled by Company or any of its Affiliates (such that Company or its Affiliate may grant access, a license or sublicense thereto) other than the Licensed Patent Rights.
  - **1.24 "Confidential Information"** has the meaning set forth in <u>Section 11.1.1</u>.
- 1.25 "Control" means, as to any Know-How, Patent Right or other intellectual property right, the possession (whether by ownership or license, other than by a license granted pursuant to this Agreement) by a Party or its Affiliates of the ability to grant to the other Party access, ownership, a license or a sublicense as required herein to such Know-How or Patent Right, without (a) violating the terms of any agreement or other arrangement with any Third Party in existence as of the time such Party or its Affiliates would be required hereunder to grant the other Party such access, ownership, license or sublicense, and (b) violating any law or regulation. Cognates of the word "Control" have their correlative meanings. Notwithstanding the foregoing, Broad shall not be deemed to Control any Know-How, Patent Right or other intellectual property right that Broad licenses from a Third Party if (a) Broad would be required to make any payment in connection with the grant of, or Company's exercise of rights under, such Know-How, Patent Right or other intellectual property right hereunder and (b) Company does not agree in writing to make any such payment to such Third Party on behalf of Broad.
- **1.26** "Covered" means, with respect to a given product, process, method or service, that a Valid Claim would (absent a license thereunder or ownership thereof) be infringed by the making, using, selling, offering for sale, importation or other exploitation of such product, process, method or service. With respect to a claim of a pending patent application, "infringed" refers to activity that would infringe or be covered by such Valid Claim if it were contained in an issued patent. Cognates of the word "Covered" shall have correlative meanings.
  - 1.27 "Deprioritization" has the meaning set forth in Section 3.4.
- **1.28** "Developing Country" means any country identified as a Low-income or Lower-middle-income economy in the World Bank "Country and Lending Groups" classification, excluding China, India and Brazil.
- **1.29 "Development Milestones"** means, with respect to a given Licensed Product, the diligence milestones for the development and commercialization of such Licensed Product, as set forth in the Development Plan.
- **1.30 "Development Plan"** means the plan for the development and commercialization of Licensed Products attached hereto as <u>Exhibit C</u>, as such plan may be adjusted from time to time pursuant to <u>Section 3.2</u>.

- 1.31 "DFCI" has the meaning set forth in the recitals.
- **1.32** "Direct License" has the meaning set forth in Section 10.3.1.2.
- **1.33** "**Dispute**" has the meaning set forth in <u>Section 11.7.1</u>.
- **1.34** "Distinct" means, with respect to a product, that such product (a) requires its own IND and Pivotal Trial when compared to another product and (b) differs from such other product on a basis other than (i) the method for producing or manufacturing such product, (ii) the adjuvant used in or with such product, (iii) the method or technology for delivery of such product or its components, or (iv) a reduction in the number of active components in such product compared to the number of active components in such other product if all active components in such product are selected from the set of active components in such other product.
  - 1.35 "Distinct IP Asset Family 1 Products" means two (2) IP Asset Family 1 Products, each of which are Distinct from one another.
  - 1.36 "Distinct IP Asset Family 2 Products" means two (2) IP Asset Family 2 Products, each of which are Distinct from one another.
- **1.37** "Distinct IP Asset Family Product" means either a Distinct IP Asset Family 1 Product or a Distinct IP Asset Family 2 Product, as the context requires.
  - **1.38** "Documentation and Approvals" has the meaning set forth in Section 10.3.3.2.
  - **1.39** "Effective Date" has the meaning set forth in the Preamble.
- **1.40** "EOS" means, with respect to a clinical study, the end of such study, as marked by the last dosing of the last subject for the purposes of final collection of data for a primary endpoint under the protocol for such study. For clarity, "dosing" shall not include any dosing related to extensions for compassionate use, expanded access or similar extensions.
  - **1.41** "Executive Officers" has the meaning set forth in Section 11.7.1.
- **1.42** "Exploit" or "Exploitation" means to research, develop, make, have made, use, have used, sell, offer for sale, have sold, modify, enhance, improve, import, export or commercialize.
  - 1.43 "Extension Request" has the meaning set forth in Section 3.4.
- 1.44 "FDA" means the United States Food and Drug Administration and any successor agency(ies) or authority having substantially the same function.
  - 1.45 "Field" means the diagnosis, prognosis, prevention or treatment of human disease.
- **1.46** "First Commercial Sale" means the date of the first sale by Company, its Affiliate or a Sublicensee of a Licensed Product to a Third Party following receipt of Regulatory

Approval (including pricing or reimbursement approvals where legally required for commercial sale) in the country in which such Licensed Product is sold; <u>provided</u>, <u>however</u>, that any exclusion from the definition of "Net Sales" under <u>Section 1.87.1</u> (including any sale or other distribution for use in a clinical study, charitable purposes or compassionate use or similar limited purposes) shall not qualify as a "sale" hereunder.

- 1.47 [\*\*\*]
- 1.48 "FPD" means, with respect to a clinical study, the first patient dosed in such clinical study.
- **1.49** "FTE" means [\*\*\*] hours of work devoted to or in direct support of marketing and sales of Licensed Products in the Field in the Territory that is carried out by one or more qualified Sublicensees of Company or its Affiliates.
  - **1.50** "FTE Cost" means, for any period, the FTE Rate multiplied by the number of FTEs in such period.
- **1.51** "FTE Rate" means a rate of \$[\*\*\*] per FTE per Calendar Year, as increased as of January 1 of each Calendar Year to account for any increase, but not decrease, in the Consumer Price Index for All Urban Consumers (CPI-U) since January 1 of the prior Calendar Year.
- **1.52** "**IND**" means an FDA Investigational New Drug application, or equivalent application or submission for approval to conduct human clinical investigations filed with or submitted to a Regulatory Authority in conformance with the requirements of such Regulatory Authority.
  - **1.53 "Indemnitees"** has the meaning set forth in Section 9.1.1.
  - **1.54** "Indemnitor" has the meaning set forth in Section 9.1.1.
  - **1.55** "Ineligible Sublicensees" has the meaning set forth in Section 10.3.1.2.
  - **1.56 "Infringement"** has the meaning set forth in Section 7.2.
- **1.57** "**Initiation**" means, with respect to a clinical study, the FPD for such clinical study. Cognates of the word "Initiation" shall have correlative meanings.
  - **1.58 "Institution"** or "**Institutions**" has the meaning set forth in the recitals.
  - **1.59** "Institution Equity" shall mean 900,000 shares of common stock of Company.
  - **1.60 "Institution Names"** has the meaning set forth in <u>Section 11.2</u>.
  - **1.61** "Invoicing Entity" has the meaning set forth in Section 1.87.
  - 1.62 "IP Asset Family 1 Patent Rights" means the Licensed Patent Rights listed in Section 1 of the attached Exhibit A.

- 1.63 "IP Asset Family 1 Product" means [\*\*\*].
- 1.64 [\*\*\*]
- 1.65 "IP Asset Family 2 Patent Rights" means the Licensed Patent Rights listed in Section 2 of the attached Exhibit A.
- 1.66 "IP Asset Family 2 Product" means, [\*\*\*].
- **1.67** "IP Asset Family 3 License" has the meaning set forth in Section 2.1.2.
- 1.68 "IP Asset Family 3 Patent Rights" means the Licensed Patent Rights listed in Section 3 of the attached Exhibit A.
- 1.69 "IP Asset Family 3 Product" means [\*\*\*].
- **1.70** "Know-How" means any and all commercial, technical, scientific and other know-how and information, knowledge, technology, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, specifications, data and results (including biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and know-how, including study designs and protocols), in all cases, whether or not confidential, proprietary, patentable, in written, electronic or any other form. Know-How shall exclude Patent Rights.
  - **1.71** "Lack of Financing" has the meaning set forth in Section 3.4.
  - **1.72** "**License Fees**" has the meaning set forth in <u>Section 4.2.1</u>.
- **1.73** "Licensed Know-How" means all Know-How Controlled by Broad regarding the research and development of Neoantigen Vaccine Products which has been disclosed by [\*\*\*] pursuant to confidential communications prior to the Effective Date under the NDA. Notwithstanding the foregoing, Licensed Know-How excludes [\*\*\*].
- **1.74** "Licensed Neoantigen Vaccine Product" means a Neoantigen Vaccine Product that is an IP Asset Family 1 Product or IP Asset Family 2 Product.
  - 1.75 "Licensed NeoVax Product" means a NeoVax Product that is an IP Asset Family 1 Product or IP Asset Family 2 Product.
- **1.76** "**Licensed Patent Rights**" means the patents and patent applications set forth on <u>Exhibit A</u> and any and all (a) substitutions, divisionals, renewals, continuations or continuations-in-part (only to the extent of claims that are entitled to the priority date of and directed specifically to the subject matter claimed in the parent application); (b) patents of addition, restorations, extensions, supplementary protection certificates, registration or confirmation patents, patents resulting from post-grant proceedings, re-issues and re-examinations; (c) other patents or patent applications claiming and entitled to claim priority to (i) any patent or patent application set forth on <u>Exhibit A</u> or specified in (a) or (b), or (ii) any patent or patent application

from which a patent or patent application set forth on Exhibit A or specified in (a) or (b) claims and is entitled to claim priority; (d) all rights of priority attendant to any of the patents and patent applications listed in (a) through (c); and (e) in each case of (a) through (c), including all counterparts and foreign equivalents thereof filed in any country in the world.

- **1.77** "Licensed Products" means any diagnostic, prognostic, preventative or therapeutic product, including any Neoantigen Vaccine Product, the manufacture, use, sale, practice, performance, importation, exportation, commercialization or other exploitation of which, in a given country in the Territory, is Covered by at least one Valid Claim of the Licensed Patent Rights in such country.
  - **1.78** "List of Countries" has the meaning set forth in Section 6.1.4.
  - **1.79** "Litigation Expenses" has the meaning set forth in Section 7.2.3.
  - 1.80 "MGH" has the meaning set forth in the recitals.
  - **1.81** "Milestone Event" means any milestone event indicated in Section 4.3.1 or Section 4.3.2.
  - **1.82** "Milestone Payment" means any milestone payment indicated in <u>Section 4.3.1</u> or <u>Section 4.3.2</u> corresponding to any Milestone Event.
- **1.83** "NDA" means that certain Mutual Non-Disclosure Agreement dated October 25, 2013, entered into by and between Broad and Third Rock Ventures, LLC.
  - **1.84** "Negotiation Period" has the meaning set forth in Section 2.7.
  - 1.85 "Neoantigen Vaccine Product" means a therapeutic vaccine product as more fully described on Schedule 1.85.
  - 1.86 "NeoVax Product" means the Neoantigen Vaccine Product more fully described on Schedule 1.86.
- **1.87** "Net Sales" means the gross amount billed or invoiced by or on behalf of Company, its Affiliates and their Sublicensees and the Sublicensees' Affiliates (in each case, the "Invoicing Entity") or if not billed or invoiced the gross amount received by the Invoicing Entity, on sales, leases, uses or other transfers of Licensed Products, less the following to the extent applicable with respect to such sales, leases, uses or other transfers and not previously deducted from the gross invoice price: (a) customary trade, quantity or cash discounts to the extent actually allowed and taken; (b) amounts actually repaid or credited by reason of rejection, return or recall of any previously sold, leased, used or otherwise transferred Licensed Products; (c) rebates, chargebacks and retroactive price adjustments granted or given; (d) allowances for non-collectible receivables; (e) customer freight charges that are paid by or on behalf of the Invoicing Entity; (f) to the extent separately stated on purchase orders, invoices or other documents of sale, any sales, value added or similar taxes, custom duties or other similar governmental charges levied directly on the production, sale, transportation, delivery or use of a Licensed Product that are paid by or on behalf of the Invoicing Entity, but not including any tax levied with respect to income and (g) fees that are imposed pursuant to the Affordable Care Act that are payable on net sales of products; provided that:

- 1.87.1 Net Sales shall not include (a) sales or other transfers of any Licensed Product used for clinical studies or other research, or (b) donations for charity or compassionate use for which an Invoicing Entity does not receive consideration;
- 1.87.2 in any transfers of Licensed Products between an Invoicing Entity and an Affiliate or Sublicensee of such Invoicing Entity not for the purpose of resale by such Affiliate or Sublicensee, Net Sales shall be equal to the fair market value of the Licensed Products so transferred, assuming an arm's length transaction made in the ordinary course of business;
- 1.87.3 in the event that (a) an Invoicing Entity receives non-cash consideration for any Licensed Products, (b) an Invoicing Entity sells Licensed Products in a transaction not at arm's length with a non-Affiliate of an Invoicing Entity, or (c) any Licensed Product is sold by an Invoicing Entity at a discounted price that is substantially lower than the customary prices charged by such Invoicing Entity, Net Sales shall be calculated based on the fair market value of such consideration or transaction, assuming an arm's length transaction made in the ordinary course of business, provided that, if a Licensed Product is sold under circumstances in which the discounted price is the result of market forces and not a quid pro quo for value other than the monetary consideration charged in such sale of Licensed Product, such discounted price shall be deemed to be a customary price;
- 1.87.4 with respect to any provision hereof requiring a calculation of fair market value, assuming an arm's length transaction made in the ordinary course of business, Invoicing Entity may use the average price of the relevant Licensed Product sold for cash during the relevant period in the relevant country; and
- 1.87.5 sales of Licensed Products by an Invoicing Entity to its Affiliate or Sublicensee or to an Affiliate of a Sublicensee for resale by such Affiliate, Sublicensee or Affiliate of a Sublicensee shall not be deemed Net Sales. Instead, Net Sales shall be determined based on the gross amount billed or invoiced by such Affiliate, Sublicensee or Affiliate of a Sublicensee upon resale of such Licensed Products to any third party that is not an Affiliate, Sublicensee or Affiliate of a Sublicensee of the Invoicing Entity.
- 1.87.6 With respect to sales of any Combination Product in a country, the Parties shall determine Net Sales for such Combination Product in such country by mutual agreement based on the relative contribution of the Licensed Product and the Other Components in the Combination Product.
  - **1.88** "Notice of Interest" has the meaning set forth in Section 2.7.
  - **1.89** "Notice Period" has the meaning set forth in Section 2.7.
- **1.90 "Operating Agreement"** means that certain Operating Agreement by and among Broad, the Massachusetts Institute of Technology and President and Fellows of Harvard College, dated July 1, 2009, as amended.

- **1.91 "Other Components"** has the meaning set forth in Section 1.18.
- **1.92** "Party" and "Parties" have the meaning set forth in the Preamble.
- **1.93** "Past Patent Costs" has the meaning set forth in Section 6.3.
- 1.94 "Patent Challenge" means any direct or indirect dispute or challenge, or any knowing or willful assistance in the dispute or challenge, of the validity, patentability, scope, priority, construction, non-infringement, inventorship, ownership or enforceability of any Licensed Patent Right or any claim thereof, or opposition or assistance in the opposition of the grant of any letters patent within the Licensed Patent Rights, in any legal or administrative proceedings, including in a court of law, before the United States Patent and Trademark Office or other agency or tribunal in any jurisdiction, or in arbitration including, without limitation, by reexamination, *inter partes* review, opposition, interference, post-grant review, nullity proceeding, preissuance submission, third party submission, derivation proceeding or declaratory judgment action; <u>provided</u>, <u>however</u>, that the term Patent Challenge shall not include Company or its Affiliates being named as an essential party or real party in interest in any patent interference proceeding before the United States Patent and Trademark Office, so long as Company either abstains from participation in, or acts in good faith to settle, the interference. For clarity, a Patent Challenge shall not include arguments made by Company that (a) distinguish the inventions claimed in Company Patent Rights from those claimed in the Licensed Patent Rights and (b) do not disparage the Licensed Patent Rights or raise any issue of Licensed Patent Rights' compliance with or sufficiency under applicable patent laws, regulations or administrative rules, in each case, (i) in the ordinary course of *ex parte* prosecution of the Company Patent Rights or (ii) in *inter partes* proceedings before the United States Patent and Trademark Office or other agency or tribunal in any jurisdiction (excluding interferences or derivation proceedings), or in arbitration, wherein the Company Patent Rights have been challenged. For further clarity, satisfaction of any requirement to submit informat
  - 1.95 "Patent Costs" has the meaning set forth in Section 6.3.
- **1.96** "Patent Rights" means patents and patent applications and any and all (a) substitutions, divisionals, renewals, continuations or continuations-in-part (only to the extent of claims that are entitled to the priority date of and directed specifically to the subject matter claimed in the parent application); (b) patents of addition, restorations, extensions, supplementary protection certificates, registration or confirmation patents, patents resulting from post-grant proceedings, re-issues and re-examinations; (c) other patents or patent applications claiming and entitled to claim priority to (i) any patent or patent application specified in (a) or (b), or (ii) any patent or patent application from which a patent or patent application specified in (a) or (b) claims and is entitled to claim priority; (d) all rights of priority attendant to any of the patents and patent applications listed in (a) through (c); and (e) in each case of (a) through (c), including all counterparts and foreign equivalents thereof filed in any country in the world.

**1.97** "PCT" has the meaning set forth in Section 2.7.

- **1.98** "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.
- **1.99** "Phase I Clinical Study" means, as to a specific Licensed Product, a study of such product in humans designed to satisfy the requirements of 21 C.F.R. § 312.21(a), as amended from time to time, or the corresponding regulation in jurisdictions other than the United States.
- 1.100 "Phase II Clinical Study" means, as to a specific Licensed Product, (a) a preliminary efficacy and safety human clinical study in any country conducted to evaluate such product for a particular indication or indications in patients with the disease or condition under study, where at least one of the primary endpoints of such study is an efficacy endpoint, or (b) any human clinical study that satisfies the requirements of 21 C.F.R. § 312.21(b), as amended from time to time, or the corresponding regulation in jurisdictions other than the United States.
- **1.101** "Phase III Clinical Study" means, as to a specific Licensed Product, (a) a human clinical study in any country, whether controlled or uncontrolled, that is performed to obtain Regulatory Approval of such Licensed Product after preliminary evidence suggesting its effectiveness under evaluation has been obtained, and intended to confirm with statistical significance the efficacy and safety of such Licensed Product, to evaluate its overall benefit-risk relationship and to provide an adequate basis for physician labeling, or (b) a human clinical study that satisfies the requirements of 21 C.F.R. § 312.21(c), as amended from time to time, or the corresponding regulation in jurisdictions other than the United States.
- **1.102** "**Pivotal Trial**" means, as to a specific Licensed Product, the first of either a Phase II Clinical Study or Phase III Clinical Study that is intended to be sufficient for obtaining Regulatory Approval for such Licensed Product in any jurisdiction.
  - 1.103 "Proprietary Software" means the software programs licensed by Broad to Company pursuant to the Software License.
- **1.104** "**Prosecution**" or "**Prosecute**" means the preparation, filing, prosecution, issuance and maintenance of Patent Rights, including continuations, continuations-in-part, divisionals, extensions, reexaminations, *inter partes* review, reissues, supplemental examinations, appeals, interferences, derivation proceedings, oppositions, all other proceedings before the United States Patent and Trademark Office (including the Patent Trial and Appeal Board) and foreign patent offices, and any judicial or other appeals of the foregoing. Cognates of the word "Prosecution" have their correlative meanings.
  - **1.105** "Record Retention Period" has the meaning set forth in Section 5.3.
- **1.106** "**Regulatory Approval**" means those clearances or approvals (including pricing or reimbursement approvals, as applicable) of a Regulatory Authority, with respect to any jurisdiction, that are legally required for the sale of Licensed Products in such jurisdiction.

- **1.107** "Regulatory Authority" means any applicable government regulatory authority involved in granting clearances or approvals for the manufacturing or marketing of a Licensed Product, including, in the United States, the FDA.
  - **1.108** "Replacement Product" has the meaning set forth in Section 4.3.6.
- **1.109** "Restricted Stock Agreement" means a Restricted Stock Agreement, substantially in the form attached hereto as Exhibit D, entered into by and between Company and an Institution in connection with the issuance of equity securities by Company under Section 4.6, and "Restricted Stock Agreements" means all of the Restricted Stock Agreements entered into by and between Company and Institutions in connection with the issuance of equity securities by Company under Section 4.6.
  - **1.110** "Royalties" has the meaning set forth in Section 4.4.1.
- **1.111** "Royalty Term" means, on a country-by-country and product-by-product basis, the period commencing on the Effective Date and ending on the later of: (a) the expiration of the last Valid Claim within the Licensed Patent Rights Covering the Licensed Product or (b) the tenth (10th) anniversary of the date of the First Commercial Sale of the Licensed Product.
  - **1.112** "Skipped Milestone" has the meaning set forth in Section 4.3.1.1.
- **1.113** "Software License" means that the software license attached hereto as <u>Exhibit B</u>, entered into by and between Company and Broad in accordance with Section 2.8.
- **1.114** "Sublicense" means an agreement in which Company (a) grants or otherwise transfers any of the rights licensed to Company hereunder or rights that are relevant to Exploiting Licensed Products, (b) agrees not to assert such rights or to sue, prevent or seek a legal remedy for the practice of same, or (c) is under an obligation to grant, assign or transfer any such rights or non-assertion, or to forebear from granting or transferring such rights to any other entity, including by means of an option. Agreements expressly considered Sublicenses include licenses, option agreements, "lock up" agreements, right of first refusal agreements, non-assertion agreements, covenants not to sue, distribution agreements that grant or otherwise transfer any rights licensed to Company hereunder, or similar agreements. Excluded from this definition of "Sublicense" are (a) a sublicense to an Affiliate of Company under Section 2.3 and (b) an assignment of this Agreement in compliance with Section 11.14. For the avoidance of doubt, if a Sublicense is entered into pursuant to an option or similar agreement that is also a Sublicense, then the date of execution of the Sublicense shall be the execution date of the Sublicense that is an option or similar agreement, not the date of the exercise of the option or similar agreement.
- 1.115 "Sublicense Income" means all consideration received by Company or its Affiliates from a Sublicensee in consideration of the grant of a Sublicense of the rights granted to Company under Section 2.1 hereunder. Sublicense Income shall include any license fees, milestone or option payments, license maintenance fees and other payments. Sublicense Income shall specifically exclude: (i) royalties on net sales of Licensed Products, (ii) future research support payments, (iii) the fair market value of amounts received as payment of equity or debt securities of Company, (iv) reimbursement for patent expenses at their out-of-pocket costs, (v) manufacturing costs, and (vi) FTE Costs. In the event that non-cash consideration is received as Sublicense Income, Sublicense Income shall be calculated based on the fair market value of such non-cash consideration at the time of the transaction.

- 1.116 "Sublicensee" means any Third Party to whom Company has granted a Sublicense.
- **1.117** "Suit" has the meaning set forth in Section 11.8.
- **1.118** "Temporary Extension" has the meaning set forth in Section 10.3.1.2.
- **1.119** "Term" means the term of this Agreement as set forth in Section 10.1.
- 1.120 "Territory" means worldwide.
- **1.121** "Third Party" means any Person that is not (a) Broad, (b) Company or (c) an Affiliate of Company.
- 1.122 "Valid Claim" means: (a) a claim of an issued and unexpired patent within the Licensed Patent Rights that has not been (i) held permanently revoked, unenforceable, unpatentable or invalid by a decision of a court or governmental body of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, (ii) disclaimed or rendered unenforceable through disclaimer or otherwise, or (iii) abandoned, or (b) a pending claim of a pending patent application within the Licensed Patent Rights, which claim has not been pending for more than [\*\*\*] years from the first substantive office action with respect to the pending claim and has not been abandoned or finally rejected without the possibility of appeal or refiling or without such appeal having been taken or refiling having been made within the applicable time periods. The invalidity of a particular claim in one or more countries shall not invalidate such claim in any remaining countries. For the avoidance of doubt, a pending claim of a patent application filed pursuant to the Patent Cooperation Treaty shall be considered pending in all designated jurisdictions.

#### 2. LICENSE.

#### 2.1 License Grants

- 2.1.1 Exclusive Patent License Grant. Subject to the terms of this Agreement, Broad hereby grants, on behalf of itself and each Institution, to Company an exclusive, royalty-bearing license, with the right to grant sublicenses in accordance with Sections 2.3 and 2.5, under each Institution's respective interest in the IP Asset Family 1 Patent Rights and the IP Asset Family 2 Patent Rights, to Exploit Licensed Products in the Field in the Territory during the Term (the "Company Exclusive License").
- 2.1.2 Non-Exclusive Patent License Grant. Subject to the terms of this Agreement, Broad hereby grants, on behalf of itself and each Institution, to Company a non-exclusive, royalty-bearing license, with the right to grant sublicenses in accordance with Sections 2.3 and 2.5, under each Institution's respective interest in the IP Asset Family 3 Patent Rights, to Exploit Licensed Products in the Field in the Territory during the Term (the "IP Asset Family 3 License").

- 2.1.3 <u>Non-Exclusive Know-How License Grant</u>. Subject to the terms of this Agreement, Broad hereby grants, on behalf of itself and each Institution, to Company a non- exclusive, fully paid up, royalty-free license, with the right to grant sublicenses in accordance with <u>Sections 2.3</u> and <u>2.5</u>, under each Institution's respective interest in the Licensed Know-How, to Exploit any diagnostic, prognostic, preventative or therapeutic product in the Field in the Territory during the Term (the "**Company Non-Exclusive License**").
  - **2.2 Reservation of Rights**. Notwithstanding anything herein to the contrary:
- 2.2.1 Government Rights. Any and all licenses and other rights granted under this Agreement are limited by and subject to any rights of the United States government and any obligations of the Institutions under 35 U.S.C. §§ 200-212 and 37 CFR Part 401 et seq.; any right granted in this Agreement greater than that permitted under 35 U.S.C. §§ 200-212 and 37 CFR Part 401 et seq. shall be subject to modification as may be required to conform to the provisions of those statutes and regulations.
- 2.2.2 <u>Research Reservation</u>. In addition to the reservation of rights under <u>Section 2.2.1</u>, the Company Exclusive License is subject to Broad's reservation of the right, for itself and other academic, government and non-profit research institutions, to make, use and practice the Licensed Patent Rights for research, teaching, or educational purposes, both in the laboratory and clinical setting.
- 2.3 Affiliates. The licenses granted to Company under Section 2.1 include the right to have some or all of Company's rights or obligations under this Agreement exercised or performed by one or more of Company's Affiliates through a written sublicense between Company and such Affiliate(s) pursuant to this Section 2.3; provided, however, that (a) Company shall notify Broad in writing in advance of any Affiliate exercising or performing any of Company's rights or obligations under this Agreement, such Affiliate shall have agreed in writing to be bound by the terms and conditions of this Agreement as if it were Company hereunder, including specific acknowledgment that Broad is an intended third party beneficiary of the provisions of such agreement and the sublicense to the extent such provisions relate to the sublicensing of rights under this Agreement, and such written agreement shall include the requirements and limitations described in clauses (c) and (d) of this Section 2.3; (c) Company shall require such Affiliate to indemnify, defend and hold harmless Indemnitees and to carry insurance under the same terms as are set forth in Article 9 of this Agreement; (d) no such Affiliate shall be entitled to grant, directly or indirectly, to any Person any right of whatever nature under, or with respect to, or permitting any use or exploitation of Licensed Patent Rights or Licensed Know-How; (e) any act or omission by an Affiliate of Company shall be deemed an act or omission by Company hereunder, and Company shall be responsible for each of its Affiliates complying with all obligations of Company under this Agreement (including without limitation all restrictions placed on Company herein); and (f) any assumption of rights or obligations by Affiliates of Company under this Agreement shall not relieve Company of any of its obligations under this Agreement.
- **2.4 Right to Subcontract.** If Company desires to exercise any of the rights or obligations that Company may have under this Agreement by subcontracting the exercise or

performance of all or any portion of such rights and obligations on Company's behalf, Company shall be entitled to do so, <u>provided</u> that (a) such contract service providers obtain no rights in or to Licensed Patent Rights or Licensed Know-How; (b) any subcontract granted or entered into by Company as contemplated by this <u>Section 2.4</u> of the exercise or performance of all or any portion of the rights or obligations that Company may have under this Agreement shall not relieve Company from any of its obligations under this Agreement; (c) any act or omission by a subcontractor of Company shall be deemed an act or omission of Company hereunder; and (d) Company shall be responsible for each of its subcontractors complying with all obligations of Company under this Agreement (including without limitation all restrictions placed on Company herein).

#### 2.5 Sublicenses

- 2.5.1 Sublicense Rights. Company shall be entitled to sublicense through multiple tiers the rights granted to it under Section 2.1 [\*\*\*].
- 2.5.2 <u>Sublicense Agreements</u>. Company shall ensure that any Sublicense shall be on terms and conditions in compliance with and not inconsistent with the terms of this Agreement. Company shall furnish Broad with a fully-executed copy of any Sublicense promptly after execution of such Sublicense; <u>provided</u> that, Company may redact from such copy confidential terms of such Sublicense that relate to the technical characteristics of any product or service or otherwise are not necessary for Broad to monitor compliance by Company or such Sublicense with the terms and conditions of this Agreement. For clarity, Broad shall use any such copies of Sublicenses solely for the purpose of monitoring Company's and Sublicensees' compliance with their obligations and enforcing Broad's rights under this Agreement in relation thereto. Any Sublicense shall require a written agreement, which shall be subject and subordinate to the terms and conditions of this Agreement, and shall contain terms sufficient to enable Company to comply with this Agreement, including the following:
- 2.5.2.1 a requirement that Sublicensee indemnify, defend and hold harmless Indemnitees, and carry insurance, under the same terms as are set forth in <a href="Article 9">Article 9</a> of this Agreement;
- 2.5.2.2 a statement that Broad is an intended third party beneficiary of such Sublicense for the purpose of enforcing all patent challenge, indemnification and insurance provisions of such Sublicense and enforcing the right to terminate such Sublicense for breach of such provisions;
- 2.5.2.3 a provision stating that in the event Sublicensee directly or indirectly brings, assumes, or participates in, or knowingly, willfully or recklessly assists in bringing, a Patent Challenge then Company shall be entitled to terminate the Sublicense;
- 2.5.2.4 a provision specifying that, in the event of termination of the licenses set forth in <u>Section 2.1</u> in whole or in part (e.g., as to one license or the other, or as to termination in a particular country), any existing Sublicense agreement shall terminate to the same extent of such terminated license, subject to Sublicensee's right to receive a Direct License from Broad in accordance with Section 10.3.1.2 hereof;

- 2.5.2.5 a provision specifying that Sublicensee may only sublicense its rights under such Sublicense agreement through [\*\*\*] (other than to Affiliates of the Sublicensee and other than may be agreed in writing by Broad) and that such sub-sublicenses are subject to all restrictions on the granting of Sublicenses herein;
  - 2.5.2.6 a provision requiring Sublicensee to comply with Section 8.1 and Section 11.2 of this Agreement; and
- 2.5.2.7 a provision prohibiting the Sublicensee from assigning the Sublicense agreement without the prior written consent of Broad, except that Sublicensee may assign the Sublicense agreement without such prior written consent to the same extent Company may assign this Agreement under Section 11.14.
- 2.5.3 <u>Company Liability</u>. Notwithstanding any Sublicense, Company shall remain primarily liable to Broad for all of Company's duties and obligations contained in this Agreement, and any act or omission of a Sublicensee which would be a breach of this Agreement if performed by Company shall be deemed to be a breach by Company of this Agreement.
- 2.5.4 <u>Termination</u>. Unless otherwise agreed in writing by Broad or provided in <u>Section 10.3.1.2</u>, all Sublicenses shall automatically terminate effective upon termination of this Agreement.

2.6 [\*\*\*].

**2.7 Notice and Good Faith Negotiation**. Broad agrees that it will promptly notify Company in writing after filing any provisional, utility or Patent Cooperation Treaty ("**PCT**") patent application for a [\*\*\*]. Where such filing is a utility or PCT filing, Broad agrees to provide a copy of such filing with the notice. With respect to any [\*\*\*], Company shall have [\*\*\*] days after receipt of such notice (the "**Notice Period**") to notify Broad in writing of its interest in receiving an exclusive license to such [\*\*\*] (the "**Notice of Interest**"). If Company delivers to Broad a Notice of Interest within the Notice Period, then Broad shall not grant any rights to a Third Party with respect to such [\*\*\*] for the period ending [\*\*\*] days after the date of the Notice of Interest (which period may be extended by mutual agreement of Company and Broad) in order to provide Company with an opportunity to negotiate a mutually acceptable exclusive license agreement with respect to such [\*\*\*] (the "**Negotiation Period**"). If (a) Company does not deliver to Broad a Notice of Interest within the Notice Period for any [\*\*\*], or (b) the Parties fail to reach agreement on and execute a definitive agreement within the Negotiation Period for such [\*\*\*], then Broad may grant rights to a Third Party with respect to such [\*\*\*] (i) after expiration of the Notice Period, in the case of clause (a) or (ii) after expiration of the Negotiation Period, in the case of clause (b). Notwithstanding the foregoing, any rights granted under this Section 2.7 shall be subject to the conflict of interest rules of Broad, as such rules exist as of the date of delivery of the Notice of Interest. For clarity, Broad shall have no obligations under this Section 2.7 with respect to any [\*\*\*] that is not [\*\*\*], other than to notify Company of such [\*\*\*] in accordance with the first sentence of this Section 2.7.

- **2.8 Software License.** Concurrently with the execution of this Agreement, the Parties have entered into the Software License attached hereto as Exhibit B, which Software License shall govern the license by Broad to Company of the Proprietary Software.
- **2.9 No Other Grant of Rights.** Except as expressly provided herein, nothing in this Agreement shall be construed to confer any ownership interest, license or other rights upon Company or its Affiliates or Sublicensees by implication, estoppel or otherwise as to any technology, intellectual property, products or biological materials of Broad or any other entity, regardless of whether such technology, intellectual property, products or biological materials are dominant, subordinate or otherwise related to any Licensed Patent Rights.

#### 3. DEVELOPMENT AND COMMERCIALIZATION.

- **3.1 Diligence; Development Milestones.** Company shall use commercially reasonable efforts and shall cause its Affiliates and Sublicensees to use commercially reasonable efforts: (a) to research and develop at least one IP Asset Family 1 Product or IP Asset Family 2 Product within the Field; (b) to introduce at least one IP Asset Family 1 Product or IP Asset Family 2 Product within the Field into the commercial market; and (c) to market at least one IP Asset Family 1 Product or IP Asset Family 2 Product within the Field following such introduction into the market and to make such IP Asset Family 1 Product or IP Asset Family 2 Product reasonably available to the public. In addition, Company, by itself or through its Affiliates or Sublicensees, shall achieve each of the Development Milestones within the time periods specified in the Development Plan attached hereto as Exhibit C, subject to the adjustment mechanism set forth in Section 3.4.
- **3.2 Development Plan; Adjustments.** The initial Development Plan for the development and commercialization of Licensed Products, including the Development Milestones and the time periods for their achievement, is attached hereto as <a href="Exhibit C">Exhibit C</a>. Company shall be entitled, from time to time, to make such commercially reasonable adjustments to the Development Plan as Company believes, in its good faith judgment, are necessary in order to meet the Development Milestones, <a href="provided">provided</a> that Company shall not be entitled to make any adjustments to the Development Milestones except as expressly set forth in <a href="Section 3.4">Section 3.4</a>.
- **3.3 Diligence Reporting.** Within [\*\*\*] days after the end of each Calendar Year, Company shall furnish Broad with a written report summarizing its, its Affiliates' and its Sublicensees' efforts during the prior Calendar Year to Exploit Licensed Products within the Field, including a summary of: (a) research and development activities, including information regarding specific Licensed Products in development and their therapeutic applications; (b) status of applications for Regulatory Approvals; and (c) commercialization efforts. The report shall also include a summary of intended efforts for the then current Calendar Year. The report shall be written in sufficient detail for Broad to assess whether Company is in compliance with its obligations under Section 3.1. Together with each report provided under this Section 3.3 Company shall provide Broad with a copy of the then-current Development Plan which shall include sufficient detail to enable Broad to assess which Licensed Products, if any, are in development and the status of any such development.

3.4 Adjustment of Development Milestones; Diligence Breach. Broad acknowledges and agrees that the technical and regulatory paths for Exploiting Neoantigen Vaccine Products are high risk and unknown and therefore it is in the best interests of the Parties to provide for adjustment to the Development Milestones on account of circumstances generally outside the direct control of Company. If Company is making commercially reasonable efforts in accordance with Section 3.1 and believes that, despite such commercially reasonable efforts, it will not achieve a Development Milestone by the applicable deadline, it may notify Broad in writing at least [\*\*\*] days in advance of such deadline of Company's request to extend or amend such Development Milestone (each, an "Extension Request"). Company shall include in such Extension Request (a) a reasonably detailed written summary of its research and development efforts with respect to IP Asset Family 1 Products and IP Asset Family 2 Products within the Field through the date of such Extension Request, (b) a reasonable explanation for the anticipated delay in achieving or failure to achieve a Development Milestone and (c) a reasonably detailed written plan for achieving a reasonably extended or amended Development Milestone (and all subsequent Development Milestones). If Company's reasons for such delay or failure are not (i) Company's inability to obtain for a continuous period lasting at least [\*\*\*] months sufficient financing to achieve such Development Milestone ("Lack of Financing") nor (ii) Company's prioritization of programs that do not involve Licensed Neoantigen Vaccine Products ahead of programs that involve Licensed Neoantigen Vaccine Products (as evidenced by Company's material diminution of resources devoted to Licensed Neoantigen Vaccine Product programs in preference to the devotion of such resources to programs that do not involve Licensed Neoantigen Vaccine Products) ("Deprioritization"), and if the proposed extended Development Milestones are commercially reasonable, Exhibit C shall be deemed amended effective [\*\*\*] days after the date of the Extension Request to reflect the extended or amended Development Milestones as set forth in such Extension Request. For clarity, Company shall not be entitled to an extension of any Development Milestone and Exhibit C shall not be deemed amended as a result of any Extension Request if Lack of Financing or Deprioritization have caused the delay or failure in connection with which such Extension Request is made or if the proposed extended Development Milestones are not commercially reasonable. Upon the request of Broad within [\*\*\*] days following receipt of any Extension Request, Company shall (A) meet with Broad to discuss the content of such Extension Request and (B) provide Broad with such additional information as Broad may reasonably request relating to Company's research and development efforts with respect to IP Asset Family 1 Products and IP Asset Family 2 Products within the Field and/or to substantiate that Lack of Financing and Deprioritization have not occurred and/or to demonstrate that the proposed extended Development Milestones are commercially reasonable. If Lack of Financing or Deprioritization have caused the delay or failure in connection with which an Extension Request is made, or if the proposed extended Development Milestones are not commercially reasonable, Broad may grant or deny such Extension Request in Broad's sole discretion, and Broad shall provide written notice of a grant or denial of any Extension Request to Company within [\*\*\*] days after receipt of such Extension Request, provided that such period may be reasonably extended by Broad in writing for an additional [\*\*\*] days if Broad has requested a meeting to discuss the content of such Extension Request or to accommodate any delays in Company's provision of any additional information requested by Broad, each as provided in the immediately preceding sentence (such [\*\*\*] period, as it may be extended in accordance with the preceding proviso, the "Broad Response Period"). Unless Broad denies such Extension Request within the Broad Response Period, Exhibit C shall

be deemed amended to reflect the extended or amended Development Milestones as set forth in such Extension Request. If Broad provides notice to Company within the Broad Response Period that Broad is denying an Extension Request, and Company fails to achieve a Development Milestone, Broad may treat such failure as a material breach and terminate this Agreement in accordance with Section 10.2.2. For clarity and in addition to the foregoing, if the FDA requires that an additional Phase I Clinical Study be conducted prior to Initiation of a Phase II Clinical Study or Phase III Clinical Study for the Licensed NeoVax Product, then the timing of the Development Milestone for Initiation of the Phase II Clinical Study or Phase III Clinical Study shall be automatically adjusted as set forth on Exhibit C, and, in such case, such adjustment shall not require, and shall not be deemed, an Extension Request by the Company, provided that, in such case, Company notifies Broad in writing promptly upon receiving notice that the FDA is requiring such additional Phase I Study.

### 4. CONSIDERATION FOR GRANT OF LICENSE.

**4.1 License Issue Fee.** Company shall pay Broad a non-refundable license fee of seventy-five thousand U.S. Dollars (\$75,000), due and payable within [\*\*\*] days after the Effective Date.

#### 4.2 Annual License Fees

4.2.1 Company agrees to pay Broad annual license maintenance fees ("License Fees") as follows:

Calendar Years	Maintena	ınce Fee
2016 – 2020	\$	[***]
2021 and each subsequent Calendar Year during the Term	\$	[***]

- 4.2.2 Each License Fee shall be due and payable on January 1st of the Calendar Year to which such fee applies and shall be creditable against any Royalties due and payable under <u>Section 4.4</u> below with respect to Licensed Products sold in the same Calendar Year that such License Fee was due.
  - 4.2.3 The License Fees include all consideration due or payable with respect to the Software License.

#### **4.3 Milestone Payments**

### 4.3.1 IP Asset Family 1 Products.

4.3.1.1 *Milestone Payments for IP Asset Family 1 Products*. Company shall pay Broad the respective Milestone Payments set forth in this <u>Section 4.3.1.1</u> for the first achievement of the specified Milestone Event for each of the first [\*\*\*] Distinct IP Asset Family 1 Products, regardless of whether such Milestone Event is achieved by Company, an Affiliate of Company, a Sublicensee, or a combination thereof:

Milestone Event	[***] <b>Di</b> sti	Payment for inct IP Asset 1 Product	[***] Dis	Payment for tinct IP Asset 1 Product
[***]	\$	[***]	\$	[***]
[***]	\$	[***]	\$	[***]
[***]	\$	[***]	\$	[***]
[***]	\$	[***]	\$	[***]
[***]	\$	[***]	\$	[***]

Company shall make the appropriate Milestone Payment within [\*\*\*] days after the achievement of such Milestone Event. The Milestone Events set forth in this Section 4.3.1.1 are intended to be successive; if a Distinct IP Asset Family 1 Product is not required to undergo the event associated with a particular Milestone Event for a Distinct IP Asset Family 1 Product ("Skipped Milestone"), such Skipped Milestone shall be deemed to have been achieved upon the achievement by such Distinct IP Asset Family 1 Product of the next successive Milestone Event ("Achieved Milestone"); provided that, the Milestone Events for [\*\*\*] shall not be deemed to be successive with each other (i.e., [\*\*\*]). Payment for any Skipped Milestone that is owed in accordance with the provisions of this Section 4.3.1.1 shall be due within [\*\*\*] days after the achievement of the Achieved Milestone.

4.3.1.2 *Annual Net Sales Milestones for IP Asset Family 1 Products*. Company shall pay Broad the respective sales Milestone Payments set forth in this <u>Section 4.3.1.2</u> within [\*\*\*] days after the end of the Calendar Year in which the following sales Milestone Events are first achieved for each of [\*\*\*] Distinct IP Asset Family 1 Products, in the Territory, regardless of whether such sales Milestone Event is achieved by Company, an Affiliate of Company or a Sublicensee, or a combination thereof:

Milestone Event	[***] Di:	e Payment for stinct IP Asset y 1 Product	[***] Dis	e Payment for stinct IP Asset y 1 Product
Upon the first occasion that aggregate annual Net				
Sales exceed \$[***]	\$	[***]	\$	[***]
Upon the first occasion that aggregate annual Net				
Sales exceed \$[***]	\$	[***]	\$	[***]
Upon the first occasion that aggregate annual Net				
Sales exceed \$[***]	\$	[***]	\$	[***]

### 4.3.2 IP Asset Family 2 Products.

4.3.2.1 *Milestone Payments for IP Asset Family 2 Products*. Company shall pay Broad the Milestone Payments set forth in this Section 4.3.2.1 for the first achievement of the specified Milestone Event for each of the [\*\*\*] Distinct IP Asset Family 2 Products, regardless of whether such Milestone Event is achieved by Company, an Affiliate of Company or a Sublicensee, or a combination thereof:

Milestone Event	[***] Dist	Payment for inct IP Asset 2 Product	[***] Dis	Payment for tinct IP Asset 2 Product
[***]	\$	[***]	\$	[***]
[***]	\$	[***]	\$	[***]
[***]	\$	[***]	\$	[***]
[***]	\$	[***]	\$	[***]
[***]	\$	[***]	\$	[***]

Company shall make the appropriate Milestone Payment within [\*\*\*] days after the achievement of such Milestone Event. The Milestone Events set forth in this Section 4.3.2.1 are intended to be successive; if a Skipped Milestone occurs with a particular Milestone Event for a Distinct IP Asset Family 2 Product, such Skipped Milestone shall be deemed to have been achieved upon the achievement by such Distinct IP Asset Family 2 Product of the next successive Milestone Event; provided that, the Milestone Events for [\*\*\*] shall not be deemed to be successive with each other (i.e., [\*\*\*]). Payment for any Skipped Milestone that is owed in accordance with the provisions of this Section 4.3.2.1 shall be due within [\*\*\*] days after the achievement of the Achieved Milestone.

4.3.2.2 *Annual Net Sales Milestones for IP Asset Family 2 Products*. Company shall pay Broad the respective sales Milestone Payments set forth in this Section 4.3.2.2, within [\*\*\*] days after the end of the Calendar Year in which the following sales Milestone Events are first achieved for each of [\*\*\*] Distinct IP Asset Family 2 Products, in the Territory, regardless of whether such Milestone Event is achieved by Company, an Affiliate of Company or a Sublicensee, or a combination thereof:

Milestone Event	[***] Di:	e Payment for stinct IP Asset v 2 Product	[***] Dis	e Payment for stinct IP Asset v 2 Product
Upon the first occasion that aggregate annual Net				
Sales exceed \$[***]	\$	[***]	\$	[***]
Upon the first occasion that aggregate annual Net				
Sales exceed \$[***]	\$	[***]	\$	[***]
Upon the first occasion that aggregate annual Net				
Sales exceed \$[***]	\$	[***]	\$	[***]

- 4.3.3 <u>Milestone Payments for IP Asset Family 1 Products and IP Asset Family 2 Products</u>. In the event that a Milestone Event is achieved by a single Licensed Product that is covered under both IP Asset Family 1 Patent Rights and IP Asset Family 2 Patent Rights, (a) with respect to a Milestone Payment described in <u>Section 4.3.1.1</u> or <u>Section 4.3.2.1</u>, such product will be characterized such that the highest applicable Milestone Payment is payable by Company with respect to such achievement and (b) with respect to a sales Milestone Event described in <u>Section 4.3.1.2</u> or <u>Section 4.3.2.2</u>, such product will be deemed to be an IP Asset Family 1 Product.
- 4.3.4 <u>Multiple Milestone Payments</u>. Notwithstanding the foregoing to the contrary, Company shall pay Broad the respective Milestone Payments set forth in this <u>Section 4.3</u> for the first achievement of the specified Milestone Event for each of the first [\*\*\*] Distinct IP Asset Family Products only and not for the achievement of the specified Milestone Event for any subsequent Distinct IP Asset Family Products, regardless of whether such Milestone Event is achieved by Company, an Affiliate of Company, a Sublicensee, or a combination thereof. For clarity and by way of example, [\*\*\*].
- 4.3.5 <u>Milestone Reporting</u>. Company shall report to Broad the dates on which it achieves the Milestone Events set forth in <u>Section 4.3.1</u> and Section 4.3.2 within [\*\*\*] days after the occurrence of each such Milestone Event.
- 4.3.6 <u>Replacement Products</u>. If (A) development of a Licensed Product is terminated after any Milestone Payment set forth in <u>Section 4.3.1.1</u> or <u>Section 4.3.2.1</u> as applicable, has been made with respect to such Licensed Product and (B) another Licensed Product is selected to replace the terminated Licensed Product and the selected Licensed Product is for the same, substantially similar or closely related indication ("**Replacement Product**"), then there shall be no payment due upon achievement of the same milestone by such Replacement Product for which Broad already received a Milestone Payment for the original Licensed Product.

#### 4.4 Royalties.

4.4.1 Royalty Rates. Company shall pay to Broad running royalties ("Royalties") on the aggregate annual Net Sales of Licensed Products during the applicable Royalty Term at the applicable royalty rates set forth below within [\*\*\*] days following the last day of the Calendar Quarter in which such Royalty accrues. If the Exploitation of any Licensed Product is Covered by more than one Valid Claim of the Licensed Patent Rights, multiple Royalties shall not be due as a result of being so Covered. For the avoidance of doubt, in the event that a single Licensed Product is covered under both IP Asset Family 1 Patent Rights and

IP Asset Family 2 Patent Rights, multiple Royalties shall not be due as a result; rather, the sale of such Licensed Product shall count as only one (1) sale of an IP Asset Family 1 Product and the applicable royalty rate set forth in <u>Section 4.4.1.1</u> shall apply.

### 4.4.1.1 Royalty Rates for IP Asset Family 1 Products

Annual Net Sales of IP Asset Family 1 Products	Royalty Rate
On the portion of worldwide annual Net Sales less than or equal to \$[***]	[***]%
On the portion of worldwide annual Net Sales greater than \$[***] but less than or	
equal to \$[***]	[***]%
On the portion of worldwide annual Net Sales greater than \$[***]	[***]%

### 4.4.1.2 Royalty Rates for IP Asset Family 2 Products

Annual Net Sales of IP Asset Family 2 Products	Royalty Rate
On the portion of worldwide annual Net Sales less than or equal to \$[***]	[***]%
On the portion of worldwide annual Net Sales greater than \$[***] but less than or	
equal to \$[***]	[***]%
On the portion of worldwide annual Net Sales greater than \$[***]	[***]%

# 4.4.1.3 Royalty Rates for IP Asset Family 3 Products

Annual Net Sales of IP Asset Family 3 Products	Royalty Rate
All worldwide annual Net Sales	[***]%

4.4.2 Third Party Royalty Offset. If Company or any of its Affiliates or Sublicensees is legally required by a future court order, settlement agreement, contract, or other legally binding written commitment to make payments to a Third Party of running royalties on net sales of Licensed Products for a license under, or the use of, Patent Rights held by such Third Party that Cover the Exploitation of such Licensed Product and are reasonably necessary for the commercialization of such Licensed Product, then Company shall be entitled to credit [\*\*\*] of the amounts actually paid by Company to such Third Party against the Royalties due to Broad for

such Licensed Products under Section 4.4.1 of this Agreement. In the event that Company is entitled to take a credit under this Section 4.4.2, and takes a credit against Royalties due to Broad under this Agreement, then in the royalty report due to Broad under Section 5.1.1 at the time such credit is taken, Company shall include a calculation of the credit taken and, with the first such royalty report on which such credit is taken, the basis for Company's determination of reasonable commercial necessity. In no event shall payments to Broad be reduced pursuant to this Section 4.4.2 such that Broad receives less than [\*\*\*] of the rates set forth in Section 4.4.1. Any amounts that are not offset during a reporting period shall not be creditable against payments arising in subsequent reporting periods. In the event that Broad disagrees with Company's credit of amounts actually paid by Company to a Third Party against the Royalties due to Broad for Licensed Products, then such Arbitration Dispute will be resolved in accordance with the procedures set forth in Sections 11.7.1 and 11.7.2.

4.4.3 Patent Challenge. Subject to the provisions of this Section 4.4.3, in the event that Company or any of its agents, Affiliates or Sublicensees is or becomes a Challenging Party, then (a) Company shall provide Broad with at least [\*\*\*] days' notice prior to Company's taking any such action and with notice no later than [\*\*\*] days after Company becomes aware of a Patent Challenge by its Affiliate or a Sublicensee; (b) Company shall pay all reasonable costs, fees and expenses associated with such Patent Challenge that are incurred by Broad (or DFCI or MGH, as applicable) and their trustees, managers, officers, agents, employees, faculty, affiliated investigators, personnel and staff, including reasonable attorneys' fees and all reasonable costs associated with administrative, judicial or other proceedings, within [\*\*\*] days after receiving an invoice from Broad for same; (c) the exclusive licenses granted in this Agreement may, as of the date of initiation of said challenge or opposition, upon notice by Broad to Company, be converted by Broad at its option into a non-exclusive license for the remainder of the Term, and in such event Broad shall have the right to grant other non-exclusive licenses under the Licensed Patent Rights to Third Parties; (d) any fees, royalties, milestones or revenues payable to Broad under Sections 4.2 - 4.5 shall double in amount if and when any Licensed Patent Right survives the Patent Challenge such that it remains valid in whole or in part; and (e) at any time after the Patent Challenge is brought, Broad may, at its option, terminate this Agreement according to Section 10.2.3; provided that if any of subsections (a) through (e) are held invalid or unenforceable for any reason, such invalidity or unenforceability shall not affect any of the other said subsections. If the Challenging Party is an Affiliate of Company or a Sublicensee, the Party that receives notice of the Patent Challenge shall notify the other Party within [\*\*\*] days of receipt of such notice, and, if requested by Broad within [\*\*\*] days after such notice by one Party to the other, the Parties shall meet and discuss Company's proposed course of action to be taken with respect to such Patent Challenge by such Affiliate or Sublicensee. If Company takes all necessary action as provided in the Sublicense to such Affiliate or Sublicensee to terminate such Sublicense, or, in the case of an Affiliate, if the Affiliate is exercising or performing Company's rights or obligations as provided in accordance with Section 2.3 and not under a Sublicense, Company takes all necessary action to terminate the right of such Affiliate to exercise or perform Company's rights or obligations, within [\*\*\*] days after Company first received notice of such Patent Challenge, subsections (c) through (e) of the first sentence of this Section 4.4.3 shall not apply. Notwithstanding any provision of this Agreement to the contrary, Company shall not have the right to assume or participate in the defense, settlement or other disposition of such Patent Challenge through its status as licensee under this Agreement, but shall pay associated costs, fees and expenses as provided in this Section 4.4.3. The Parties agree

that any challenge or opposition to a Licensed Patent Right by Company may be detrimental to Broad (or DFCI or MGH, as applicable), and that the above provisions shall constitute reasonable liquidated damages to reasonably compensate Broad (or DFCI or MGH, as applicable) for any loss it may incur as a result of Company taking such action.

**4.5 Sublicense Income.** Company shall pay Broad a percentage of Sublicense Income within [\*\*\*] days following the last day of the Calendar Quarter in which such Sublicense Income is received by Company, in accordance with the rates set forth in Section 4.5.1. [\*\*\*]. Company agrees that all rights relevant to making, using, selling, offering to sell or importing particular Licensed Products shall be included in or deemed to be included in the same Sublicense under which the rights granted or otherwise transferred to Company hereunder are granted with respect to such Licensed Products for the purpose of calculating Sublicense Income.

### 4.5.1 Sublicense Income Rates.

Rate Adjustment Event	Sublicense Income
[***]	[***]%
[***]	[***]%
[***]	[***]%

**4.6 Issuance of Equity.** In accordance with the terms of the Restricted Stock Agreements, Company shall, on the Effective Date and concurrent with the execution of this Agreement, as partial consideration for the licenses granted hereunder under [\*\*\*] with respect to the Neoantigen Vaccine Products, issue to Broad the Institution Equity, which Broad has directed be split among the Institutions, with [\*\*\*] of the Institution Equity issued to [\*\*\*].

#### 5. REPORTS; PAYMENTS; RECORDS.

#### 5.1 Reports and Payments

- 5.1.1 Reports. Within [\*\*\*] days after the conclusion of each Calendar Quarter commencing with the first Calendar Quarter in which Net Sales are generated or Sublicense Income is received, Company shall deliver to Broad a report containing, as applicable, the following information, on a Licensed Product-by-Licensed Product and country-by-country basis (and, in the case of the requirement under Section 5.1.1(c), to the extent such itemized listing of allowable deductions is available from Sublicensees under the terms of the relevant Sublicensees):
  - (a) quantity of Licensed Products sold or otherwise transferred by Invoicing Entities for the applicable Calendar Quarter;
- (b) the gross amount billed or invoiced for Licensed Products sold or otherwise transferred by Invoicing Entities during the applicable Calendar Quarter;

- (c) a calculation of Net Sales for the applicable Calendar Quarter, including an itemized listing of allowable deductions;
- (d) a reasonably detailed accounting of all Sublicense Income received during the applicable Calendar Quarter; and
- (e) the total amount payable to Broad in U.S. Dollars on Net Sales and Sublicense Income for the applicable Calendar Quarter, together with the exchange rates used for conversion.

Company shall use reasonable efforts to include in each Sublicense a provision requiring the Sublicensee to provide the information required under this Section 5.1.1. Each such report shall be certified on behalf of Company as true, correct and complete in all material respects with respect to the information required under Sections 5.1.1(a) through 5.1.1(e). If no amounts are due to Broad for a particular Calendar Quarter, the report shall so state.

- **5.2 Payment Currency.** All payments due under this Agreement shall be paid in U.S. Dollars. Conversion of foreign currency to U.S. Dollars shall be made as of the last working day of the applicable Calendar Quarter at the applicable conversion rate existing in the United States (as reported in the *Wall Street Journal*) or, solely with respect to Sublicenses, at another commercially reasonable, publicly available, applicable conversion rate as may be provided in a Sublicense.
- **5.3 Records.** Company shall maintain, and shall cause its Affiliates and Sublicensees to maintain, customary records relating to the use, research, development and commercialization of the Licensed Products, including records of activities conducted to meet Company's diligence obligations under this Agreement, and complete and accurate records of the Licensed Products sold or otherwise transferred and any amounts payable to Broad in relation thereto, and records relating to all sublicense arrangements under this Agreement, which records shall contain sufficient information to permit Broad to confirm the accuracy of any reports delivered to Broad under Section 4.3.5, Section 4.5 or Section 5.1, as applicable. Company, its Affiliates or its Sublicensees, as applicable, shall retain such records relating to a given Calendar Year for at least [\*\*\*] years after the conclusion of that Calendar Year (the "Record Retention Period").
- 5.3.1 <u>Audit of Company and Affiliates</u>. During the Record Retention Period, Broad shall have the right, at its sole expense, during normal business hours, to cause an independent, certified public accountant (or, in the case of a non-financial audit, other appropriate auditor) chosen by Broad and reasonably acceptable to Company to inspect such records of Company or its Affiliates for the purposes of verifying the accuracy of any reports and payments delivered under this Agreement (which, for clarity, shall include any reports and payments from Sublicensees) and Company's compliance with the terms hereof; <u>provided</u> that, Broad shall give Company or its Affiliates reasonable prior written notice (which shall be at least [\*\*\*] days) prior to conducting any such audit. Company may require the auditor to sign a customary nondisclosure agreement prior to undertaking any such inspection, and any and all books, records, reports and other documents inspected by such accountant shall be deemed Company's Confidential Information. The accountant shall not disclose to Broad any information other than information relating to the accuracy of reports and payments delivered

under this Agreement, and any such information delivered to Broad, including in the form of an audit report, shall be deemed Company's Confidential Information. Broad may exercise the rights under this Section 5.3.1 only [\*\*\*] and may audit any given period only once.

- 5.3.2 <u>Audit of Sublicensees</u>. During the Record Retention Period, Company shall, to the extent practicable under any Sublicense, cause each Sublicensee to provide Broad with a right of audit comparable to that set forth in <u>Section 5.3.1</u>; <u>provided</u> that, in any such audit event, the same protections afforded to Company and its Affiliates shall apply to any Sublicensee, *mutatis mutandis*. If Company does not have the right to allow Broad to conduct an audit of such Sublicensee for a relevant Calendar Year, Company and Broad shall meet and use reasonable efforts to agree on an appropriate course of action.
- 5.3.3 <u>Audit Payment Terms</u>. With respect to any audit performed under <u>Section 5.3.1</u> or <u>Section 5.3.2</u>, the Parties shall reconcile any underpayment or overpayment within [\*\*\*] days after the accountant delivers the results of the audit. If such audit reveals an underpayment in excess of [\*\*\*] in any Calendar Year, Company shall reimburse Broad for its out-of-pocket expenses incurred in connection with such audit.
- **5.4 Late Payments.** Any payments by Company that are not paid on or before the date such payments are due under this Agreement and which have not been disputed by Company in good faith shall bear interest at the lower of (a) [\*\*\*] and (b) the maximum rate allowed by law. Interest shall accrue beginning on the first day following the due date for payment and shall be compounded [\*\*\*]. Any such overdue payment when made shall be accompanied by all interest so accrued.
- **5.5 Payment Method.** Each payment due to Broad under this Agreement shall be paid by check or wire transfer of funds to Broad's account in accordance with written instructions provided by Broad. If made by wire transfer, such payments shall be marked so as to refer to this Agreement.
- **5.6 Withholding and Similar Taxes.** All amounts to be paid to Broad pursuant to this Agreement shall be without deduction of exchange, collection, or other charges, and, specifically, without deduction of withholding or similar taxes imposed on Company or other government imposed fees or taxes imposed on Company, except as permitted in the definition of Net Sales.

### 6. PATENT FILING, PROSECUTION AND MAINTENANCE.

#### 6.1 Control

6.1.1 Broad shall be responsible for the Prosecution of the Licensed Patent Rights during the Term. Subject to Section 6.1.4 and Section 6.1.5, Broad shall, with respect to such Licensed Patent Rights: (a) choose patent counsel; (b) instruct such patent counsel to furnish Company with copies of all correspondence relating to the Licensed Patent Rights received from or sent to the United States Patent and Trademark Office and any other patent office, as well as copies of all proposed responses to such correspondence received from any patent office in time for Company to review and comment on such response; (c) supply Company with a copy of any application as filed, together with notice of its filing date and serial number; (d) supply Company with a draft copy of any proposed preliminary amendment to be filed subsequent to the filing of a non-provisional application within the Licensed Patent Right; and (e) keep Company advised of the status of actual patent filings related to the Licensed Patent Rights. Subject to Section 6.1.2 and Section 6.1.3, Broad shall give Company the opportunity to provide comments on and make requests of Broad concerning the Prosecution of the Licensed Patent Rights, and shall consider such comments and requests in good faith; [\*\*\*].

6.1.2 Broad shall provide notice to Company in the event Prosecution of the Licensed Patent Rights involves an interference or derivation proceeding. If Company has an interest, such as by ownership, license or option to acquire ownership or a license, in opposing patents or applications involved in the interference or derivation proceeding, then upon declaration of any such interference or initiation of any such derivation proceeding, Company's rights under Section 6.1.1, including the right to receive correspondence to or from a patent office and the right to review draft responses, shall be suspended with respect to the Patent Rights involved in the interference or derivation proceeding. Notwithstanding the foregoing, any such interference or derivation proceeding is considered Prosecution of the Licensed Patent Rights and Company remains responsible for Broad's expenses in connection with such Prosecution, including costs and expenses associated with settlement or attempts to settle the interference. Notwithstanding the foregoing, if Company does not have an interest, such as by ownership, license or option to acquire ownership or a license, in opposing patents or applications involved in the interference or derivation proceeding, Broad shall enter into a common interest agreement to facilitate the sharing of the materials set forth in Section 6.1.1(b) with Company. Notwithstanding anything to the contrary in this Section 6.1.2, if Company has a non-exclusive license or option to acquire a non-exclusive license in opposing patents or applications involved in an interference or derivation proceeding, Company and Broad shall discuss in good faith whether there is sufficient commonality of interest between Company and Broad for Broad to enter into a common interest agreement to facilitate the sharing of the materials set forth in Section 6.1.1(b) with Company and to permit Company to continue exercising the rights set forth in Section 6.1.1.

6.1.3 Notwithstanding the foregoing, if Company or any of its agents, Affiliates or Sublicensees is or becomes a Challenging Party, then Company's rights to participate in Prosecution under Section 6.1.1, including the right to review draft responses, shall be suspended during the pendency of the relevant Patent Challenge with respect both to the Licensed Patent Rights that are the subject of the Patent Challenge and to any related Licensed Patent Rights.

6.1.4 No later than [\*\*\*] days prior to the deadline for entering into the national/regional phase with respect to any PCT application included in the Licensed Patent Rights, Company shall provide Broad with a list of countries in which Company would like Broad to file the patent application (each, a "List of Countries"). Broad shall consider each List of Countries in good faith and, except as provided below in this Section 6.1.4, shall file national/regional phase applications in all countries on each List of Countries. Notwithstanding anything to the contrary contained in this Agreement, Broad reserves the right: (i) to decline to initiate Prosecution of any of the Licensed Patent Rights in a Developing Country(ies) included in a List of Countries or (ii) to initiate, at its sole expense and in its discretion, Prosecution of any of the Licensed Patent Rights in a Developing Country(ies), whether or not included on a List of Countries; provided that, in each case of (i) and (ii), Broad provides Company with [\*\*\*] days' advance notice of its intention to take such action, provides Company an opportunity to meet with Broad to discuss and reasonably considers Company's comments regarding its intention. Broad shall thereafter notify Company of the taking of any action described in the foregoing clause (i) or (ii) at least [\*\*\*] days before the taking of such action. If Broad takes the action described in clause (ii) of this Section 6.1.4, then Broad expressly reserves the right, upon notice to Company, either (A) to remove the applicable Licensed Patent Right in such Developing Country(ies) from the scope of the Company Exclusive License, effective upon such notice, and to include such Licensed Patent Right within the scope of the Company Non-Exclusive License, or (B) treat the applicable Licensed Patent Right as an Abandoned Patent Right, in which case under this clause (B) all licenses granted to Company under such Licensed Patent Right in such Developing Country(ies) shall terminate upon such notice. Thereafter, Broad shall be free, without further notice or obligation to Company, to grant a non-exclusive (in the event Broad proceeds under the preceding clause (A)) or non-exclusive or exclusive (in the event Broad proceeds under the preceding clause (B)) rights in and to such Licensed Patent Right to Third Parties for all purposes within such Developing Country(ies). Further, Broad may, in its sole discretion, file additional national/regional phase applications (the "Additional National Stage Filings") in countries not included on a List of Countries provided by Company, and all expenses, including translation fees associated with Prosecution of such Additional National Stage Filings shall be expenses associated with Prosecution under this Agreement, in accordance with Section 6.3. If Company does not wish to reimburse Broad for all expenses associated with Prosecution of such Additional National Stage Filings, such Additional National Stage Filings shall be deemed Abandoned Patent Rights and treated in accordance with Section 6.4.

6.1.5 Notwithstanding the foregoing, (a) Company shall have the right, at Company's sole expense and discretion, to Prosecute all Company Patent Rights and (b) in the event that any invention is created or reduced to practice by any Institutions' or their Affiliates' employees, agents or faculty together with one or more employees or agents of Company, solely to the extent that Broad has an ownership interest in, or otherwise controls, such Patent Rights, the Parties shall discuss in good faith on a case-by-case basis which Party shall control Prosecution of any Patent Rights that describe such invention.

**6.2 Common Interest**. All non-public information disclosed by Broad or Broad's outside patent counsel to Company regarding Prosecution of the Licensed Patent Rights,

including information regarding [\*\*\*], shall be deemed Confidential Information of Broad. In addition, the Parties acknowledge and agree that, with regard to such Prosecution of the Licensed Patent Rights, the interests of the Parties as licensors and licensee are aligned in desiring the [\*\*\*] and are legal in nature. The Parties agree and acknowledge that they have not waived, and nothing in this Agreement constitutes a waiver of, any legal privilege concerning the Licensed Patent Rights or their Confidential Information, including privilege under the common interest doctrine and similar or related doctrines.

**6.3 Expenses.** Company shall reimburse Broad for its unreimbursed, documented, out-of-pocket expenses, including attorneys' fees, translation costs and official fees, incurred in the Prosecution of the Licensed Patent Rights ("Patent Costs") prior to execution of the Agreement; as of the Effective Date, the past costs for Prosecution of such Licensed Patent Rights are approximately [\*\*\*] U.S. Dollars and [\*\*\*] cents (\$[\*\*\*]) ("Past Patent Costs"). Company shall reimburse Broad for [\*\*\*] of the Past Patent Costs within [\*\*\*] days after the Effective Date, and shall reimburse Broad for the remainder amount by no later than the first anniversary of the Effective Date, provided that, solely with respect to the IP Asset Family 3 Patent Rights, if Broad enters into a license agreement with any Third Party for such IP Asset Family 3 Patent Rights (each such Third Party, an "Additional Family 3 Licensee"), Broad shall use good faith efforts to seek payment by such Additional Family 3 Licensee of [\*\*\*] portion of the Past Patent Costs and any additional Patent Costs reimbursed or reimbursable by Company between the Effective Date and the effective date of such license agreement under this Section 6.3 with respect to the Prosecution of the IP Asset Family 3 Patent Rights, and Broad shall credit any amounts that Broad receives pursuant to the foregoing against future payments owed by Company to Broad with respect to the Patent Costs for the Licensed Patent Rights. In addition, subject to Section 6.4 hereof, Company shall reimburse Broad for all Patent Costs incurred by Broad in the Prosecution of the Licensed Patent Rights, including Prosecution of the Licensed Patent Rights pursuant to any of Sections 6.1.1 - 6.1.5, incurred after the Effective Date within [\*\*\*] days after the date of each invoice from Broad for such expenses; provided that, solely with respect to the IP Asset Family 3 Patent Rights, Company shall only be responsible for [\*\*\*] of such Patent Costs incurred after the Effective Date, taking into account the number of Additional Family 3 Licensees at the time such Patent Costs are incurred (e.g., if after the Effective Date, Broad enters into a license agreement with one Additional Family 3 Licensee, effective upon execution of such license agreement, Company shall only be responsible for [\*\*\*] percent ([\*\*\*]%) of such Patent Costs for the duration of the license agreement with such Additional Family 3 Licensee; if after the Effective Date, Broad enters into a license agreement with a second Additional Family 3 Licensee, effective upon execution of such license agreement, Company shall only be responsible for [\*\*\*] percent ([\*\*\*]%) of such Patent Costs while both license agreements with the Additional Family 3 Licensees are in effect; and so on). Broad shall provide to Company invoices for all Patent Costs for which Company is responsible for reimbursing Broad, which invoices shall (a) identify the Licensed Patent Rights to which the invoice relates, (b) include Company reference numbers (to be provided by Company) and (c) be accompanied by copies of invoices received by outside patent counsel(s), providing the associated detailed time and expense entries from patent counsel(s).

### 6.4 Abandonment.

- 6.4.1 <u>Abandonment by Company.</u> If Company decides that it does not wish to pay for the Prosecution of any Licensed Patent Rights in a particular country ("**Abandoned Patent Rights**"), Company shall provide Broad with prompt written notice of such election. [\*\*\*] days after receipt of such notice by Broad, Company shall be released from its obligation to reimburse Broad for the expenses incurred thereafter as to such Abandoned Patent Rights; <u>provided</u>, <u>however</u>, that expenses authorized prior to the receipt by Broad of such notice shall be deemed incurred prior to the notice period. In the event of Company's abandonment of any Licensed Patent Rights, any license granted to Company hereunder with respect to such Abandoned Patent Rights shall terminate, and Company shall have no rights whatsoever to exploit such Abandoned Patent Rights. Broad shall then be free, without further notice or obligation to Company, to grant rights in and to such Abandoned Patent Rights to Third Parties without limitation.
- 6.4.2 <u>Abandonment by Broad</u>. Broad agrees to maintain all applications and patents within the Licensed Patent Rights for as long as (a) Company continues to meet its obligation to reimburse expenses associated with such application or patent in accordance with <u>Section 6.3</u> and (b) there is a good faith basis for doing so. For the avoidance of doubt, this <u>Section 6.4.2</u> shall not apply and shall not limit Broad's right to cease Prosecution of a given application within the Licensed Patent Rights in lieu of a continuation or continuation-in-part application, whether by filing a new continuing application or request for continued examination, that is also within the Licensed Patent Rights.
- **6.5 Marking.** To the extent commercially feasible and consistent with prevailing business practices, Company shall, and shall cause its Affiliates and Sublicensees to, mark all Licensed Products manufactured or sold under this Agreement with the number of each issued patent under the Licensed Patent Rights that applies to such Licensed Product.
- **6.6 CREATE** Act. No Party shall have the right to use this Agreement as a joint research agreement to make an election under the Cooperative Research and Technology Enhancement Act of 2004, 35 U.S.C. § 103(c)(2)-(c)(3), as amended by the America Invents Act and set forth in 35 U.S.C. § 102(b)(2)(C) and § 102(c), without the prior written consent of each other Party having an ownership interest in a patent or patent application involved in such election, such consent to be granted or withheld in the sole discretion of each such other Party.

#### 7. ENFORCEMENT OF PATENT RIGHTS.

- **7.1 Notice.** In the event either Party becomes aware of any possible or actual infringement of any Licensed Patent Rights with respect to Licensed Products, that Party shall promptly notify the other Party and provide it with details regarding such infringement.
- **7.2 Suit by Company.** So long as Company remains the exclusive licensee of the IP Asset Family 1 Patent Rights and IP Asset Family 2 Patent Rights with respect to Licensed Products in the Field in the Territory, Company shall have the first right, but not the obligation, to prosecute, at its sole expense, any infringement of the IP Asset Family 1 Patent Rights or IP Asset Family 2 Patent Rights by a Third Party with respect to Licensed Products in the Field

("Infringement"); provided that, prior to initiating action against such Third Party with respect to such Infringement, Company shall provide Broad with the underlying facts demonstrating that there is a good faith basis for so doing. By way of example and not limitation, such evidence may consist of Company's determination that a Third Party is marketing or has specific plans and is preparing to market an infringing product that competes with a Licensed Product in the Field in the Territory. [\*\*\*]. Company shall use the same degree of diligence in prosecuting such Infringement as it uses or would use in prosecuting infringement of its own patent rights. For clarity, Company shall not have the right, unless given in writing by Broad, nor shall it have any obligation to prosecute any infringement of IP Asset Family 3 Patent Rights. With respect to any Infringement relating to an IP Asset Family 3 Patent Right, Broad shall consider in good faith prosecuting such infringement at the request of Company.

- 7.2.1 <u>Developing Countries</u>. Before Company commences an action with respect to any Infringement in a Developing Country, Company shall consult with Broad with respect to the proposed course of action and shall consider in good faith Broad's views. Company shall also consider potential effects on the public interest and the locally-affordable availability of Licensed Products or equivalents thereof, e.g., generic products, in Developing Countries, in deciding whether to take such action. Notwithstanding the foregoing or anything to the contrary contained in this Agreement, Company agrees that, consistent with <u>Section 6.1.4</u> and solely with respect to any Developing Country, Broad shall hold final decision-making authority, to be exercised in good faith, on a case-by-case basis, as to whether Company shall be permitted to enforce the Licensed Patent Rights in such Developing Country.
- 7.2.2 <u>Consultation</u>. Before Company commences an action with respect to any Infringement in the Territory, Company shall notify Broad with respect to its proposed course of action to address the Infringement and shall consider in good faith the views of Broad and potential effects on the public interest in making its decision whether to take such action. Should Company elect (or, with respect to prosecution in a Developing Country pursuant to <u>Section 7.2.1</u>, be permitted) to take action against an actual or potential infringer, Company shall select counsel reasonably acceptable to Broad, shall keep Broad reasonably informed of the progress of the action and shall give Broad a reasonable opportunity in advance to consult with Company and offer their views about major decisions affecting the action. Company shall give careful consideration to those views, but shall have the right to control the Infringement action, subject to Broad's rights set forth in <u>Section 7.3</u>.
- 7.2.3 <u>Joinder</u>. If required under applicable law to establish standing for the initiation or maintenance of an infringement action by Company, the relevant Institution(s) shall, upon request of Company or as required by a court or procedural rules, or may voluntarily, join or be joined as a party to such action, <u>provided</u> that, none of the Institutions shall be the first named party in such action unless required in order for Company to bring, maintain or prove damages in any such action. Notwithstanding the foregoing, no Institution shall have any obligation to cause any other Institution to join or be joined as a party to any such action. Company shall (a) hold Institutions harmless from, and indemnify Institutions against, any costs and expenses, including attorneys' fees, incurred in connection with such action and any related appeals, remands or other related proceedings ("Litigation Expenses") and (b) reimburse any and all Litigation Expenses incurred by Institutions within [\*\*\*] days after receiving an invoice (including a copy of detailed time and expense entries from applicable attorneys) from Institutions for same. Company shall not compromise or settle such litigation without the prior written consent of Institutions, which shall not be unreasonably withheld or delayed.

7.2.4 Expenses. The expenses of Company with respect to any suit or suits that Company elects to bring in accordance with this Section 7.2 shall be paid for entirely by Company. Any recovery obtained in an action brought by Company pursuant to this Section 7.2 shall be distributed as follows: (a) Broad shall first be reimbursed for any unreimbursed Litigation Expenses; (b) Company shall recover for itself all of its litigation expenses incurred in the prosecution of any such suit; and (c) any remainder shall be divided as follows: (i) Company shall receive an amount equal to its lost profits or a reasonable royalty on the infringing sales, whichever measure of damages the court shall have applied; (ii) Broad shall receive an amount equal to the royalties and other amounts that Company would have paid to Broad if Company, rather than the infringer, had sold the infringing products, provided that (A) amounts payable under clause (ii) shall in no event exceed the amounts payable under clause (i) above and (B) in the event that the remainder of any sums recovered is insufficient to fully satisfy both of the foregoing clauses (i) and (ii) then Company and Broad shall receive a pro rata share of such remainder in relative proportion to the amounts that would have been payable to Company and Broad under clauses (i) and (ii); and (iii) the balance, if any, remaining after Company and Broad have been compensated under the foregoing clauses (i) and (ii) shall be shared by the Parties as follows: [\*\*\*] percent ([\*\*\*]%) to Company and [\*\*\*] percent ([\*\*\*]%) to Broad.

**7.3 Suit by Broad.** If Company does not take action in the prosecution, prevention, or termination of any Infringement of IP Asset Family 1 Patent Rights or IP Asset Family 2 Patent Rights pursuant to Section 7.2 above, and has not commenced negotiations with the suspected infringer for the discontinuance of said Infringement, within [\*\*\*] days after receipt of notice of the existence of an Infringement Broad may elect to do so; provided that, Broad shall consider in good faith Company's reasons for not initiating a lawsuit or otherwise making or prosecuting a claim. Subject to Section 7.4, any and all expenses, including reasonable attorneys' fees, incurred by Broad with respect to the prosecution, adjudication or settlement of a suit in accordance with this Section 7.3, including any related appeals, shall be paid for entirely by the Broad. In the event Broad exercises its right to sue pursuant to this Section 7.3, it shall retain all sums recovered in such suit or in settlement thereof.

**7.4 Own Counsel.** The Party initiating the suit shall have the sole and exclusive right to elect counsel for any suit that it initiates pursuant to Section 7.2 or Section 7.3; provided that, such counsel is reasonably acceptable to the other Party. The non-initiating Party shall have the right to participate in and be represented by counsel of its own selection in any suit instituted under this Article 7 by the other Party for Infringement and shall bear its own Litigation Expenses in connection with such participation, provided that, if Broad is the non-initiating Party, Company shall be solely responsible for all Litigation Expenses incurred by Broad in connection with Broad's participation in such suit at the request of Company [\*\*\*].

**7.5 Cooperation.** To the extent legally practicable, each Party agrees to cooperate fully in any action under this <u>Article 7</u> that is controlled by the other Party, including executing legal papers and cooperating in the prosecution as may be reasonably requested by the controlling Party; <u>provided</u> that the controlling Party reimburses the cooperating Party promptly for any costs and expenses incurred by the cooperating Party in connection with providing such requested cooperation within [\*\*\*] days after receiving an invoice from the cooperating Party for same.

- **7.6 Patent Validity Challenge.** Each Party shall promptly notify the other Parties in the event it receives notice of any legal or administrative action by any Third Party against a Licensed Patent Right, including any opposition, nullity action, revocation, *inter partes* review, post-grant review, compulsory license proceeding, or declaratory judgment action. Except as provided in the following sentence, oppositions, nullity actions, revocations, post-grant review and *inter partes* review shall be addressed as provided in Section 6.1. Company shall have the first right, at its expense, to defend (a) all compulsory license proceedings, (b) all declaratory judgment actions, and (c) any post-grant proceedings before the USPTO (including the Patent Trial and Appeal Board) and foreign patent offices that arise in response to any action by Company pursuant to Section 7.2 hereof. If Company elects not to participate in a compulsory license proceeding or to defend the invalidity or unenforceability of the Licensed Patent Rights included in such declaratory judgment action or related post-grant proceeding, it shall promptly and in writing notify Broad of its election, including in its notice the reasons for its decision, and Broad may then elect, upon written notice to Company, to do so at its own expense.
- 7.6.1 For the avoidance of doubt, oppositions, post-grant reviews, *inter partes* reviews and other proceedings before the United States Patent and Trademark Office or a foreign patent office, whether controlled by Broad pursuant to Section 6.1 or defended by Company pursuant to this Section 7.6, are Prosecution of the Licensed Patent Rights and Company shall be responsible for Broad's expenses as set forth in Section 6.3.
- 7.6.2 If Company exercises its right to defend a Licensed Patent Right under this <u>Section 7.6</u>, then, with respect to the defense of such Licensed Patent Right: (i) the rights granted to Company under <u>Section 6.1.1</u> shall apply to Broad and (ii) the obligations of Broad under <u>Section 6.1.1</u> shall apply to Company, *mutatis mutandis*.

### 8. COMPLIANCE WITH LAWS; WARRANTIES; LIMITATION OF LIABILITY.

- **8.1 Compliance with Laws.** Company shall comply, and ensure that its Affiliates and Sublicensees comply, with all local, state, federal and international laws and regulations applicable to the Exploitation of Licensed Products.
- **8.2 Export Control.** Company shall, and shall cause its Affiliates and Sublicensees to, comply with all applicable United States laws and regulations controlling the export of certain commodities and technical data, including all Export Administration Regulations of the United States Department of Commerce. Among other things, these laws and regulations prohibit or require a license for the export of certain types of commodities and technical data to specified countries. Company hereby agrees that it bears sole responsibility for any violation of such laws and regulations by itself or its Affiliates or Sublicensees, and that it shall indemnify, defend, and hold harmless Indemnitees (in accordance with Section 9.1) for the consequences of any such violation.

## 8.3 Representations and Warranties

8.3.1 By Broad. Broad represents and warrants that (a) it has the authority and right to enter into this Agreement, to grant the licenses granted to Company herein, and to perform its obligations under Section 2.7, Section 6.1, Section 6.3, Section 6.4.2, Section 7.1, Section 7.2.3, Section 7.3, Section 7.5, Section 7.6 and Section 11.1.2, (b) it has not granted a license under any Licensed Patent Rights that would conflict with the rights granted to Company hereunder, (c) as of the Effective Date, to the best of the knowledge of Broad's Office of Strategic Alliances and Partnering, the execution, delivery and performance of this Agreement by Broad does not conflict with, or constitute a breach of, any order, judgment, agreement or instrument to which it is a party or is otherwise bound, and (d) as of the Effective Date, to the best of the knowledge of Broad's Office of Strategic Alliances and Partnering, no consent of MGH, DFCI or any Third Party, including without limitation any governmental authority, is required for Broad to execute, deliver and perform under this Agreement, including to grant the licenses granted to Company herein, except for such consents as may have been obtained prior to the Effective Date.

8.3.2 By Company. Company represents and warrants that (a) Company has the authority and right to enter into and perform its obligations under this Agreement, (b) as of the Effective Date, to the best of Company's knowledge, the execution, delivery and performance of this Agreement by Company does not conflict with, or constitute a breach of, any order, judgment, agreement or instrument to which it is a party or, to its knowledge, is otherwise bound, and (c) as of the Effective Date, to the best of Company's knowledge, no consent of any Third Party, including without limitation any governmental authority, is required for Company to execute, deliver and perform under this Agreement, except for such consents as may have been obtained prior to the Effective Date.

#### 8.4 Disclaimer

8.4.1 NOTHING CONTAINED HEREIN SHALL BE DEEMED TO BE A WARRANTY BY BROAD THAT IT CAN OR WILL BE ABLE TO OBTAIN PATENTS ON PATENT APPLICATIONS INCLUDED IN THE LICENSED PATENT RIGHTS, OR THAT ANY OF THE LICENSED PATENT RIGHTS WILL AFFORD ADEQUATE OR COMMERCIALLY WORTHWHILE PROTECTION. BROAD MAKES NO WARRANTIES WHATSOEVER AS TO THE COMMERCIAL OR SCIENTIFIC VALUE OF THE LICENSED PATENT RIGHTS.

8.4.2 BROAD MAKES NO REPRESENTATION THAT THE PRACTICE OF THE LICENSED PATENT RIGHTS OR THE DEVELOPMENT, MANUFACTURE, USE, SALE OR IMPORTATION OF ANY LICENSED PRODUCT, OR ANY ELEMENT THEREOF, WILL NOT INFRINGE ANY PATENT OR PROPRIETARY RIGHTS OF A THIRD PARTY.

8.4.3 EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER COMPANY NOR BROAD MAKES ANY WARRANTY WITH RESPECT TO ANY TECHNOLOGY, PATENTS, GOODS, SERVICES, RIGHTS OR OTHER SUBJECT MATTER OF THIS AGREEMENT AND EACH OF COMPANY AND BROAD HEREBY DISCLAIMS WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT WITH RESPECT TO ANY AND ALL OF THE FOREGOING.

### 8.5 Limitation of Liability

8.5.1 EXCEPT WITH RESPECT TO MATTERS FOR WHICH COMPANY IS OBLIGATED TO INDEMNIFY INDEMNITEES UNDER <u>ARTICLE 9</u>, IN NO EVENT SHALL EITHER PARTY, ITS DIRECTORS, OFFICERS, EMPLOYEES OR AGENTS BE LIABLE TO THE OTHER WITH RESPECT TO ANY SUBJECT MATTER OF THIS AGREEMENT UNDER ANY CONTRACT, NEGLIGENCE, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES OR LOST PROFITS, REGARDLESS OF WHETHER SUCH PARTY SHALL HAVE KNOWN OF THE POSSIBILITY OF THE FOREGOING.

8.5.2 Broad's aggregate liability for all damages of any kind arising out of or relating to this Agreement or its subject matter under any contract, negligence, strict liability or other legal or equitable theory shall not exceed the amounts paid to Broad under this Agreement.

#### . INDEMNIFICATION AND INSURANCE.

### 9.1 Indemnification

9.1.1 <u>Indemnity</u>. Company shall, and shall cause its Affiliates and Sublicensees to, indemnify, defend and hold harmless each Institution and each of its and their respective current and former directors, governing board members, trustees, officers, faculty, affiliated investigators, medical and professional staff, employees, students and agents and their respective successors, heirs and assigns (collectively, the "**Indemnitees**") from and against any claim, suit, investigation, action, demand, judgment and related liabilities, costs, expenses, damages, deficiencies, losses or obligations of any kind or nature (including reasonable attorneys' fees and expenses of litigation or defense), brought by a Third Party (other than an Indemnitee) to the extent arising out of, or otherwise relating to (a) the exercise of any rights granted to Company under this Agreement or any breach of this Agreement by Company or its Affiliates or Sublicensees or (b) any cause of action relating to product liability concerning any product or process made, used, sold or performed pursuant to any right or license granted under this Agreement (collectively, "**Claims**") except to the extent any such Claim results from or arises out of the gross negligence or willful misconduct of an Indemnitee or material breach of this Agreement by an Institution. Each of Company, its Affiliates and its Sublicensees are referred to as "**Indemnitor**" below.

9.1.2 <u>Procedures</u>. The Indemnitees agree to provide Company with prompt written notice of any Claim for which indemnification is sought under this Agreement. Indemnitor agrees, at its own expense, to provide attorneys reasonably acceptable to Institutions to defend against any such Claim. The Indemnitees shall cooperate with Indemnitor, at Indemnitor's expense, in such defense and shall permit Indemnitor to conduct and control such defense and the disposition of such Claim (including without limitation all decisions relative to litigation, appeal, and settlement); <u>provided</u>, <u>however</u>, that any Indemnitee shall have the right to

retain its own counsel, at the expense of Indemnitor, if representation of such Indemnitee by the counsel retained by Indemnitor would be inappropriate because of actual or potential differences in the interests of such Indemnitee and any other party represented by such counsel; and provided, further that, in such event, Institutions agree to use diligent efforts to select counsel, and to cause any other Indemnitees affiliated with their respective institutions to select counsel, that minimizes the number of counsel retained by all Indemnitees. Indemnitor agrees to keep counsel(s) for Indemnitees informed of the progress in the defense and disposition of such Claim and to consult with Institutions with regard to any proposed settlement. Company shall not settle any Claim that has an adverse effect on the rights of any Indemnitee hereunder that is not immaterial or that admits any liability by or imposes any obligation on any Indemnitee without the prior written consent of such Indemnitee, which consent shall not be unreasonably withheld, conditioned or delayed. An Indemnitee may not settle any Claim without the prior written consent of Company, which consent shall not be unreasonably withheld, conditioned or delayed.

### 9.2 Insurance.

- 9.2.1 Beginning at the time any Licensed Product is being commercially distributed or sold (other than for the purpose of obtaining Regulatory Approval) by Company, its Affiliate or its Sublicensee, Company shall, at its sole cost and expense, procure and maintain commercial general liability insurance in amounts not less than \$[\*\*\*] per incident and \$[\*\*\*] annual aggregate and naming the Indemnitees as additional insureds. During clinical studies of any such Licensed Product, Company shall, at its sole cost and expense, procure and maintain commercial general liability insurance in such equal or lesser amount as Broad shall require, naming the Indemnitees as additional insureds. Such commercial general liability insurance shall provide: (a) product liability coverage and (b) broad form contractual liability coverage for Company's indemnification obligations under Section 9.1 of this Agreement.
- 9.2.2 If Company elects to self-insure all or part of the limits described above in <u>Section 9.2.1</u> (including deductibles or retentions that are in excess of \$[\*\*\*] annual aggregate) such self-insurance program must be acceptable to Broad and its insurer in its sole discretion. The minimum amounts of insurance coverage required shall not be construed to create a limit of Company's liability with respect to its indemnification obligations under <u>Section 9.1</u> of this Agreement.
- 9.2.3 Company shall provide Broad with written evidence of such insurance upon request. Company shall provide Broad with written notice at least [\*\*\*] days prior to the cancellation, non-renewal or material change in such insurance. If Company does not obtain replacement insurance providing comparable coverage within such [\*\*\*] day period, Broad shall have the right to terminate this Agreement effective at the end of such [\*\*\*] day period without notice or any additional waiting periods.
- 9.2.4 Company shall maintain such commercial general liability insurance beyond the expiration or termination of this Agreement during: (a) the period that any Licensed Product is being commercially distributed or sold (other than for the purpose of obtaining Regulatory Approval) by Company, its Affiliate or Sublicensee; and (b) a reasonable period after the period referred to in (a) above which in no event shall be less than [\*\*\*] years.

### 10. TERM AND TERMINATION.

**10.1 Term.** The term of this Agreement shall commence on the Effective Date and, unless earlier terminated as provided in this Article 10, shall continue in full force and effect until the expiration of the last to expire Valid Claim (the "**Term**"). Upon such expiration, Company shall have a worldwide, perpetual, irrevocable, fully paid up, sublicensable license under the rights and licenses granted to Company under <u>Section 2.1</u>, subject to <u>Section 10.3.4</u>.

#### 10.2 Termination

10.2.1 <u>Termination Without Cause</u>. Company shall have the right to terminate this Agreement for any reason, with or without cause (i) in its entirety or with respect to the IP Asset Family 1 Patent Rights together with the IP Asset Family 2 Patent Rights, upon one hundred twenty (120) days' prior written notice to Broad or (ii) with respect to the IP Asset Family 3 Patent Rights, upon sixty (60) days' prior written notice to Broad.

### 10.2.2 Termination for Default.

10.2.2.1 Except as set forth in Section 10.2.2.2, in the event that either Party commits a material breach of its material obligations under this Agreement and fails to cure such breach within one hundred five (105) days (or forty-five (45) days in the case of failure to make any payment or in the case of a breach of Company's diligence obligations as set forth in Section 3.1) after receiving written notice thereof from the other Party, the other Party may terminate this Agreement immediately upon written notice to the Party in breach; provided that, if any portion of a Royalty or Milestone Payment is the subject of a good faith dispute between the Parties regarding an underpayment by Company to Broad, such disputed portion may be withheld by Company pending resolution of the dispute and Broad may not terminate this Agreement solely due to such underpayment, until such dispute is resolved, following which Company shall pay the relevant underpayment to Broad within forty-five (45) days to the extent such resolution is that such underpayment is due and payable.

10.2.2.2 If Company defaults in its material obligations under Section 9.2 to procure and maintain insurance, or if Company has in any event failed to comply with the notice requirements contained therein, and fails to cure such default within [\*\*\*] days after receiving written notice thereof from Broad, then Broad may terminate this Agreement immediately upon written notice to Company. If such default of Company's material obligations under Section 9.2 arises as a result of a breach by a Sublicensee of the terms of a Sublicense, Company may cure such breach by purchasing additional insurance that covers the gaps in coverage created by virtue of such Sublicensee's breach.

10.2.3 <u>Termination for Patent Challenge</u>. If Company or any of its Affiliates or Sublicensees directly or indirectly brings, assumes or participates in, or knowingly or willfully assists in bringing a Patent Challenge (except as required under a court order or subpoena), then the following shall apply: (a) if Company or any of its Affiliates is the party so bringing, assuming, participating in or assisting in such Patent Challenge, then Broad shall be entitled to (i) immediately terminate this Agreement upon written notice to Company in the event such Patent Challenge relates to IP Asset Family 1 Patent Rights or IP Asset Family 2 Patent Rights or

- (ii) immediately terminate the IP Asset Family 3 License if such Patent Challenge relates to IP Asset Family 3 Patent Rights, and (b) if a Sublicensee is the party so bringing, assuming, participating in or assisting in such Patent Challenge, then (i) Broad shall be entitled to immediately terminate the rights hereunder as and to the extent sublicensed to a Sublicensee upon written notice to Company and (ii) Broad shall grant Company a period not to exceed [\*\*\*] days from the date of notice by Broad to Company of its intention to terminate the Agreement due to such Sublicensee bringing, assuming, participating in or assisting in a Patent Challenge that relates to IP Asset Family 1 Patent Rights or IP Asset Family 2 Patent Rights or terminate the IP Asset Family 3 License if such Patent Challenge relates to IP Asset Family 3 Patent Rights, during which period Company may terminate any and all Sublicenses with such Sublicensee. If, pursuant to the foregoing clause (b)(ii), during such [\*\*\*] day period, Company terminates such agreement(s) if such Patent Challenge that relates to IP Asset Family 1 Patent Rights or IP Asset Rights or terminates the sublicense under the IP Asset Family 3 License if such Patent Challenge relates to IP Asset Family 3 Patent Rights, then Broad shall not be entitled to terminate this Agreement in its entirety by virtue of such Sublicensee bringing, assuming, participating in or assisting in such Patent Challenge that relates to IP Asset Family 1 Patent Rights or IP Asset Family 2 License, as applicable, during such [\*\*\*] day period, then Broad shall be entitled to immediately terminate this Agreement in its entirety upon written notice to Company thereof in the event such Patent Challenge relates to IP Asset Family 1 Patent Rights or IP Asset Family 2 Patent Rights or terminate the IP Asset Family 3 License if such Patent Challenge relates to IP Asset Family 1 Patent Rights or IP Asset Family 2 Patent Rights or terminate the IP Asset Family 3 License if such Patent Challenge relates to
- 10.2.4 <u>Bankruptcy</u>. Broad may terminate this Agreement upon notice to Company if Company becomes subject to a Bankruptcy Event or in the event of dissolution or cessation of operations of the Company, <u>provided</u> that Broad shall have no right to terminate this Agreement in the event of any cessation of operations of the Company where (a) Company is continuing to fulfill its diligence obligations as set forth in <u>Section 3.1</u> through its Affiliates or Sublicensees or (b) Company has ceased its operations and is actively seeking financing or a sale of its assets or business (whether by merger, sale of assets or otherwise), <u>provided</u>, in the case of this clause (b), that such cessation does not continue for more than [\*\*\*] days.
- 10.2.5 <u>Termination without Prejudice</u>. Either Party's right of termination in this <u>Section 10.2</u> shall be in addition and without prejudice to, and shall not constitute a waiver of, any other right or remedy such Party may have at law, in equity or under this Agreement.

### 10.3 Effect of Termination

10.3.1 <u>Termination of Rights</u>. Upon expiration or termination of this Agreement by either Party pursuant to any of the provisions of Section 10.2:

10.3.1.1 the rights and licenses granted to Company under <u>Article 2</u> shall terminate, all rights in and to and under the Licensed Patent Rights shall revert to Broad (or DFCI or MGH, as applicable) and neither Company nor its Affiliates may make any further use or exploitation of the Licensed Patent Rights; and

10.3.1.2 all existing Sublicenses shall automatically terminate [\*\*\*] days following the effective date of termination of this Agreement; provided that, if any Sublicensee is (i) an Affiliate of Company or (ii) in material default of any material provision of the applicable Sublicense such that Company would have the right to terminate the Sublicense ((i) and (ii) together, "Ineligible Sublicensees") then the applicable Sublicense to which such Sublicensee is a party shall terminate effective immediately upon termination of this Agreement. Upon termination of this Agreement pursuant to any of the provisions of Section 10.2, (A) Company shall promptly provide notice of such termination to any Sublicensee, (B) each Sublicensee that is not an Ineligible Sublicensee shall have the right to enter into a separate license agreement directly with Broad (a "Direct License") on substantially the same non-economic terms and conditions set forth in the Sublicense and on economic terms providing for the payment by such Sublicensee to Broad of the consideration that otherwise would have been payable to Broad if the applicable Sublicense and this Agreement were still simultaneously in effect, and (C) Broad shall automatically grant each such Sublicensee a temporary continuation (to expire upon the earlier of (x) execution of the Direct License or (y) the date that is [\*\*\*] days following termination of this Agreement) of the rights and obligations such Sublicensee had as a Sublicensee under this Agreement (a "**Temporary Extension**"); <u>provided</u> that, under both the Direct License and the Temporary Extension, (a) Broad shall not have (i) any obligations that are greater than or inconsistent with the obligations of Broad under this Agreement or the nature of Broad as an academic or non-profit entity; or (ii) any fewer rights than Broad has under this Agreement; (b) there shall be no representations, warranties, expenses or liabilities of or on Broad that are not included in this Agreement; (c) all obligations arising prior to execution of the Direct License and grant of the Temporary Extension shall remain the responsibility of Company and Broad shall be released from any and all liability relating to such obligations; (d) the terms of such Direct License and Temporary Extension shall provide for payment to Broad of the same consideration that would have been payable to Broad if the applicable Sublicense and this Agreement were still simultaneously in effect; and (e) such modifications shall be included as are reasonably necessary to accommodate the functional and structural differences between Company and Broad. By way of example and not limitation of the foregoing clause (d), if the Sublicense required payment to Company of a license fee and Broad would have been entitled to receive a percentage of such payment under Section 4.5 of the Agreement, then Broad shall continue to be entitled, under the Temporary Extension or Direct License, to the same share of that same license fee payment under the Sublicense that Broad would have received had this Agreement and the Sublicense been simultaneously in effect. If any Sublicensee desires to enter into a Direct License, it shall wholly be the responsibility of that Sublicensee to notify Broad of such desire no later than [\*\*\*] days after the effective date of termination of this Agreement. If Broad and the applicable Sublicensee, for any reason, do not enter into a Direct License within [\*\*\*] days after the effective date of termination of the Agreement, the applicable Sublicense and Temporary Extension, and all rights granted thereunder, shall automatically terminate.

10.3.2 <u>Accruing Obligations</u>. Termination or expiration of this Agreement shall not relieve the Parties of obligations accruing prior to such termination or expiration, including obligations to pay amounts accruing hereunder up to the effective date of termination or expiration. After the effective date of termination or expiration (except in the case of termination by Broad pursuant to <u>Section 10.2</u>), Company, its Affiliates and Sublicensees may sell Licensed Products then in stock; <u>provided</u> that Company shall pay the applicable Royalties and other payments to Broad in accordance with <u>Article 4</u>, provide reports and audit rights to Broad pursuant to <u>Article 5</u> and maintain insurance in accordance with <u>Section 9.2</u>.

10.3.3 <u>Disposition of Company Developments</u>. In the event this Agreement is terminated prior to expiration of the Term, Company shall:

10.3.3.1 at Broad's request, negotiate in good faith with Broad during the [\*\*\*] day period after such termination the terms on which Company will grant Broad a sublicensable license to any Company Patent Rights that improve or are otherwise related to the Licensed Patent Rights or that cover a Licensed Product that Broad is interested in pursuing either themselves or through a licensee; <u>provided</u> that, the terms of any such license shall not conflict with Company's obligations under its then existing contracts and applicable law and its officers' and directors' fiduciary obligations;

10.3.3.2 provide Broad with access to and, at Broad's request, deliver to Broad all documents, filings, data and other information in Company's or its Affiliates' possession or control (other than documents, filings, data and other information owned by Sublicensees or Third Parties) relating to any of the Licensed Patent Rights or Licensed Products, including all records required by Regulatory Authorities to be maintained with respect to Licensed Products, all regulatory filings, approvals, reports, records, correspondence and other regulatory materials (including any related to reimbursement or pricing approvals), and all documents, data and other information related to clinical studies and other studies of Licensed Products (collectively, "Documentation and Approvals") if and to the extent that the provision of, access to and delivery of such Documentation and Approvals shall not conflict with Company's obligations under its then existing contracts and applicable law; and

10.3.3.3 permit Broad and its licensees and sublicensees to utilize, reference, cross reference, have access to, incorporate in applications and filings (including with any Regulatory Authority in furtherance of applications for regulatory approval), and otherwise have the benefit of all Documentation and Approvals if and to the extent that the foregoing right to utilize, reference, cross reference, have access to, incorporate such Documentation and Approvals shall not conflict with Company's obligations under its then existing contracts and applicable law; provided, however, that notwithstanding anything in the foregoing to the contrary, the right to utilize, reference, cross reference, have access to, incorporate such Documentation and Approvals shall not be deemed or construed as a grant of any license or other right under any patent or patent application Controlled by Company, its Affiliates or any Third Party.

10.3.4 Effects of Termination of IP Asset Family 1 and IP Asset Family 2 License. If this Agreement is terminated by Company pursuant to Section 10.2.1 solely with respect to the IP Asset Family 1 Patent Rights and IP Asset Family 2 Patent Rights, then the IP Asset Family 3 License as set forth in Section 2.1.2 shall automatically be amended, with no further action by the Parties, as follows: the term "Licensed Products" shall be replaced with the term "IP Asset Family 3 Products".

**10.4 Survival.** The Parties' respective rights, obligations and duties under <u>Articles 5</u>, <u>10</u> and <u>11</u>, <u>Sections 8.3, 8.4</u>, <u>8.5</u>, <u>9.1</u>, the first sentence of <u>9.2.3</u>, and <u>9.2.4</u>, as well as any rights,

obligations and duties which by their nature extend beyond the expiration or termination of this Agreement, shall survive any expiration or termination of this Agreement. In addition, Company's obligations under <u>Section 4.3</u> and <u>Section 4.4</u>, with respect to any sale, performance or other transfer of Licensed Products occurring under <u>Section 10.3.2</u> after the Term, shall survive such expiration or termination.

### 11. MISCELLANEOUS.

## 11.1 Confidentiality

11.1.1 "**Broad Confidential Information**" means (a) any information related to Prosecution of Licensed Patent Rights provided to Company by Broad; (b) any information or material in tangible form provided to Company by Broad in accordance with the terms of and in connection with the exercise by Broad of its rights or fulfillment by Broad of its obligations under this Agreement that is marked as "confidential" or proprietary by an Broad at the time it is disclosed to Company or is of such a nature as would be understood by a reasonable person to be confidential or proprietary; and (c) information that is furnished orally by Broad to Company in accordance with the terms of and in connection with the exercise by Broad of its rights or fulfillment by Broad of its obligations under this Agreement if Broad identifies such information as "confidential" or proprietary in writing by a memorandum delivered to Company within [\*\*\*] days after the date of disclosure. "**Company Confidential Information**" means (i) the Development Plan; (ii) any reports or notices prepared by Company and provided to Broad pursuant to Section 3.3, Section 3.4, Section 4.3.5, Section 4.5 or Section 5.1.1, (iii) any information disclosed to Broad pursuant to Section 5.3, Section 6.1.2 or Section 6.1.4 and (iv) any copies of Sublicenses, or information extracted therefrom, provided by Company to Broad under Section 2.5.2. The terms of this Agreement constitute the Confidential Information of both Parties. "**Confidential Information**" means the Broad Confidential Information and the Company Confidential Information, as applicable. For clarity, Company shall have no obligation to disclose to Broad any confidential information of Company that does not constitute Company Confidential Information hereunder.

11.1.2 During the Term and for a period of [\*\*\*] after the termination or expiration of this Agreement, (a) Company shall maintain in confidence and shall not disclose to any Third Party any Broad Confidential Information, and (b) Broad shall maintain in confidence and shall not disclose to any Third Party any Company Confidential Information; provided that Broad may disclose to DFCI and MGH (i) this Agreement including any Exhibits, and (ii) such Confidential Information of Company as DFCI or MGH, as the case may be, reasonably requests, provided that any disclosure under the foregoing clause (i) shall be made in confidence to DFCI or MGH, as the case may be, and that any disclosure under the foregoing clause (ii) shall be under terms of a written confidentiality agreement prohibiting the use and further disclosure by DFCI or MGH, as the case may be, of such Confidential Information on terms as least as restrictive as those contained herein. Each Party shall take all reasonable steps to protect the Confidential Information of the other Party with the same degree of care used to protect its own confidential or proprietary information. Neither Party shall use the Confidential Information of the other Party for any purpose other than those contemplated by this Agreement.

The foregoing obligations under this <u>Section 11.1.2</u> shall not apply to:

- (i) information that is known to the receiving Party or independently developed by the receiving Party prior to the time of disclosure without use of or reference to the other Party's Confidential Information, in each case, to the extent evidenced by contemporaneous written records;
- (ii) information that is independently developed by the receiving Party at or after the time of disclosure without use of or reference to the other Party's Confidential Information, to the extent evidenced by contemporaneous written records;
- (iii) information disclosed to the receiving Party by a Third Party that is not legally prohibited from making such disclosure; or
- (iv) information that is publicly disclosed at or prior to the time of disclosure hereunder or becomes patented, published or otherwise known to the general public, except through breach of this Agreement by the receiving Party, its employees, agents, successors or assigns.
- 11.1.3 Permitted Disclosures. Notwithstanding Section 11.1.2, either Party may disclose Confidential Information of the other Party to such Party's Affiliates and (a) [\*\*\*]; (b) its and their employees, consultants, agents, and advisors, on a need to know basis, each of whom prior to disclosure must be bound by written obligations of confidentiality and non-use of substantially equivalent or greater scope and duration than those set forth in this Article 11; and (c) its and their accountants and lawyers, on a need to know basis, each of whom prior to disclosure must be bound by written or legally enforceable professional ethical obligations of confidentiality and non-use of substantially equivalent or greater scope and duration than those set forth in this Article 11; provided that, the scope of Confidential Information that may be disclosed to any Person under this Section 11.1.3 is limited to the terms of this Agreement and any notices given hereunder and not any other Confidential Information of such other Party unless otherwise agreed to in writing by such other Party. In addition, notwithstanding Section 11.1.2, either Party may disclose Confidential Information of the other Party to the extent such disclosure is reasonably necessary in the following instances set forth below. In any such event, to the extent legally practicable, the receiving Party shall (i) give reasonable advance notice to the other Party of such disclosure; and (ii) take reasonable steps to avoid or minimize the scope of such disclosure by securing confidential treatment of such Confidential Information prior to its disclosure (whether through protective orders or otherwise):
- 11.1.3.1 in the case of Broad or Company as the receiving Party, prosecuting or defending litigation in accordance with <u>Article 7</u> of this Agreement;
- 11.1.3.2 in the case of Company as the receiving Party, making filings with the Securities and Exchange Commission or foreign equivalent, any stock exchange or market, or any Regulatory Authorities, which shall include publicly disclosing or filing this Agreement as a "material agreement" in accordance with applicable law or applicable stock exchange regulations; and
- 11.1.3.3 in the case of Broad or Company as the receiving Party, complying with applicable laws, rules, regulations or orders requiring submission of such information to governmental authorities, including disclosures ordered by the FDA or similar authorities, courts of competent jurisdiction or other government authorities or agencies.

- 11.2 Use of Name. Except as provided below, Company shall not, and shall ensure that its Affiliates and Sublicensees shall not, use or register the name "The Broad Institute, Inc.," "Dana Farber Cancer Institute," "The Massachusetts General Hospital," or any variation, adaptation, or abbreviation thereof (alone or as part of another name) or any logos, seals, insignia or other words, names, symbols or devices that identify any Institution or any Institution's affiliated school, unit, division or affiliate ("Institution Names") for any purpose except with the prior written approval of, and in accordance with restrictions required by, the applicable Institution; provided that, Company may use Institution Names in accordance with Section 11.1 as required to convey that this Agreement, and the licenses granted hereunder, exist and have been entered into, between Company and Broad. Without limiting the foregoing, Company shall, and shall ensure that its Affiliates and Sublicensees shall, cease all use of Institution Names as permitted under or in connection with this Agreement on the termination or expiration of this Agreement except as otherwise approved in writing by Broad. This restriction shall not apply to any information required by law to be disclosed to any governmental entity.
- 11.3 Press Release. Notwithstanding the provisions of Section 11.2, in addition to (and not in limitation of) the disclosure permitted under Section 11.1.3, the Parties may issue a press release in a mutually agreeable form acceptable to the Parties. Each Party agrees that it will not issue a press release or other public statement without obtaining the prior written approval of the other Parties.
- 11.4 No Security Interest. Company shall not enter into any agreement under which Company grants to or otherwise creates in any Third Party a security interest in this Agreement or any of the rights granted to Company herein. Any grant or creation of a security interest purported or attempted to be made in violation of the terms of this Section 11.4 shall be null and void and of no legal effect.
- 11.5 Entire Agreement. This Agreement (including any exhibits and schedules attached hereto) is the sole agreement with respect to the subject matter hereof and except as expressly set forth herein, supersedes all other agreements and understandings between the Parties with respect to the same.
- 11.6 Notices. Unless otherwise specifically provided, all notices required or permitted by this Agreement shall be in writing and shall be delivered personally, by confirmed facsimile transmission, electronic mail if an email address is provided below or subsequently provided by a Party pursuant to a notice in accordance with this Section 11.6, expedited delivery or certified mail, postage prepaid, return receipt requested, to the following addresses, unless the Parties are subsequently notified of any change of address in accordance with this Section 11.6:

If to Company: Neon Therapeutics, Inc.

> 215 First Street Cambridge, MA 02142 Facsimile: (866) 548-5990

Attn: Chief Executive Officer

With a copy to:

WilmerHale 60 State Street Boston, MA 02019 Facsimile: 617-526-5000 Attn: Richard Hoffman

If to Broad: The Broad Institute, Inc.

Senior Director of Strategic Alliances

415 Main Street Cambridge, MA 02142

Email: [\*\*\*]
Attn: [\*\*\*]

Any notice shall be deemed to have been received as follows: (a) by personal delivery or expedited delivery, upon receipt; (b) by facsimile, one business day after transmission or dispatch; (c) by certified mail, as evidenced by the return receipt. If notice is sent by facsimile, a confirming copy of the same shall be sent by mail to the same address.

## 11.7 Dispute Resolution; Special Arbitration

11.7.1 <u>Dispute Resolution</u>. Except as otherwise specified, the Parties agree that in the event of any dispute arising out of or relating to this Agreement (each, a "**Dispute**"), either Party by written notice to the other Party may have such Dispute referred for resolution to the Chief Executive Officer of Company and the Chief Operating Officer of Broad (together, the "**Executive Officers**"). The Executive Officers shall meet promptly to discuss the matter submitted and to determine a resolution. If the Executive Officers are unable to resolve the Dispute within [\*\*\*] days after it is referred to them, then either Party may seek to resolve such Dispute through mediation conducted in the English language under the then current Center for Public Resources (CPR) Model Procedure for Mediation of Business Disputes. If mediation is pursued under the foregoing sentence but fails to lead to a mutual resolution of the Dispute within [\*\*\*] days after the commencement of mediation proceedings, or if mediation is not pursued under the foregoing sentence, the Parties shall thereafter refer an Arbitration Dispute to arbitration in accordance with <u>Section 11.7.2</u> and, with respect to any other Dispute, may thereafter pursue all other rights and remedies available to them under this Agreement, including the right to terminate the Agreement, and the matter may be brought by a Party as a Suit in a court of competent jurisdiction in accordance with <u>Section 11.8</u> hereof.

11.7.2 <u>Special Arbitration</u>. Any Arbitration Dispute will be finally settled by binding arbitration in accordance with the procedures set forth in this <u>Section 11.7.2</u> and the Commercial Arbitration Rules of the AAA then in effect, by three (3) arbitrators, one of whom will be designated by each Party (and will be required to have commercial experience in the licensing of biopharmaceutical technologies) and the third of whom will be designated by the two so designated (such panel, the "**Arbitrators**"). The arbitration shall be conducted in English

and held in Boston, Massachusetts. Each Party will prepare and submit a written summary of such Party's position and any relevant evidence in support thereof to the Arbitrators within [\*\*\*] days of selection of the Arbitrators. Upon receipt of such summaries from both Parties, the Arbitrators will provide copies of the same to the other Party. The Arbitrators will be authorized to solicit briefing or other submissions on particular questions. Within [\*\*\*] days of the delivery of such summaries by the Arbitrators, each Party will submit a written rebuttal of the other Party's summary and may also amend and re-submit its original summary. Oral presentations will not be permitted unless otherwise requested by the Arbitrators. The Arbitrators will make a final decision with respect to the Arbitration Dispute within [\*\*\*] days following receipt of the last of such rebuttal statements submitted by the Parties. In the case of an Arbitration Dispute arising under Section 4.5, the Arbitrators will make a determination of the relative value to be attributed to a Sublicense of the Licensed Patent Rights as part of an overall sublicense agreement, which determination shall be fair and reasonable to the Parties in light of the totality of the circumstances (without taking into account the sublicense income rates set forth in Section 4.5.1) and shall comply with the terms of this Agreement. In the case of an Arbitration Dispute arising under Section 4.4.2, the Arbitrators will make a determination of the credit against the Royalties due to Broad for Licensed Products under Section 4.4.1 of this Agreement that Company may take on account of the amounts actually paid by Company to a Third Party, which determination shall be fair and reasonable to the Parties in light of the totality of the circumstances (without altering the percentage of such Third Party payments for which Company may take a credit as set forth in Section 4.4.1) and shall comply with the terms of this Agreement. The Arbitrators will provide the Parties with a written statement setting forth the basis of the determination in connection therewith. Each Party shall bear its own attorneys' fees, costs, and disbursements arising out of the arbitration, and shall pay an equal share of the fees and costs of the Arbitrators. The decision of the Arbitrators shall be final and may be entered in and enforced by any court of competent jurisdiction. Notwithstanding anything in this Agreement to the contrary, a Party may seek a temporary restraining order or a preliminary injunction from any court of competent jurisdiction in order to prevent immediate and irreparable injury, loss, or damage on a provisional basis, pending the award of the Arbitrators on the ultimate merits of any Arbitration Dispute. All proceedings and decisions of the Arbitrators shall be deemed Confidential Information of each of the Parties, and shall be subject to Section 11.1.

11.8 Governing Law and Jurisdiction. This Agreement shall be governed by, and construed in accordance with the substantive laws of the Commonwealth of Massachusetts, without giving effect to any choice or conflict of law provision, except that questions affecting the construction and effect of any patent shall be determined by the law of the country in which the patent shall have been granted. Any action, suit or other proceeding arising under or relating to this Agreement (a "Suit") shall be brought in a court of competent jurisdiction in the Commonwealth of Massachusetts, and the Parties hereby consent to the personal jurisdiction of the state and federal courts sitting in the Commonwealth of Massachusetts. Each Party agrees not to raise any objection at any time to the laying or maintaining of the venue of any Suit in any of the specified courts, irrevocably waives any claim that Suit has been brought in any inconvenient forum and further irrevocably waives the right to object, with respect to any Suit, that such court does not have any jurisdiction over such Party.

**11.9 Binding Effect.** This Agreement shall be binding upon and inure to the benefit of the Parties and their respective legal representatives, successors and permitted assigns.

- **11.10 Headings**. Section and subsection headings are inserted for convenience of reference only, do not form a part of this Agreement and shall not be considered in construing this Agreement.
- **11.11 Counterparts**. The Parties may execute this Agreement 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.
- **11.12 Amendment; Waiver**. This Agreement may be amended, modified, superseded or canceled, and any of the terms may be waived, only by a written instrument executed by each Party or, in the case of waiver, by the Party waiving compliance. The delay or failure of either Party at any time or times to require performance of any provisions hereof shall in no manner affect the rights at a later time to enforce the same. No waiver by either Party of any condition or of the breach of any term contained in this Agreement, whether by conduct, or otherwise, in any one or more instances, shall be deemed to be, or considered as, a further or continuing waiver of any such condition or of the breach of such term or any other term of this Agreement.
- **11.13 No Agency or Partnership**. Nothing contained in this Agreement shall give either Party the right to bind the other, or be deemed to constitute either Party as agent, partner or joint venturer of the other or any third party.
- 11.14 Assignment and Successors. This Agreement may not be assigned by Company, whether by operation of law or otherwise, without the consent of Broad, except that Company may assign or transfer the Agreement without the consent of Broad, to a successor in interest of all or substantially all of Company's assets or business related to the Licensed Products or the Agreement, whether by merger, consolidation, sale of assets, or Change of Control or other transaction, provided that (a) Company shall provide Broad with a written notice of such assignment or Change of Control including the identity of the assignee, transferee or controlling party, and a copy of the assignment and assumption agreement or other documentary evidence sufficient to demonstrate Company's compliance with this Section 11.14 within [\*\*\*] days after such assignment or Change of Control, and (b) such assignee or transferee agrees in writing to assume the obligations to Broad that are being assigned or transferred. Failure of an assignee to agree to be bound by the terms hereof or failure of Company to notify Broad and provide copies of assignment documentation as specified above shall be grounds for termination of this Agreement for default. Any attempted assignment in contravention of this Section 11.14 shall be null and void.
- **11.15 Force Majeure**. Neither Party shall be responsible for delays resulting from causes beyond the reasonable control of such Party, including fire, explosion, flood, war, strike, or riot, <u>provided</u> that the nonperforming Party uses commercially reasonable efforts to avoid or remove such causes of nonperformance and continues performance under this Agreement with reasonable dispatch whenever such causes are removed.
- **11.16 Interpretation**. Each Party hereto acknowledges and agrees that: (a) it or its counsel reviewed and negotiated the terms and provisions of this Agreement and has contributed to its revision; (b) the rule of construction to the effect that any ambiguities are resolved against the drafting Party shall not be employed in the interpretation of this Agreement; and (c) the terms

and provisions of this Agreement shall be construed fairly as to both Parties hereto and not in favor of or against either Party, regardless of which Party was generally responsible for the preparation of this Agreement. Except as otherwise explicitly specified to the contrary, (i) words in the singular or plural form include the plural and singular form, respectively; (ii) the word "or" has the inclusive meaning that is typically associated with the phrase "and/or"; (iii) the terms "including", "include(s)", "such as", "e.g." and "for example" will be deemed to be followed by "without limitation"; (iv) the term "will" means "shall"; and (v) words of any gender will be applicable to all genders.

**11.17 Severability**. If any provision of this Agreement is or becomes invalid or is ruled invalid by any court of competent jurisdiction or is deemed unenforceable, it is the intention of the Parties that the remainder of this Agreement shall not be affected.

[The remainder of this page intentionally left blank; signature page follows]

**IN WITNESS WHEREOF**, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the date first written above.

## THE BROAD INSTITUTE, INC.:

Title:

President

By:	/s/ Issi Rozen
Name:	Issi Rozen
Title:	Sr. Div, Strategic Alliances
NEON	THERAPEUTICS, INC.:
	THERAPEUTICS, INC.: /s/ Cary Pfeffer

[Signature Page to License Agreement]

## Exhibit A

## **Licensed Patent Rights**

This <u>Exhibit A</u> shall be updated from time to time by mutual written agreement of the Parties. Any Licensed Patent Rights that come into existence after the Effective Date shall be categorized into the appropriate IP asset family and included in this <u>Exhibit A</u> accordingly. [\*\*\*].

# 1. <u>IP Asset Family 1 Patent Rights</u>

Broad Ref#	Cntry	AppNumber	FilDate	PubDate	PubNumber	AppTitle
[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]			[***]
[***]	[***]	[***]	[***]			[***]
[***]	[***]	[***]	[***]			[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]			[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]			[***]
[***]	[***]	[***]	[***]			[***]

[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]			[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]			[***]
[***]	[***]	[***]	[***]			[***]
[***]	[***]	[***]	[***]			[***]
[***]	[***]	[***]	[***]			[***]
[***]	[***]	[***]	[***]			[***]
[***]	[***]	[***]	[***]			[***]

[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
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[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]

[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]			[***]
[***]	[***]	[***]	[***]			[***]

## 2. IP Asset Family 2 Patent Rights

Broad Ref#	Cntry	AppNumber	FilDate	PubDate	PubNumber	AppTitle
[***]	[***]	[***]	[***]			[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]			[***]

## 3. IP Asset Family 3 Patent Rights

Broad Ref#	Cntry	AppNumber	FilDate	PubDate	PubNumber	AppTitle
[***]	[***]	[***]	[***]			[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]					[***]
[***]	[***]	[***]	[***]			[***]
[***]	[***]	[***]	[***]			[***]
[***]	[***]	[***]	[***]			[***]
[***]	[***]	[***]	[***]			[***]
[***]	[***]					[***]

Exhibit B

**Software License** 

[Attached.]

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## END USER LICENSE AGREEMENT

This End User License Agreement ("Agreement") is made between The Broad Institute, Inc. with a principal address at 415 Main Street, Cambridge, MA 02142 ("Broad") and Neon Therapeutics, Inc., with a principal place of business at 215 First Street, Cambridge, MA 02142 ("Licensee") and is effective November 13, 2015 ("Effective Date").

WHEREAS, Licensee desires to license the Programs (as defined below) and Broad wishes to have the Programs utilized in the public interest, subject only to the royalty-free, nonexclusive, nontransferable license rights of the United States Government pursuant to 48 CFR 52.227-14; and

WHEREAS, Broad desires to grant a license on the following terms and conditions.

NOW, THEREFORE, in consideration of the promises and covenants made herein, the parties hereto agree as follows:

#### 1. DEFINITIONS

- 1.1 "Control" shall mean, with respect to a Program, the ability to grant a commercial license or sublicense for such Program without (a) violating the terms of any third party agreement, (b) violating any applicable law or (c) being required to make any payment to any third party in connection with such grant. Cognates of the word "Control" shall have correlative meanings.
- 1.2 "Licensed Product" shall mean any diagnostic, prognostic, preventative or therapeutic product or service for humans, in each case that is owned or controlled by Neon.
- 1.3 "Licensed Use" shall mean performance in the field(s) of (a) in the case of a not-for-profit licensee, research and/or services that apply the Programs in analyses of nucleic acid sequences as a contract service or in patient care for which Licensee intends to seek payment from third parties, or (b) in the case of a for-profit licensee, research and/or services, which services may include diagnostic and/or companion diagnostic services, that apply the Programs in [\*\*\*] in connection with the development, manufacture, use, sale, practice, performance, importation, exportation, commercialization or other exploitation of any Licensed Product.
- 1.4 "Patent License" shall mean the License Agreement entered into by the parties on even date herewith.
- 1.5 "Programs" shall mean the object and source code for the following software programs: [\*\*\*] if any, as they exist on the Effective Date and can be downloaded from [\*\*\*] on the Effective Date as well as any updated releases of such Programs that Broad, in its sole discretion, makes generally available to end users while Broad is Controlling such Programs and such updated releases.

1.6 "Term" shall commence on the Effective Date and shall continue in effect for a period of one (1) year from the Effective Date. The Term shall be automatically extended for additional (1) year period(s) for so long as Licensee maintains the Company Exclusive License (as defined in the Patent License), unless Licensee notifies Broad at least [\*\*\*] days prior to the end of a Term that it does not want to renew the Agreement. Notwithstanding the foregoing, the Term shall terminate automatically upon termination or expiration of the Company Exclusive License under the Patent License.

### 2. LICENSE

- 2.1 Grant. Subject to the terms of this Agreement, Broad hereby grants to Licensee, solely to conduct a Licensed Use, a non-exclusive, sublicensable (solely in accordance with Section 2.2 below) license to download, reproduce, display, execute, prepare derivative works of and distribute (solely in accordance with Section 2.2 below) the Programs.
- 2.2 No Sublicensing or Additional Rights. Licensee shall not sublicense or distribute the Programs or any derivative works thereof, in whole or in part, without prior written permission from Broad, except that Licensee shall have the right to sublicense the rights granted to Licensee under Section 2.1 (a) to an entity performing outsourced services for Licensee or its sublicensees, (b) to an entity that is a licensee of, or is collaborating with, Licensee to develop and/or commercialize one or more Licensed Product(s), or (c) to an entity developing or enhancing the Programs for Licensee; provided that, (i) in the case of the foregoing clauses (a) and (c), Licensee shall only be entitled to sublicense and distribute the rights granted to Licensee under Section 2.1 to one tier of sublicensees (i.e., such entity performing outsourced services or developing or enhancing the Programs shall not have the right to further sublicense or distribute the Programs) and (ii) in the case of the foregoing clause (b), [\*\*\*]. Licensee shall ensure that all of its users are bound by the terms of this Agreement and that all of its sublicensees agree in a written agreement to be bound by the terms of this Agreement applicable to Licensee. Each such permitted sublicensee shall agree in such written agreement not to assign, sublicense, distribute or otherwise transfer the Programs in any manner, except with respect to any permitted sublicensee covered by clause (b) above, [\*\*\*]. Any such written agreement shall contain a statement that Broad is an intended third party beneficiary of such agreement for the purpose of enforcing such agreement against such sublicensee. Notwithstanding any such sublicense agreement, Licensee shall remain primarily liable to Broad for all of Licensee's duties and obligations contained in this Agreement, and any act or omission of a direct or indirect sublicensee which would be a breach of this Agreement if performed by Licensee shall be deemed to be a breach by Licensee of this Agreement. Licensee further agrees that it shall not put any Program or derivative work thereof on a network, server, or other similar technology that may be accessed by anyone other than the Licensee, its employees and its permitted sublicensees who are bound by the terms of this Agreement.
- 2.3 License Limitations. Nothing in this Agreement shall be construed to confer any rights upon Licensee by implication, estoppel, or otherwise to any computer software, trademark, intellectual property, or patent rights of Broad, or of any other entity, except as expressly granted herein. Licensee agrees that the Programs, in whole or part, shall not be used as the basis of a commercial software or hardware product. For clarity, the foregoing sentence shall not be

interpreted to limit Licensee's right to use the software in connection with the commercialization of any Licensed Product in accordance with the Licensed Use. Licensee further agrees not to: (a) assign, sublicense, distribute or otherwise transfer (except as expressly set forth in Section 2.2) to any third party the Programs or any derivative works thereof; (b) use or reproduce the Programs in violation of the license grant in Section 2.1; (c) remove any proprietary notices on or in the Programs; (d) use the Programs in an illegal or fraudulent manner; (e) take an action or fail to take an action that would make any Program subject to an open source or similar license; or (f) disclose the source code of the Programs to any person or entity, other than a permitted sublicensee.

- 2.4 Technical Support for [\*\*\*]. During the Term, Broad shall endeavor to provide technical support for [\*\*\*] through [\*\*\*], solely to the extent and for so long as Broad, in its sole discretion, generally provides such support to end-users of [\*\*\*], in a manner that is reasonable and standard for routine Program technical support operations at Broad.
- 2.5 Components. The Programs may include components that may be accompanied by separate license terms. Some of the components may be open source packages, developed independently, and accompanied by separate license terms. Licensee's license rights with respect to individual components accompanied by separate license terms are defined by those terms; nothing in this Agreement shall restrict, limit, or otherwise affect any rights or obligations Licensee may have, or conditions to which Licensee may be subject, under such license terms.

### 3. OWNERSHIP OF INTELLECTUAL PROPERTY

Licensee acknowledges that title to the Programs shall remain with Broad or its licensors, as applicable. The Programs are marked with the following Broad copyright notice and notice of attribution to contributors. Licensee shall retain such notices on all copies of the Programs. Licensee agrees to include appropriate attribution if any results obtained from use of the Programs are included in any publication.

Copyright Notice:
[***]
[***]
[***]
[***]
[***]
[***]
[***]
[***]
Notice of attribution:

The [*Program name*] program was made available by The Broad Institute, Inc.

Except as stated above for notice and attribution purposes, Licensee shall not use the name of "The Broad Institute, Inc." or any variation, adaptation, or abbreviation thereof, or of any of its directors, officers, faculty, employees, agents, or affiliated investigators or any trademark owned by Broad, or any terms of this Agreement in any promotional material or other public announcement or disclosure without the prior written consent of Broad. The foregoing notwithstanding, Licensee may make factual statements during the term of this Agreement that a license has been granted by Broad as provided in this Agreement.

Licensee acknowledges that the Programs may require the use of third party databases or software, and it is Licensee's responsibility to obtain such licenses directly from such third parties for such databases and software.

### 4. INDEMNIFICATION AND INSURANCE

- 4.1 Licensee shall indemnify, defend, and hold harmless Broad, and its respective directors, officers, faculty, students, employees, affiliated investigators, and agents, and their respective successors, heirs and assigns ("Indemnitees"), against any liability, damage, loss, or expense (including reasonable attorneys' fees and expenses) incurred by or imposed upon any of the Indemnitees in connection with any claims, suits, actions, demands or judgments arising out of any theory of liability (including, without limitation, actions in the form of tort, warranty, or strict liability and regardless of whether such action has any factual basis) ("Claim") pursuant to (a) any right, license or sublicense granted under this Agreement or (b) Licensee's performance or exercise of rights under this Agreement.
- 4.2 The Indemnitees agree to provide Licensee with prompt written notice of any Claim for which indemnification is sought under this Agreement. Licensee agrees, at its own expense, to provide attorneys reasonably acceptable to Broad to defend against any such Claim. The Indemnitees shall cooperate with Licensee, at Licensee's expense, in such defense and shall permit Licensee to conduct and control such defense and the disposition of such Claim (including without limitation all decisions relative to litigation, appeal, and settlement); provided, however, that any Indemnitee shall have the right to retain its own counsel, at the expense of Licensee, if representation of such Indemnitee by the counsel retained by Licensee would be inappropriate because of actual or potential differences in the interests of such Indemnitee and any other party represented by such counsel; and provided, further that, in such event, Broad agrees to use diligent efforts to select counsel, and to cause any other Indemnitees to select counsel, that minimizes the number of counsel retained by all Indemnitees. Licensee agrees to keep counsel(s) for Indemnitees informed of the progress in the defense and disposition of such Claim and to consult with Broad with regard to any proposed settlement. Licensee shall not settle any Claim that has an adverse effect on the rights of any Indemnitee hereunder that is not immaterial or that admits any liability by or imposes any obligation on any Indemnitee without the prior written consent of such Indemnitee, which consent shall not be unreasonably withheld, conditioned or delayed. An Indemnitee may not settle any Claim without the prior written consent of Licensee, which consent shall not be unreasonably withheld, conditioned or delayed.
- 4.3 Licensee shall obtain and carry in full force and effect commercial general liability insurance, including product liability and errors and omissions insurance which shall protect Licensee and Indemnitees. At such time as any process or service relating to, or developed

pursuant to, this Agreement is being sold, offered for sale, developed, practiced, or performed by Licensee, Licensee shall, at its sole cost and expense, procure and maintain policies of commercial general liability insurance naming Indemnitees as additional insureds. The limits of the commercial general liability insurance shall not be less than [\*\*\*] per occurrence with an aggregate of [\*\*\*] for bodily injury including death, property damage, and products/completed operations coverage. Such general liability insurance must provide (a) liability coverage and (b) broad form contractual liability coverage for Licensee indemnification under Section 4.1 of this Agreement. The minimum amounts of insurance coverage required under these provisions may not be construed to create a limit of Licensee's liability with respect to its indemnification obligation under Section 4.1 this Agreement. Licensee shall provide Broad with written evidence of such insurance upon request. Licensee shall provide Broad with written notice at least [\*\*\*] days prior to the cancellation, non-renewal or material change in such insurance; if Licensee does not obtain replacement insurance providing comparable coverage within such [\*\*\*] day period, Broad has the right to terminate this Agreement effective at the end of such [\*\*\*] day period without any notice or additional waiting periods. Licensee shall maintain such comprehensive general liability insurance beyond the expiration or termination of this Agreement during: (i) the period that any service, relating to, or developed pursuant to, this Agreement is being sold, offered for sale, developed, practiced, or performed by Licensee and (ii) a reasonable period after the period referred to in Section 4.3(i) above, which in no event shall be less than [\*\*\*] years.

### 5. NO REPRESENTATIONS OR WARRANTIES; LIMITATION OF LIABILITY.

THE PROGRAMS AND TOOLS ARE DELIVERED "AS IS". BROAD MAKES NO REPRESENTATIONS OR WARRANTIES OF ANY KIND CONCERNING THE PROGRAMS, TOOLS OR THE COPYRIGHT, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT, OR THE ABSENCE OF LATENT OR OTHER DEFECTS, WHETHER OR NOT DISCOVERABLE. BROAD EXTENDS NO WARRANTIES OF ANY KIND AS TO CONFORMITY OF PROGRAMS OR TOOLS WITH WHATEVER USER MANUALS OR OTHER LITERATURE MAY BE ISSUED FROM TIME TO TIME. IN NO EVENT SHALL BROAD OR ITS DIRECTORS, OFFICERS, EMPLOYEES, AFFILIATED INVESTIGATORS AND AFFILIATES BE LIABLE FOR DAMAGES OF ANY KIND, WHETHER DIRECT, INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL, INCLUDING, WITHOUT LIMITATION, ECONOMIC DAMAGES OR INJURY TO PROPERTY AND LOST PROFITS, REGARDLESS OF WHETHER BROAD SHALL BE ADVISED, SHALL HAVE OTHER REASON TO KNOW, OR IN FACT SHALL KNOW OF THE POSSIBILITY OF THE FOREGOING. EXCEPT WITH RESPECT TO MATTERS FOR WHICH LICENSEE IS OBLIGATED TO INDEMNIFY INDEMNITEES UNDER SECTION 4, IN NO EVENT SHALL LICENSEE, ITS DIRECTORS, OFFICERS, EMPLOYEES OR AGENTS BE LIABLE TO BROAD WITH RESPECT TO ANY SUBJECT MATTER OF THIS AGREEMENT UNDER ANY CONTRACT, NEGLIGENCE, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES OR LOST PROFITS, REGARDLESS OF WHETHER SUCH PARTY SHALL HAVE KNOWN OF THE POSSIBILITY OF THE FOREGOING.

## 6. ASSIGNMENT

This Agreement is personal to Licensee and any rights or obligations assigned by Licensee without the prior written consent of Broad shall be null and void, <u>provided</u> that Licensee shall have the right to assign this Agreement without the consent of Broad in connection with a permitted assignment of the Patent License to the same entity to which the Patent License is assigned. Licensee shall notify Broad in writing within [\*\*\*] days of any such assignment.

#### 7. MISCELLANEOUS

- 7.1 General Compliance with Laws. Licensee shall comply with all government statues and regulations that relate to the Licensed Use. These include but are not limited to FDA statutes and regulations, the Export Administration Act of 1979, as amended, 50 App. U.S.C. 2041 et. seq., and the regulations promulgated thereunder or other applicable export statutes or regulations. Licensee bears sole responsibility for any violation of such laws and regulations and shall indemnify, defend and hold Broad harmless for the consequences of any such violation. Licensee gives assurance that it will comply with all United States export control laws and regulations controlling the export of the Programs, including, without limitation, all Export Administration Regulations of the United States Department of Commerce. Among other things, these laws and regulations prohibit, or require a license for, the export of certain types of software to specified countries.
- 7.2 Termination. Licensee shall have the right to terminate this Agreement for any reason upon prior written notice to Broad. If Licensee breaches any provision hereunder, and fails to cure such breach within [\*\*\*] days, Broad may terminate this Agreement immediately. Upon termination, Licensee shall provide Broad with written assurance that the original and all copies of the Programs have been destroyed.
- 7.3 Survival. The following provisions shall survive the expiration or termination of this Agreement: Articles 1, 3, 4, 5, and Sections 2.2, 2.3, 2.5, 7.3, 7.4 and 7.8. All existing sublicenses under this Agreement shall survive to the same extent as the corresponding sublicense under the Patent License survives, and if a Direct License (as defined in the Patent License) is granted under the Patent License to any sublicensee under this Agreement, then a license on substantially the same non-economic terms and conditions set forth in the applicable sublicense granted by Licensee shall be granted by Broad to such sublicensee.
- 7.4 Notice. Any notices under this Agreement shall be in writing, shall specifically refer to this Agreement, and shall be sent by hand, recognized national overnight courier, confirmed facsimile transmission, confirmed electronic mail, or registered or certified mail, postage prepaid, return receipt requested. All notices under this Agreement shall be deemed effective upon receipt.
- 7.5 Amendment and Waiver; Entire Agreement. This Agreement may be amended, supplemented, or otherwise modified only by means of a written instrument signed by all parties. Any waiver of any rights or failure to act in a specific instance shall relate only to such instance and shall not be construed as an agreement to waive any rights or fail to act in any other instance, whether or not similar. This Agreement constitutes the entire agreement among the parties with respect to its subject matter and supersedes prior agreements or understandings between the parties relating to its subject matter.

7.6 Binding Effect; Headings. This Agreement shall be binding upon and inure to the benefit of the parties and their respective permitted successors and assigns. All headings are for convenience only and shall not affect the meaning of any provision of this Agreement.

7.7 Counterparts. This Agreement and any amendment hereto may be executed in counterparts and all such counterparts taken together shall be deemed to constitute one and the same instrument. If this Agreement is executed in counterparts, no signatory hereto will be bound until all the parties named below have duly executed a counterpart of this Agreement.

7.8 Governing Law. This Agreement shall be construed, governed, interpreted and applied in accordance with the internal laws of the Commonwealth of Massachusetts, U.S.A., without regard to conflict of laws principles.

Neon Therapeutics, Inc.		The Broad Institute, Inc.		
By: Name:	Cary Pfeffer	By: Name:	Issi Rozen	
Signature:	/s/ Cary Pfeffer	Signature:	/s/ Issi Rozen	
Date:	11-13-15	Date:	11/13/15	

# Exhibit C Development Plan

Latest date of achievement	Description(s)
December 31, 2016	Prepare and file Neon-sponsored IND for the Licensed NeoVax Product.
	Complete Neon-sponsored study protocol design.
	• Prepare for Neon-sponsored Phase I Clinical Study initiation.
	<ul> <li>Establish supply agreements with vendors or develop Company capabilities to enable Licensed NeoVax Product supply for Neon-sponsored Phase I Clinical Study.</li> </ul>
June 30, 2017	• Initiate Neon-sponsored Phase I Clinical Study for the Licensed NeoVax Product.
	• Evaluate production improvements for Licensed NeoVax Product supply.
December 31, 2017	• Continue to execute and evaluate patient data for Neon-sponsored Phase I Clinical Study.
	• Evaluate production improvements for Licensed NeoVax Product supply.
[***]	• [***]
	• [***]
[***]	• [***]

The following table lists the Development Milestones.

Latest date of achievement	Description(s)		
December 31, 2016	Prepare and file Neon-sponsored IND for the Licensed NeoVax Product.		
June 30, 2017	• Initiate Neon-sponsored Phase I Clinical Study for the Licensed NeoVax Product.		
[***]	• [***]		
[***]	• [***]		

Exhibit D
Restricted Stock Agreement

[Attached.]

## NEON THERAPEUTICS, INC.

## RESTRICTED STOCK PURCHASE AGREEMENT

**THIS RESTRICTED STOCK PURCHASE AGREEMENT** (this "*Agreement*") dated as of November 13, 2015 (the "*Effective Date*"), is made by and between Neon Therapeutics, Inc., a Delaware corporation (the "*Company*"), and The Broad Institute, Inc., a not-for-profit corporation organized under the laws of the Commonwealth of Massachusetts ("*Purchaser*").

WHEREAS, the Company and Purchaser are parties to that certain License Agreement, dated as of even date herewith (the "License Agreement"); and

**WHEREAS**, the Company desires to issue to Purchaser, and Purchaser desires to receive from the Company, an aggregate of 300,000 shares of the Company's Common Stock, par value \$0.001 per share ("Common Stock") in consideration for licenses granted to the Company under the License Agreement.

**NOW, THEREFORE**, in consideration of the premises and the promises set forth herein, and for other good and valuable consideration, the receipt and legal sufficiency of which is hereby acknowledged, accepted and agreed to, the parties agree as follows:

1. <u>Definitions</u>. As used in this Agreement, the following terms will have the following meanings:

Act: The Securities Act of 1933, as amended.

*Initial Public Offering*: the consummation of the first firm commitment underwritten public offering pursuant to an effective registration statement under the Act covering the offer and sale by the Company of its equity securities, as a result of or following which the Common Stock shall be publicly held.

*Shares*: The shares of Common Stock issued to Purchaser hereunder and any other securities of the Company which may be issued in exchange for or in respect of such shares of Common Stock, whether by way of stock split, stock dividend, combination of shares, reclassification, recapitalization, reorganization or any other means.

- 2. <u>Issuance of Shares</u>. Pursuant to the terms and conditions set forth in this Agreement, the Company hereby issues to Purchaser, and Purchaser hereby accepts from the Company, 300,000 shares of the Company's Common Stock, in consideration for licenses granted to the Company under the License Agreement.
  - 3. Representations, Warranties and Covenants.
- (a) <u>Representations and Warranties of Purchaser</u>. Purchaser represents to the Company as of the Effective Date, and agrees that the Company is entitled to rely on such representations, as follows:
- (i) Purchaser is acquiring the Shares for investment for Purchaser's own account only and not with a view to, or for resale in connection with, any "distribution" thereof within the meaning of the Act.

- (ii) Purchaser understands that the Shares have not been registered under the Act, or registered or qualified under the securities or "Blue Sky" laws of any jurisdiction, and are being sold pursuant to exemptions contained in the Act and exemptions contained in other applicable securities or "Blue Sky" laws. Purchaser understands further that the Company's reliance on these exemptions is based in part on the representations made by Purchaser in this Agreement.
- (iii) Purchaser understands the term "accredited investor" as used in Regulation D promulgated under the Act and represents and warrants to the Company that Purchaser is an "accredited investor" for purposes of acquiring the Shares. Purchaser understands that the Shares are an illiquid investment, which may not become freely transferable by reason of any "change of circumstances" whatever. Purchaser has no need for liquidity in Purchaser's investment.
- (iv) Purchaser further acknowledges and understands that the Shares must be held indefinitely unless the Shares are subsequently registered under the Act or an exemption from such registration is available. Purchaser further acknowledges and understands that the Company is under no obligation to register the Shares. Purchaser understands that the certificate evidencing the Shares will be imprinted with a legend which prohibits the transfer of the Shares unless the Shares are registered or such registration is not required in the opinion of counsel reasonably satisfactory to the Company.
- (v) The Shares may be resold by Purchaser in certain limited circumstances subject to the provisions of Rule 144 of the Act ("*Rule 144*"), which may require, among other things: (i) the availability of certain public information about the Company and (ii) the resale occurring following the required holding period under Rule 144 after the Purchaser has purchased, and made full payment for (within the meaning of Rule 144), the securities to be sold.
- (vi) Purchaser further understands that at the time Purchaser wishes to sell the Shares there may be no public market upon which to make such a sale, and that, even if such a public market then exists, the Company may not be satisfying the current public information requirements of Rule 144, and that, in such event, Purchaser may be precluded from selling the Shares under Rule 144 even if the minimum holding period requirement had been satisfied.
- (vii) In connection with Purchaser's acquisition of the Shares, Purchaser accepts the condition that the Company may maintain "stop transfer" orders with respect to the Shares and that each certificate or other document evidencing the Shares will bear conspicuous legends in substantially the form set forth in <u>Section 5</u> of this Agreement.

- (viii) Purchaser acknowledges that the Company has granted Purchaser and Purchaser's attorney or accountant access to all information about the Company which they have requested and has offered each of them access to all further information which they deemed relevant to an investment decision with respect to the Shares. Purchaser and Purchaser's attorney or accountant have had the opportunity to ask questions of, and receive answers from, representatives of the Company concerning such information and the Company's financial condition and prospects.
- (b) <u>Representations and Warranties of Company</u>. Company represents to the Purchaser as of the Effective Date, and agrees that the Purchaser is entitled to rely on such representations, as follows:
- (i) The Company is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware and has all requisite corporate power and authority to carry on its business as presently conducted and as proposed to be conducted. The Company is duly qualified to transact business and is in good standing in each jurisdiction in which the failure to so qualify would have a material adverse effect on the business, assets (including intangible assets), liabilities, financial condition, property or results of operations of the Company.
- (ii) Exhibit A hereto sets forth the true and complete fully diluted capitalization of the Company immediately following issuance of the Shares to Purchaser, including, without limitation, issued and outstanding Common Stock, granted stock options, shares of Common Stock reserved for future award grants under the Company's stock option plan, each series of Preferred Stock, and convertible securities, warrants and any other stock purchase rights. All outstanding shares of the Company's Common Stock and all shares of the Company's Common Stock underlying outstanding options are subject to (i) a right of first refusal in favor of the Company upon any proposed transfer (other than transfers for estate planning purposes); and (ii) a lock-up or market standoff agreement of not less than one hundred eighty (180) days following the Company's initial public offering pursuant to a registration statement filed with the Securities and Exchange Commission under the Act.
- (iii) All corporate action required to be taken by the Company's Board of Directors and stockholders in order to authorize the Company to enter into the License Agreement or this Agreement, and to issue the Shares to the Purchaser, has been taken. All action on the part of the officers of the Company necessary for the execution and delivery of the License Agreement and this Agreement and the issuance and delivery of the Shares has been taken. The License Agreement and this Agreement, when executed and delivered by the Company, shall constitute valid and legally binding obligations of the Company, enforceable against the Company in accordance with their respective terms except as limited by applicable bankruptcy, insolvency, reorganization, moratorium, fraudulent conveyance, or other laws of general application relating to or affecting the enforcement of creditors' rights generally.
- (iv) The Shares, when issued, sold and delivered in accordance with the terms and for the consideration set forth in this Agreement and the License Agreement, will be validly issued, fully paid and nonassessable and free of restrictions on transfer other than as set forth in Section 4 hereof, applicable state and federal securities laws and liens or encumbrances created by or imposed by Purchaser. Assuming the accuracy of the representations of the Purchasers in Section 3(a) of this Agreement, the Shares will be issued in compliance with all applicable federal and state securities laws.

- (c) <u>Covenants of Company</u>. Company shall not subject Purchaser or its affiliates to, or permit or cause Purchaser or its affiliates to be subjected to, any limitations on their activities (such as exclusivity, non-competition, non-solicit, or other limitations) under any agreements, instruments or documents in connection with the Purchaser's interest in the Shares (whether pursuant to investment agreements, stockholder agreements, provisions in organizational documents, provisions imposed in connection with any merger, consolidation, sale of shares of the Company or otherwise), other than as may be consented to in advance in a writing solely between the Purchaser and the Company specifically referencing this <u>Section 3(c)</u> of this Agreement. In addition, Company acknowledges and agrees that Purchaser shall not be required to enter into any agreement, instrument or document in connection with the Shares other than this Agreement. In the event Purchaser nonetheless agrees, in its sole discretion, to enter into any such agreement, instrument or document, Company shall ensure that such agreement, instrument or document shall provide that it may not be amended in a manner that affects Purchaser differently and adversely as compared to other holders of equity of the Company that are a party or subject thereto without the prior written consent of the Purchaser.
  - 4. Restrictions on Transfer. The following restrictions on transfer of the Shares will apply:
- (a) <u>Securities Laws</u>. No Shares, nor any interest therein, may be sold, assigned, pledged or otherwise transferred at any time or under any circumstances unless: (i) the Shares proposed to be transferred have been registered under the Act and qualified under applicable state securities laws, or (ii) the Company has received, or agreed to waive, an opinion of counsel reasonably acceptable to the Company to the effect that such transfer may be effected without registration under the Act or qualification under the securities laws of relevant states and the proposed transferee has made such representations and agreements as the Company will require to assure compliance with the Act and such laws.

## (b) Right of First Refusal.

- (i) Offer of Sale; Notice of Proposed Sale or Transfer. In the event that at any time prior to the Company's Initial Public Offering, Purchaser desires to sell, assign or otherwise transfer any Shares or any interest therein, it will first deliver written notice of its desire to do so (the "Notice") to the Company. The Notice must specify the number of Shares proposed to be transferred, the name of the person or persons to whom he proposes to transfer such Shares (to the extent disclosure of such name is not prohibited by any confidentiality obligation of Purchaser to the proposed transferee), the price at which such Shares are intended to be transferred and any other material terms of the transaction, which must be bona fide.
- (ii) <u>Company's Option to Purchase</u>. The Company will have an option to purchase all of the Shares offered in the Notice for the price and on the terms specified in such Notice. The Company must exercise such option in full and by giving written notice to Purchaser no later than [\*\*\*] days after receipt of such Notice.

- (iii) <u>Closing of Purchase by Company</u>. In the event the Company duly exercises its option to purchase all of the Shares, the closing of such purchase will take place within five (5) days after the expiration of the aforesaid ten (10) day period, and all payments from the Company shall have been delivered to the Purchaser by this time.
- (iv) <u>Failure to Exercise Options to Purchase</u>. If within the [\*\*\*] day time period specified in <u>Section 4(b)(iii)</u> the Company does not exercise its option to purchase all of the offered Shares, the Company shall be deemed to have forfeited any right to purchase such Shares, and the Purchaser shall be free to complete the proposed transfer, but such transfer will be made only to the proposed transferee or transferees on substantially similar terms as stated in such Notice. Shares that are so transferred will remain subject to <u>Sections 4</u> through <u>6</u>, inclusive, of this Agreement, and as a condition to any transfer Purchaser will obtain a written agreement from the transferee by which the transferee agrees to be bound by <u>Sections 4</u> through <u>6</u>, inclusive, of this Agreement.
- (v) <u>Permitted Transfers</u>. Any portion or all of the Shares may, without compliance with the provisions of <u>Section 4(b)</u>, be transferred by the Purchaser to an affiliate or to the Purchaser's or its affiliates' stockholders, members, partners or other equity holders, provided that the Shares that are so transferred will remain subject to this <u>Section 4</u> and as a condition to any transfer Purchaser will obtain a written agreement from the transferee by which the transferee agrees to be bound by this <u>Section 4</u>.
- (c) <u>Remedies</u>. No sale, assignment, pledge or other transfer of Shares will be effective or given effect on the books of the Company unless all of the applicable provisions of this <u>Section 4</u> have been duly complied with. If any transfer of Shares is made or attempted in violation of such restrictions, or if Shares are not offered to the Company as required hereby, the Company will have the right to purchase such Shares from the purported owner thereof or his transferee at any time before or after the transfer, as herein provided. In addition to any other legal or equitable remedies which it may have, the Company may enforce its rights by actions for specific performance (to the extent permitted by law) and may refuse to recognize any transferee as one of its stockholders for any purpose, including, without limitation, for purposes of dividend and voting rights, until all applicable provisions hereof have been complied with.
- (d) <u>Lock-Up</u>. Purchaser shall not, without the prior written consent of the managing underwriter, sell, dispose of, transfer, make any short sale of, grant any option for the purchase of, or enter into any hedging or similar transaction with the same economic effect as a sale, the Shares (the "*Restricted Securities*"), during the 180-day period following the date of the final prospectus relating to the Company's Initial Public Offering (or such longer period, not to exceed 34 days after the expiration of the 180-day period, as the underwriters or the Company shall request in order to facilitate compliance with NASD Rule 2711 or NYSE Member Rule 472 or any successor or similar rule or regulation) (the "*Lock-Up Period*"). Purchaser agrees to execute and deliver such agreements as may be reasonably requested by the Company or the managing underwriters which are consistent with the foregoing or which are necessary to give further effect thereto. In order to enforce the foregoing covenant, the Company may impose stop-transfer instructions with respect to Purchaser's Restricted Securities until the end of such period. The underwriters of the Company's stock are intended third-party beneficiaries of this <u>Section 4(d)</u> and shall have the right, power and authority to enforce the provisions hereof as

though they were a party hereto. The foregoing provisions of this Section 4(d) shall apply only to the Initial Public Offering, shall not apply to the sale of any shares to an underwriter pursuant to an underwriting agreement, and shall be applicable to the Purchaser only if all officers and directors are subject to the same restrictions and the Company obtains a similar agreement from all stockholders individually owning more than five percent (5%) of the Company's outstanding Common Stock on a fully diluted basis. Any discretionary waiver or termination of the restrictions of any or all of such agreements by the Company or the underwriters shall apply pro rata to all stockholders subject to such agreements, based on the number of shares subject to such agreements.

- 5. <u>Legends</u>. Each certificate representing the Shares will prominently bear legends in substantially the following forms (in addition to any other legend which may be required by other agreements between the parties hereto):
  - a) "THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE BEEN ACQUIRED FOR INVESTMENT AND HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED. SUCH SECURITIES MAY NOT BE SOLD, TRANSFERRED, PLEDGED OR HYPOTHECATED UNLESS THE REGISTRATION PROVISIONS OF SAID ACT HAVE BEEN COMPLIED WITH OR UNLESS THE CORPORATION HAS RECEIVED AN OPINION OF COUNSEL REASONABLY SATISFACTORY TO THE CORPORATION THAT SUCH REGISTRATION IS NOT REQUIRED."
  - b) "THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE BEEN ACQUIRED FOR INVESTMENT AND HAVE NOT BEEN REGISTERED OR QUALIFIED UNDER THE SECURITIES OR "BLUE SKY" LAWS OF ANY JURISDICTION. SUCH SECURITIES MAY NOT BE SOLD, TRANSFERRED, PLEDGED OR HYPOTHECATED UNLESS THE REGISTRATION, QUALIFICATION AND FILING REQUIREMENTS OF ALL APPLICABLE JURISDICTIONS HAVE BEEN SATISFIED OR THE CORPORATION HAS RECEIVED AN OPINION OF COUNSEL REASONABLY SATISFACTORY TO THE CORPORATION THAT THE PROPOSED TRANSACTION WILL BE EXEMPT FROM REGISTRATION, QUALIFICATION, AND FILINGS IN ALL SUCH JURISDICTIONS."
  - c) "THE CORPORATION IS AUTHORIZED TO ISSUE MORE THAN ONE CLASS OF STOCK. THE POWERS,
    DESIGNATIONS, PREFERENCES AND RELATIVE PARTICIPATING, OPTIONAL OR OTHER SPECIAL RIGHTS, AND THE
    QUALIFICATIONS, LIMITATIONS OR RESTRICTIONS OF SUCH PREFERENCES AND/OR RIGHTS OF EACH CLASS OF
    STOCK OR SERIES OF ANY CLASS ARE SET FORTH IN THE CERTIFICATE OF INCORPORATION OF THE
    CORPORATION. THE CORPORATION WILL FURNISH A COPY OF THE CERTIFICATE OF INCORPORATION OF THE
    CORPORATION TO THE HOLDER HEREOF WITHOUT CHARGE UPON WRITTEN REQUEST."

- d) "THE SECURITIES REPRESENTED BY THIS CERTIFICATE ARE SUBJECT TO RESTRICTIONS ON TRANSFER PURSUANT TO THE TERMS OF A RESTRICTED STOCK PURCHASE AGREEMENT, AS AMENDED FROM TIME TO TIME, BETWEEN THE OWNER OF THIS CERTIFICATE AND THE CORPORATION. THE CORPORATION WILL FURNISH A COPY OF THIS AGREEMENT TO THE HOLDER HEREOF WITHOUT CHARGE UPON WRITTEN REQUEST."
- e) Any legend required by appropriate blue sky officials.

### 6. Miscellaneous.

- (a) <u>Entire Agreement</u>. This Agreement constitutes the entire agreement between the parties with respect to the subject matter hereof, and supersedes all prior agreements, negotiations, representations and proposals, written or oral, relating to such subject matter.
- (b) <u>Amendments</u>. Neither this Agreement nor any provision hereof may be changed or modified except by an agreement in writing executed by Purchaser and on behalf of the Company.
- (c) <u>Binding Effect of the Agreement</u>. This Agreement will inure to the benefit of, and be binding upon, the Company, Purchaser and their respective estates, heirs, executors, transferees, successors, assigns and legal representatives.
- (d) <u>Provisions Severable</u>. In the event that any one or more of the provisions contained herein will, for any reason, be held to be invalid, illegal, or unenforceable in any respect, such invalidity, illegality, or unenforceability will not affect any other provisions of this Agreement, and all other provisions will remain in full force and effect. If any of the provisions of this Agreement is held to be excessively broad, it will be reformed and construed by limiting and reducing it so as to be enforceable to the maximum extent permitted by law.
- (e) Notices. All notices under this Agreement will be effective (i) upon personal or facsimile delivery, (ii) two (2) business days after deposit in the United States mail as registered or certified mail postage fully prepaid, or (iii) one (1) business day after pickup by any overnight commercial courier service, in each case sent or addressed to the Company at its principal office or to Purchaser at his record address as carried in the stock records of the Company, as the case may be, or at such other address as either may from time to time designate in writing to the other.
- (f) <u>Construction</u>. A reference to a Section will mean a Section of this Agreement unless otherwise expressly stated. The titles and headings herein are for reference purposes only and will not in any manner limit the construction of this Agreement which will be considered as a whole. The words "<u>includes</u>" and "<u>including</u>" when used herein will be deemed in each case to be followed by the words "without limitation." Whenever the context may require, any pronouns used herein will include the corresponding masculine, feminine or neuter forms, and the singular form of names and pronouns will include the plural and vice-versa.

- (g) <u>Applicable Law</u>. This Agreement will be construed and enforced in accordance with the laws of the Commonwealth of Massachusetts, without regard to its principles of conflicts of laws that would require the application of laws of any other jurisdiction. Purchaser consents to jurisdiction and venue in any state or federal court in the Commonwealth of Massachusetts for the purposes of any action relating to or arising out of this Agreement or any breach or alleged breach hereof, and to service of process in any such action by certified or registered mail, return receipt requested.
- (h) <u>Disposition of Shares; Purchase by Nominee or Designee</u>. Any Shares that the Company elects to purchase hereunder may be disposed of by it in such manner as it deems appropriate with or without restrictions on the transfer thereof, and the Company may require their transfer to a nominee or designee as part of any purchase of Shares from Purchaser.
- (i) Arbitration. In the event of any dispute, controversy, disagreement or claim arising out of or relating to this Agreement or interpretation of any of the provisions, the same shall be submitted to final and binding arbitration for resolution in accordance with the following procedures: The parties shall first attempt to mediate the matter. If the matter has not been satisfactorily resolved within [\*\*\*] days after written notice by either party to the other requesting mediation, then the matter shall be referred to arbitration for resolution before a single arbitrator under the then commercial arbitration rules of the American Arbitration Association (the "A.A.A."), and the decision of the arbitrator shall be final and binding on the parties. If the parties are unable to agree on a single neutral arbitrator, such arbitrator shall be appointed by the A.A.A. The arbitrator shall not have any current or past business or financial relationships with any party to the arbitration or its Affiliates, and shall have experience in the arbitration or mediation of contract disputes. Each party shall be responsible for its proportionate share of the filing fee and the arbitrator's fee; and otherwise, each party shall be responsible for its own costs and expenses, including travel, consultants, witnesses and attorneys' fees and disbursements. The arbitrator shall be authorized only to interpret and apply the provisions of this Agreement or any related agreements entered into under this Agreement and shall have no power to modify or change any of the above in any manner. The arbitrator shall have no authority to award punitive, special or consequential damages or any damages inconsistent with this Agreement. The arbitrator shall, within [\*\*\*] days of the conclusion of the hearing, unless such time is extended by agreement of the parties, notify the parties in writing of his or her decision, stating his or her reasons for such decision and separately listing his or her findings of fact and conclusions of law. The arbitration shall be conducted in Boston, Massachusetts, and shall be governed by the laws of the Commonwealth of Massachusetts, and the decision of the arbitrator shall be final and binding and may be entered in any court of competent jurisdiction. Nothing in this Section 6(i) shall in any way limit the right of a party to seek preliminary and permanent injunctive relief from any court of competent jurisdiction pending an award being issued. The parties agree that all applicable statutes of limitation and time based defenses (i.e. estoppel and laches) shall be tolled whole the procedures set forth in this Section 6(i) are pending. The parties shall cooperate in taking any actions necessary to achieve this result. Each party shall continue to perform its undisputed obligations under this Agreement pending resolution of any dispute arising out of or relating to this Agreement.

- REMAINDER OF PAGE INTENTIONALLY LEFT BLANK -

IN WITNESS WHEREOF, the parties hereto have executed this Restricted Stock Purchase Agreement as of the date first above written.

NEON THERAPEUTICS, INC.
By: Name: Title:
PURCHASER:
THE BROAD INSTITUTE, INC.
By: Name: Title:

[Signature page to Restricted Stock Purchase Agreement]

## Schedule 1.85 Neoantigen Vaccine Product

Neoantigen Vaccine Product means a therapeutic product described as follows:

- [\*\*\*]
- [\*\*\*]
- a) [\*\*\*].
- b) [\*\*\*].
- c) [\*\*\*].
- d) [\*\*\*].

## Schedule 1.86 NeoVax Product

NeoVax Product means a therapeutic vaccine product described as follows:

- [\*\*\*]
- [\*\*\*]:
  - a) [\*\*\*].
  - b) [\*\*\*].
  - c) [\*\*\*].
  - d) [\*\*\*].
  - e) [\*\*\*].
  - f) [\*\*\*].

## FIRST AMENDMENT TO THE LICENSE AGREEMENT (BROAD REFERENCE NO. OLC2015079)

This First Amendment to the License Agreement (the "Amendment"), effective as of January 16, 2018 (the "Amendment Effective Date"), is between The Broad Institute, Inc. ("Broad") and Neon Therapeutics, Inc. ("Company").

WHEREAS, Broad and Company have entered into a certain License Agreement (the "Agreement") effective November 13, 2015;

WHEREAS, Broad and Company are amending the license to add additional Licensed Patent Rights;

WHEREAS, in addition to DFCI and MGH, the Massachusetts Institute of Technology with a principal office at 77 Massachusetts Avenue, Cambridge, MA 02139 ("MIT") and the President and Fellows of Harvard College having a principle office at Smith Campus Center, Suite 727, 1350 Massachusetts Avenue, Cambridge, Massachusetts 02138 ("Harvard") are also co-owners of certain of the Licensed Patent Rights;

NOW THEREFORE, in consideration of the mutual promises set forth herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Broad and Company hereby agree as follows:

- 1. **AMENDMENT TO EXHIBIT A.** The Agreement is hereby amended by deleting the existing Exhibit A and replacing in its entirety with the Exhibit A to this Amendment.
- 2. **AMENDMENT TO AGREEMENT.** The Agreement is hereby amended by deleting the existing first recital in its entirety and replacing in its entirety with the following:

WHEREAS, the technology taught in the Licensed Patent Rights (as defined below) was discovered by researchers at Broad, individually or collectively with researchers at Dana-Farber Cancer Institute, Inc., a not-for-profit Massachusetts corporation with a principal office at 44 Binney Street, Boston, MA 02115 ("**DFCI**"), The General Hospital Corporation d/b/a Massachusetts General Hospital, a not-for-profit Massachusetts corporation with a principal office at 55 Fruit Street, Boston, MA 02114 ("**MGH**"), the Massachusetts Institute of Technology with a principal office at 77 Massachusetts Avenue, Cambridge, MA 02139 ("**MIT**") or the President and Fellows of Harvard College having a principle office at Smith Campus Center, Suite 727, 1350 Massachusetts Avenue, Cambridge, Massachusetts 02138 ("**Harvard**");

- 3. <u>Amendment to Article 1</u>. Article 1 of the Agreement is hereby amended by deleting the existing Section 1.58 in its entirety and replacing in its entirety with the following:
- **1.58 "Institutions"** means, collectively, (i) Broad, DFCI and MGH for purposes of Sections 1.47, 1.109, 2.1.1, 2.1.3 and 4.6 of this Agreement, and (ii) Broad, DFCI, MGH, MIT and Harvard for all other purposes of this Agreement. Each of Broad, DFCI, MGH, MIT and Harvard may be referred to as an "**Institution**."
- 4. Amendment to Article 1. Article 1 of the Agreement is hereby amended by inserting the following after Section 1.122:
  - **1.123 "Harvard"** has the meaning set forth in the recitals.
  - **1.124 "MIT"** has the meaning set forth in the recitals.
- 5. **Amendment to Article 8.** Article 8 of the Agreement is hereby amended by deleting the existing Sections 8.4 and 8.5 and replacing in their entirety with the following:

#### 8.4 Disclaimer.

8.4.1 NOTHING CONTAINED HEREIN SHALL BE DEEMED TO BE A WARRANTY BY THE INSTITUTIONS THAT THEY CAN OR WILL BE ABLE TO OBTAIN PATENTS ON PATENT APPLICATIONS INCLUDED IN THE LICENSED PATENT RIGHTS, OR THAT ANY OF THE LICENSED PATENT RIGHTS WILL AFFORD ADEQUATE OR COMMERCIALLY WORTHWHILE PROTECTION. THE INSTITUTIONS MAKE NO WARRANTIES WHATSOEVER AS TO THE COMMERCIAL OR SCIENTIFIC VALUE OF THE LICENSED PATENT RIGHTS.

8.4.2 THE INSTITUTIONS MAKE NO REPRESENTATION THAT THE PRACTICE OF THE LICENSED PATENT RIGHTS OR THE DEVELOPMENT, MANUFACTURE, USE, SALE OR IMPORTATION OF ANY LICENSED PRODUCT, OR ANY ELEMENT THEREOF, WILL NOT INFRINGE ANY PATENT OR PROPRIETARY RIGHTS OF A THIRD PARTY.

8.4.3 EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER COMPANY NOR ANY INSTITUTION MAKES ANY WARRANTY WITH RESPECT TO ANY TECHNOLOGY, PATENTS, GOODS, SERVICES, RIGHTS OR OTHER SUBJECT MATTER OF THIS AGREEMENT AND EACH OF COMPANY AND EACH INSTITUTION HEREBY DISCLAIMS WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT WITH RESPECT TO ANY AND ALL OF THE FOREGOING.

#### 8.5 Limitation of Liability.

8.5.1 EXCEPT WITH RESPECT TO MATTERS FOR WHICH COMPANY IS OBLIGATED TO INDEMNIFY INDEMNITES UNDER ARTICLE 9, IN NO EVENT SHALL EITHER PARTY OR THE INSTITUTIONS, THEIR DIRECTORS, OFFICERS, EMPLOYEES OR AGENTS BE LIABLE TO THE OTHERS WITH RESPECT TO ANY SUBJECT MATTER OF THIS AGREEMENT UNDER ANY CONTRACT, NEGLIGENCE, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES OR LOST PROFITS, REGARDLESS OF WHETHER SUCH PARTY SHALL HAVE KNOWN OF THE POSSIBILITY OF THE FOREGOING.

8.5.2 The Institutions' aggregate liability for all damages of any kind arising out of or relating to this Agreement or its subject matter under any contract, negligence, strict liability or other legal or equitable theory shall not exceed the amounts paid to Broad under this Agreement.

- 6. **AMENDMENT TO SECTION 11**. Section 11 of the Agreement is hereby amended by deleting the existing Section 11.2 in its entirety and replacing in its entirety with the following::
- 11.2 Use of Name. Except as provided below, Company shall not, and shall ensure that its Affiliates and Sublicensees shall not, use or register the name "The Broad Institute, Inc.," "Dana-Farber Cancer Institute, Inc.," "The Massachusetts General Hospital," the "Massachusetts Institute of Technology," "Lincoln Laboratory," "Wyss Institute for Biologically Inspired Engineering at Harvard University," "President and Fellows of Harvard College," or any variation, adaptation, or abbreviation thereof, or of any of their trustees, officers, faculty, students, employees, or agents (alone or as part of another name) or any logos, seals, insignia or other words, names, symbols or devices that identify any Institution or any Institution's affiliated school, unit, division or affiliate, or any trademark owned by any Institution ("Institution Names") for any purpose except with the prior written approval of, and in accordance with restrictions required by, the applicable Institution; provided that, Company may use Institution Names in accordance with Section 11.1 as required to convey that this Agreement, and the licenses granted hereunder, exist and have been entered into, between Company and Broad. Without limiting the foregoing, Company shall, and shall ensure that its Affiliates and Sublicensees shall, cease all use of Institution Names as permitted under or in connection with this Agreement on the termination or expiration of this Agreement except as otherwise approved in writing by Broad or the applicable Institution. This restriction shall not apply to any information required by law to be disclosed to any governmental entity.

- 7. **REFERENCES TO MIT and Harvard**. Except for the first Recital and Sections 1.31 (DFCI), 1.47 [\*\*\*], 1.58 (Institutions), 1.73 (Licensed Know-How), 1.80 (MGH) and 4.6 (Issuance of Equity), in which sections references to DFCI and/or MGH, in any order, shall remain references only to DFCI and/or MGH, all other references in the Agreement:
- a. to "DFCI and MGH," in any order, shall mean "DFCI, MGH, MIT and Harvard," in any order;
- b. to "DFCI's and MGH's," in any order, shall mean "DFCI's, MGH's, MIT's and Harvard's," in any order.
- c. to "DFCI or MGH," in any order, shall mean "DFCI, MGH, MIT or Harvard," in any order; and
- d. to "MGH, DFCI or any Third Party," shall mean "MGH, DFCI, MIT, Harvard or any Third Party."
- 8. **DEFINED TERMS**. Any capitalized terms used but not defined in this Amendment shall have the meaning set forth in the Agreement.
- 9. **AGREEMENT RATIFICATION**. Except as specifically amended hereby, all provisions of the Agreement shall remain in full force and effect.

[Signatures Follow]

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its authorized representative in its name and on its behalf.

THE BROAD INSTITUTE NEON THERAPEUTICS, INC.

By: /s/ Issi Rozen

By: /s/ Robert Ang

Name: Issi Rozen

Name: Robert Ang

Title: Chief Business Officer, The Broad Institute Title: Chief Business Officer

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# SECOND AMENDMENT TO LICENSE AGREEMENT (BROAD REFERENCE NO. OLC2015079)

This Second Amendment to License Agreement (this "Amendment"), effective as of November 14, 2018 (the "Amendment Effective Date"), is made by and between The Broad Institute, Inc., a non-profit Massachusetts corporation, with a principal office at 415 Main Street, Cambridge, MA 02142 ("Broad"), and Neon Therapeutics, Inc., a Delaware corporation with a principal office at 40 Erie Street, Suite 110, Cambridge, MA 02139 ("Company"). Company and Broad are each referred to herein as a "Party" and collectively as the "Parties."

WHEREAS, Broad and Company have entered into that certain License Agreement as of November 13, 2015 (the "License Agreement");

WHEREAS, Broad and Company wish to amend the License Agreement to provide for the non-exclusive license to Company of the Class 1 Epitope Data (as defined below) as Licensed Know-How (as defined in the License Agreement) in accordance with the terms of the License Agreement;

WHEREAS, in addition to Broad, Dana Farber Cancer Institute, a not-for-profit Massachusetts corporation with a principal office at 44 Binney Street, Boston, MA 02115 ("**DFCI**"), and The General Hospital Corporation d/b/a Massachusetts General Hospital, a not-for-profit Massachusetts corporation with a principal office at 55 Fruit Street, Boston, MA 02114 ("**MGH**") are also co-owners of the Class 1 Epitope Data;

NOW THEREFORE, in consideration of the mutual promises set forth herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Broad and Company hereby agree as follows:

- 1. **Amendment to Section 1.73**. Effective as of the Amendment Effective Date, the License Agreement is hereby amended by deleting Section 1.73 in its entirety and replacing it with the following:
- **"1.73 "Licensed Know-How"** means all Know-How Controlled by Broad (a) regarding the research and development of Neoantigen Vaccine Products which has been disclosed by [\*\*\*] pursuant to confidential communications prior to the Effective Date under the NDA, or (b) specifically described in <u>Exhibit E</u> to this Agreement (the "**Class 1 Epitope Data**"). Notwithstanding the foregoing, Licensed Know-How described in clause (a) of the immediately preceding sentence excludes [\*\*\*]."
- 2. <u>Amendment Adding Exhibit E to the License Agreement</u>. Effective as of the Amendment Effective Date, the License Agreement is hereby amended by adding a new <u>Exhibit E</u> to the License Agreement in the form attached to this Amendment as <u>Exhibit E</u>.
- 3. **Transfer of Class 1 Epitope Data**. Within [\*\*\*] days after the Amendment Effective Date, Broad shall transfer, or have transferred, to Company the Class 1 Epitope Data. Such transfer shall be accomplished by file data transfer or such other means as reasonably agreed by the Parties.
- 4. **Payment**. Company shall pay Broad a non-refundable license fee of [\*\*\*], due and payable within [\*\*\*] days after the successful transfer of Class I Epitope Data.
- 5. **Publication**. Company acknowledges and agrees that the Class I Epitope Data may be published or presented, or otherwise disclosed, in whole or in party, publically or case-by-case, by faculty, employees and staff of Broad, DFCI and MGH at any time and from time to time without prior notice to or right of review by Company.
- 6. **Defined Terms**. Any capitalized terms used but not defined in this Amendment shall have the meaning set forth in the License Agreement.

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7. Agreement Ratification. Except as specifically amended hereby, all provisions of the License Agreement shall remain in full force and effect.

[Signatures Follow]

**EXECUTION COPY** 

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its authorized representative in its name and on its behalf.

THE BROAD INSTITUTE NEON THERAPEUTICS, INC.

By: /s/ Issi Rozen

By: /s/ Hugh O'Dowd

Name: Issi Rozen

Name: Hugh O'Dowd

Title: Chief Business Officer Title: CEO

**EXECUTION COPY** 

## Exhibit E

Description of Certain Licensed Know-How

[\*\*\*]

Subsidiary	Jurisdiction of Incorporation
BioNTech RNA Pharmaceuticals GmbH	Germany
BioNTech Delivery Technologies GmbH	Germany
BioNTech Diagnostics GmbH	Germany
BioNTech Small Molecules GmbH	Germany
BioNTech Manufacturing GmbH	Germany
BioNTech Innovative Manufacturing Services GmbH	Germany
JPT Peptide Technologies GmbH	Germany
BioNTech Cell & Gene Therapies GmbH	Germany
BioNTech Real Estate Holding GmbH	Germany
BioNTech Real Estate Verwaltungs GmbH	Germany
BioNTech Real Estate GmbH & Co. KG	Germany
BioNTech Austria Beteiligungen GmbH	Austria
reBOOST Management GmbH	Germany
JPT Inc.	Delaware
BioNTech USA Holding, LLC	Delaware
BioNTech Research and Development Inc.	Delaware
BioNTech US Inc.	Delaware

#### Consent of Independent Registered Public Accounting Firm

We consent to the reference to our firm under the caption "Experts" and to the use of our report dated March 31, 2020, in the Registration Statement (Form F-1) and related Prospectus of BioNTech SE for the registration of its ordinary shares.

We also consent to the incorporation by reference therein of our report dated March 31, 2020 with respect to the financial statements of BioNTech SE for the years ended December 31, 2019, 2018, and 2017 included in the Annual Report (Form 20-F) for 2019 filed with the Securities and Exchange Commission.

/s/ Titus Zwirner Wirtschaftsprüfer (German Public Auditor) /s/ Andreas Weigel Wirtschaftsprüfer (German Public Auditor)

Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft Cologne, Germany July 21, 2020

## CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in this Registration Statement on Form F-1 of BioNTech SE of our report dated March 2, 2020, relating to the financial statements of Neon Therapeutics, Inc., which appears in Neon Therapeutics, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2019. We also consent to the reference to us under the heading "Experts" in such Registration Statement.

/s/ PricewaterhouseCoopers LLP Boston, Massachusetts July 21, 2020