BIONTECH

MOMENTUM

BioNTech SE

Annual Report on Form 20-F
for the year ended December 31, 2025

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 20-F

☐ **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2025

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

☐ **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission file number: 001-39081

BioNTech SE

(Exact name of Registrant as specified in its charter)

Federal Republic of Germany
(Jurisdiction of incorporation or organization)

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Securities registered or to be registered, pursuant to Section 12(b) of the Act

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American Depositary Shares, each Representing one ordinary share	BNTX	The Nasdaq Stock Market LLC
Ordinary shares, no par value, with a notional amount attributable to each ordinary share of €1*	—	The Nasdaq Stock Market LLC*

Securities registered or to be registered pursuant to Section 12(g) of the Act: **None**

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: **None**

Indicate the number of outstanding shares of each of the issuer's classes of capital stock or common stock as of the close of business covered by the annual report.

Ordinary shares, no par value, with a notional amount attributable to each share of €1 outstanding up until March 3, 2025, the most recent practicable date, no par value: 239,970,804

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐ 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 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☐ International Financial Reporting Standards as issued by the International Accounting Standards Board ☒ Other ☐

If "Other" has been checked in response to the previous question indicate by check mark which financial statement item the registrant has elected to follow. Item 17 ☐ Item 18 ☐

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No ☒

* Listed not for trading or quotation purposes, but only in connection with the registration of American Depositary Shares representing such ordinary shares pursuant to the requirements of the Securities and Exchange Commission. The American Depositary Shares are registered under the Securities Act of 1933, as amended, pursuant to a separate registration statement on Form F-6 (File No. 333-233898).

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GENERAL INFORMATION

In this Annual Report on Form 20-F, or the Annual Report, "BioNTech," the "Group," the "Company," "we," "us," and "our" refer to BioNTech SE and its consolidated subsidiaries, except where the context otherwise requires.

In response to the fact that our consolidated financial statements are published in Euro, the selected consolidated financial data is presented in Euro as well. Amounts in U.S. dollar are translated into Euro using the exchange rates as per period end or average exchange rates for the periods indicated as published by the German Central Bank (Deutsche Bundesbank).

All references in this Annual Report to "$" mean U.S. dollars and all references to "€" mean Euros.

This Annual Report contains references to our trademarks and to trademarks belong to other entities. Solely for convenience, trademarks and trade names referred to, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Our trademark portfolio includes, but is not limited to, *BioNTech, Comirnaty*, *BioNTainer*, *FixVac*, *RiboCytokine*, and *RiboMab*, including logo versions of some of these trademarks. Brand names appearing in italics throughout this report are trademarks owned by BioNTech. All other trademarks are the property of their respective owners.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report 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. Any statements that are not of historical facts may be deemed to be forward-looking statements. Many of the forward-looking statements contained in this Annual Report can be identified by the use of forward-looking words such as “believes”, “estimates”, “anticipates”, “expects”, “plans”, “intends”, “may”, “could”, “might”, “will”, “should”, “aims” or other similar expressions that convey uncertainty of future events or outcomes.

These forward-looking statements are subject to known and unknown risks, uncertainties, assumptions and other factors that could cause our actual results of operations, financial condition, liquidity, performance, prospects, opportunities, achievements or industry results, as well as those of the markets we serve or intend to serve, to differ materially from those expressed in, or suggested by, these forward-looking statements. These forward-looking statements are based on assumptions regarding our present and future business strategies and the environment in which we expect to operate in the future. Important factors that could cause those differences include, but are not limited to:

- the extent to which COVID-19 vaccines continue to be necessary in the future and any effects of reduced demand for our COVID-19 vaccine, including the write-down of inventory and costs relating to contract manufacturing production capacities that become redundant or unutilized;
- our expected revenues and net profit related to sales of our COVID-19 vaccine (also referred to as *Comirnaty* in the United States and in the European Union to the extent authorized for use), respectively, in territories controlled by our collaboration partners, particularly for those figures that are derived from preliminary estimates provided by our partners;
- 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;
- our pricing and coverage negotiations for our COVID-19 vaccine with governmental authorities, private health insurers and other third-party payors after our initial sales to national governments;
- competition from other COVID-19 vaccines or related to our other product candidates, including those with different mechanisms of action and different manufacturing and distribution constraints, on the basis of, among other things, efficacy, cost, convenience of storage and distribution, breadth of approved use, safety, side-effect profile and durability of immune response;
- the timing and ability of us and our collaborators to obtain regulatory approval for our COVID-19 vaccine and our product candidates, and to commercialize our approved and investigational product candidates, if approved;
- the pricing and reimbursement of our COVID-19 vaccine and our product candidates, if approved;

- the rate and degree of market acceptance of our COVID-19 vaccine and our product candidates, if approved;
- our ability to identify research opportunities and discover and develop product candidates;
- our ability to utilize our resources on-hand and to focus on the development of product candidates that will maximize shareholder value and our corporate pillars;
- our measures anticipated to be taken in connection with our strategic vision, including estimated FTE increases and decreases;
- the ability and willingness of our third-party collaborators to continue research and development activities relating to our product candidates;
- our expectations regarding the size of the patient populations for our product candidates, if approved for commercial use;
- unforeseen safety issues and claims for personal injury or death arising from the use of our COVID-19 vaccine and other products and product candidates developed or manufactured by us;
- our estimates of our expenses, 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, our ability to protect and defend against potential claims of others' intellectual property, and the scope of such protection;
- the development of and projections relating to our competitors or our industry;
- the amount of and our ability to use net operating losses and research and development credits to offset future taxable income;
- our ability, and that of our collaboration partners, as applicable, to manage development and expansion;
- regulatory developments in the United States and foreign countries;
- political uncertainty;
- our ability to effectively scale our production capabilities and manufacture our products, including our COVID-19 vaccine, and our product candidates;
- our expectations with respect to the timing and amount of any dividends and any potential repurchases of our outstanding American Depositary Shares, or ADSs;
- our expectations regarding the timing of customer payments for delivered COVID-19 vaccine;
- our ability to implement, maintain and improve effective internal controls; and
- other factors not known to us at this time.

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 Annual Report speak only as of the date of this report, 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.

PART I

Item 1. Identity of Directors, Senior Management and Advisers

Not applicable.

Item 2. Offer Statistics and Expected Timetable

Not applicable.

Item 3. Key Information

A. [Reserved]

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

Our business is subject to various risks, including those described below. You should consider carefully the risks and uncertainties described below and in our future filings. If any such risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. Additionally, risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition, results of operations and/or prospects.

Risk Factor Summary

- Our business is dependent on the successful development, regulatory approval and commercialization of new medicinal product candidates based on our technology platforms, particularly our oncology assets including BNT327 and our antibody-drug conjugate, or ADC, clinical assets. If we and our collaborators are unable to obtain approval for and to effectively commercialize our product candidates for the treatment of patients in their intended indications, our business would be significantly harmed.

- We are developing product candidates and services, including our oncology pipeline and ADC product candidates, in an environment of rapid technological and scientific change, including evolving standards of care, 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.

- Our product candidates may not work as intended, may cause undesirable 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, and we may have difficulty recruiting patients to participate in clinical trials, any of which can affect our ability to fund our company and would have a material adverse impact on our business.

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

- Demand for our COVID-19 vaccine, though difficult to predict, is expected to continue to decrease in the near future. Changing market dynamics, including as a result of government policy and public sentiment, will impact our revenue, which currently depends heavily on sales of our COVID-19 vaccine, and result in challenges relating to production of our COVID-19 vaccine.

- Our reported revenue is partially based on preliminary estimates of COVID-19 vaccine sales and costs from Pfizer Inc., or Pfizer, that are likely to change in future periods, which may impact our reported financial results.

- Other companies or organizations may challenge our intellectual property rights or may assert intellectual property rights that prevent us from developing and commercializing our COVID-19 vaccine or our product candidates and other technologies, or that negatively affect our results of operations.

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

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

- If we identify material weaknesses in our internal control over financial reporting and fail to remediate such material weaknesses, we may not be able to report our financial results accurately or to prevent fraud.

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

- Our approved product and product candidates are based on novel technologies and they 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.

- If our efforts to obtain, maintain, protect, defend and/or enforce the intellectual property related to our COVID-19 vaccine or our product candidates and technologies are not adequate, we may not be able to compete effectively in our market.

- We have experienced and may continue to experience significant volatility in the market price of the ADSs representing our ordinary shares.

- 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.

Risks Related to our Business

Our business is dependent on the successful development, regulatory approval and commercialization of new medicinal product candidates based on our technology platforms, particularly our oncology assets including BNT327 and our antibody-drug conjugate, or ADC, clinical assets. If we and our collaborators are unable to obtain approval for and to effectively commercialize our product candidates for the treatment of patients in their intended indications, our business would be significantly harmed.

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain, and we may not be able to obtain full approvals, or may only obtain partial approvals, in the requested indication for the commercialization of product candidates we may develop. Any product candidates we may develop and the activities associated with their development and commercialization, including design, testing, manufacture, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and by comparable global health authorities. To obtain the requisite regulatory approvals required to commercialize any of our product candidates, we and our collaborators must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective for their intended use in the relevant target population. Successful completion of clinical trials is a prerequisite to submitting a biologics license application, or BLA, or a new drug application, or NDA, to the FDA, a Marketing Authorization Application, or MAA, to the EMA, and similar marketing applications to comparable global regulatory authorities, for each product candidate and, consequently, the ultimate approval and commercial marketing of any product candidates.

Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. Although our COVID-19 vaccine has received emergency use authorization and/or regulatory approvals in certain countries, it is possible that none of our other product candidates, or any product candidates we may seek to develop in the future, will ever obtain regulatory approval. We have limited experience in filing and supporting the applications necessary to gain marketing approvals and may need to rely on third-party contract research organizations, or CROs, regulatory consultants or collaborators to assist us in this process. We expect to submit initial BLAs/MAAs for our product candidates in the United States, the European Union and in other countries globally. In some of these jurisdictions, mRNA-based medicinal products may be classified in different ways and may be subject to specific requirements. Securing regulatory approval requires the submission of extensive quality, preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Clinical benefit and risk are regularly assessed during development, and any new medicinal product we develop may turn out to be insufficiently, i.e., not clinically meaningfully, effective, or may prove to have unacceptable adverse effects, or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals in the United States, the European Union and elsewhere is expensive, and if additional clinical trials are required, may take many years. Timing can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies and standards of care during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application. The FDA, EMA and comparable regulatory authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that the data are insufficient for approval and require additional preclinical, clinical or other trials. In addition, varying interpretations of the data obtained from preclinical and clinical testing

could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. Additional delays or non-approval may result if an FDA panel of experts, referred to as an Advisory Committee, or other regulatory authority recommends non-approval or restrictions on approval. For example, the FDA's approval of our LP.8.1-adapted monovalent COVID-19 vaccine is in a narrower population than our previous variant-adapted vaccines. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical trials, and the review process. Officials appointed by the U.S. presidential administration to oversee the agencies involved with approval of drugs and biologics may seek to change regulatory requirements for approval or the approach to reviewing applications. Together with changes of regulatory policy priorities and allocated resources, this could cause further delays, expense or non-approvals.

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

The FDA, EMA and other regulatory agencies review the Quality or Chemistry, Manufacturing and Controls, or CMC, section of regulatory filings. Any aspects found unsatisfactory by regulatory agencies may result in delays in clinical trials and commercialization. In addition, the regulatory agencies typically conduct pre-approval inspections at the time of a BLA, MAA or comparable filing. Any findings by regulatory agencies and failure to comply with requirements may lead to delay in approval and failure to commercialize the potential mRNA product candidate.

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

We are developing product candidates and services, including our oncology pipeline and ADC product candidates, in an environment of rapid technological and scientific change, including evolving standards of care, and geopolitical uncertainties, and our failure to effectively compete would prevent us from achieving significant market penetration. Most of our competitors have significantly greater resources than we do and we may not be able to compete successfully.

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

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

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

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

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

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

Following our acquisition of InstaDeep Ltd., or InstaDeep, we also face competition in the rapidly growing and developing artificial intelligence, or AI, industry. Our competitors may develop or commercialize products and services with significant advantages over any products we develop based on any of the factors listed above or on other factors. In addition, our competitors may develop collaborations with or receive funding from larger pharmaceutical, biotechnology or technology companies, providing them with an advantage over us. Our competitors therefore may be more successful in commercializing their products and services than we are, which could adversely affect our competitive position and business. Competitive products and services may make any products and services we develop obsolete or non-competitive before we can recover the expenses of developing and commercializing such products, if approved, and services.

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

As with most medicinal products, use of our product candidates could be associated with undesirable effects or adverse events which can vary in severity from minor reactions to death and in frequency from infrequent to prevalent. The potential for adverse events is especially acute in the oncology setting, where patients may have advanced disease, impaired organ function, compromised immune and other systems and may be receiving

numerous other therapies. Undesirable side effects or unacceptable toxicities caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, the EMA or comparable regulatory authorities. Results of our trials could reveal a high and unacceptable severity and prevalence of adverse reactions that negatively affect the benefit/risk assessment .

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

Clinical trials are strictly regulated and monitored by sponsors, independent data and safety monitoring boards, ethics committees, and regulatory agencies. Despite adequate risk minimization measures, unexpected events may occur that could adversely impact patients' safety and/or affect our ability to obtain regulatory approvals and, if approved, commercialize our product candidates.

In our ongoing and planned clinical trials, we have contracted, and are expected to continue to contract, with academic medical centers and hospitals experienced in the assessment and management of toxicities arising during clinical trials. Nonetheless, these centers and hospitals may have difficulty observing patients and treating toxicities, which may be more challenging due to personnel changes, inexperience, shift changes, house staff coverage or related issues. This could lead to more severe or prolonged toxicities or even patient deaths, which could result in us or the FDA, the EMA or other comparable regulatory authority delaying, suspending or terminating one or more of our clinical trials, and which could jeopardize regulatory approval. The centers using our products, if and when approved, could also have difficulty managing any adverse effects of our products, or use medicines that do not adequately control such undesirable effects or that have a detrimental impact on the efficacy of the treatment.

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

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

- regulatory authorities may withdraw their approval of the product;
- we may be required to recall a product or change the way such product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;

- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- we may be required to implement a Risk Evaluation and Mitigation Strategy, or REMS, or create a Medication Guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may be negatively impacted.

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

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

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

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

Clinical testing is expensive and complex and can take many years to complete. Its outcome is inherently uncertain. We may not be able to initiate, may experience delays in, or may have to discontinue clinical trials for our product candidates. We and our collaborators also may experience numerous unforeseen events during, or

as a result of, any clinical trials that we or our collaborators conduct that could delay or prevent us or our collaborators from successfully developing our product candidates, including:

- the FDA, other regulators, IRBs or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site for any number of reasons, including concerns regarding safety and aspects of the clinical trial design;
- we may experience delays in reaching, or fail to reach, agreement on favorable terms with prospective trial sites and prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- we have optimized in the past and may in the future optimize our manufacturing processes, including through changes to the scale and site of manufacturing, which may lead to additional studies (including bridging and bioequivalence studies) or potentially significant changes in our clinical trial designs, requiring additional cost and time, and, as a consequence, lead to a delay in plans for progressing one or more product candidates;
- the outcome of our preclinical studies and our early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results;
- we may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful;
- in an effort to optimize product features, we have made in the past and may continue to make changes to our product candidates after we commence clinical trials of a medicine which may require us to repeat earlier stages of clinical testing or delay later-stage testing of the medicine;
- clinical trials of any product candidates may fail to show safety or efficacy, or may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional nonclinical studies or clinical trials, or we may decide to abandon product development programs;
- differences in trial design between early-stage clinical trials and later-stage clinical trials may make it difficult to extrapolate the results of earlier clinical trials to later clinical trials;
- preclinical and clinical data are often susceptible to varying interpretations and analyses, and many product candidates believed to have performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval;
- our product candidates may have undesirable effects or other unexpected characteristics. One or more of such effects or events could cause regulators to impose a clinical hold on the applicable trial, or cause us or our investigators, IRBs or ethics committees to suspend or terminate the trial of that product candidate or any other of our product candidates for which a clinical trial may be ongoing;
- the number of trial participants required for clinical trials of any product candidates may be larger than we anticipate, identification of trial participants for such trials may be limited, enrollment in these clinical trials may be slower than we anticipate due to perceived adverse effects, limited patient populations, competitive trials, or other reasons, or participants may withdraw from clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- despite robust sponsor oversight, our and our collaborators' third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations in a timely manner, or at all, or may deviate from the clinical trial protocol or withdraw from the trial, which may require the addition of new clinical trial sites;

- regulators may elect to impose a clinical hold, or we, our investigators, IRBs or ethics committees may elect to suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to an unacceptable benefit-risk ratio;

- with respect to infectious disease vaccine trials in particular, we have to wait for a particular level of infection in the placebo arm in order to assess protection provided by vaccine, and we cannot control the rate of exposure or infection which can make timing uncertain;

- patient characteristics, the rate of disease progression, and other external influences beyond our control can make the timing of analysis uncertain, particularly in the case of later-stage oncology trials;

- the cost of preclinical or nonclinical testing and studies and clinical trials of any product candidates may be greater than we anticipate;

- the supply or quality of our product candidates or other materials necessary to conduct clinical trials may be insufficient or inadequate;

- safety or efficacy concerns regarding our product candidates may result from any concerns arising from nonclinical or clinical testing of other therapies targeting a similar disease state or other therapies, such as gene therapy, that are perceived as similar to ours; and

- the FDA or other regulatory authorities may require us to submit additional data, such as long-term toxicology studies, or impose other requirements before permitting us to initiate a clinical trial.

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

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

We must also complete extensive work on CMC activities that require extensive manufacturing processes and analytical development, which are uncertain and lengthy. The FDA and other regulatory authorities have indicated that, prior to commencing later stage clinical trials for our mRNA-based product candidates, we will need to scale up and further refine assays to measure and predict the potency of a given dose of these product candidates. Any delay in the scaling and refining of assays that are acceptable to the FDA or other regulatory authorities could delay the start of future clinical trials. Further, the FDA or other regulatory authorities may disagree with our clinical trial design and our interpretation of data for our clinical trials or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials.

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

In addition, on June 28, 2024, the Supreme Court overturned the *Chevron* doctrine in the combined cases of *Loper Bright Enterprises v. Raimondo* and *Relentless Inc. v. Department of Commerce*. The *Chevron* doctrine gave deference to regulatory agencies in litigation against the FDA and other agencies. In addition, the Supreme Court decided *Corner Post, Inc. v. Board of Governors of the Federal Reserve System*, which lengthened the time in which some challenges to agency rules can be initiated. As a result of these cases, more plaintiffs may bring lawsuits against the FDA to challenge longstanding decisions and policies of the FDA, which could undermine the FDA's authority, lead to uncertainties in the industry, and disrupt the FDA's normal operations, which could delay the FDA's review of our marketing applications.

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

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

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

- severity of the disease under investigation;
- complexity and design of the study protocol;
- size of the patient population;

- eligibility criteria for the study in question;
- proximity and availability of clinical study sites for prospective trial participants;
- availability of competing therapies and clinical trials, including between our own clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- ability to monitor trial participants adequately during and after treatment;
- ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and trial participants' perceptions of the potential advantages and side effects of the product candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating;
- our ability to obtain and maintain participant informed consent;
- major changes in the approval status of competitor investigational products during the clinical trial period; and
- the risk that trial participants enrolled in clinical trials will not complete a clinical trial.

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

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

We, our collaborators, and other third parties on whom we rely conduct various activities, including research, clinical trials, manufacturing and, where approved, marketing, in jurisdictions across the globe. Such activities are subject to a variety of risks which could materially and adversely affect our business.

Our activities increasingly span different jurisdictions. For example, clinical trials of our product candidates are currently being conducted in several countries, and we plan to commercialize our product candidates, if

approved, globally. Accordingly, we are subject to additional risks related to operating in multiple countries, including:

- differing regulatory requirements in such countries;
- differences in the standard of care across jurisdictions, which complicates the choice of adequate comparator therapies in global trials;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- increased difficulties in managing the logistics and transportation of storing and shipping product candidates produced in Germany and shipping the product candidate to the patient abroad;
- import and export requirements and restrictions;
- restrictions on transfers of information, including certain technologies and personal data;
- economic weakness, including inflation, or changes to the political climate, public sentiment, and government policy preferences in certain economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- taxes, including withholding of payroll taxes;
- currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing operations outside of Germany;
- workforce uncertainty in countries where labor unrest is more common;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems, and price controls;
- potential liability under the U.S. Foreign Corrupt Practices Act of 1977 or comparable regulations in other jurisdictions;
- challenges enforcing our contractual and intellectual property rights, especially in those countries that do not respect and protect intellectual property rights to the same extent as Germany and the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or public health epidemics or pandemics.

As part of our global operations, we and our collaborators rely on relationships with entities based in various jurisdictions, including for clinical research and manufacturing activities and other regional operational needs. Such relationships may involve the use of our or others' intellectual property. We expect to continue to rely on such entities, which include locally-based contract manufacturing organizations, or CMOs, and CROs, in the future. For example, we and our collaborators rely on WuXi Biologics Co., Ltd. and its affiliates for outsourcing activities related to manufacturing and the supply chain, research and development, certain IP, and commercialization readiness for certain of our product candidates. Such entities are subject to evolving local regulatory requirements, and may also be subject to U.S. and EU legislation, including the recently enacted U.S.

BIOSECURE Act, sanctions, trade restrictions, and/or other regulations. Such requirements could increase the cost or reduce the supply of material available to us, delay or restrict the procurement or supply of such material, or have an adverse affect on our ability to secure significant commitments from governments to purchase our potential therapies.

Further, governments may turn, and have turned, to trade barriers to protect their domestic industries against foreign imports, thereby increasing our cost to operate globally. If significant tariffs or other restrictions are imposed on imports by the United States and related countermeasures are taken by impacted countries, our business, including operating results, cash flows, and financial condition, may be adversely affected. Recently, trade and tariff policies among the United States and other countries have been unsettled and are subject to frequent changes. The U.S. government has imposed tariffs and other trade restrictions on goods across a range of industries, and such actions have at times prompted retaliatory measures by affected countries such as China, Canada and the European Union. While tariffs with certain countries have been temporarily reduced or paused, the imposition of new tariffs will likely be met with further reciprocal tariffs, thus increasing the possibility of a global trade war. If further tariffs are imposed on a broader range of imports, or if retaliatory trade measures are enacted by affected countries, these factors could significantly increase the cost to our global clinical research and manufacturing activities, adversely affect the commercial sale of our COVID-19 vaccines, and harm our competitive position in key markets. Additionally, ongoing trade tensions and uncertainty regarding future trade policies could negatively impact global economic conditions and consumer confidence, further affecting our global operations.

As noted above, we and our partners have conducted and are expecting in the future to conduct clinical trials for our product candidates at clinical sites located outside of the United States. Although the FDA may accept data from clinical trials outside the United States that are not conducted under an IND, acceptance of this data in support of a marketing application or IND requires the clinical trial to have been conducted in accordance with GCPs, and that the FDA is able to validate the data from the clinical trial through an onsite inspection if it deems such inspection necessary. Where data from non-U.S. clinical trials are intended to serve as the sole basis for marketing approval in the United States, the FDA will not approve the application on the basis of non-U.S. data alone unless those data are considered applicable to the U.S. patient population and U.S. medical practice, the clinical trials were performed by clinical investigators of recognized competence, and the data is considered valid without the need for an onsite inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an onsite inspection or other appropriate means. There can be no assurance the FDA will accept data from clinical trials conducted outside of the United States in support of a marketing application. If the FDA does not accept data from our clinical trials of our product candidates, it would likely result in the need for additional clinical trials, which would be costly and time-consuming and delay or permanently halt our development of a product candidate.

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

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

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

preliminary data should be viewed with caution until the final data are available. Additionally, interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

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

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

Success in preclinical studies and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in clinical trials, even after positive results in earlier preclinical studies or clinical trials. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. Notwithstanding any potential promising results in earlier studies and trials, we cannot be certain that we will not face similar setbacks. Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval for our product candidates. In addition, the results of our preclinical studies may not be predictive of the results of outcomes in human clinical trials. For example, our tumor-specific cancer immunotherapy candidates and any future product candidates may demonstrate different chemical, biological and pharmacological properties in patients than they do in laboratory studies or may interact with human biological systems in unforeseen or harmful ways. Product candidates in later stages of clinical trials may fail to show the desired pharmacological properties or safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Even if we are able to initiate and complete clinical trials, the results may not be sufficient to obtain regulatory approval for our product candidates.

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

There is typically an extremely high rate of attrition for product candidates across categories of medicines proceeding through clinical trials.

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

Many of our product candidates are being developed or are intended to be co-administered with other developmental therapies or approved medicines. For example, autogene cevumeran (BNT122/RO7198457) is being developed to be co-administered with checkpoint inhibitors. Such combinations may have additional side effects, which may be difficult to predict in future clinical trials.

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

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

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

- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete;
- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- a product candidate may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- we may discontinue the development of a product candidate;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- an approved product may not be accepted as safe and effective by trial participants, the medical community or third-party payors.

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

mRNA drug development carries substantial clinical development and regulatory risks due to limited regulatory experience with mRNA immunotherapies.

To our knowledge, other than our, Moderna, Inc.'s and Arcturus Therapeutics' vaccines, no mRNA immunotherapies have been approved or received emergency use authorization or conditional marketing authorization to date by the FDA or the EMA. Successful discovery and development of mRNA-based (and other) immunotherapies by either us or our collaborators is highly uncertain and depends on numerous factors, many of which are beyond our or their control. Our product candidates that appear promising in the early phases of development may fail to advance, experience delays in the clinic or clinical holds, or fail to reach the market for many reasons, including:

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

For administrative purposes, some mRNA products may be classified together with gene therapy products by the FDA or other regulatory agencies. Unlike certain gene therapies that irreversibly alter cell DNA and may be subsequently subject to specific safety concerns, mRNA products are not designed to localize to the cell nucleus or interact with the genome. Side effects observed in other gene therapies, however, could negatively impact the perception of immunotherapies despite the differences in mechanism. In addition, unclear or inconsistent regulatory classification of mRNA products may result in uncertainties regarding the regulatory requirements and pathways for marketing approval. On the other hand, mRNA-based vaccines for the prevention of infectious diseases, like our COVID-19 vaccine, are not currently classified as gene therapies in most regions. The regulatory pathway for an individualized therapy, such as our Individualized Neoantigen Specific Immunotherapy, or iNeST, an mRNA-based immunotherapy where each patient receives a different combination of mRNAs, remains undetermined. The number and design of the clinical and preclinical studies required for the approval of

these types of medicines have not been established, may be different from those required for advanced medicinal therapy products or therapies that are not individualized or may require safety testing like gene therapy products. Moreover, the length of time necessary to complete clinical trials and submit an application for marketing approval by a regulatory authority varies significantly from one pharmaceutical product to the next and may be difficult to predict.

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

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent upon members of our management and scientific teams. We may not be able to retain these persons due to the competitive environment in the biotechnology industry, as well as a current global shortage of these highly qualified individuals. The loss of any of these persons' services may adversely impact the achievement of our research, development, financing and commercialization objectives. We are also aware of physical threats made against certain of these people. In response to these threats, we have deployed personal protection for such individuals and increased our security generally. We currently do not have "key person" insurance on any of our employees.

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

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

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

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

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

Employment-related disputes, including employee litigation and unfavorable publicity, could negatively affect our future business.

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

The illegal distribution and sale by third parties of counterfeit versions of our COVID-19 vaccine, or, if approved, our other product candidates, could have a negative impact on our financial performance or reputation.

Third parties have in the past and may continue to illegally distribute and sell counterfeit versions of COVID-19 vaccines. Counterfeit products are frequently unsafe or ineffective, and may even be life-threatening. Counterfeit medicines may contain harmful substances or the wrong dosage. However, to distributors and users, counterfeit products may be visually indistinguishable from the authentic version.

Reports of adverse reactions to counterfeit products, increased levels of counterfeiting, or unsafe vaccines could materially affect public confidence in our COVID-19 vaccine or other product candidates. It is possible that adverse events caused by unsafe counterfeit vaccines will mistakenly be attributed to our COVID-19 vaccine, or, if approved, our other product candidates. In addition, thefts of inventory at warehouses, plants or while in-transit, which are subsequently improperly stored and which are sold through unauthorized channels, could adversely impact patient safety, our reputation, and our business. Public loss of confidence in the integrity of our COVID-19 vaccine or, if approved, our other product candidates, as a result of counterfeiting or theft could have a material adverse effect on our business, results of operations, and financial condition.

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

Our internal computer systems and those of our current and any future collaborators, vendors, and other contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, cybersecurity threats, war, and telecommunication and electrical failures. If any such material system failure, accident or security breach were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from one or more ongoing or completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, because of our approach of running multiple clinical trials in parallel, any breach of our computer systems may

result in a loss of data or compromised data integrity across many of our programs in many stages of development. Any such breach, loss or compromise of clinical trial participant personal data may also subject us to civil fines and penalties, including under the EU General Data Protection Regulation, or the GDPR, relevant law of an EU member state, HIPAA, and other relevant state and federal privacy laws in the United States or in other jurisdictions. To the extent that any disruption or security breach were to result in a loss of, or damage to, data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed, and the further development and commercialization of our product candidates could be delayed.

While we have not experienced any material system failures, accidents or security breaches to date, in December 2020, we were informed by the EMA that the agency was subject to a cyberattack and that some documents relating to our regulatory submission for our COVID-19 vaccine candidate, which was stored on an EMA server, had been unlawfully accessed. None of our systems were breached in connection with this incident and we are unaware that any study participants were identified through the data being accessed.

We have put systems and procedures in place to minimize the likelihood of such incidents reoccurring; however, we cannot guarantee that third parties will not be able to gain unauthorized access to or otherwise breach our systems in the future. Any such unauthorized access or breach could adversely affect our business, results of operations and financial condition.

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

We face an inherent risk of product liability exposure related to the testing of any of our current or future product candidates in clinical trials, and an even greater risk related to any commercialized products, such as our COVID-19 vaccine. We have received product liability claims against our COVID-19 vaccine, and expect to receive additional product liability claims in the future. If we cannot successfully defend ourselves against claims that our products and/or our product candidates have caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

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

We carry clinical trial insurance and product liability insurance, which we believe to be sufficient in light of our current clinical programs and commercial operations. However, the amount of coverage we have obtained may not be adequate, and we may seek to further increase insurance coverage limits as our pipeline moves towards commercialization. As we evolve, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. On occasion, large judgments have been awarded in class action lawsuits based on drugs or medical treatments that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause the price of the ADSs to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

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

The FDA and similar governmental authorities in other jurisdictions have the authority to require the recall of certain commercialized products. In the case of the FDA, the authority to require a recall of a biologic product must be based on an FDA finding that a batch, lot or other quantity of the biologic product presents an imminent or substantial hazard to the public health. In addition, some governmental bodies outside the United States have the authority to require the recall of any product or product candidate in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a product is found. A government-mandated or voluntary recall by us could occur as a result of manufacturing errors, design or labeling defects or other deficiencies and issues.

Recalls of any of our products or, if approved, our product candidates, would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. A recall announcement could harm our reputation with customers and negatively affect our sales, if any.

Issues in the development and use of AI, combined with an uncertain regulatory environment, may result in reputational harm, liability or other adverse consequences to our business.

We are investing in AI technology systems, including through our acquisition of InstaDeep, and such systems are complex and rapidly changing. We face significant competition from other companies with respect to our AI and machine learning services, along with an evolving regulatory landscape. The introduction of AI into the development and manufacturing of our product candidates, or the provision of services relating to AI technologies and applications, may result in new or enhanced governmental or regulatory scrutiny, litigation, intellectual property risks, confidentiality or security risks, ethical concerns or other complications that could harm our business, reputation or financial condition.

Uncertainty around AI may require additional investment in the development and maintenance of proprietary datasets and development of appropriate protections and safeguards for handling the use of customer data with AI technologies, which may be costly and could impact our expenses. In addition, AI may create content that appears correct but is inaccurate or flawed, and if created by third parties, may be mistakenly attributed to us. Our customers or others may rely on or use this flawed content to their detriment, which may expose us to brand or reputational harm, competitive harm or legal liability.

Our ability to effectively monitor and respond to the rapid and ongoing developments and expectations relating to environmental, social and governance, or ESG, matters, including related social expectations and concerns, may impose unexpected costs or result in reputational or other harm that could have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the price of ADSs representing our ordinary shares to decline.

There are rapid and ongoing developments and changing, sometimes conflicting, expectations relating to ESG matters and factors such as the environmental impact of our operations, access to our COVID-19 vaccine, corporate governance, our product stewardship practices, management of business ethics, human rights due diligence in our own operations and our supply chain, and workforce development. At the same time, ESG matters, including climate change, are the subject of increased politicization, particularly in the United States. These factors may result in increased regulatory, social or other scrutiny on us.

We believe we must address climate risks from our own contribution to climate change (inside-out perspective), risks to our own operations due to physical effects of climate change as well as transition risks (outside-in perspective), and interactions between both perspectives. To this end, we have set ourselves near-term scienced-based emissions reduction targets for our own operations (scope 1, 2) and for our supply chain (supplier engagement target for scope 3), validated by the Science Based Targets initiative, or SBTi, in early February 2024.

Additionally, we are addressing increasingly complex regulatory requirements with respect to human rights risks. These requirements include German legislation, such as the Act on Corporate Due Diligence Obligations for the Prevention of Human Rights Violations in Supply Chains (Lieferkettensorgfaltspflichtengesetz – LkSG), potential legislative planning by the European Union, and local or regional regulations. Regulatory frameworks require us to identify, prevent, mitigate and ideally end the extent of any potential adverse impacts or violations throughout our own operations and value chain.

Finally, we are faced with increasing ESG related transparency and reporting obligations. These requirements arise, for example, from the EU Corporate Sustainability Reporting Directive regulation, the European Sustainability Reporting Standards, and the respective German implementation law and other possible obligations.

Should we fail to meet our climate protection targets or if we are unable to adequately recognize and respond to such developments and governmental, societal, investor and NGO expectations relating to such ESG matters, we may have to pay substantial fines, forego corporate opportunities, become subject to additional scrutiny, incur unexpected costs or experience damage to our reputation or our various brands. If any of these events were to occur, there may be a material adverse effect on our business, financial condition, cash flows and results of operations, and the price of ADSs representing our ordinary shares may decline.

We have observed that in addition to the importance of their financial performance, companies are increasingly being judged by their performance on ESG matters. A variety of organizations measure the performance of companies on such ESG topics, and the results of these assessments are widely publicized. We may fail to comply with standards or best practices put forth by such organizations or by governmental or regulatory bodies. There can be no certainty that we will manage such issues successfully, or that we will successfully meet society's expectations as to our proper role. Any failure or perceived failure by us in this regard could have a material adverse effect on our reputation and on our business, the price of ADSs representing our ordinary shares, financial condition, or results of operations, including the sustainability of our business over time.

Risks Related to our COVID-19 Vaccine and the Commercialization of our Pipeline

Demand for our COVID-19 vaccine, though difficult to predict, is expected to continue to decrease in the near future. Changing market dynamics, including as a result of government policy and public sentiment, will impact our revenue, which currently depends heavily on sales of our COVID-19 vaccine, and result in challenges relating to production of our COVID-19 vaccine.

Prior to the commercialization of our COVID-19 vaccine, we had not sold or marketed any products in our pipeline. As a result, a majority of our total revenues to date are attributable to sales of our COVID-19 vaccine. However, we have experienced and we expect to continue to experience increasing reductions in demand for COVID-19 vaccination generally, including for our vaccine, now that the virus has entered an endemic stage and as a growing proportion of the population becomes vaccinated. We expect that future revenues from sales of our COVID-19 vaccine will decrease as demand for vaccination wanes. Such revenues will depend on numerous factors, including:

- the extent to which a COVID-19 vaccine, including any booster shot, continues to be necessary while COVID-19 remains an endemic virus;
- competition from other COVID-19 vaccines, including those with different mechanisms of action and different manufacturing and distribution constraints, on the basis of, among other things, efficacy, cost, convenience of storage and distribution, breadth of approved use, side-effect profile and durability of immune response;
- our ability to successfully and timely develop effective vaccines targeting new variants and mutations of COVID-19;

- the extent to which changes in local, national and state government policy preferences in the United States and other jurisdictions, including changes in vaccine recommendations, and evolving public sentiment affect demand for COVID-19 vaccines or mRNA therapeutics and our ability to successfully commercialize our product candidates, if approved;

- our ability to receive full regulatory approvals where we currently have, or previously have had, emergency use authorizations or equivalents;

- our ability to expand our geographic customer base;

- our pricing and reimbursement negotiations with governmental authorities, private health insurers and other third-party payors after our initial sales to national governments, including the transition towards ordinary-course insurance coverage in the public and private sectors;

- the ability of countries and jurisdictions to store and distribute doses of our COVID-19 vaccine to end users at cold temperatures;

- the safety profile of our COVID-19 vaccine, including if previously unknown undesirable effects or increased incidence or severity of known undesirable effects are identified with our COVID-19 vaccine;

- intellectual property litigation involving our COVID-19 vaccine and COVID-19 vaccines in general; and

- our manufacturing and distribution capabilities for our COVID-19 vaccine.

We cannot accurately predict the revenues our COVID-19 vaccine will generate in future periods or for how long our COVID-19 vaccine will continue to generate material revenues, and we cannot ensure it will maintain its competitive position. Uncertainty in the demand for our COVID-19 vaccine and difficulties in targeting appropriate supply of our COVID-19 vaccines have in the past resulted, and may in the future result, in significant inventory write-downs and cancellations of contract manufacturing orders. Our business and financial condition could be materially affected by lowered COVID-19 vaccine revenues resulting from any of the above factors, or by production and supply chain difficulties. In addition, if our revenues or market share of, or other financial metrics relating to, our COVID-19 vaccine do not meet the expectations of investors or securities analysts, the market price of the ADSs representing our ordinary shares may decline.

Our reported revenue is based in part on preliminary estimates of COVID-19 vaccine sales and costs from Pfizer that are likely to change in future periods, which may impact our reported financial results.

Our reported revenue is based in part on preliminary estimates from Pfizer and other assumptions and judgments that we have made, which may be subject to significant uncertainties. Our revenue includes preliminary estimates in part due to a difference in Pfizer's financial quarter for subsidiaries outside the United States, which consequently creates an additional time lag between the recognition of revenues and the receipt of payment. Although our revenue recognition policy is based on facts and circumstances known to us and various other assumptions that we believe to be reasonable under the circumstances, our actual results may deviate from such reported revenue.

We depend on Pfizer to determine and provide estimates of the costs and profits to be shared with us in the countries where it is commercializing our COVID-19 vaccine under our collaboration agreement with Pfizer for our COVID-19 vaccine, which we refer to as the Pfizer Agreement. Because the information supplied by Pfizer is preliminary and subject to change, the revenue we report based on such information is also subject to finalization. This is particularly true for vaccine sales outside of the United States, where Pfizer has a different reporting cycle than ours. As a result, we may not have the complete sales and costs results outside of the United States for months not covered by the reporting period, but we are nonetheless required to report estimated figures.

Pfizer has historically provided us with profit figures for our COVID-19 vaccine sales in the United States using standard U.S. transfer prices and manufacturing and shipping cost variances (as far as those have been identified) that could be subject to adjustment (e.g., due to changes in manufacturing costs or the price of our COVID-19 vaccine). Pfizer has also provided estimated profits for COVID-19 vaccine sales outside of the United States that were preliminary in nature for the last month of a quarter, as Pfizer's subsidiaries outside of the United States have a different reporting cycle than ours. These estimated figures have changed, and in the future such estimated figures are likely to change, as we receive final data from Pfizer for the applicable period in accordance with the reporting cycle of Pfizer's ex-U.S. subsidiaries and as actual costs become known. Further, to the extent that Pfizer does not provide such preliminary information in the future, our provisional sales figures for territories outside of the United States will be subject to an even greater level of estimate and judgment. Any changes to the preliminary data we report herein may have an impact on our reported revenues and expenses, profitability or financial position.

We may be unsuccessful in adapting our COVID-19 vaccine or developing future versions of our COVID-19 vaccine to protect against variants of the SARS-CoV-2 virus, and even if we are successful, a market for vaccines against these variants may not develop and our ability to continue to generate income from sales of our COVID-19 vaccine is uncertain.

The COVID-19 disease itself is unpredictable and each variant comes with varying levels of transmissibility and severity. Consequently, the burden of the disease may wane or dissipate such that our and other COVID-19 vaccines may be considered less essential from individual and public health perspectives.

Our COVID-19 vaccine was initially developed based upon the genetic sequence of the original SARS-CoV-2 virus that was first detected. The SARS-CoV-2 virus continues to evolve, and new strains of the virus or those that are already in circulation may prove more transmissible or cause more severe forms of COVID-19 disease than the predominant strains observed to date. Our vaccine may not be as effective in protecting against existing and future variant strains of the SARS-CoV-2 virus as it is against the original virus or currently known strains of the SARS-CoV-2 virus. We and Pfizer intend to continue to observe our COVID-19 vaccine, including variant-adapted vaccine candidates, in global clinical trials. It is possible that subsequent data from these clinical trials may not be as favorable as data we submitted to regulatory authorities to support our applications for emergency use authorization or marketing or conditional marketing approval or that concerns about the safety of our variant-adapted COVID-19 vaccines will arise from widespread use outside of clinical trials. While we continue to monitor emerging SARS-CoV-2 strains, undertake investigations into the immunogenicity of our COVID-19 vaccine against new variants as they emerge and develop modified versions of our COVID-19 vaccine against new variants, these efforts may be unsuccessful, and failure to timely and successfully adapt our vaccine to variants of the SARS-CoV-2 virus could lead to significant reputational harm and adversely affect our financial results. Furthermore, variant-adapted COVID-19 vaccines may not receive approval or emergency use authorization in all jurisdictions, which could adversely affect our business prospects. It is also possible that we may expend significant resources adapting our COVID-19 vaccine to protect against certain variants of the SARS-CoV-2 virus, but that a market for adapted vaccines does not develop for one or more variants or that demand does not align with our projections or cost expenditures. Moreover, even if we are successful in developing an adapted vaccine and there is a market for the new vaccine, new variants continue to emerge and any adapted vaccine may not be as effective in protecting against such future variant strains.

If we discover safety issues with our products, including our COVID-19 vaccine, that were not known at the time of approval, commercialization efforts for our products could be negatively affected, approved products could lose their approval or sales could be suspended, we could be subject to product liability claims and our business and reputation could be materially harmed.

Our COVID-19 vaccine and any other product candidates for which we receive approval or emergency use authorization are subject to continuing regulatory oversight, including the review of additional safety information. Billions of doses of our COVID-19 vaccine have been delivered worldwide, and our COVID-19 vaccine is being more widely used by patients as an authorized product than it was used in clinical trials. As a result, undesirable

effects and other problems may be observed that were not seen or anticipated, or were not as prevalent or severe, during clinical trials. We cannot provide assurance that newly discovered or developed safety issues will not arise, and we have received, and expect to continue to receive, product liability claims relating to our COVID-19 vaccine. 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 clinical trials 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. Safety events that arise outside of a clinical trial setting are difficult to monitor, and given the widespread use of our COVID-19 vaccine, we have experienced difficulty tracking potential treatment-related adverse events on a global basis. Any 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. The subsequent discovery of previously unknown problems with a product could negatively affect commercial sales of the product, result in restrictions on the product or lead to the withdrawal of the product from the market. The reporting of adverse safety events involving our products or public speculation about such events could cause the price of the ADSs representing our ordinary shares to decline or experience periods of volatility.

Unexpected safety issues, including any that we have not yet observed in our clinical trials or in real world data, could lead to significant reputational damage for us and our product development 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.

Failure to comply with continuing regulatory requirements by us or our collaboration partners could adversely impact regulatory approvals for our products, result in product recalls or suspensions, and/or subject us to fines and/or other types of liabilities.

If we or our collaborators fail to comply with applicable continuing regulatory requirements, including good industry practices, such as good manufacturing practices, or GMP, we or our collaborators may be subject to fines, suspension or withdrawal of regulatory approvals for specific drugs, product recalls and seizures, operating restrictions and/or criminal prosecutions. We and the manufacturers we engage to make our products and the manufacturing facilities in which our products are made are subject to periodic review and inspection by the U.S. Food and Drug Administration, or the FDA, and other regulatory authorities. If problems are identified during a review or inspection, we or our collaborators may be the subject of adverse regulatory action, including the issuance of untitled or warning letters, which could result in our inability to use the facility to make our product or a determination that inventories are not safe for commercial sale. Any of these factors could adversely affect our business prospects and our financial position could be materially harmed.

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

The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford certain treatments, including our COVID-19 vaccine and other product candidates we may develop and sell. In addition, because our mRNA product candidates represent an entirely new therapeutic modality, we cannot accurately estimate how future products we may develop and sell would be priced, whether reimbursement could be obtained, or any potential revenue. Sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or

maintain pricing sufficient to realize an adequate return on our investment in any of our products. Additionally, even if pricing terms with governmental authorities are agreed upon, there may be delayed or denied payments.

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

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

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. The Inflation Reduction Act, or IRA, enacted in August 2022 allows HHS to negotiate the price of certain drugs and biologics that CMS reimburses under Medicare Part B and Part D. The IRA's negotiation program will apply to high-expenditure single-source drugs that have been approved for at least 7 years (11 years for biologics), among other negotiation selection criteria. The negotiated prices, which became effective in 2026 for the first round of selected drugs, are capped at a statutorily-determined ceiling price. The IRA also penalizes drug manufacturers that increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation. In addition, the law eliminates the "donut hole" under Medicare Part D beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and requiring manufacturers to subsidize, through a newly established manufacturer discount program, once the out-of-pocket maximum has been reached. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. These IRA provisions have begun to take effect progressively starting in 2023, although the drug negotiation provisions of the IRA are currently the subject of legal challenges. The effects of the IRA on our business and the healthcare industry in general are not yet known. In addition, the Center for Medicare and Medicaid Innovation, or CMMI, has announced two new mandatory models that propose MFN pricing for certain products covered by Medicare and one new voluntary model that proposes MFN pricing for products covered by Medicaid. These models, or other models announced by CMMI, could result in significantly lower prices for our products. These laws and regulations may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our products for which we may obtain regulatory approval or the frequency with which any such product is

prescribed or used. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importing from other countries and bulk purchasing. Officials appointed by the current presidential administration to oversee the implementation of the IRA may take a different approach, and the administration and Congress could also pursue statutory changes to the program, either of which could negatively affect our revenues.

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

Government policies, including relating to manufacturing, export controls, or tariffs, and negative public perception regarding vaccines and mRNA-based therapeutics could severely and adversely impact the manufacturing and sales of our COVID-19 vaccine and other product candidates we may develop, if approved.

There is a heightened risk that vaccines could be subject to export controls, adverse emergency actions or supply requirements by governmental and other authorities. In the past, the European Union and other regions have imposed, or threatened to impose, export controls that would limit or block the delivery of COVID-19 vaccines manufactured in or outside their territories in instances where manufacturers have been delayed or have not fully satisfied their delivery obligations to such governments, which could have prohibited us from delivering our COVID-19 vaccine to other jurisdictions. Recently, trade and tariff policies among the United States and other countries have been unsettled and are subject to frequent changes. The U.S. government has imposed tariffs and other trade restrictions on goods across a range of industries, and such actions have at times prompted retaliatory measures by affected countries such as China, Canada and the European Union. While tariffs with certain countries have been temporarily reduced or paused, the imposition of new tariffs will likely be met with further reciprocal tariffs, thus increasing the possibility of a global trade war. If trade restrictions or tariffs reduce global economic activity, potential impacts could include declining sales; increased costs; volatility in foreign exchange rates; and a decline in the value of our financial assets. Issued or future executive orders or other new or changes in laws, regulations or policy regarding tariffs could have a material adverse effect on our business, earnings and financial guidance. The actual impact of the new tariffs on our business is subject to a number of factors including, but not limited to, restrictions on trade, the effective date and duration of such tariffs, countries included in the scope of tariffs, changes to amounts of tariffs, potential retaliatory tariffs imposed by other countries, and the extent to which tariffs are imposed on finished or unfinished pharmaceutical products. Vaccines are also at risk of being subject to adverse emergency actions taken by governmental entities in certain countries, including intellectual property expropriation, compulsory licenses, strict price controls or other actions, such as the requirement that specific quantities of vaccine doses be set aside for designated purposes or geographic areas. Additional changes in governmental policy preferences and regulatory decision-making may have an adverse effect on our ability to commercialize products or, if approved, product candidates. For example, the FDA's approval of our LP.8.1-adapted monovalent COVID-19 vaccine is in a narrower population than our previous variant-adapted vaccines.

Furthermore, public sentiment regarding commercialization of vaccines, the safety and efficacy of our COVID-19 vaccine, other COVID-19 vaccines and treatments, and other public perceptions and misinformation relating to COVID-19, mRNA technology, and our and other COVID-19 vaccines may limit our ability to generate income from sales of our COVID-19 vaccine and other product candidates we may develop and sell, including due to changes in local, national and state government policies in the U.S. and other jurisdictions, and cause reputational damage.

We face significant competition with other makers of COVID-19 vaccines and may be unable to maintain a competitive market share for our COVID-19 vaccine.

A number of competitors currently have programs to develop COVID-19 vaccine candidates, including vaccines developed by Moderna, Inc. and Novavax, Inc. 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 invest heavily to accelerate discovery and development of their vaccine candidates.

Our efforts to continue successful commercialization of our COVID-19 vaccine may fail if competitors develop and commercialize COVID-19 vaccines that are safer, more effective, produce longer immunity against COVID-19, require fewer administrations, have fewer or less severe undesirable effects, have broader market acceptance, are more convenient to administer or distribute or are less expensive than any vaccine candidate that we have developed or we may develop.

Our COVID-19 vaccine is sensitive to temperature, shipping and storage conditions and could be subject to risk of loss or damage.

Our COVID-19 vaccine is, and other product candidates we develop could be, sensitive to temperature, storage and handling conditions. In particular, while we have improved the required shipping and storage conditions of our COVID-19 vaccine, it must be shipped and stored at cold temperatures. Loss in supply of our COVID-19 vaccine and our product candidates could occur if the product or product intermediates are not stored or handled properly. Shelf life for our product candidates may vary by product, and it is possible that supply of our COVID-19 vaccine or our product candidates could be lost due to expiration prior to use. This has in the past led, and could in the future lead, to additional manufacturing costs and delays in our ability to supply required quantities for clinical trials or for commercial purposes. Such distribution challenges may make our COVID-19 vaccine a less attractive product than other COVID-19 vaccines that do not require as cold storage, and our COVID-19 vaccine may become increasingly less competitive as additional other vaccines become authorized for emergency use. If we, our partners and customers are unable to adequately manage these issues, we may be exposed to product liability claims and the market opportunity for our COVID-19 vaccine may be reduced, each of which could adversely affect our business prospects and materially harm our financial condition.

The market opportunities for some of our product candidates may be small due to the rarity of the disease, or limited to those patients who are ineligible for or have failed prior treatments. As the target patient populations for some of our programs are small, we may be unable to achieve or maintain profitability in future periods without obtaining regulatory approval for additional indications.

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

Our projections of the number of people who have or will have the diseases we may be targeting may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of trial participants may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. Even if we obtain significant market share for our products, if approved, because the potential target populations may be small, we may be unable to achieve or maintain profitability in future periods without obtaining regulatory approval for additional indications.

If we are unable to continue to increase our marketing and sales capabilities on our own or through third parties, we may not be able to market and sell our product candidates effectively in the United States and other jurisdictions, if approved, or generate sufficient product sales revenue.

We have only relatively recently developed our sales, distribution or marketing capabilities in Germany and Türkiye. With respect to our COVID-19 vaccine, we rely heavily on the sales, distribution, and marketing capabilities of our partners, except in Germany and Türkiye. To successfully commercialize any other products that may result from our development programs, several of which are undergoing pivotal clinical trials, we will need to continue developing sales and marketing capabilities in the United States, Europe and other regions, either on our own or with others. We may enter into collaborations with other entities to utilize their mature marketing and distribution capabilities, but we may be unable to enter into marketing agreements on favorable terms, if at all. If our current and future collaborators do not commit sufficient resources to further commercialize our COVID-19 vaccine and our future products, if any, and we are unable to develop the necessary marketing capabilities on our own, we may be unable to generate sufficient product sales revenue to sustain our business. We compete with many companies that currently have extensive and well-funded marketing and sales operations. Without continuing to grow our internal team or obtaining the support of third parties to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

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

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

- obtaining, on a country-by-country basis, the applicable marketing authorization from the competent regulatory authority;
- the burden of complying with complex and changing regulatory, tax, accounting, labor and other legal requirements in each jurisdiction that we or our collaborators pursue;
- reduced protection for intellectual property rights;
- differing medical practices and customs affecting acceptance in the marketplace;
- import or export licensing requirements;
- governmental controls, trade restrictions or changes in tariffs;
- economic weakness, including inflation, or political instability;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers;

- foreign currency exchange rate fluctuations;
- the impact of epidemics, pandemics and other public health developments, such as COVID-19, on employees and the global economy;
- reimbursement, pricing and insurance regimes; and
- the interpretation of contractual provisions governed by local laws in the event of a contract dispute.

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

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

Even with the requisite approvals, the commercial success of our products will depend in part on the medical community, patients, and third-party or governmental payors accepting immunotherapies in general, and our products in particular, as medically useful, cost-effective and safe.

Any product that we bring to the market may not gain market acceptance by physicians, trial participants, third-party payors, and others in the medical community. Additionally, ethical and legal concerns and social preferences about research involving mRNA could result in additional regulations restricting or prohibiting the products and processes we may use. If these products do not achieve an adequate level of acceptance, we may not generate significant product sales revenue and may not be able to achieve or maintain profitability in future periods. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the potential efficacy and potential advantages over alternative treatments;
- the ability to offer our products, if approved, at competitive prices;
- the prevalence and severity of any undesirable effects, including any limitations or warnings contained in a product's approved labeling;
- the prevalence and severity of any undesirable effects resulting from checkpoint inhibitors or other drugs or therapies with which our products are administered;
- the relative convenience and ease of transportation, storage and administration;
- any restrictions on the use of our products, if approved, together with other medications;
- the willingness of the target patient population to try new therapies, such as mRNA vaccines and therapies, and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- the extent to which changes in local, national and state government policy preferences in the United States and other jurisdictions resulting from new elected leadership and evolving public sentiment affect demand for COVID-19 vaccines or mRNA therapeutics and our ability to successfully commercialize our product candidates, if approved;

- publicity concerning our products or competing products and treatments; and
- sufficient third-party insurance coverage or reimbursement, and patients' willingness to pay out-of-pocket in the absence of third-party coverage or adequate reimbursement.

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

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

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

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

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

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

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

Obtaining coverage and reimbursement of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. Third-party payors could require us to conduct additional

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

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

We intend to seek approval to market our product candidates in the United States, the European Union and other selected jurisdictions. If we obtain approval for our product candidates in any particular jurisdiction, we will be subject to rules and regulations in that jurisdiction. In some countries, particularly those in Europe, the pricing of biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. Some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new products into the marketplace. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

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

The advancement of healthcare reform legislation and changes to the regulatory environment in the United States, the European Union and elsewhere may increase the difficulty and cost for us to obtain marketing approval of and commercialize any product candidates we or our collaborators develop and may adversely affect the prices for such product candidates.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs.

In August 2022, the IRA was enacted, which sets forth meaningful changes to drug product reimbursement by Medicare. The IRA is anticipated to have significant effects on the pharmaceutical industry and may reduce the prices we can charge and reimbursement we can receive for our products in the United States, among other effects. Any reduction in reimbursement from Medicare resulting from the IRA or other legislative or policy changes or from other government programs may result in a similar reduction in payments from private payers.

On August 16, 2024, CMS announced the results of a first round of discounted prices effectively set by CMS under the IRA, applicable to ten products of other manufacturers; those discounted prices, set to take effect for calendar year 2026, were as high as 79% from 2023 list prices. Additional products will be discounted in future years. We cannot be sure whether additional legislative changes will be enacted, or the effect of forthcoming guidance implementing the IRA, or what the impact of such changes on our products and product candidates may be. Officials appointed by the current presidential administration to oversee the implementation of the IRA or other statutes may take a different approach, and the administration and Congress could also pursue statutory changes to this or other programs, either of which could negatively affect our revenues.

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

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

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

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

Our COVID-19 vaccine is currently approved in the United States, the European Union, and other jurisdictions, and we intend to seek approval to market other product candidates in the United States, the European Union and other selected jurisdictions. If we obtain approval for our products or product candidates in a particular jurisdiction, we will be subject to rules and regulations in that jurisdiction. In some countries, particularly those in the European Union, the pricing of biologics is subject to governmental control and other market regulations that could put pressure on the pricing and usage of our products or product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future healthcare reform measures.

In addition, in most countries outside the United States, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Reference pricing used by various member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In some countries, we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of any of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and, generally, prices tend to be significantly lower in the European Union. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales by us or our collaborators and the potential profitability of any of our product candidates in those countries would be negatively affected.

Risks Related to our Financial Condition and Capital Requirements

Long-term sustainable profitability is difficult to achieve and maintain over time and is highly dependent on various factors.

Our ability to continue to generate revenues and achieve and maintain long-term sustainable profitability depends on our ability, alone or with collaborators, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, our product candidates. We continue to generate revenues from sales of our COVID-19 vaccine and additional limited revenues from other transactions. While we expect to maintain revenue from ongoing COVID-19 vaccine sales, future demand for COVID-19 vaccination is subject to uncertainty. Variations driven by factors such as new virus variants, legal developments, policy changes, public health measures and public sentiment may impact long-term demand of our COVID-19 vaccine. Consequently, our revenue projections are influenced by this inherent unpredictability. The amount of long-term revenue from such sales, including the sales of our COVID-19 vaccine, is uncertain at this time. Our ability to generate future revenues from pharmaceutical product sales and sales of our other products and services depends heavily on our and our collaborators' success in:

- completing research and preclinical and clinical development of our product candidates;
- seeking and obtaining U.S. and non-U.S. marketing approvals for product candidates for which we complete clinical trials;
- seeking and obtaining market access and favorable pricing terms in the United States, the European Union, and other key geographies;
- furthering the development of our own manufacturing capabilities and manufacturing relationships with third parties in order to provide adequate (in amount and quality) products and services to support clinical development and the market demand for our approved products and product candidates, if approved;
- obtaining market acceptance of our approved products and product candidates as a treatment option;

- launching and commercializing products for which we obtain marketing approval and reimbursement, either through collaborations or, if launched independently, by establishing a sales force, marketing and distribution infrastructure;
- addressing any competing technological and market developments, in particular, declining demand for any of our approved products;
- implementing additional internal systems and infrastructure;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- managing our expenses;
- maintaining, defending, protecting, enforcing and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

Additionally, we have incurred significant costs associated with the commercialization of our COVID-19 vaccine. Our expenses could increase beyond our expectations if we are required by the FDA, the European Medicines Agency, or EMA, or other regulatory agencies to perform clinical and other trials or make changes to our manufacturing or quality systems in addition to those that we currently anticipate. Accordingly, such costs could adversely affect our future ability to achieve and maintain profitability.

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

Our financial condition and operating results have varied in the past and will continue to fluctuate from one financial period to the next due to a variety of factors, many of which are beyond our control.

Factors relating to our business that may contribute to these fluctuations include the following, as well as other factors described elsewhere in this report:

- the size and timing of orders for our COVID-19 vaccine;
- delays or failures in advancement of existing or future product candidates into the clinic or in clinical trials;
- the occurrence of adverse events during our clinical trials or post marketing authorization;
- our ability to develop and manufacture our product candidates and commercialize and manufacture our COVID-19 vaccine and, if approved, our product candidates, at commercial scale, including risks associated with quality compliance, such as product design, manufacturing processes, supply chain management, and compliance with regulatory requirements;
- our ability to manage our growth and spending;
- our ability to execute our corporate objectives;
- strategic decisions related to portfolio prioritization, which may result in certain potential one-time effects and charges and other material adverse effects on our financial condition and results of operations;

- the outcomes of research programs, clinical trials, or other product development or approval processes conducted by us and our collaborators;
- the ability of our collaborators to develop and successfully commercialize products developed from our suite of therapeutic classes;
- our relationships, and any associated exclusivity terms, with collaborators;
- our contractual or other obligations to provide resources to fund our product candidates, and to provide resources to our collaborators or to the collaborations themselves, including take-or-pay or similar obligations;
- the extent to which we repurchase outstanding ADSs under any share repurchase plans we may enter into in the future;
- risks associated with the international aspects of our business, including the conduct of clinical trials in multiple locations, and the risks associated with potential international commercialization, including regulatory approval, market competition, public sentiment and consumer demand, supply chain disruptions, and changes to the law and regulatory policy, such as increases in tariffs, in different jurisdictions, such as the United States;
- our ability to minimize and manage product recalls or inventory losses caused by unforeseen events, cold chain interruption, testing difficulties or decreased demand, and our ability to write down certain inventory;
- our ability to report our financial results accurately and in a timely manner;
- our dependence on, and the need to attract and retain, key management and other personnel;
- our ability to obtain, protect, maintain, defend and enforce our intellectual property rights;
- our ability to prevent the theft or infringement, misappropriation or other violation of our intellectual property, trade secrets, know-how or technologies;
- our and our collaborators' ability to defend against claims of infringement of the intellectual property rights of third parties;
- potential advantages that our competitors and potential competitors may have in securing funding, obtaining the rights to critical intellectual property or developing competing technologies or products;
- our ability to obtain additional capital that may be necessary to expand our business;
- our collaborators' ability to obtain and devote additional capital that may be necessary to develop and commercialize products under our collaboration agreements, including our COVID-19 vaccine;
- our ability to minimize and manage product liability claims arising from the use of our COVID-19 vaccine and our product candidates and other future products, if approved;
- business interruptions such as power outages, strikes, acts of terrorism or natural disasters;
- our ability to use our net operating loss carryforwards to offset future taxable income;
- risks of counterparty defaults within our asset management portfolio; and
- increased or unpredictable pricing for the commodities we rely on, including as a result of inflation.

Each of the factors listed above may be affected by the changing impact of COVID-19 on the global community and the global economy.

Due to the various factors mentioned above, and others, the results of any of our periods should not be relied upon as indications of our future operating performance. Our operating results may fluctuate significantly from one reporting period to the next, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance.

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

We have incurred significant losses in the past and we may incur significant losses in the future.

Prior to the first full year of commercialization of our COVID-19 vaccine, and for the years ended December 31, 2024 and December 31, 2025, we incurred significant losses from operations due to our significant research and development expenses and our investment in our manufacturing capabilities. Prior to commercialization of our COVID-19 vaccine, we funded our operations primarily from private placements or issuances of ordinary shares (including in the form of ADSs) in connection with our public offerings, generation of proceeds under our collaboration agreements, secured bank loans and issuance of a convertible note.

We have experienced, and we expect to continue to experience, increasing reductions in demand for COVID-19 vaccination generally, including for our vaccine. We expect that future revenues from sales of our COVID-19 vaccine will decrease as demand for vaccination wanes. We plan to continue to invest heavily in research and development as we make a strong drive to build out our global development organization and diversify our therapeutic area footprint. Additionally, we plan to enhance capabilities through complementary acquisitions, technologies, infrastructure and manufacturing. Even for those products for which we have obtained or may obtain regulatory approval or emergency use authorization, our future revenues will depend upon the size of any markets in which such products have received approval or authorization to market, our ability to achieve sufficient market acceptance, reimbursement from third-party payors, and adequate market share in those markets.

If achieved, profitability is difficult to maintain over time and is highly dependent on various factors. Our future financial results will depend, in part, on the rate of our future expenditures, the extent to which we experience long-term success of our commercial products and our ability to obtain funding through revenue from commercial sales, equity or debt financings, sales of assets, collaborations or grants.

As part of our capital allocation strategy, we expect to continue to incur significant and increasing operating expenses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we and our collaborators:

- continue, expand, or modify the research or development of our programs in preclinical development;
- continue, expand, or modify the scope of our clinical trials for our product candidates;

- initiate additional preclinical, clinical, or other trials for our product candidates, including under our collaboration agreements;
- execute on our strategic decisions related to portfolio prioritization, which may result in certain potential one-time effects and charges and other material adverse effects on our financial condition and results of operations;
- continue to invest in our immunotherapy platforms to conduct research to identify novel technologies;
- change our manufacturing capacity or capability;
- change or add additional suppliers;
- make changes to our infrastructure in connection with our quality control, quality assurance, legal, compliance and other groups to support our operations as a public company and our product development and commercialization efforts, including changes to our sites globally;
- attract and retain skilled personnel;
- seek marketing approvals and reimbursement for our product candidates;
- develop our sales, marketing, and distribution infrastructure for our COVID-19 vaccine and any other products for which we may obtain marketing approval or emergency use authorization;
- seek to identify and validate additional product candidates;
- acquire or in-license other product candidates and technologies;
- acquire other companies;
- make milestone or other payments under any in-license agreements;
- maintain, protect, defend, enforce and expand our intellectual property portfolio; and
- experience any delays or encounter issues with any of the above.

The amount of, and our ability to use, net operating losses and research and development credits to offset future taxable income may be subject to certain limitations and uncertainty. In addition, pending and future tax audits within our Group, disputes with tax authorities and changes in tax law or fiscal regulations could lead to additional tax liabilities. We are subject to routine tax audits by the respective local tax authorities. Any additional tax liability could have an adverse effect on our business, financial conditions, results of operations or prospects.

In Germany, we have unused German tax loss carryforwards for corporate taxes for German group entities with pre tax group losses, though we generally have not recognized deferred tax assets related to such loss carryforwards for International Financial Reporting Standards, or IFRS, reporting purposes as of December 31, 2025. Deferred tax assets are recognized for unused tax losses only to the extent that it is probable that taxable profit will be available against which the losses can be utilized. In general, net operating loss, or NOL, carryforwards in Germany do not expire. Furthermore, under current German tax laws, certain substantial changes in the Company's ownership and business may further limit the amount of NOL carryforwards that can be used annually to offset future taxable income.

For the German tax group, we incurred tax losses up to and including December 31, 2020. Even though we recognized deferred tax assets on a majority of German tax loss carry forwards in 2020 which were fully utilized in 2021, they are, however, subject to review and possible adjustment by the German tax authorities. In addition, the incurred tax losses up to and including December 31, 2024 also remain subject to review.

In addition, we have U.S. federal and state NOL carryforwards due to our subsidiaries in the United States, which may be subject to limitations on use after an ownership change.

We may not be able to utilize a material portion of our historic or current NOLs or credits in either Germany (resulting from our German tax group or non-tax group entities in Germany) or the United States until these have been finally assessed by the tax authorities or when the limitation period has passed. In addition, the rules regarding the timing of revenue and expense recognition for tax purposes in connection with various transactions are complex and uncertain in many respects, and, if challenged, our recognition may be subject to a revised assessment. In the event any such challenge is sustained, our NOLs could be materially reduced or we could be determined to be a material cash taxpayer for one or more years, which could have an adverse effect on our business, financial conditions, results of operations or prospects.

Furthermore, our ability to use our NOLs or credits is conditioned upon our attaining profitability and generating taxable income. Taxable income exceeding NOLs will be subject to taxation resulting in tax liabilities. As described above, we incurred significant net losses in every year since our inception other than 2018, 2021, 2022 and 2023 and anticipate that in the future, we may incur losses for the majority of the group entities. Our ability to utilize our NOL or credit carryforwards in the United States and for some other group entities is uncertain. Therefore, we do not recognize deferred tax assets on NOLs and tax credit carryforwards in the United States, as the requirements of IAS 12 are not fulfilled.

Under German tax laws, we are obligated to withhold a percentage of wage tax and social security contributions on personnel expenses if contract services providers are considered to be our internal employees and remit those withholdings to German tax authorities and social security institutions. Late payments may subject us to penalties and fees.

Under German tax and social security laws, we are obligated to withhold a percentage of payments we make to third parties in consideration of the services provided, in case these are considered employment payments, and remit those withholdings to German tax authorities and social security institutions. After a significant volume of service providers were engaged to assist with research, development, manufacturing and supply of our COVID-19 vaccine, we discovered after internal review that we and certain of our subsidiaries did not withhold, report and remit certain German wage taxes and social security contributions in connection with certain contract service providers engaged in a manner comparable to internal employees, which we notified tax authorities about. If we do not properly and timely make required payments in the future, we could be subjected to fees, administrative offenses or other proceedings or penalties.

It is not possible to seek the refund of these wage taxes or social security contributions from either the German tax authorities or social security institutions after filing returns. In Germany, employers are considered secondarily liable for wage taxes.

In addition, value added taxes, or VAT, on invoices received by contract services providers who are considered internal employees are considered non-deductible and must be repaid to the German tax authorities. It is possible to reclaim the VAT repaid to the German tax authorities from the service provider. There is a possibility that the relevant input VAT claims against the contract service providers may, in some instances, not be enforceable as a result of a contract service provider no longer existing, the lapse of time or any other facts preventing the enforcement of such claims.

We may 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.

Our operating plans may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, government or other third-party funding, sales of assets, marketing and distribution arrangements, other collaborations and licensing arrangements, or a combination of these approaches. We may require additional capital to obtain regulatory approval for, and to commercialize, future product candidates. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations. Our spending will vary based on new and ongoing development and corporate activities. Due to the high uncertainty of the length of time and activities associated with discovery and development of our product candidates, we are unable to estimate the actual funds we will require for development, marketing and commercialization activities.

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

- the initiation, progress, timing, costs, and results of preclinical or nonclinical studies and clinical trials for our product candidates;
- the amount and timing of revenues and associated costs from sales of our COVID-19 vaccine;
- the results of research and our other platform activities;
- the clinical development plans we establish for our product candidates;
- the terms of any agreements with our current or future collaborators, and the achievement of any milestone payments under such agreements to be paid to us or our collaborators;
- the terms of any other strategic transactions, including relating to any acquisitions, into which we enter;
- the number and characteristics of product candidates that we develop or may in-license;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, the EMA and other comparable regulatory authorities;
- the cost of filing, prosecuting, obtaining, maintaining, protecting, defending and enforcing our patent claims and other intellectual property rights, including actions for patent and other intellectual property infringement, misappropriation and other violations brought by third parties against us regarding our products or product candidates or actions by us challenging the patent or intellectual property rights of others;
- the effect of competing technological and market developments, including other products that may compete with one or more of our product candidates;
- the cost and timing of completion and further expansion of clinical and commercial scale manufacturing activities sufficient to support all of our current and future programs, including the development of modular production and clinical facilities in various markets via our BioNTainer network; and
- the cost of establishing sales, marketing, and distribution capabilities for any product candidates for which we may receive marketing approval and reimbursement in regions where we choose to commercialize our products on our own.

To date, we have financed our operations primarily through the sale of equity securities, revenue from collaborations, and revenue from sales of our COVID-19 vaccine. While we are currently generating product sales and royalty revenue to finance our operations, we cannot be certain that we will continue to generate sufficient revenue from product sales and royalties to finance our operations. If we were to seek financing from outside sources, that additional funding may not be available on favorable terms, or at all. Should our revenues sufficiently decrease in the future, we expect to finance our future cash needs through a combination of product sales, public or private equity offerings, debt financings, collaborations, licensing arrangements, and other marketing or distribution arrangements. Any fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts, at the right time, on favorable terms, or at all, including as a result of the impact that the shift of COVID-19 towards an endemic phase and other global events, such as political upheavals and economic downturns, may have on the capital markets.

Negative clinical trial data or setbacks, or perceived setbacks, in our programs or with respect to our technology could impair our ability to raise additional financing on favorable terms, or at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our shareholders, and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of the ADSs representing our ordinary shares to decline. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that may adversely affect our shareholders' rights.

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

We may encounter difficulties in developing and expanding our company and managing such development and expansion, which could disrupt our operations.

To manage our anticipated development and expansion, we must continue to implement and improve our managerial, operational, legal, compliance and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. This includes our acquisitions of Biotheus in January 2025 and CureVac in December 2025, as well as strategic initiatives more generally. In addition, our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these development activities.

As an evolving biotechnology company, we are actively pursuing drug classes, platforms and product candidates in many therapeutic areas and across a wide range of diseases. Successfully developing products for, and fully understanding the regulatory and manufacturing pathways to, all of these therapeutic areas and disease states requires a significant depth of talent, resources and corporate processes in order to allow simultaneous

execution across multiple areas. Due to our limited resources, we may not be able to effectively manage this simultaneous execution and the expansion of certain operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure and/or give rise to operational mistakes, legal or regulatory compliance failures, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The physical expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of our product candidates. If our management is unable to effectively manage our expected development, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to effectively implement our business strategy. Our future financial performance and our ability to compete effectively and commercialize our COVID-19 vaccine and our product candidates, if approved, will depend in part on our ability to effectively manage the current and future development of our company.

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

As a public company, we incur significant legal, accounting and other expenses. The U.S. federal securities laws, including the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and rules subsequently implemented by the SEC and the Nasdaq Stock Market LLC, or Nasdaq, have imposed various requirements on public companies, including requirements to file annual and event-driven reports with respect to our business and financial condition, and to establish and maintain effective disclosure and financial controls and corporate governance practices. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations result in substantial legal and financial compliance costs and have made some activities time-consuming and costly. We may not be able to produce reliable financial statements or file these financial statements as part of a periodic report in a timely manner with the SEC or comply with Nasdaq listing requirements. In addition, we could make errors in our financial statements that could require us to restate our financial statements.

Pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting, including the attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To maintain compliance with Section 404, we document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we have needed to continue to dedicate internal resources, have engaged outside consultants, and have adopted a detailed work plan to assess and document the adequacy of internal control over financial reporting. We will continue to implement steps to improve control processes as appropriate, validate through testing that controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that in the future neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Shareholder activism, the current political environment, and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. For example, effective March 18, 2026, pursuant to the Holding Foreign Insiders Accountable Act, directors and officers of foreign private issuers, including us, are required to comply with the beneficial ownership reporting requirements of Section 16(a) of the Exchange Act. In addition, the SEC has issued a concept release in June 2025 soliciting comment on potential changes to the regulatory framework

applicable to foreign private issuers, including potential modification or elimination of certain accommodations currently available to foreign private issuers. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives.

If we identify material weaknesses in our internal control over financial reporting and fail to remediate such material weaknesses, we may not be able to report our financial results accurately or to prevent fraud.

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

If we fail to comply with the relevant rules and regulations or otherwise fail to prepare our financial statements in accordance with international financial reporting standards, a material weakness may arise. If we are unable to successfully remediate any material weaknesses, our financial statements could contain material misstatements discovered in the future that could cause us to fail to meet our future reporting obligations and cause the price of the ADSs to decline.

If we fail to appropriately account for complex terms in our collaboration and licensing agreements, we could be required to restate our financial statements.

Our collaboration and licensing agreements involve complex terms and significant judgment in determining the appropriate accounting treatment. The accounting for such agreements is often subject to interpretation and evolving guidance. If our accounting assessments are later determined to be incorrect, we may be required to restate previously issued financial statements, which could have a material adverse effect on our financial condition and results of operations.

We have various international trade obligations, including customs value calculation, customs tariff number classification and other related securities requirements. Late payments to customs authorities may subject us to penalties and fees.

Our supply chain, production and distribution network across the globe creates an increasing level of complexity in customs and foreign trade processes. The requirements for internal control systems are increasing and must be developed simultaneously. The risk management system for customs and foreign trade, which we are continuously improving, determines which stakeholders, goods, and means of transport should be examined and to what extent. These risks include the potential for non-compliance with customs value calculation, customs tariff number classification, trade restrictions, security regulations as well as the potential failure to facilitate international trade. We have in the past discovered that certain of our and our subsidiaries' customs value calculations were not applied correctly, following which we notified the customs authorities of potential late payments.

We are, and will likely continue to be, subject to various audits that arise from time to time, including customs and potential future foreign trade audits. If we do not properly address our international trade and customs requirements, we could be subjected to penalties and fees.

As a "foreign private issuer," we are exempt from a number of rules under the U.S. securities laws, as well as Nasdaq rules, and we are permitted to file less information with the SEC than U.S. companies.

This may limit the information available to holders of the ADSs and may make our ordinary shares and the ADSs less attractive to investors.

We are a "foreign private issuer," as defined in the rules and regulations of the SEC, and, consequently, we are not subject to all of the disclosure requirements applicable to companies organized within the United States. Although the SEC in June 2025 issued a concept release soliciting public comment on the definition of "foreign private issuer" and has signaled interest in exploring other rules relating to foreign private status, we currently remain exempt from certain rules under the U.S. Securities Exchange Act of 1934, as amended, or the Exchange Act, that regulate disclosure obligations and procedural requirements related to the solicitation of proxies, consents or authorizations applicable to a security registered under the Exchange Act. Effective March 18, 2026, pursuant to the Holding Foreign Insiders Accountable Act, directors and officers of foreign private issuers, including us, are required to comply with the beneficial ownership reporting requirements of Section 16(a) of the Exchange Act. However, our officers and directors are exempt from the "short-swing" profit recovery and short sale prohibition provisions of Section 16 of the Exchange Act. Moreover, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. public companies. Accordingly, there may be less publicly available information concerning our company than there is for U.S. public companies.

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

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

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

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

requirements of Nasdaq in certain respects. In particular, we follow German corporate governance practices in connection with the distribution of annual and interim reports to shareholders, the application of our code of conduct to our employees and the Supervisory Board, executive remuneration disclosure, proxy solicitation in connection with shareholders' meetings, and obtaining shareholder approval in connection with the establishment of, or material amendment to, certain equity-based compensation plans.

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

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

We face risks related to catastrophic global events including natural disasters, political crises, or public health epidemics and pandemics and other public health developments, that could adversely affect our operations.

Our business could be adversely impacted by the effects of catastrophic global events, including natural disasters such as an earthquake, fire, hurricane, tornado, flood or significant power outage; public health crises such as the COVID-19 pandemic; political crises, such as terrorist attacks, war and other political instability, including the ongoing geopolitical conflicts in the Middle East and Ukraine, and resulting sanctions imposed and retaliatory actions taken in response to such sanctions; or other catastrophic events.

For example, prolonged or expanded conflicts, and political responses to global actions, could destabilize oil and gas supply and demand patterns, increase energy volatility and have severe adverse effects on regional and global supply chains and economies and our business. We also continue to evaluate the impacts that energy shortages may have on our partners, suppliers and service providers. Were any of these parties to experience significant impacts from any energy shortage, our business could be materially harmed. We cannot predict with certainty the impact that volatility in energy prices could have on our or their operations, including on the manufacturing of our COVID-19 vaccine and the manufacturing and testing of our product candidates.

Although we have generated revenues from sales of our COVID-19 vaccine, there remains uncertainty regarding other potential effects of COVID-19 on our business. For example, if a new variant of COVID-19 emerges for which existing vaccines, including our COVID-19 vaccine, are ineffective, infections may become even more widespread, negatively impact our ability to enroll patients in clinical studies and complete clinical trials on the timelines we currently anticipate, or result in an economic downturn that could affect demand for our products and services or our ability to raise capital, which could have a material adverse effect on our business, operating results and financial condition. Our suppliers, licensors or collaborators could also be disrupted by conditions related to COVID-19 or other pandemics and epidemics, possibly resulting in disruption to our supply chain, clinical trials, partnerships or operations.

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

We maintain insurance coverage that we believe is appropriate for our business; however, such coverage involves significant costs, is increasingly expensive, and does not cover all potential risks, which may expose us to uninsured or underinsured liabilities. We do not carry insurance for all categories of risk that our business may encounter and insurance coverage is becoming increasingly expensive. We do not know if we will be able to maintain existing insurance with adequate levels of coverage, and any liability insurance coverage we acquire in

the future may not be sufficient to reimburse us for any expenses or losses we may suffer. We currently maintain insurance coverage for losses relating to property damage, business interruption, transportation, product liability, cyber matters, clinical trials, and several other areas of coverage. For example, attracting and retaining qualified individuals to serve on our Supervisory Board and our Management Board requires that we obtain and maintain adequate director and officer liability insurance, which has increased in cost as our operations have evolved. We are dedicating resources to exploring additional avenues for more adequate coverage as our business evolves. However, the coverage or coverage limits of our insurance policies may not be adequate. If our losses exceed our insurance coverage, our financial condition would be adversely affected. In the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources. Clinical trials or regulatory approvals for any of our product candidates could be suspended, which could adversely affect our results of operations and business, including by preventing or limiting the development and commercialization of any product candidates that we or our collaborators may develop.

Adverse developments affecting financial institutions, companies in the financial services industry or the financial services industry generally, such as actual events or concerns involving liquidity, defaults or non-performance, could adversely affect our operations and liquidity.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds, have in the past and may in the future lead to market-wide liquidity problems.

There is no guarantee that the U.S. Department of Treasury, the Federal Deposit Insurance Corporation, and Federal Reserve Board will provide access to uninsured funds in a timely fashion, or at all, in the event of the closure of banks or financial institutions.

While we maintain our cash and cash equivalents in multiple financial institutions worldwide, our access to our cash and cash equivalents in amounts adequate to finance our operations could be significantly impaired by the financial institutions with which we have arrangements directly facing liquidity constraints or failures. In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any material decline in available funding or our ability to access our cash and cash equivalents could adversely impact our ability to meet our operating expenses, result in breaches of our contractual obligations or result in violations of federal or state wage and hour laws, any of which could have material adverse impacts on our operations and liquidity.

Risks Related to the Manufacturing of our COVID-19 Vaccine, our Product Candidates and Future Pipeline

Our COVID-19 vaccine and product candidates are based on novel technologies and they may be complex and difficult to manufacture. We may encounter difficulties in manufacturing, product release, shelf life, testing, storage, supply chain management or shipping. If we or any of the third-party manufacturers we work with encounter such difficulties, our ability to supply materials for clinical trials or any approved product could be delayed or stopped.

The manufacturing processes for our COVID-19 vaccine and our product candidates are novel and complex. Due to the novel nature of this technology and the recency of our experience at larger scale production, we may encounter difficulties in manufacturing, product release, shelf life, testing, storage and supply chain management, or shipping. These difficulties could be due to any number of reasons, including, but not limited to, complexities of producing batches at larger scale, equipment failure, choice and quality of raw materials and excipients, analytical testing technology, and product instability. In an effort to optimize product features, we have in the past and may in the future make changes to our product candidates in their manufacturing and stability

formulation and conditions. This has resulted in the past, and may in the future result, in our having to resupply batches for preclinical, clinical, or commercial activities when there is insufficient product stability during storage and insufficient supply. Insufficient stability or shelf life of our products or product candidates could materially delay our or our collaborators' ability to continue the clinical trial for that product candidate or require us to begin a new clinical trial with a newly formulated drug product, due to the need to manufacture additional preclinical, clinical or commercial supply.

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

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

As we continue developing new manufacturing processes for our drug substance and drug product, the changes we implement to the manufacturing process may impact, in turn, specification and stability of the drug product. Changes in our manufacturing processes may lead to failure of lots and this could lead to a substantial delay in our clinical trials or an inability to supply sufficient commercial quantities of drug product. Our mRNA product candidates may prove to have a stability profile that leads to an unfavorable shelf life. This poses risk in supply requirements, wasted stock and higher cost of goods.

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

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

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

We are utilizing a number of raw materials and excipients that are either new to the pharmaceutical industry or are being employed in a novel manner. Some of these raw materials and excipients have not been scaled to a level to support commercial supply and could experience unexpected manufacturing or testing failures, or supply shortages. Such issues with raw materials and excipients could cause delays or interruptions to clinical and commercial supply of our COVID-19 vaccine and our product candidates. Further, now and in the future, one or more of our programs may have a single source of supply for raw materials and excipients. Some of our

suppliers are located in countries different from our manufacturing sites. Export restrictions could lead to unplanned interruptions in manufacturing, thus impacting supply of both clinical and commercial material.

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

Our product and product intermediates are extremely temperature sensitive, and we may learn that any or all of our products are less stable than desired. We may also find that transportation conditions negatively impact product quality. This may require changes to the formulation or manufacturing process for one or more of our products or product candidates and result in delays or interruptions to clinical or commercial supply. In addition, the cost associated with such transportation services and the limited pool of vendors may also add additional risks of supply disruptions. As we transport intermediate products with holding times in refrigeration (TIR) and allowed times out of refrigeration (TOR) across long distances and crossing borders, traffic issues and customs delays could lead to the loss of batches which would need to be replaced.

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 such product candidates for clinical trials or, if approved, products for patients could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

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

- logistics associated with the collection of a patient's tumor, blood or other tissue sample;
- shipping such samples to a facility for genetic sequencing;
- next-generation sequencing of the tumor mRNA;
- biopsy of a sufficient quantity of cancerous tissue to allow for proper sequencing and identification of tumor-specific mutations;
- identification of appropriate tumor-specific mutations;
- the use of a software program, including proprietary and open source components, which is hosted in the cloud and a part of our product candidate, to assist with the design of the patient-specific mRNA, which software must be maintained and secured;
- effective design of the patient-specific mRNA that encodes for the required neoantigens;
- batch-specific manufacturing failures or issues that arise due to the uniqueness of each patient-specific batch that may not have been foreseen;
- quality control testing failures;
- unexpected failures of batches placed on stability;

- shortages or quality control issues with single-use assemblies, consumables or critical parts sourced from third-party vendors that must be changed out for each patient-specific batch;
- significant costs associated with individualized manufacturing that may adversely affect our ability to continue development;
- successful and timely manufacture and release of the patient-specific batch;
- shipment issues encountered during transport of the batch to the site of patient care;
- the ability to define a consistent safety profile at a given dose when each participant receives a unique treatment; and
- our reliance on single source suppliers.

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

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

Our inability to manufacture sufficient or appropriate quantities of our COVID-19 vaccine or any of our product candidates, or our failure to comply with applicable regulatory requirements, could materially and adversely affect our business.

Manufacturing is a vital component of our individualized immunotherapy approach, and we have invested significantly in our manufacturing facilities, including the acquisition of a manufacturing site in Marburg, Germany, the construction of a novel modular manufacturing facility that we refer to as a "BioNTainer," and the construction of a facility to support manufacturing of our Individualized Vaccines Against Cancer candidates. All internal manufacturing is performed under GMP guidelines. We also rely on a network of CMOs for the manufacture of our COVID-19 vaccine. We do not rely on any external CMOs for the manufacture of our individualized product candidates and at this time, and we have limited redundancy among our facilities. Due to the individualized nature of our product candidates, we do not maintain product reserves. If any of our or our external CMOs' manufacturing facilities, including our BioNTainer units, experience difficulties, including related to manufacturing, product release, shelf life, testing, storage and supply chain management or shipping, our clinical development programs may be delayed or suspended until we or our external CMOs can resume operations. We may also be required to incur significant expenditures to resolve such difficulties.

We and our collaboration partner also have experienced, and continue to face the risk of, inventory write-downs or redundant production capacities with respect to our COVID-19 vaccine. Planned new formulations of our COVID-19 vaccine, including versions that could protect against new variants of COVID-19, have resulted or may result in significant research and development expense that was not or may not be recouped. In addition, we have experienced in the past, and may experience in the future, redundant production capacities under our agreements with CMOs due to planned new formulations, adaptations of our COVID-19 vaccine and increased internal manufacturing capacities. Significant inventory write-downs or redundant manufacturing expenses would negatively impact our results of operations.

Our facilities are subject to various regulatory requirements and may be subject to announced or unannounced inspections by the FDA or other regulatory authorities at any time during the development or commercialization phase. If we or our external CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, the EMA or comparable regulatory authorities in other jurisdictions, we may not be able to rely on our or our external CMOs' manufacturing facilities for the manufacture of our product candidates. If the FDA, the EMA or another comparable regulatory authority finds our or our external CMOs' facilities inadequate for the manufacture of our COVID-19 vaccine or our product candidates or otherwise deficient, including as a result of a site inspection, such facilities may be the subject of adverse regulatory action, including the issuance of untitled or warning letters. If such facilities are subject to enforcement action in the future or are otherwise inadequate, we may need to find alternative manufacturing facilities, which would significantly delay or otherwise impact our ability to develop, obtain regulatory approval for or market our COVID-19 vaccine or our product candidates.

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

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

The designs of our facilities are based on current standards for biotechnology facilities. They have been reviewed and approved by local authorities and have also received GMP manufacturing licenses. We have designed our facilities to incorporate a significant level of automation of equipment with integration of several digital systems to improve efficiency of operations. We have attempted to achieve a high level of digitization for clinical and commercial manufacturing facilities relative to industry standards. While this is meant to improve operational efficiency, this may pose additional risk of process equipment malfunction and even overall manufacturing system failure or shutdown due to internal or external factors including, but not limited to, design issues, system compatibility or potential cybersecurity breaches. This may lead to a delay in supply or shutdown of our facilities. Any disruption in our manufacturing capabilities could cause delays in our production capacity for our drug substances or drug products, impose additional costs, or require us to identify, qualify and establish an alternative manufacturing site, the occurrence of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Our COVID-19 vaccine and certain of our product candidates rely on the availability of specialty raw materials, which may not be available to us on acceptable terms or at all.

Our product candidates require many specialty raw materials, some of which are manufactured by small companies with limited resources and experience to support a commercial product, and suppliers may not be able to deliver raw materials to our specifications. In addition, some such suppliers normally support blood-based hospital businesses and generally do not have the capacity to support commercial products manufactured under GMP by biopharmaceutical firms. These suppliers may be ill-equipped to support our needs, especially in non-routine circumstances like an FDA inspection or medical crisis, such as widespread contamination. We also do not have contracts with many of these suppliers, and we may not be able to contract with them on acceptable terms or at all. Accordingly, we have experienced and we may in the future experience delays in receiving key raw materials to support clinical or commercial manufacturing.

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

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

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

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

- failed or defective components or consumables.

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

Regulatory authorities typically require representative manufacturing site inspections to assess adequate compliance with GMPs and manufacturing controls as described in the filing. If either we or one of our third-party manufacturing sites fail to provide sufficient quality assurance or control, approval to continue delivery of our commercial product or to commercialize our product candidates may not be granted. Inspections by regulatory authorities may be announced or unannounced and may occur at any time during the development or commercialization phase. The inspections may be product-specific or facility-specific for broader GMP inspections, or as a follow up to market or development issues that the regulatory agency may identify. Deficient inspection outcomes may result in adverse regulatory action, including the issuance of untitled or warning letters, which could influence our ability, or the ability of our third-party manufacturers or suppliers, to fulfill supply obligations, impacting or delaying supply or delaying programs. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including, but not limited to, clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect supplies of our products and product candidates (including those of our collaborators) and our overall business operations.

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

In addition, we may not have direct control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. Furthermore, all of our CMOs are engaged with other companies to supply or manufacture materials or products for such companies, which exposes our CMOs to regulatory risks for the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may generally affect the regulatory status of our CMOs' facilities, and could result in the sanctions and other adverse outcomes described above. Our potential future dependence upon others for the manufacture of our products, product candidates and raw materials may adversely affect our future operating results and our ability to commercialize any products that receive regulatory approval on a timely and competitive basis.

The FDA, the EMA and other regulatory authorities may require us to submit product samples of any lot of any approved product together with the protocols showing the results of applicable tests at any time. Under some circumstances, the FDA or other regulatory authorities may require that we do not distribute a lot or lots until the relevant agency authorizes such release. Deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Our CMOs have, in the past, experienced lot failures and some may have experienced

product recalls. Lot failures or product recalls with respect to product produced by either our own facilities or those of our third-party manufacturers could cause us and our collaborators to delay clinical trials, product launches or product supply, which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects.

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

Risks Related to our Reliance on Third Parties

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

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

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

Moreover, the FDA requires us to comply with GCP for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We are also required to register ongoing clinical trials and post the results of completed clinical trials on a U.S. government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity, and civil and criminal sanctions. For any violations of laws and regulations during the conduct of our preclinical studies and clinical trials, we could be subject to warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

We and our CROs are required to comply with regulations, including GCP, for conducting, monitoring, recording and reporting the results of preclinical studies and clinical trials to ensure that the data and results are scientifically credible and accurate and that the trial participants are adequately informed, among other things, of the potential risks of participating in clinical trials. We are also responsible for ensuring that the rights of our clinical trial participants are protected. These regulations are enforced by the FDA, the regulatory authorities of the EU member states, and comparable regulatory authorities of other jurisdictions for any product candidates in clinical development. The FDA enforces GCP regulations through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable regulatory authorities of other jurisdictions may require us to perform additional clinical trials before approving our marketing applications.

We cannot be sure that, upon inspection, the FDA will determine that any of our future clinical trials will comply with GCP. In addition, our clinical trials must be conducted with product candidates produced in accordance with the requirements of GMP regulations. Our failure or the failure of our CROs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action.

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

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

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

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

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

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

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

- future relationships may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing shareholders, or disrupt our management and business;
- we could face significant competition in seeking appropriate collaborators, and the negotiation process is time-consuming and complex; and
- our international operations through any future collaborations, acquisitions or joint ventures may expose us to certain operating, legal and other risks not encountered in Germany or the United States.

If our collaborations do not result in the successful development and commercialization of programs, or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone, earn-out, royalty or other contingent payments, or otherwise yield the expected benefits under the collaborations. As a result, our development of product candidates and commercialization efforts could be delayed and we may need additional resources to develop and commercialize our product candidates. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and the perception of us in the business and financial communities could be adversely affected. All of the risks relating to product development, regulatory approval and commercialization described in this report apply to the activities of our collaborators.

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

Our research and product development programs and the potential commercialization of any product candidates we develop alone or with collaborators will require substantial additional cash to fund expenses, and we expect that we will continue to seek collaborative arrangements with others in connection with the development and potential commercialization of current and future product candidates or the development of ancillary technologies. We face significant competition in establishing relationships with appropriate collaborators. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Whether or not we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include, among other things and as applicable for the type of potential product or technology, an assessment of the opportunities and risks of our technology, the design or results of studies or trials, the likelihood of approval, if necessary, of the FDA or comparable regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products and technologies and industry and market conditions generally.

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

Collaborations are complex and time-consuming to negotiate and document. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we do enter into additional collaboration agreements, the negotiated terms may force us to relinquish rights that diminish our potential profitability from development and commercialization of the subject product candidates or others. If we are unable to enter into

additional collaboration agreements, we may have to curtail the research and development of the product candidate or technology for which we are seeking to collaborate, reduce or delay research and development programs, delay potential commercialization timelines, reduce the scope of any sales or marketing activities or undertake research, development or commercialization activities at our own expense. If we elect to increase our expenditures to fund research, development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all.

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

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

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

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

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

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

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

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

Although we expect to continue using our own clinical manufacturing facilities where available, we also rely on outside vendors to manufacture supplies and process our product candidates. We only manufacture our COVID-19 vaccine on a commercial scale and may not be able to achieve commercial-scale manufacturing and processing for our other product candidates, if approved, and may be unable to create an inventory of mass-produced, off-the-shelf product to satisfy demands for our product candidates, if approved.

We do not yet have sufficient information to reliably estimate the cost of the commercial manufacturing and processing of our product candidates, and the actual cost to manufacture and process our product candidates could materially and adversely affect the commercial viability of our product candidates. As a result, we may not be able to develop commercially viable products other than our COVID-19 vaccine.

In addition, our reliance on a limited number of CMOs exposes us to the following risks:

- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA or other regulatory authorities may have questions regarding any replacement contractor. This may require new testing and regulatory interactions. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of regulatory authority questions, if any;

- our CMOs might be unable to timely formulate and manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any;

- CMOs may not be able to execute our manufacturing procedures appropriately;

- our future CMOs may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products;

- manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the U.S. Drug Enforcement Administration and corresponding state agencies and by regulatory authorities in other jurisdictions to ensure strict compliance with GMP and other government regulations and corresponding standards in other jurisdictions. We do not have control over CMOs' compliance with these regulations and standards;

- we may not own, or may have to share, the intellectual property rights to any improvements made in the manufacturing process for our products;

- our CMOs could breach or terminate their agreement with us; and

- our CMOs would also be subject to the same risks we face in developing our own manufacturing capabilities, as described above.

Each of these risks could delay our clinical trials, the approval, if any, of our COVID-19 vaccine or product candidates by the FDA or regulatory authorities in other jurisdictions or the commercialization of our COVID-19 vaccine or product candidates, or result in higher costs or deprive us of potential product sales revenue. In addition, we will rely on third parties to perform release tests on our COVID-19 or our product candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm.

We and certain of our collaborators currently rely on CMOs located outside of the United States to manufacture clinical materials. Such ex-U.S. CMOs may be subject to or affected by U.S. legislation, executive orders, regulations, or investigations, including but not limited to the recently enacted BIOSECURE Act, the Department of Justice's Final Rule issued on January 8, 2025 implementing the Executive Order on Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern, sanctions, trade restrictions and other U.S. and other regulatory requirements, which could increase the cost or reduce the supply of material available to us, delay or restrict the procurement or supply of such material, delay or impact clinical trials, have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies and adversely affect our financial condition and business prospects.

We are dependent on single source suppliers for some of the components and materials used in, and the processes required to develop, our COVID-19 vaccine and our product candidates.

We currently depend on single source suppliers for some of the components and materials used in, and manufacturing processes required to develop, our COVID-19 vaccine and our product candidates. We cannot ensure that these suppliers or service providers will remain in business, or have sufficient capacity or supply to meet our needs, or that they will not be purchased by one of our competitors or another company that is not interested in continuing to work with us. Our use of single source suppliers of raw materials, components, key processes and finished goods exposes us to several risks, including disruptions in supply, price increases or late deliveries. There are, in general, relatively few alternative sources of supply for substitute components. These vendors may be unable or unwilling to meet our future demands for our clinical trials or commercial sale. Establishing additional or replacement suppliers for these components, materials and processes could take a substantial amount of time and it may be difficult to establish replacement suppliers who meet regulatory requirements. Any disruption in supply from any single source supplier or service provider could lead to supply delays or interruptions which would damage our business, financial condition, results of operations and prospects.

If we have to switch to a replacement supplier, the manufacture and delivery of our product candidates could be interrupted for an extended period, which could adversely affect our business. Establishing additional or replacement suppliers for any of the components or processes used in our COVID-19 vaccine and our product candidates, if required, may not be accomplished quickly. If we are able to find a replacement supplier, the replacement supplier would need to be qualified and may require additional regulatory authority approval, which could result in further delay. While we seek to maintain adequate inventory of the single source components and materials used in our COVID-19 vaccine and our product candidates, any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand for our COVID-19 vaccine and product candidates.

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

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

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

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

Risks Related to Intellectual Property

If our efforts to obtain, maintain, protect, defend and/or enforce the intellectual property related to our COVID-19 vaccine or our product candidates and technologies are not adequate, we may not be able to compete effectively in our market.

Our commercial success depends in part on our ability to obtain, maintain, protect, defend and enforce patent and other intellectual property, including trade secret and know-how, protection for our COVID-19 vaccine and for our product candidates, proprietary technologies and their uses, as well as our ability to operate, develop, manufacture and commercialize our COVID-19 vaccine or one or more of our product candidates without infringing, misappropriating or otherwise violating the intellectual property or other proprietary rights of our competitors or any other third parties, including any non-practicing entities or patent assertion entities. We generally seek to protect our intellectual property position by filing and/or licensing patent applications in the European Union, the United States and elsewhere related to our product candidates, proprietary technologies (including methods of manufacture) and their uses that are important to our business. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent that the issued claims cover third parties' activities in the countries in which they are performed. We cannot be certain that the claims in any of our patent applications will be considered patentable by the United States Patent and Trademark Office, or the USPTO, courts in the United States or the patent offices and courts in other jurisdictions, including Europe, nor can we be certain that any claim in our issued patents will not be found invalid or unenforceable if challenged. Accordingly, there can be no assurance that our patent applications or those of our licensors will result in additional patents being issued or that issued patents will adequately cover our COVID-19 vaccine or our product candidates, or otherwise afford sufficient protection against competitors with similar technology, nor can there be any assurance that issued patents will not be infringed, designed around, invalidated or held unenforceable. Furthermore, we may not be able to apply for patents on certain aspects of our current or future products or product candidates,

proprietary technologies and their uses in a timely fashion, at a reasonable cost, in all jurisdictions, or at all, and any potential patent protection we obtain may not be sufficient to prevent substantial competition.

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

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

- the USPTO and various other governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patenting process, the noncompliance with which can result in abandonment or lapse of a patent or patent application or a finding that a patent is unenforceable, and partial or complete loss of patent rights in the relevant jurisdiction;

- patent applications may not result in any patents being issued;

- claims of issued patents that we own (solely or jointly) or have in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;

- other parties may have designed around our patent claims or developed technologies that may be related or competitive to our COVID-19 vaccine or to our product candidates or other technologies, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent filings, either by claiming the same or overlapping methods, products, reagents, tools or devices or by claiming subject matter that could dominate one or more of our patent claims;

- any successful opposition to claims of any patents owned by or in-licensed to us could deprive us of rights necessary for the development and exploitation of our COVID-19 vaccine or our product candidates and other technologies, or the successful commercialization of any product candidates and other technologies that we may develop;

- because patent applications in the United States and most other jurisdictions are confidential for a period of time after filing, we cannot be certain that we, our co-owners or our licensors were the first to file any patent application related to our product candidates, proprietary technologies and their uses;

- a court or patent office proceeding, such as a derivative action or interference, can be provoked or instituted by a third party or a patent office, and might determine that one or more of the inventions described in our patent filings, or in those we licensed, was first invented by someone else, so that we may lose rights to such invention(s);

- a court or other patent proceeding, such as an inter partes review, post grant review or opposition, can be instituted by a third party to challenge the inventorship, scope, validity and/or enforceability of our patent

claims and might result in invalidation or revision of one or more of our patent claims, or in a determination that such claims are unenforceable;

- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; existing legislation (for example, in the United States, the Public Readiness and Emergency Preparedness Act, etc.) may be interpreted, and new legislation may be passed, to permit third-party use of patented technologies relating to a public health concern, with little or no compensation to the patent holder(s); and

- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing competitors a better opportunity to create, develop and market competing product candidates.

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

Furthermore, the patent prosecution process is expensive and time-consuming, and we may not be able to file, prosecute, maintain, protect, defend, enforce or license all necessary or desirable patents or patent applications, as applicable, at a reasonable cost or in a timely manner. It is possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, CMOs, consultants, advisors and other third parties, if any of these parties were to breach such agreements and improperly disclose such output before a patent application is filed, this could jeopardize our ability to seek patent protection. We also rely to a certain extent on trade secrets, know-how, and technology, which are not protected by patents, to maintain our competitive position. If any trade secret, know-how or other technology not protected by a patent were to be disclosed to or independently developed by a competitor, our business and financial condition could be materially adversely affected.

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

new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Furthermore, our pending and future patent applications may not result in patents being issued which protect our technology or our product(s) or product candidates, or which effectively prevent others from commercializing competitive technologies and products. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

Furthermore, patents or other intellectual property rights that we may be able to secure for our COVID-19 vaccine or our other COVID-19 vaccine candidates could be restricted or preempted if governments determine that they will not enforce, or will require compulsory licensing of, technologies useful to address the spread of COVID-19.

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

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

- any of our patents, or any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect our product(s), our product candidates and other technologies;
- any of our pending patent applications or those of our licensors may issue as patents;
- others will not or may not be able to make, use, offer to sell or sell products that are the same as or similar to our own but that are not covered by the claims of the patents that we own or license;
- we will be able to successfully commercialize our products on a substantial scale, if approved, before the relevant patents that we own or license expire;
- we were the first to make the inventions covered by each of the patents and pending patent applications that we own or license;

- we, our co-owners or our licensors were the first to file patent applications for these inventions;
- others will not develop similar or alternative products or technologies that do not infringe the patents we own or license;
- any of the claims of patents we own or license will be found to ultimately be valid and enforceable;
- any patents issued to us or our licensors will provide a basis for an exclusive market for our commercially viable product candidates and other technologies or will provide us with any competitive advantages;
- a third party may not challenge the claims of patents we own or license and, if challenged, a court would hold that such patent claims are valid, enforceable and infringed;
- we may develop or in-license additional proprietary technologies that are patentable;
- the patents of others will not have an adverse effect on our ability to issue patents, or otherwise on our business;
- our competitors do not conduct research, development, testing or commercialization activities in countries where we do not have enforceable patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we will develop additional proprietary technologies, product(s) or product candidates that are separately patentable; and
- our, or our collaborators', development and commercialization activities, including our manufacturing processes, or products will not infringe patents of our competitors or any other third parties, including any non-practicing entities or patent assertion entities.

Other companies or organizations may challenge our intellectual property rights or the intellectual property rights of our partners or may assert intellectual property rights that prevent us or our partners from developing and commercializing our COVID-19 vaccine or 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, tools 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, testing, manufacture and commercialization of therapeutic modalities and our delivery technologies, including lipid nanoparticles, or LNPs. If we, our co-owners or our licensors are unable to obtain, maintain, protect, defend or enforce patent protection with respect to our products, product candidates and other technology and any other products, product candidates and technology that we may 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, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents, and they have filed and will continue to file patent applications claiming inventions in the fields in the United States and elsewhere. This may limit, interfere with or eliminate our and our partners' ability to make, use, sell, import or otherwise exploit our COVID-19 vaccine or our product candidates or other technologies. 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, our partners or our licensors may in the future become a party to patent proceedings or priority disputes in the United States, Europe or other jurisdictions. In the United States, the Leahy-Smith America Invents Act, or the America Invents Act, includes a number of significant changes that affect the way patent applications are 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.

Additionally, we face ongoing COVID-19 vaccine-related patent litigation. We filed a nullity action in the Federal Patent Court of Germany seeking a declaration that EP1857122B1, or EP'122, is invalid, initiated cancellation actions against the CureVac IP in the German Patent and Trademark Office, and filed opposition proceedings in the European Patent Office, or EPO, seeking the revocation of EP3708668B1, or EP'668, and EP4023755B1, or EP'755. ModernaTX, Inc., or Moderna, has brought litigation against us and Pfizer regarding European patents 3590949B1, or EP'949, and 3718565B1, or EP'565, in Germany, England and Wales (only EP'949 currently at issue), the Netherlands, Ireland, and Belgium, and regarding U.S. Patent Nos. 10,898,574, 10,702,600, and 10,933,127 in the United States. BioNTech and Pfizer also initiated proceedings seeking the revocation of EP'949 in the Business and Property Courts of England and Wales and have filed opposition proceedings in the EPO seeking the revocation of EP'949 and EP'565. BioNTech and Pfizer have filed petitions for inter partes review before the Patent Trial and Appeal Board in the United States with respect to U.S. Patent Nos. 10,702,600 and 10,933,127. Arbutus Biopharma Corp., or Arbutus, and Genevant Sciences GmbH, or Genevant, have brought litigation against us and Pfizer in the United States regarding U.S. Patent Nos. 9,504,651, 8,492,359, 11,141,378, 11,298,320, and 11,318,098. Promosome LLC, or Promosome, has initiated litigation against us and Pfizer in the Unified Patent Court (Munich Division) regarding one European patent, EP 2 401 365. GlaxoSmithKline Biologicals SA and GlaxoSmithKline LLC, or collectively, GSK, have brought litigation against us and Pfizer in the United States regarding U.S. Patent Nos. 11,638,693, 11,638,694, 11,666,534, 11,766,401, 11,786,467, 11,759,422, 11,655,475, and 11,851,660, and in the High Court of Ireland, as well as the United Patent Court, regarding European Patent Nos. 2,590,626, 4,066,856, and 4,226,941. BioNTech and Pfizer also initiated proceedings seeking the revocation of EP'626, EP'856, and EP'941 in the Business and Property Courts of England and Wales and have filed opposition proceedings in the EPO seeking the revocation of EP'856 and EP'941. Bayer CropScience LLC, or Bayer, Monsanto Company, and Monsanto Technology, LLC, or Monsanto, have initiated litigation against us and Pfizer in the United States District Court for the District of Delaware regarding one U.S. Patent No. 7,741,118. We cannot guarantee that we will not become subject to additional COVID-19 vaccine patent infringement lawsuits in the future. In addition, should Pfizer not prevail in any of the ongoing COVID-19 vaccine patent infringement lawsuits to which it is a party, Pfizer may seek to require us to indemnify Pfizer for losses suffered therefrom as well as any losses from future COVID-19 vaccine patent infringement lawsuits in which it does not prevail. We believe we have strong defenses against each of these claims and intend to vigorously defend ourselves in each proceeding, but we can make no assurances regarding the ultimate outcome of any of these matters. Additionally, as we continually evaluate these various proceedings, we may from time to time make strategic decisions to settle or otherwise resolve certain proceedings despite our continued belief in the strengths of our defenses.

We expect that we will continue to be subject to similar proceedings or priority disputes, including oppositions, in Europe or other jurisdictions relating to patents and patent applications in our portfolio.

If we, our co-owners, our partners 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. 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, technical personnel and other employees 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 products or 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, as evidenced by the lawsuits brought against Moderna, Pfizer and us, there may be additional 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, testing and commercialization of our COVID-19 vaccine or 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, if we fail to invalidate relevant patents, or if a court or other governing body determines 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, testing and commercialization of one or more of the product candidates we may develop. Any of the foregoing could result in a material adverse effect on our business, financial condition, results of operations or prospects.

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

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

We sometimes collaborate with academic institutions and/or utilize services of CROs and CMOs in certain aspects of our research or development under written agreements with these parties. These agreements may not ensure protection of intellectual property rights in developed technology, or may fail to provide us with

sufficient control of or access to such intellectual property rights. For example, agreements with these academic institutions typically provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. However, these institutions may not honor our option and right of first negotiation for intellectual property rights or we may otherwise be unable to negotiate a license within the specified time frame or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program or otherwise continue to develop certain product candidates or other technologies. CROs and/or CMOs may control certain technologies that were utilized in and/or developed through work on our behalf, and may not pursue protection of such technologies, or may provide us with only non-exclusive rights in such technologies, so that relevant technologies may be shared with other parties including our competitors. In any relationship with a third party, there is a risk of disagreement over intellectual property rights (including inventorship or ownership of, rights to protect and/or enforce, and/or rights to use) in utilized or developed technologies.

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

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

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

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first effective non-provisional filing date, assuming maintenance fees are timely paid after the patent has issued. Most other jurisdictions also provide a 20-year nominal patent term, though many require payment of regular, often annual, annuities to maintain pendency of an application or viability of an issued patent. In some jurisdictions, one or more options for extension of a patent term may be available, but even with such extensions, the lifespan of a patent, and the protection it affords, is limited. Even if patents covering our product candidates, proprietary technologies and their uses are obtained, once the patent term has expired, we may be subject to competition from third parties that can then use the inventions included in such patents to create competing products and technologies. In addition, although upon issuance in the United States a patent's life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. The USPTO can also require, in certain circumstances, that the expiration date of a subject patent be shortened by the filing of a terminal disclaimer over one or more patents that may expire sooner than the subject patent. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such candidates are commercialized. If any patents that we own or in-license expire, we would not be able to stop others from using or commercializing similar or identical technology and products, and our competitors could market competing products and technology. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

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

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process for a drug product subject to the provisions of the Hatch-Waxman Act. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. For example, we did not extend any patent for our COVID-19 vaccine. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

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

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

Where we obtain licenses from, or collaborate with, third parties, in some circumstances we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications covering the technology that we license from, or that arises through collaboration with, such third parties, or such activities, if controlled by us, may require the input of such third parties. In some cases, patent prosecution (including preparation and filing) of our in-licensed intellectual property or of intellectual property developed through collaboration, is controlled solely by the licensor or collaborator. We may also require the agreement and/or cooperation of our licensors and collaborators to protect, enforce, utilize, or defend any in-licensed patent rights, and such agreement and/or cooperation may not be provided. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, protected, enforced or defended in a manner consistent with the best interests of our business. Any patents or patent applications that we in-license may be challenged, narrowed, circumvented, invalidated or held unenforceable, or our licensors may not properly maintain such patents or patent applications and they may expire. If our licensors fail to obtain, maintain, defend, protect or enforce the intellectual property we license from them, we could lose our rights to the intellectual property and our competitors could market competing products using the inventions in such intellectual property. In certain cases, we control the prosecution of patents included from in-licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our collaborators. If we and our licensors or collaborators disagree over IP protection strategies for relevant technologies, disputes may arise, and we could lose access to or control over protection

of technologies important to our business. If so, we may not be able to adequately protect our product(s) or product candidates, including not being able to prevent a competitor or other third party from developing the same product(s) or product candidates for the same or a different use. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Moreover, we may disagree from time to time with licensors or collaborators regarding, among other things, the interpretation of each party's obligations or the amounts payable under our agreements. For example, we were in discussions with the University of Pennsylvania, or UPenn, and the National Institutes of Health, or the NIH, concerning royalties and other related amounts allegedly owed on sales of our COVID-19 vaccine since commercialization. UPenn subsequently filed suit against us in the U.S. District Court for the Eastern District of Pennsylvania in connection with this dispute. On December 20, 2024, we entered into a Settlement Agreement with the NIH pursuant to which we agreed, among other things, to pay $791.5 million to the NIH. On March 27, 2025, we entered into a Settlement Agreement with UPenn pursuant to which we agreed, among other things, to pay up to $467.0 million to UPenn, consisting of $400.0 million as royalties for calendar years 2020-2023, up to $15.0 million in funding for a three-year extension of the research term of our and UPenn's vaccine alliance, and $52.0 million as a contribution to a research and development investment fund to be jointly managed by us and UPenn. For more information regarding our settlements with the NIH and UPenn, see Note 12.2 of our consolidated financial statements included elsewhere in this Annual Report.

If we are found to have failed to satisfy obligations or materially breached any of our agreements, such as licenses to third-party intellectual or any disagreements between us and our licensors, a licensor could potentially have the right or reason to terminate the license or to exercise the option of a non-exclusive license, which would allow our competitors to have access to the same intellectual property and technology licensed to us. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone and royalty payment, exclusivity and other obligations on us. If we fail to comply with our obligations under these agreements, including royalty payments, or we are subject to a bankruptcy, the licensor may have the right to terminate the license agreement, in which event we would not be able to develop, market and commercialize product(s) or product candidates covered by the license agreement. In spite of our best efforts and even if we disagree, our licensors might still conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop, test and commercialize the product(s) or product candidates covered by these license agreements. In the event that any of our license agreements were to be terminated by the licensor, we may need to negotiate new or reinstated agreements, which may not be available to us on equally favorable terms, or at all. If these license agreements are rightfully terminated, or if the underlying patents or other intellectual property fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market and commercialize, products similar or identical to ours, and our licensors may be able to seek additional judicial remedies. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing license agreements in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses. Failure to prevail with respect to any contractual disagreements could result in a material adverse effect on our competitive position, business, financial conditions, results of operations or prospects, particularly if discussions result in legal or other dispute resolution proceedings.

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

affected product(s) or product candidates, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Certain intellectual property rights that have been in-licensed, including patent applications and patents that we in-license from the University of Pennsylvania, the Louisiana State University, the Broad Institute, the NIH, Genevant, and CellScript, have been generated through the use of U.S. government funding and are therefore subject to certain federal regulations. The U.S. government may have certain rights to intellectual property embodied in our current or future product candidates pursuant to the Bayh-Dole Act of 1980, or the Bayh-Dole Act. These U.S. government rights may include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions covered by that Act for any governmental purpose. In addition, the U.S. government may have the right, under certain limited circumstances, to require the licensor to grant exclusive, partially exclusive or non-exclusive licenses to any of these inventions to a third party if it determines that (i) adequate steps have not been taken to commercialize the invention, (ii) government action is necessary to meet public health or safety needs or (iii) government action is necessary to meet requirements for public use under federal regulations (also collectively referred to as "march-in rights"). The U.S. government may also have the right to take title to these inventions if the licensor fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Any exercise by the government of such rights could harm our competitive position, business, financial condition, results of operations and prospects. Intellectual property generated under a government-funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources.

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

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

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

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

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

Because our products and product candidates are still in early stages of development, testing or commercialization, and one or more features of the products or product candidates, or related technologies such as their manufacture, formulation, testing or use, may still change, we cannot be confident that we are aware of all third-party intellectual property that might be relevant to products that we eventually hope to commercialize. Furthermore, even if all aspects of our product(s) or product candidates, or of other technology, were known, it is possible that third-party intellectual property, which may or may not currently be public, could develop in a manner (for example, through issuance of additional patents) that could impede our ability to make or use relevant products or product candidates, or other technology. Various third-party competitors practice in relevant spaces, and may have issued patents, or patent applications that will issue as patents in the future, that will impede or preclude our ability to commercialize products. Furthermore, while U.S. patent laws provide a “safe harbor” to our clinical product candidates under 35 U.S.C. § 271(e)(1), which exempts from patent infringement activities related to pursuing FDA approval for a drug product, that exemption expires when an NDA or BLA is submitted. Accordingly, after such submission (including for certain formulations of our COVID-19 vaccine), the 271(e)(1) safe harbor may no longer provide the same level of protection from third party patent infringement claims for that product. We may become exposed to lawsuits from third parties who consider our COVID-19 vaccine to infringe their patents. More generally, given the uncertainty of clinical trials, we cannot be certain of the timing of their completion and it is possible that we might want to submit an NDA or BLA at a time when one or more relevant third-party patents is in force. Thus, it is possible that at the time that we commercialize our product candidates, one or more third parties may have issued patent claims that cover such products or critical features of their production, testing or use. We may not be able to commercialize our products if patents issued to third parties or other third-party intellectual property rights cover, or may be alleged to cover, our products or elements thereof, or their methods of manufacture, testing or use at the time that we seek to commercialize them. In such cases, we may not be in a position to develop, test or commercialize product candidates unless we successfully pursue litigation to nullify or invalidate the third-party intellectual property right concerned, successfully design around their claims, or enter into a license agreement with the intellectual property right holder(s). Such litigation or licenses could be costly, licenses could not be available on commercially reasonable terms or at all, and design-around could be prohibitively expensive or impossible.

Additionally, with respect to our products, product candidates and related technologies that may play a role in addressing a pandemic or other public health emergency, it is unclear whether governments around the world will protect vaccine manufacturers for liability from infringement of third party intellectual property, at least during the period of such public health emergency. Thus, it is possible that third parties may assert intellectual property rights against us relating to our COVID-19 vaccine, and that we will not be successful in arguing that commercialization of our COVID-19 vaccine is exempted from infringement and/or liability for infringement (for example, under 35 U.S.C. § 271(e)(1), discussed above, or under the Public Readiness and Emergency

Preparedness Act, or the PREP Act, etc.). Furthermore, even if such commercialization was deemed protected from infringement during the period of the pandemic crisis, now that various global and U.S. agencies have declared an end to the global COVID-19 public health emergency, any such exemption may be terminated so that continuing commercialization could expose us to liability, and might even be precluded if third party(ies) who hold relevant intellectual property rights are able to secure injunction(s) or are unwilling to license to us on commercially feasible terms.

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

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

There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, ex parte reexaminations, post-grant review, and inter partes review proceedings before the USPTO and corresponding European and other non-U.S. patent offices.

Competitors and other third parties may infringe, misappropriate or otherwise violate our intellectual property rights or those of our licensors. To prevent infringement, misappropriation or other unauthorized use, we may be required to file claims, which can be expensive and time-consuming. In certain instances, we have instituted and may in the future institute inter partes review proceedings against issued U.S. patents and opposition proceedings against European patents owned by third parties. We have a number of opposition proceedings ongoing at the EPO against third-party patents related to mRNA technologies. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our products, product candidates and services may be subject to claims of infringement of the patent rights of third parties.

In addition, in a patent infringement proceeding, our owned or in-licensed patents may be challenged and a court may decide that a patent we own or in-license is not valid, is unenforceable and/or is not infringed. If we or any of our potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at one of our product(s) and/or product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including novelty, non-obviousness, enablement or written description. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise similar claims before the USPTO, even outside the context of litigation. Similar mechanisms for challenging the validity and enforceability of a patent exist in ex-U.S. patent offices and may result in the revocation, cancellation or amendment of any ex-U.S. patents we hold in the future. The outcome following legal assertions of invalidity and unenforceability is unpredictable, and prior art could render our patents or those of our licensors invalid. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we could lose at least part, and perhaps all, of the patent protection on a product and/or product candidate. Such a loss of patent protection would have a material adverse impact on our competitive position, business, financial conditions, results of operations and prospects.

Third parties, including our competitors to non-practicing entities or patent assertion entities, may assert that we are employing their intellectual property and other proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, testing, methods of manufacture or methods for treatment related to the use, development, testing, manufacture or commercialization of our COVID-19 vaccine or product candidates. For example, BioNTech SE and certain of our wholly owned subsidiaries are defendants in litigations initiated by CureVac, Moderna, Arbutus, Genevant, GSK, and Promosome regarding *Comirnaty*. See "Legal Proceedings" in this Annual Report. As patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product(s) and/or product candidates may infringe. In addition, third parties may obtain patents in the future and claim that our technologies infringe upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the testing or manufacturing processes of any of our product(s) and/or product candidates, any molecules formed during the testing and manufacturing processes or any final product itself, the holders of any such patents may obtain injunctive or other equitable relief, which could effectively block our ability to develop, test and commercialize such product and/or product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our formulations, processes for testing or manufacture or methods of use, including combination therapy, the holders of any such patents may be able to block our ability to develop, test and commercialize the applicable product and/or product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms, or at all, or may be non-exclusive.

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

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

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

Such licenses are likely to be non-exclusive and, therefore, our competitors may have access to the same intellectual property and technology licensed to us. If we fail to obtain a required license and are unable to design around a patent, we may be unable to effectively market some of our technology and product(s) and/or product candidates, which could limit our ability to generate revenues or achieve or maintain profitability and

possibly prevent us from generating revenue sufficient to sustain our operations. Moreover, certain of our collaborations provide, and we expect additional collaborations to provide, that royalties payable to us for licenses to our intellectual property may be offset by amounts paid by our collaborators to third parties for licenses to such third parties' intellectual property in the relevant fields, which could result in significant reductions in our revenues from products developed through collaborations.

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

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

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

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

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

As is the case with other biotechnology companies, our success is heavily dependent on our intellectual property rights, particularly patents that we own and in-license. Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity, and therefore obtaining and enforcing biotechnology patents is costly, time-consuming and inherently uncertain. Moreover, there are periodic changes in patent law. For example, after March 2013, under the America Invents Act, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The America Invents Act also includes a number of significant changes that have affected the way patent applications are prosecuted and also affect patent litigation. Such legislation and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

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

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

We seek to protect these trade secrets, know-how and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, CROs, CMOs, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants and require all of our employees and key consultants who have access to our trade secrets, proprietary know-how, information or technology to enter into confidentiality agreements. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. To the extent we become involved in litigation that may require discovery of our trade secrets, know-how and other proprietary technology, we seek to secure protective orders from the court that bind the parties with access to the discovered information. Despite our best efforts, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Any of these parties who may have access to our trade secrets, know-how and other proprietary technology may breach such agreements or orders. For example, a former employee of our COVID-19 vaccine collaborator, Pfizer, has reportedly misappropriated trade secrets on our COVID-19 vaccine. We may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret or know-how is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets and know-how. In addition, we cannot be certain that our proprietary technical information and related confidential documents that we have shared with our collaborators and/or have submitted to governmental agencies, including regulatory agencies, for evaluation and supervision of pharmaceutical products will be kept confidential. For example, certain documents relating to our COVID-19 vaccine were unlawfully accessed after a cyberattack on the EMA in December 2020. If any of our trade secrets or know-how were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results, financial condition and prospects.

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

We have received confidential and proprietary information from third parties in the course of our research and other collaborations with others in the industry, academic institutions and other third parties. In addition, many of our employees, consultants and advisors are currently or were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants, independent contractors and advisors do not use the confidential or proprietary information, trade secrets or know-how of others in their work for us, we may be subject to claims that we have inadvertently or otherwise used or disclosed confidential or proprietary information, trade secrets or know-how of these third parties, or that our employees, consultants, independent contractors or advisors have inadvertently or otherwise used or disclosed confidential information, trade secrets or know-how of such individual's current or former employer. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management, technical personnel and other employees. Claims that we or our employees, consultants or advisors have misappropriated the confidential or proprietary information, trade secrets or know-how of third parties could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

In the future, we may be subject to claims that current or former employees, consultants, independent contractors, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. While it is our policy to require our employees, consultants, independent contractors, collaborators and other third parties who may be involved in the conception, development or reduction to practice of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives, develops or reduces to practice such intellectual property that we regard as our own. In addition, certain such agreements, even if successfully executed may distribute ownership or control of intellectual property rights between or among parties, for example based on subject matter, relationship to other intellectual property, and/or one or more aspects of development of the intellectual property; after the agreements are in place disputes may arise over such distribution principles or over proper treatment of particular developed intellectual property in accordance with them. Disagreements may be difficult or impossible to resolve, may be expensive to address, and may result in our failing to secure or maintain ownership in or control of intellectual property necessary or important to our business.

The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached. For example, we may have inventorship or ownership disputes arise from conflicting obligations of employees, consultants, independent contractors, collaborators or other third parties who are involved in developing and commercializing our product(s) and/or product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business, operating results and financial condition. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management, technical personnel and other employees.

Furthermore, the laws of some other countries do not protect intellectual property and other proprietary rights or establish ownership of inventions to the same extent or in the same manner as the U.S. laws. A majority of our

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

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

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

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain jurisdictions, particularly outside of Europe and the United States. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement, misappropriation or other violation of our patents and other intellectual property or development, testing, marketing and commercialization of competing products in violation of our owned or in-licensed intellectual property and other proprietary rights generally. Proceedings to enforce our intellectual property rights in such jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or in-license. In particular, the validity, enforceability and scope of protection of intellectual property in China, where we derive net sales and maintain collaboration partnerships including licensing, are still evolving and historically, have not protected and may not protect in the future, intellectual property rights to the same extent as laws developed in Europe, including Germany, and the United States. Consequently, the time required to enforce our intellectual property rights in the legal regime of China may be lengthy and delay our recovery.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially

diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

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

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential collaborators or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours or collaborators may fail to use our trade names or trademarks appropriately or at all, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors and collaborators. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse or failure to use of our trademarks and trade names by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks, and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, know-how, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

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

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

- others may be able to make COVID-19 vaccines or therapies, and/or individualized cancer immunotherapies that are similar to our COVID-19 vaccine and/or any product candidates we may develop and commercialize or utilize similar technologies that are not covered by the claims of the patents that we now or may in the future own or have exclusively in-licensed;
- we, our co-owners or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or have exclusively in-licensed;
- we, our co-owners or our licensors or future collaborators might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or in-licensed intellectual property rights;
- it is possible that our pending patent applications or those that we may own or in-license in the future will not lead to issued patents;
- claims of issued patents that we own or have exclusively in-licensed may be held invalid or unenforceable, including as a result of legal challenges by our competitors;

- our competitors might conduct research, development, testing or commercialization activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may have an adverse effect on our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

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

Risks Related to Government Regulation

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

Administration of some of our product candidates may require the use of immuno-assays and bioinformatic tools in which patients are screened for optimal target antigens of our product candidates. If safe and effective use of a biologic product depends on an in vitro diagnostic, then the FDA generally requires approval or clearance of the diagnostic, known as a companion diagnostic, concurrently with approval of the therapeutic product. To date, the FDA has generally required in vitro companion diagnostics intended to select the patients who will respond to cancer treatment to obtain a pre-market approval, or PMA, for that diagnostic, which can take up to several years, simultaneously with approval of the biologic product. Similarly, in the European Union, an in vitro companion diagnostic may be placed on the market only if it conforms to certain “essential requirements” and bears the Conformité Européene Mark, or CE Mark. The conformity assessment process to obtain the CE Mark can be lengthy and we may fail to demonstrate such conformity. Further, the applicable regulatory framework for in vitro diagnostics in the EU changed in May 2022 when a new EU regulation with stricter regulatory requirements for in vitro diagnostics became applicable. Under the regulation, all new in vitro companion diagnostics must undergo conformity assessment by a notified body prior to obtaining their CE Mark.

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

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

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

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

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

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

- the FDA, the EMA or comparable regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA, the EMA or comparable regulatory authorities that our product candidates are safe and effective for any of their proposed indications;
- the results of clinical trials may not meet the level of statistical significance required by the FDA, the EMA or comparable regulatory authorities for approval, including due to the heterogeneity of patient populations;
- we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;
- the FDA, the EMA or comparable regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;

- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA, the EMA or comparable regulatory authorities to support the submission of a BLA or other comparable submissions or to obtain regulatory approval in the United States or elsewhere;

- the FDA, the EMA or comparable regulatory authorities will inspect our manufacturing facilities and may not approve our facilities or our manufacturing processes and controls;

- the approval policies or regulations of the FDA, the EMA or comparable regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval; and

- appointees of the presidential administration in the United States may seek to change regulatory requirements for the approval of products or the approach to the review of product applications.

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

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

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

Our strategy includes filing for Orphan Drug Designation where available for our product candidates. Under the U.S. Orphan Drug Act, the FDA may grant Orphan Drug Designation to a drug or biologic intended to treat a rare disease or condition, which is defined as one occurring in a patient population of fewer than 200,000 in the United States, or a patient population of 200,000 or greater in the United States where there is no reasonable expectation that the cost of developing the drug or biologic will be recovered from sales in the United States. In the United States, Orphan Drug Designation entitles a party to financial incentives, such as opportunities for grant funding toward clinical trial costs, tax advantages, and user-fee waivers. In addition, if a product that has Orphan Drug Designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a full new drug application or a BLA, to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the original manufacturer is unable to assure sufficient product quantity. Similar rules apply in the European Union with respect to drugs or biologics designated as orphan medicinal products.

In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not protect the product effectively from competition because different drugs with different active moieties may receive and be approved for the same condition, and only the first applicant to receive approval will

receive the benefits of marketing exclusivity. Even after an orphan-designated product is approved, the FDA can subsequently approve a later drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior if it is shown to be safer, more effective, or makes a major contribution to patient care. Similar considerations apply in the European Union with respect to drugs or biologics designated as orphan medicinal products. Orphan Drug Designation neither shortens the development time or regulatory review time of a drug, nor gives the drug any advantage in the regulatory review or approval process. In addition, while we may seek Orphan Drug Designation for our product candidates, we may never receive such designations.

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

We may seek a Breakthrough Therapy Designation in the United States for one or more of our product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for priority review if supported by clinical data at the time of the submission of the BLA. Although priority review shortens the goal date by which FDA intends to decide on an application, it does not guarantee any particular action by FDA, or even FDA action by that date.

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

We may also seek Fast Track Designation in the United States for some of our product candidates. If a therapy is intended for the treatment of a serious or life-threatening condition and the therapy demonstrates the potential to address significant unmet medical needs for this condition, the drug sponsor may apply for Fast Track Designation. The FDA has broad discretion whether to grant this designation, and even if we believe a particular product candidate is eligible for this designation, we cannot be sure that the FDA would decide to grant it. Even if we do receive Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track Designation alone does not guarantee qualification for the FDA's priority review procedures.

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

The ACA includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or the BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first approved

by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first approved.

During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of the other company's product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty.

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

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

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

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

These various regulatory review committees and advisory groups and new or revised guidelines that they promulgate from time to time may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. As the regulatory landscape for our CAR-T-cell immunotherapy product candidates is new, we may face even more cumbersome and complex regulations than those emerging for gene therapy products and

cell therapy products. Furthermore, even if our product candidates obtain required regulatory approvals, such approvals may later be withdrawn as a result of changes in regulations or the interpretation of regulations by applicable regulatory agencies.

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

We may be unable to obtain regulatory approval for our product candidates under applicable international regulatory requirements.

The denial or delay of such approval would delay commercialization of our product candidates and adversely impact our potential to generate revenue, our business and our results of operations.

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

Seeking regulatory approval in other jurisdictions could result in difficulties and costs for us and require additional preclinical studies or clinical trials which could be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. The European Union and other jurisdictions' regulatory approval processes involve all of the risks associated with the FDA approval. If we fail to comply with regulatory requirements in certain markets or to obtain and maintain required approvals, or if regulatory approvals in certain markets are delayed, our target market will be reduced and our ability to realize the full market potential of our products will be unrealized.

Certain jurisdictions may have submission requirements for drug clinical trial and marketing applications that require us or our partners to submit substantial detailed materials related to non-clinical and clinical development and manufacturing and quality control to drug regulators or testing laboratories. This can include confidential standard operating procedures or executed batch records for the production of biological products or other records or documents that set forth detailed information about the manufacturing process and the manufacturing site. If these materials are disclosed in an unauthorized manner, lost, or otherwise diverted to third parties or competitors during the application preparation process, this could negatively affect our ability to protect our intellectual property.

Our partners in different countries are subject to local regulatory requirements and standards on the manufacturing and distribution of drugs and the implementation of clinical and non-clinical research. These include but are not limited to good manufacturing, distribution, laboratory, clinical practice, and pharmacovigilance rules. If these companies do not comply with applicable standards, they could become the subjects of inspections, investigations and enforcement, including orders to cease the activities pending remediation that is acceptable to the government. Such an order or other similar enforcement could interfere with our clinical development and marketing activities both in that jurisdiction and others, if it impacts supply or the quality and transfer of data.

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

We are developing several of our product candidates to be used in combination with our and third-party product candidates. Even if any product candidate we develop were to receive marketing approval or be commercialized

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

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

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

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

Regulatory requirements governing gene and cell therapy products have evolved and may continue to change in the future, and the implications for mRNA-based therapies is unknown. For example, the FDA has established the Office of Tissues and Advanced Therapies within CBER to consolidate the review of gene therapy and related products, and convenes the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. In the European Union, mRNA has been characterized as a gene therapy medicinal product. In certain countries, mRNA therapies have not yet been classified or any such classification is not known to us. Notwithstanding the differences between our mRNA product candidates and gene therapies, the classification of some of our mRNA product candidates as gene therapies in the United States, the European Union and potentially other counties could adversely impact our ability to develop our product candidates, and could negatively impact our platform and our business. For instance, a potential future clinical hold on gene therapy products across the field due to risks associated with altering cell DNA irreversibly could apply to our mRNA product candidates irrespective of the mechanistic differences between gene therapies and mRNA.

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

Our COVID-19 vaccine and any other product candidates for which we receive approval or emergency use authorization are subject to continuing regulatory oversight, and we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. We may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products or product candidates.

Our COVID-19 vaccine and any other product candidates for which we receive approval or emergency use authorization are subject to continuing regulatory oversight, including the review of additional safety information, and the applicable regulatory authority may still impose significant restrictions on the indicated uses or marketing of our product or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. For example, the holder of an approved BLA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. The holder of an approved BLA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Similar requirements apply to holders of (conditional) approvals in other countries. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws. In other countries outside of the United States, advertising and promotional material may be subject to similar or more onerous rules. For example, direct-to-consumer advertising of prescription medicinal products is prohibited in many jurisdictions outside of the United States, including the European Union.

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

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

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

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

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

Additionally, following regulatory approval of a product candidate, the FDA or other regulatory authority could require us to adopt a REMS or a risk management plan to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a medication guide outlining the risks of the product for distribution to patients, a communication plan to health care practitioners, extensive patient monitoring, or distribution systems and processes that are highly controlled, restrictive, and more costly than what is typical for the industry.

Furthermore, if we or others later identify undesirable side effects caused by any product that we develop, several potentially significant negative consequences could result, including:

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

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

Upon the successful approval of a product candidate, we will continue to face significant regulatory oversight of its manufacturing and distribution. Product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with

GMP and adherence to commitments made in the BLA or comparable approval. If we or a regulatory agency discovers previously unknown problems with a product such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

Governmental investigations and inquiries with respect to our COVID-19 vaccine and any other product candidates for which we receive approval or emergency use authorization may adversely affect our business, financial condition and results of operations.

In April 2025, we, along with several other pharmaceutical companies, received a letter from the Chairman of the Permanent Subcommittee on Investigations of the U.S. Senate Homeland Security and Governmental Affairs Committee, or the Subcommittee, that requested certain information and documents relating to the respective COVID-19 vaccines we developed (in our case, *Comirnaty*). This and other governmental investigations or inquiries in which we may become involved may result in additional claims and lawsuits being brought against us by governmental agencies or private parties. It is not possible at this time to predict either the outcome or the potential financial impact of the congressional investigation mentioned above or any further investigations or inquiries of us that may result from such investigation. It is also not possible at this time to predict the additional expenses related to such investigation, which may be significant. The initiation of any additional investigation relating to us, the costs and expenses associated therewith, or any assertion, claim or finding of wrongdoing by us, could:

- adversely affect our business, financial condition and results of operations;
- result in reputational harm and reduced market acceptance and demand for our products;
- harm our ability and our commercial partners' ability to market our products;
- harm our ability to develop our product candidates;
- cause us to incur significant liabilities, costs and expenses; and
- cause our senior management to be distracted from execution of our business strategy.

Furthermore, the pending congressional investigation could negatively affect our ability to raise capital and impair our ability to engage in strategic transactions.

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

We may be subject to additional healthcare regulation and enforcement by the U.S. federal government and by authorities in the United States, the European Union and other jurisdictions in which we conduct our business. Our operations may be directly, or indirectly through our prescribers, customers and purchasers, subject to various federal and state fraud and abuse laws and regulations, including, without limitation, the federal Health Care Program Anti-Kickback Statute, the federal civil and criminal False Claims Act, and the Physician Payments Sunshine Act and regulations. Many states and other jurisdictions have similar laws and regulations, some of which may be broader in scope. These laws will impact, among other things, our proposed sales, marketing and educational programs. In addition, we may be subject to patient privacy laws enacted by both the federal government and the states in which we conduct our business. The laws that will affect our operations include, but are not limited to the following:

- The U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in return for the purchase, recommendation, leasing or furnishing of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers, and formulary managers on the other. The ACA amends the intent requirement of the federal Anti-Kickback Statute to provide that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it;

- The U.S. federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment or approval from Medicare, Medicaid or other government payors. The ACA provides, and recent government cases against pharmaceutical and medical device manufacturers support, the view that federal Anti-Kickback Statute violations and certain marketing practices, including off-label promotion, may implicate the False Claims Act;

- The U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit a person from knowingly and willfully executing a scheme or making false or fraudulent statements to defraud any healthcare benefit program, regardless of the payor (e.g., public or private);

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and their implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization by entities subject to the rule, such as health plans, health care clearinghouses and health care providers;

- The U.S. Federal Food, Drug, and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;

- The U.S. Public Health Service Act, which prohibits, among other things, the introduction into interstate commerce of a biological product unless a biologics license is in effect for that product;

- Federal transparency laws, including the federal Physician Payment Sunshine Act, which require disclosure of payments and other transfers of value provided to physicians and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations;

- U.S. state law equivalents of each of the above federal laws, state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, and state laws governing the privacy and security of health information in certain circumstances which are also applicable to us, and many of them differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts in certain circumstances;

- The U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, U.S. companies and their employees and agents, as well as non-U.S. companies that are registered with the SEC, from authorizing, promising, offering or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof; and

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

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

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

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

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

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

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

We receive, generate and store significant and increasing volumes of sensitive information, such as employee, personal and patient data.

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

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

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

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

Other jurisdictions outside the European Union are similarly introducing or enhancing privacy and data security laws, rules and regulations, which could increase our compliance costs and the risks associated with non-compliance. In particular, in China, where some of our clinical data are originated, the cybersecurity, data privacy, data protection, or other data-related laws and regulations, including the Personal Information Protection Law, Regulations on Network Data Security Management, Provisions on Promoting and Regulating Cross-Border Data Flows, and Human Genetic Resources Regulation (which regulates the collection and transfer human biospecimens and genetic data derived from them in clinical research to foreign or foreign controlled parties), may require approvals or filings prior to transferring those data to foreign-owned or controlled entities in China or overseas, and these regimes are continually evolving, meaning their interpretation and enforcement may be uncertain. These rules establish mechanisms such as governmental security assessment, certification, and standard contractual clauses for certain cross-border data transfers. Depending on the nature and volume of data processed in China, we or our partners may be required to complete one or more of these transfer mechanisms as a condition to exporting relevant data. Compliance with these requirements could affect our operations, including data flows necessary for clinical development, manufacturing, or other activities conducted in China. The scope and practical application of these rules continue to develop, and there is uncertainty regarding how regulators will apply them in specific circumstances. In the United States, we may be subject to restrictions and requirements under the Department of Justice's Final Rule issued on December 27, 2024 implementing the Executive Order on Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern, signed on February 28, 2024. Practices regarding the collection, use, storage, transmission and security of personal information by companies have also been subject to increasing regulatory focus. As such, we cannot assure you that we will be compliant with such new

regulations in all respects, and we may be ordered to rectify and terminate any actions that are deemed illegal by the government authorities and become subject to fines and other government sanctions, which may materially and adversely affect our business, financial condition, and results of operations. In addition, the uncertainties regarding further interpretation and implementation of these laws and regulations may adversely affect the secure storage of documented work as well as the cross-border transfer of important data and personal information originated from our clinical trial activities, which are critical to the development of our pipelines.

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

Although we take measures to protect sensitive data from unauthorized access, use or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other malicious or inadvertent disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, manipulated, publicly disclosed, lost or stolen. Any such access, breach or other loss of information could result in legal claims or proceedings, and liability under federal or state laws that protect the privacy of personal information, as well as regulatory penalties. In many jurisdictions, there are legal requirements to provide notice of breaches to affected individuals and/or regulators in certain circumstances. Such a notice could harm our reputation and our ability to compete. Regulators may also have the discretion to impose penalties without attempting to resolve violations through informal means. Although we have implemented security measures to prevent unauthorized access to patient data, such data is currently accessible through multiple channels, and there is no guarantee we can protect our data from breach. Unauthorized access, loss or dissemination could also damage our reputation or disrupt our operations, including our ability to conduct our analyses, deliver test results, process claims and appeals, provide customer assistance, conduct research and development activities, collect, process and prepare company financial information, provide information about our tests and other patient and physician education and outreach efforts through our website, and manage the administrative aspects of our business.

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

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

our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

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

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

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

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

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

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

Risks Related to Ownership of the ADSs

We have experienced and may continue to experience significant volatility in the market price of the ADSs representing our ordinary shares.

Biopharmaceutical companies such as BioNTech SE that are developing potential therapeutics and vaccines to combat COVID-19, as well as conducting mRNA-based research in oncology and infectious disease more generally, 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 and commercialization activities. For example, during 2025, the closing sales price of the ADSs representing our ordinary shares on the Nasdaq Global Select Market ranged from $86.65 to $126.88. In addition, volatility in the overall market and in the market price of a particular company's securities can result in securities litigation, including shareholder class action lawsuits. Any securities litigation can result in substantial costs and a diversion of our management's attention and resources.

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

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

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

In addition, if we undertake acquisitions, we may utilize our cash, issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. For example, in July 2023, we acquired InstaDeep, a leading global technology company in the field of AI and machine learning, for upfront consideration of cash and BioNTech shares, and potential future milestone payments. Although we believe that AI and machine learning technology has the potential to accelerate the development of therapeutic programs and further optimize manufacturing and supply chain processes, it is possible that our use of the acquired technology will not achieve the desired results, and that we will not be able to retain and grow InstaDeep's business around the world. If demand for the services developed by InstaDeep does not continue, or if we are unable to improve our AI and machine learning technology in a timely, effective and competitive manner, we may not be able realize the expected outcomes from the InstaDeep acquisition. In January 2025, we acquired Biotheus, a clinical-stage biotechnology company, for upfront consideration predominantly of cash, with a small portion in our ADSs, and potential future milestone payments. Although the Biotheus acquisition expands our operations in China, our expectations regarding the creation of long-term value for shareholders and potential future commercialization in oncology may not be realized. In December 2025, we acquired CureVac N.V., a biotechnology company focused on the development of mRNA therapeutics, through a public exchange offer. While we believe the acquisition has the potential to enhance our capabilities in mRNA research, development, manufacturing and commercialization, there can be no assurance that we will realize the anticipated benefits from the transaction. There is no guarantee that we will realize any anticipated benefits of these or future acquisitions, or that the diversification of our business through acquired technology or products will be successful.

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

Following the acquisition of CureVac, we may be required to repay monies received under the Advance Purchase Agreement with the European Commission for its first-generation COVID-19 vaccine candidate.

On November 30, 2020, prior to our acquisition of CureVac, CureVac AG entered into an Advance Purchase Agreement, which we refer to as the APA, with the EU Commission, acting on behalf of all Member States of the European Union, for the supply of up to 405 million doses of its first-generation COVID-19 vaccine candidate, which we refer to as CVnCoV. Under the APA, CureVac AG received an upfront payment of €450 million for development and commercial supply activities of CVnCoV. In October 2021, CureVac AG notified the EU Commission of the withdrawal of its regulatory approval application for CVnCoV, which notification automatically terminated the APA. According to the APA, in such case of termination, CureVac AG would be required to return any unspent amount of the upfront payment. In the context of the APA, "spent" means either costs incurred, or commitments made in connection with the purposes set forth in the APA.

On July 24, 2024, the EU Commission informed CureVac SE that it had engaged Deloitte, S.L., which we refer to as Deloitte, to conduct an audit of CureVac SE's compliance with the APA. On September 17, 2025, the EU Commission provided CureVac SE with Deloitte's draft audit report, which included preliminary findings alleging missing documentation, absence of project cost allocation, cost traceability and reconciliations, as well as inconsistencies between information submitted during the audit and financial information previously provided to the EU Commission. CureVac SE is cooperating fully with the EU Commission and Deloitte and submitted a detailed response and objections on October 17, 2025. The EU Commission subsequently issued its final audit report.

CureVac SE contested the findings in Deloitte's draft audit report and believes it can refute the issues raised.

However, it remains uncertain to what extent Deloitte and the EU Commission will accept CureVac SE's position. It is also unclear whether the EU Commission will rely on Deloitte's final audit report to seek recovery of any portion or all of the €450 million upfront payment. As the successor to CureVac following the acquisition, we cannot exclude the possibility of being required to repay a portion or all of the €450 million upfront payment. Should we be unsuccessful in contesting any such repayment claims, or the payment of related fines, this could materially affect our financial position, cash flows, and results of operations.

Our Articles of Association designate specific courts in the United States as the exclusive forum for certain U.S. litigation that may be initiated by our shareholders, which could limit our shareholders' ability to obtain a favorable judicial forum for disputes with us.

Our Articles of Association provide that the United States District Court for the Southern District of New York shall be the competent court of jurisdiction for the resolution of any litigation on the grounds of or in connection with U.S. federal or state capital market laws. In the absence of these provisions, under the Securities Act of 1933, as amended, or the Securities Act, U.S. federal and state courts have been found to have concurrent jurisdiction over suits brought to enforce duties or liabilities created by the Securities Act.

The choice of forum provision contained in our Articles of Association may limit a shareholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our executive officers, directors, or other employees, or impose additional litigation costs on shareholders in pursuing any such claims, particularly if the shareholders do not reside in or near the state of New York, which may discourage such lawsuits. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are "facially valid" under Delaware law, there is uncertainty as to whether other U.S. or German courts will enforce our choice of forum provision. The enforceability of similar choice of forum provisions in other companies' governing documents has been challenged in recent legal proceedings, and it is possible that a court in the relevant jurisdictions with respect to us could find the choice of forum provision contained our Articles of Association to be inapplicable or unenforceable. If the relevant court were to find the choice of forum provision contained in our articles of association to be inapplicable or unenforceable, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition and operating results. The choice of forum provision may also impose additional litigation costs on shareholders who assert that the

provision is not enforceable or invalid. The United States District Court for the Southern District of New York may also reach different judgments or results than would other courts, including courts where a shareholder considering a U.S.-based action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our shareholders.

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

Under German law, the existing shareholders of a company 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. For example, ADS holders were unable to participate in our summer 2020 rights offering. 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.

The amount and frequency of our dividends and ADS repurchases may fluctuate.

The amount, timing and execution of any ADS repurchase program we conduct in the future and the amount and timing of any dividends we pay may fluctuate based on our priorities for the use of cash for other purposes, and any ADS repurchases would be subject to the parameters contained in the applicable repurchase plan. These purposes may include operational spending, capital spending, acquisitions and repayment of debt. Additionally, we may choose to repurchase ADSs so that such ADSs may be used to settle outstanding and future equity awards granted to our employees. Changes in cash flows, tax laws and the price of the ADSs could also impact any ADS repurchase program. Additionally, we may enter into a Rule 10b5-1 trading plan governing the repurchases, and if we do, we would have no discretion over the particular purchases made and would only be able to set minimum price floors and maximum ADS count ceilings.

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 a majority of our ordinary shares (including ordinary shares represented by ADSs) as of December 31, 2025, and 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 shareholders may believe are in their best interest. Such insiders may also act in concert to waive rights to participate in rights offerings, as was done in our summer 2020 rights offering, which would have the effect of permitting the ADSs or shares underlying such waived rights to be offered to the public in an underwritten offering without contravening German law pricing requirements.

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.

We have filed registration statements on Form S-8 under the Securities Act to register all ordinary shares issued or issuable under our equity plans. Such Form S-8 registration statements have become, and any other registration statements on Form S-8 we file in the future will become, effective upon filing, upon which shares registered under such registration statements become available for sale in the open market.

Additionally, certain sales of ADSs or our ordinary shares that we have made have included, and we may in the future make sales including, holding period restrictions or registration rights. 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 to sell the ADSs on favorable terms.

If we are a "passive foreign investment company" for U.S. federal income tax purposes, there may be adverse U.S. federal income tax consequences to U.S. investors.

Based on our income and assets, we believe that we should be treated as a "passive foreign investment company," or PFIC, for the preceding taxable year. However, the determination of our PFIC status is made annually based on the factual tests described below. Consequently, while we may be a PFIC in future years, we cannot estimate with certainty at this stage whether or not we are likely to be treated as a PFIC in the current taxable year or any future taxable years. Generally, if, for any taxable year, at least 75 percent of our gross income is "passive income" or at least 50 percent of our gross assets during the taxable year (based on the average of the fair market values of the assets determined at the end of each quarterly period) are assets that produce or are held for the production of passive income, we will be characterized as a PFIC for U.S. federal income tax purposes. 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 should not be considered passive income for purposes of the PFIC test. For example, if we were to be characterized as a PFIC for U.S. federal income tax purposes in any taxable year during which a U.S. Holder (as defined in "Taxation —Material United States federal income tax considerations" in this Annual Report) holds ordinary shares or ADSs, such U.S. Holder could be subject to additional taxes and interest charges upon certain distributions by us and any gain recognized on a sale, exchange or other disposition of our shares, whether or not we continue to be characterized as a PFIC. Certain adverse consequences of PFIC status can be mitigated if a U.S. Holder makes a "mark to market" election or a "Qualified Electing Fund," or QEF, election. We have made available to U.S. Holders the information necessary to make and maintain a QEF election for the year ended December 31, 2024, and intend to provide U.S. holders with the necessary information for any taxable year in which we are treated as a PFIC. See "Taxation —Material United States federal income tax considerations —Passive foreign investment company considerations" in this Annual Report.

Whether we are a PFIC for any taxable year will depend on the composition of our income and the composition and value of our assets from time to time. Each U.S. Holder is strongly urged to consult their tax advisor regarding these issues and any available elections to mitigate such tax consequences.

The acquisition of a substantial interest in the Company by non-EU/non-EFTA investors requires government approval, which may restrict certain investments and limit demand for the BioNTech ADSs.

As the Company is considered an operator of "critical infrastructure" within the meaning of the Ordinance on the Designation of Critical Infrastructure pursuant to the BSI Act (Verordnung zur Bestimmung Kritischer Infrastrukturen nach dem BSI-Gesetz), it falls within the scope of the cross-sector review of the German foreign investment screening regime under the German Foreign Trade and Payments Ordinance (Außenwirtschaftsverordnung). As a result, non-EU/non-EFTA investors intending to acquire, directly or indirectly, at least 10% of the voting rights in the Company or who already hold voting rights in the Company and will

acquire further voting rights reaching or exceeding 20%, 25%, 40%, 50% or 75% of the voting rights in the Company must notify the planned acquisition to the German Federal Ministry for Economic Affairs and Energy (Bundesministerium für Wirtschaft und Energie, or the BMWE). The BMWE will then assess whether the acquisition likely adversely affects the public order or security of Germany or other EU member states or projects or programs of Union interest within the meaning of Article 8 of Regulation (EU) 2019/452 of the European Parliament and of the Council of 19 March 2019 establishing a framework for the screening of foreign direct investments into the Union. Clearance by the BMWE qualifies as a closing condition for all over-the-counter transactions. If the acquisition has been made via the stock exchange, the acquirer is prohibited from exercising its voting rights until the transaction has been cleared or is deemed cleared. If the BMWE identifies likely adverse effects, the acquisition of voting rights in the Company could be restricted or prohibited or, if the acquisition has been made via the stock exchange, the BMWE may order a sell-down of the voting rights in the Company acquired via the stock exchange or a transfer to a trustee within a certain period of time and/or prohibit the exercise of voting rights until such time as the acquisition is finally reversed.

Item 4. Information on the Company

A. History and Development of the Company

We are committed to improving the health of people worldwide with our fundamental research and development of immunotherapies. Scientific rigor, innovation and passion are our driving forces. BioNTech was founded by scientists and physicians to translate science into survival by combining fundamental research and operational excellence.

We were founded and incorporated on June 2, 2008 as Petersberg 91, 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 www.biontech.com. The information contained on, or that can be accessed through, our website is not part of this document. Our agent for service of process solely for the purpose of notices and communications from the SEC in the United States is c/o BioNTech US Inc., 40 Erie Street, Suite 110, Cambridge, Massachusetts 02139, +1 (617) 337-4701. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC at http://www.sec.gov.

For information on our principal capital expenditures and divestitures, see Item 5 of this Annual Report.

B. Business Overview

I. Overview

We are a global next-generation immunotherapy company aiming to pioneer novel medicines against cancer, infectious diseases and other serious diseases. Since our founding in 2008, we have focused on harnessing the power of the immune system to address human diseases with unmet medical needs and major global health burdens. Our fully integrated model combines decades of research in immunology with a multi-technology innovation engine, GMP manufacturing, translational drug discovery, clinical development, commercial capabilities, computational medicine, data science and artificial intelligence, or AI, and machine learning, or ML, capabilities to discover, develop and commercialize our marketed product and product candidates.

We have built a broad toolkit across multiple technology platforms, including a diverse range of potentially first-in-class therapeutic approaches. This includes investigational messenger ribonucleic acid, or mRNA immunotherapies and protein-based therapeutics (including targeted antibodies such as monoclonal, bispecific and antibody-drug conjugates, or ADCs).

Our multi-technology combination of platforms and product candidates aims to position us as pioneers in the field of individualized, patient-centric therapeutic approaches in oncology and infectious diseases. We believe that by combining complementary treatment modalities, we can leverage the potential of each technology to provide precise and personalized treatments to patients. Such treatments, if approved, could both increase the likelihood of therapeutic success and reduce the risk of therapeutic resistance.

Our primary focus is oncology, where we endeavor to address the full continuum of cancer from early to late disease stages. The root causes of cancer treatment failure are cancer heterogeneity and interindividual variability. Driven by random sequential mutations, every patient's cancer is different and within one patient's tumor, every cell is different. Addressing these two challenges is the core of our strategy. To augment anti-tumor activity and to counteract resistance mechanisms, we seek to combine compounds with non-overlapping, potentially synergistic mechanisms of action.

In infectious diseases, our goal is to develop vaccines and therapeutics caused by respiratory viruses, latent viruses, bacteria and parasites. We believe our scientific approach and our mRNA technology have the potential to significantly contribute to the fight against global health threats caused by infectious diseases. We have pursued both strategic partnerships and corporate collaborations to partially fund our infectious disease global health programs and aim to continue to do so. Our infectious disease programs aim to contribute to equitable access to innovative vaccines for high medical need indications.

Our approach has generated a robust and diversified product candidate pipeline across a range of technologies in oncology and infectious disease, and has led to the approval of our first marketed pharmaceutical product, *Comirnaty.* Innovation is at the core of our company, and we see potential for our technologies to expand beyond oncology and infectious diseases.

II. Execution of BioNTech's Strategy

In 2025, we made important progress across key strategic areas of the company to strengthen our technology platforms, capabilities and infrastructure, through strategic investments, acquisitions and partnerships impacting patients, shareholders and other stakeholders.

1. Advanced Oncology Pipeline

We continued to develop our innovative oncology pipeline. In 2025, we started multiple clinical trials and brought several assets into mid- and late-stage development, namely Phase 2 and Phase 3 clinical trials, across a range of technologies and indications. Today, our pipeline consists of 16 clinical programs in oncology, with more than 25 Phase 2 and Phase 3 clinical trials and 10 novel combination trials ongoing with our investigational bispecific antibody pumitamig. In 2025, we and our partners reported data across our portfolio at multiple medical meetings and published manuscripts in peer reviewed journals.

2. COVID-19 Vaccine Market Leadership

We continued to build our COVID-19 vaccine franchise and maintained market leadership in multiple key geographies. In 2025, we and Pfizer successfully launched our SARS-CoV-2 variant-adapted vaccine for the 2025/2026 vaccination season in 69 markets globally. We maintained our leadership position in the global COVID-19 vaccine market, achieving a market share of over 50% during the fall 2025 vaccination season.

3. Strategic Transactions and Partnerships

In February 2025, we announced the completion of our acquisition of Biotheus. With the acquisition, we obtained full global rights to the late-stage clinical asset pumitamig. In June 2025, we entered into a global co-development and co-commercialization agreement with Bristol Myers Squibb Company, or Bristol Myers Squibb, to jointly develop, manufacture and commercialize pumitamig across numerous solid tumor types. The collaboration leverages both partners' expertise, resources and global footprint to accelerate pumitamig's path towards potential regulatory approvals and market launches

In December 2025, we announced our acquisition of CureVac N.V., or CureVac. The strategic transaction complements BioNTech's capabilities and proprietary technologies in mRNA design and delivery formulations.

4. Maintained Strong Financial Position

In 2025, we maintained a strong balance sheet through disciplined financial performance, ending the year with approximately €17.2 billion in total cash, cash equivalents and security investments. With a strong financial position, leading COVID-19 vaccine franchise and innovative oncology and infectious disease pipeline, we believe we are well positioned to continue executing our vision of pioneering novel medicines against cancer, infectious diseases and other serious diseases.

On March 10, 2026, we announced plans for an independent company to be established and led by BioNTech co-founders Prof. Ugur Sahin, M.D., and Prof. Özlem Türeci, M.D. The new company with distinct resources, operations and funding options, will advance next-generation mRNA innovations. We plan to contribute related rights and mRNA technologies to the new company to enable and support the prioritized development of next-generation mRNA innovations with disruptive potential. With both companies focusing on their respective strategic priorities, we expect to maximize value for patients and shareholders alike. Our CEO and CMO will transition into the management of their new company by the end of 2026 after their current service agreements end. Our Supervisory Board has initiated an executive search to identify successors for the positions to ensure a smooth transition and seamless execution of our strategy.

III. Company Evolution

We are committed to translating science into survival for patients by advancing BioNTech's strategy and executing it to become a global immunotherapy powerhouse with multiple approved products and revenue streams.

As part of this continued approach, we have built a unique pipeline that includes technologies and candidates with disruptive potential. In oncology, we focus on potentially synergistic therapeutic approaches, including innovative immunomodulators, targeted therapies, and mRNA cancer immunotherapies. We plan to continue to significantly invest in their broad clinical evaluation across multiple cancer indications with significant (unmet) medical needs, as well as their commercialization in key markets. We aim to further enhance the therapeutic profile of our investigational therapies through the evaluation of novel-novel combinations, including our differentiated portfolio targeted therapy candidates such as ADCs.

As we continue to invest in executing our vision, we remain committed to cost-effective value generation. We actively manage our whole pipeline and assess all sites across BioNTech, including newly acquired assets, according to key criteria: strategic alignment, operational efficiency, and sustainable value creation. For 2026, we consequently plan to continue to significantly invest in essential areas while optimizing capacities in others.

The consolidation and adjustment of capacities announced in 2025 are ongoing and are expected to span through 2027. We currently expect that this will involve consolidating and adjusting capacities within our manufacturing network. We will continue to drive progress with a focus on our highest potential opportunities and we believe we are well-positioned to continue advancing our strategic vision. We look forward to another year of meaningful progress building on our achievements in 2025.

IV. Marketed Products: *Comirnaty*, our COVID-19 Vaccine Program (BNT162)

COVID-19 vaccination has played an important role in saving lives and livelihoods across the world. Our commercial product, developed in 2020, *Comirnaty*, was the first-ever approved mRNA-based product, and, to our knowledge, remains the fastest ever developed prophylactic vaccine from viral sampling to approval. As of March 2026, our COVID-19 vaccine products have been authorized or approved for emergency or temporary use or granted marketing authorization in more than 180 countries and regions worldwide. Our efforts have resulted in over 5 billion doses shipped globally.

Under our collaboration with Pfizer, we are the Marketing Authorization Holder in the United States, the European Union, or EU, the UK, Canada and other countries. Additionally, we are the holder of emergency use authorizations or equivalents in the United States (jointly with Pfizer) and other countries for the COVID-19 vaccine program. Pfizer has marketing and distribution rights worldwide apart from Greater China, Germany, and Türkiye. We have the marketing and distribution rights to *Comirnaty* in Germany and Türkiye.

Under our collaboration with Fosun Pharmaceutical Industrial Development, Co., Ltd, or Fosun Pharma, Fosun Pharma has marketing and distribution rights in Mainland China, Hong Kong Special Administrative Region, or SAR, Macau SAR and Taiwan region.

1. Commercial, Manufacturing and Distribution Updates

We expect that as SARS-CoV-2 continues to evolve, and the risk of severe COVID-19 disease and deaths persists, there will be continued demand for primary and seasonal vaccinations, especially for at-risk and immunocompromised populations. Studies have demonstrated that natural immunity acquired by SARS-CoV-2 infection is variable across individuals and wanes over time due to viral escape mutations and decreasing antibody titers. The risk of severe COVID-19 disease remains high in vulnerable populations. Vaccination not only reduces the risk of severe COVID-19 but may also mitigate the risk of health impairments related to COVID-19. Given this, and our current understanding of COVID-19's burden on healthcare systems during the fall and winter season, along with its observed peaks at other times of the year, we anticipate the need for annual adapted vaccines to be a long-term component of COVID-19 vaccination practices.

In 2025, we and Pfizer continued our global COVID-19 vaccine leadership with the commercial launch of our SARS-CoV-2 variant-adapted vaccine for the 2025/2026 vaccination season. Since the declaration of the pandemic, we have developed and commercialized multiple COVID-19 vaccine products, including our most recently developed COVID-19 vaccine targeting the LP.8.1 strain. Each is referred to as *Comirnaty*.

In 2025, we continued transitioning from an advanced purchase agreement framework to commercial market ordering in some geographies.

We and Pfizer have an ongoing COVID-19 Vaccine Purchase Agreement with the European Commission, or the EC, to deliver COVID-19 vaccines to the EU. The agreement reflects our and Pfizer's commitment to working collaboratively to help address ongoing public health needs. The 2023 agreement rephased delivery of doses annually through 2026. In addition, the agreement includes an aggregate volume reduction, providing additional flexibility for EU Member States. The EC will maintain access to future adapted COVID-19 vaccines and the ability to donate doses.

We and Pfizer have established an efficient and robust global vaccine supply chain and manufacturing network capable of meeting global demand.

More details on our manufacturing operations and facilities can be found in "VII. Manufacturing."

2. Clinical Development and Regulatory Updates

While JN.1 and KP.2 variant-adapted vaccines provided some protection against a range of outcomes from JN.1-lineage related COVID-19 disease, evidence suggests that vaccines better matched to currently circulating SARS-CoV-2 sublineages may provide improved protection against symptomatic and severe COVID-19 disease.

- In May 2025, the WHO, EMA and FDA each issued recommendations to update the antigenic composition of authorized COVID-19 vaccines for the 2025-2026 vaccination season. The WHO advised manufacturers that monovalent JN.1 or KP.2 vaccines remain appropriate vaccine antigens and that monovalent LP.8.1 is a suitable alternative vaccine antigen. The EMA recommended that marketing authorization holders adapt vaccines to target the LP.8.1 variant of the JN.1 family of Omicron subvariants, and vaccines targeting JN.1 or KP.2 strains could be considered for the vaccination campaigns in 2025 until the updated LP.8.1 vaccines become available. The FDA advised manufacturers that COVID-19 vaccines for use in the United States in the fall of 2025 should be a monovalent JN.1-lineage-based composition, preferentially targeting the LP.8.1 strain.

- In July 2025, the EMA's Committee for Medicinal Products for Human Use, or CHMP, recommended marketing authorization for the companies' LP.8.1-adapted monovalent COVID-19 vaccine. In August 2025, following authorization by the EC, the new variant-adapted COVID-19 vaccine was made available for shipment to applicable EU member states.

- In August 2025, the FDA approved the supplemental Biologics License Application for our and Pfizer's LP.8.1-adapted monovalent COVID-19 vaccine for use in adults aged 65 years and older, as well as in individuals aged five through 64 years with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19. The new variant-adapted COVID-19 vaccine was shipped promptly following approval and was made available in pharmacies, hospitals, and clinics across the United States.

Ahead of the 2025-2026 COVID-19 vaccination season, we initiated a Phase 3 (NCT07069309) study to investigate the safety, tolerability, and immunogenicity of our LP.8.1-adapted COVID-19 vaccine in adults 65 and older and adults aged 18 through 64 with at least one underlying risk condition for severe COVID-19. In September 2025, we announced positive topline results from the Phase 3 trial. The preliminary data show a robust increase in neutralizing antibodies targeting the LP.8.1 sublineage of SARS-CoV-2 following vaccination. The safety profile of the vaccine was consistent with previous studies, with no new safety concerns identified. Three post-marketing commitment clinical trials are ongoing, with a fourth planned.

We and Pfizer intend to continue to monitor the evolving epidemiology of COVID-19 and remain prepared to develop modified vaccine formulas as the data support and as regulatory agencies recommend.

V. Pipeline of Product Candidates

Below is a summary of active clinical trials evaluating our product and clinical product candidates, organized by platform and indication.

Oncology[1,2]

Phase 1	Phase 1/2		Phase 2			Phase 2/3	Phase 3
BNT116 Adv. NSCLC	BNT324/DB-1311[5] Multiple solid tumors	Pumitamig[3] + BNT3213 1L HCC[4,11]	Autogene cevumeran[6] Adj. CRC	Pumitamig[3] 2L ES-SCLC[11]	Pumitamig[3] or BNT325/DB-1305[5] + BNT324/DB-1311[5] Multiple solid tumors[4]	BNT113 1L HPV16+ HNSCC	Gotistobart[7] Met. NSCLC
BNT211 Multiple solid tumors	BNT325/DB-1305[5] Multiple solid tumors	Pumitamig[3] + BNT324/DB-1311[5] Adv./met. NSCLC and SCLC[4]	Autogene cevumeran[6] Adj. PDAC	Pumitamig[3] 2L+ EGFRm NSCLC[11]		Pumitamig[3] 1L met. CRC	Pumitamig[3] 1L ES-SCLC
BNT314/GEN1059[9] Multiple solid tumors	BNT329 Multiple solid tumors	Pumitamig[3] + BNT325/DB-1305[5] Multiple solid tumors[4]	BNT116[10] 1L adv. NSCLC	Pumitamig[3] 2L Glioblastoma[11]		Pumitamig[3] 1L NSCLC	Pumitamig[3] 2L SCLC[11]
BNT317 Multiple solid tumors	Gotistobart[7] Met. CRPC	Pumitamig[3] + BNT326/YL202[8] Multiple solid tumors	BNT326/YL202[8] Multiple solid tumors[11]	Pumitamig[3] 1L HCC[11]			Pumitamig[3] 1L adv./met.TNBC[11]
BNT326/YL202[8] Multiple solid tumors	Gotistobart[7] Multiple solid tumors	Pumitamig[3] + BNT326/YL202[8] Adv. NSCLC	BNT326/YL202[8] Adv./met. BC[11]	Pumitamig[3] 1L MPM[11]			Trastuzumab pamirtecan[5] Met. BC
	Pumitamig[3] Multiple solid tumors	Pumitamig[3] + Trastuzumab pamirtecan[5] Adv./met. BC[4]	Gotistobart[7] PROC	Pumitamig[3] 2L NEN[11]			Trastuzumab pamirtecan[5] 2L EC
	Pumitamig[3] 1L adv./met. TNBC[11]	Trastuzumab pamirtecan[5] Multiple solid tumors	Pumitamig[3] 1L met. CRC[11]	Pumitamig[3] 2L adv./met. NSCLC			
	Pumitamig[3] + BNT314/GEN1059[9] Met. CRC[4]		Pumitamig[3] 1L ES-SCLC[11]	Pumitamig[3] 1L met. PDAC[11]			
	Pumitamig[3] + BNT3212 Multiple solid tumors		Pumitamig[3] 1L/2L+ ES-SCLC	Pumitamig[3] 1L/2L adv./met. TNBC			

Next generation immunomodulator | Targeted therapy | mRNA cancer immunotherapy | Novel-novel combination

Infectious Diseases[1,2]

Phase 1	Phase 1/2	Phase 2	Commercial
BNT163[12] HSV	BNT162 + BNT161[13] COVID-19 - Influenza combination	BNT166[16] Mpox	BNT162[13,14] COVID-19
BNT351 HIV	BNT164[15] Tuberculosis		
	BNT165 Malaria		
	BNT166[16] Mpox		

Antibody | mRNA

(1) For further details about BioNTech's rights, see elsewhere in this Annual Report.
(2) Abbreviations are defined in the corresponding trial descriptions.
(3) Partnered with Bristol Myers Squibb.
(4) Trial is currently being conducted by or on behalf of BioNTech. Bristol Myers Squibb holds co-exclusive rights to pumitamig.
(5) Partnered with DualityBio.
(6) Partnered with Genentech, a member of the Roche Group.
(7) Partnered with OncoC4.
(8) Partnered with MediLink Therapeutics.
(9) Partnered with Genmab.
(10) In collaboration with Regeneron.
(11) Trial ongoing in China only.
(12) Partnered with University of Pennsylvania.
(13) Partnered with Pfizer.
(14) Partnered with Fosun Pharma.
(15) Funded by the Gates Foundation.
(16) Funded by the Coalition for Epidemic Preparedness Innovations (CEPI).

A. Oncology Programs

1. Pumitamig (BNT327/BMS986545), a Bispecific Immunomodulator Candidate Targeting PD-L1 and VEGF-A

Pumitamig is a bispecific immunomodulator candidate targeting both PD-L1 and VEGF-A. Pumitamig is currently being evaluated in multiple Phase 2 and Phase 3 global and China-only clinical trials to assess its efficacy and safety as monotherapy or in combination with chemotherapy, ADCs or mRNA-based cancer immunotherapies in various indications. We and our partner, BMS, expect to have eight global registrational trials for pumitamig ongoing by the end of 2026. Pumitamig is also being evaluated in combination with next-generation ADC candidates trastuzumab pamirtecan (BNT323/DB-1303), BNT324/DB-1311, BNT325/DB-1305, BNT326/YL202 and BNT3212, and in combination with bispecific antibody candidates BNT314/GEN1059 and BNT3213.

ROSETTA Lung-01 Phase 3 Clinical Trial in First-Line Extensive-Stage Small Cell Lung Cancer, or ES-SCLC

A global Phase 3 clinical trial (NCT06712355) is being conducted to evaluate pumitamig in combination with chemotherapy compared to atezolizumab in combination with chemotherapy as a first-line treatment for patients with ES-SCLC.

- In June 2025, pumitamig received Orphan Drug Designation from the FDA for the treatment of small cell lung cancer.

Phase 3 Clinical Trial in Second-Line Small-Cell Lung Cancer, or SCLC

A Phase 3 clinical trial (NCT06616532) is being conducted in China to evaluate pumitamig in combination with chemotherapy compared to investigator's choice chemotherapy as a second-line treatment for patients with SCLC.

Phase 2 Clinical Trial in ES-SCLC

A global Phase 2 clinical trial (NCT06449209) is being conducted to evaluate pumitamig in combination with chemotherapy in patients with untreated ES-SCLC and in patients with SCLC that progressed after first- or second-line treatment. The trial is fully enrolled and treatment is ongoing.

- In September 2025, interim data from this trial were presented at the IASLC 2025 WCLC. The data, which are consistent with data presented at European Lung Cancer Congress, or ELCC, 2025 from a Phase 2 clinical trial conducted in China (NCT05844150), showed encouraging anti-tumor responses and a positive trend in

progression free survival. Pumitamig plus chemotherapy was observed to have a manageable safety profile with no new safety signals and a low discontinuation rate.

Phase 2 Clinical Trial in First-Line ES-SCLC

A Phase 2 clinical trial (NCT05844150) is being conducted in China to evaluate pumitamig in combination with chemotherapy as a first-line treatment for patients with ES-SCLC.

- In March 2025, data from this trial were presented at the ELCC 2025 in Paris, France. Preliminary data showed anti-tumor activity and an acceptable safety profile with no new safety signals beyond those typically described for chemotherapy agents and anti-PD-(L)1 and anti-VEGF monotherapies. These data were the first presented for pumitamig as a potential first-line treatment in ES-SCLC supporting the ongoing global randomized Phase 3 clinical trial ROSETTA Lung-01 (NCT06712355).

- Updated data from this trial are expected to be presented at the ELCC 2026 taking place on March 25-28, 2026 in Copenhagen, Denmark.

Phase 2 Clinical Trial in Second-Line SCLC

A Phase 2 clinical trial (NCT05879068) is being conducted in China to evaluate pumitamig in combination with chemotherapy as a second-line treatment for patients with SCLC.

- In March 2025, data from this trial were presented at the ELCC 2025. Preliminary data showed anti-tumor activity, which was observed regardless of prior immuno-oncology treatment, and an acceptable safety profile.

ROSETTA Lung-201 Phase 3 Clinical Trial in Unresectable Stage III NSCLC

A global Phase 3 clinical trial (NCT07361497) to evaluate pumitamig compared to durvalumab following concurrent chemoradiation therapy in patients with unresectable stage III NSCLC is planned to start in 2026.

ROSETTA Lung-202 Phase 3 Clinical Trial in First-Line NSCLC

A global Phase 3 clinical trial (NCT07361510) to evaluate pumitamig compared to pembrolizumab as a first-line treatment for patients with advanced PD-L1 ≥ 50% NSCLC is planned to start in 2026.

ROSETTA Lung-02 Phase 2/3 Clinical Trial in First-Line NSCLC

A global Phase 2/3 clinical trial (NCT06712316) is being conducted to evaluate pumitamig in combination with chemotherapy compared to pembrolizumab and chemotherapy as a first-line treatment for patients with NSCLC. The Phase 2 portion of the trial is fully enrolled, and the Phase 3 portion is underway.

- We expect data from the Phase 2 part of this trial in 2026.

ROSETTA Lung-107 Phase 2 Clinical Trial in Second-Line NSCLC

A global Phase 2 clinical trial (NCT06841055) is being conducted to evaluate pumitamig in combination with docetaxel as a second-line treatment for patients with NSCLC.

Phase 2 Clinical Trial in EGFR-mutant Non-Squamous NSCLC

A Phase 2 clinical trial (NCT05756972) is being conducted in China to evaluate pumitamig in combination with chemotherapy in patients with EGFR-mutant non-squamous NSCLC who progressed after EGFR-tyrosine kinase inhibitor treatment.

- Updated data from this trial are expected to be presented at the ELCC 2026 taking place on March 25-28, 2026 in Copenhagen, Denmark.

ROSETTA Breast-01 Phase 3 Clinical Trial in Locally Advanced or Metastatic First-Line TNBC

A global Phase 3 clinical trial (NCT07173751) is being conducted to evaluate pumitamig in combination with chemotherapy compared to chemotherapy alone as a first-line treatment for patients with PD-L1 combined positive score, or CPS, ≤ 10 TNBC.

Phase 3 Clinical Trial in Locally Advanced or Metastatic First-Line TNBC

A Phase 3 clinical trial (NCT06419621) is being conducted in China to evaluate pumitamig in combination with chemotherapy compared to chemotherapy alone as a first-line treatment for patients with locally advanced or metastatic TNBC.

- Based on current event accrual projections, we expect first interim data from this trial in 2026.

Phase 2 Clinical Trial in Locally Advanced or Metastatic TNBC

A global Phase 2 clinical trial (NCT06449222) is being conducted to evaluate pumitamig in combination with chemotherapy as a first- and second-line treatment for patients with locally advanced or metastatic TNBC.

- In December 2025, the first data from this trial were presented at the 2025 San Antonio Breast Cancer Symposium, or SABCS. The data showed encouraging anti-tumor responses and a manageable safety profile for pumitamig plus chemotherapy in first- and second-line treatment setting.

Phase 1/2 Clinical Trial in Locally Advanced/Metastatic TNBC

A Phase 1/2 clinical trial (NCT05918133) is being conducted in China to evaluate pumitamig in combination with chemotherapy in patients with locally advanced or metastatic TNBC without previous systematic treatment.

ROSETTA CRC-203 Phase 2/3 Clinical Trial in Metastatic First-Line CRC

A global Phase 2/3 clinical trial (NCT07221357) is being conducted to evaluate pumitamig as a first-line treatment for patients with microsatellite stable, or MSS, or Microsatellite Instability-Low and Proficient Mismatch Repair, or MSI-L/pMMR, metastatic colorectal cancer.

Phase 2 Clinical Trial in Metastatic First-Line CRC

A Phase 2 clinical trial (NCT07133750) is being conducted in China to evaluate pumitamig in combination with chemotherapy as a first-line treatment in patients with MSS or MSI-L/pMMR metastatic colorectal cancer.

- We expect data from this trial in 2026.

ROSETTA Gastric-204 Phase 2/3 Clinical Trial in Metastatic First-Line Gastric Cancer

A global Phase 2/3 clinical trial (NCT07221149) is being conducted to evaluate pumitamig in combination with chemotherapy compared to nivolumab in combination with chemotherapy as a first-line treatment for patients with metastatic gastric cancer.

ROSETTA HNSCC-205 Pivotal Clinical Trial in First-Line HNSCC

A global pivotal clinical trial evaluating pumitamig as a first-line treatment for patients with HNSCC is planned to start in 2026.

Phase 2 Clinical Trial in First-Line Hepatocellular Carcinoma, or HCC

A Phase 2 clinical trial (NCT05864105) is being conducted in China to evaluate pumitamig in combination with chemotherapy as a first-line treatment for patients with unresectable HCC.

- We expect data from this trial in 2026.

ROSETTA HCC-206 Phase 1/2 Clinical Trial in First-Line HCC

A Phase 1/2 clinical trial (NCT07291076) is being conducted to evaluate pumitamig alone or in combination with ipilimumab as a first-line treatment for patients with advanced or unresectable HCC.

Phase 2 Clinical Trial in First-Line Malignant Mesothelioma

A Phase 2 clinical trial (NCT05918107) is being conducted in China to evaluate pumitamig in combination with chemotherapy as a first-line treatment for patients with malignant mesothelioma.

- In June 2025, the first data from this trial were presented at the 2025 ASCO Annual Meeting. The preliminary data indicated anti-tumor activity and a manageable safety profile.

Phase 2 Clinical Trial in Second-Line Neuroendocrine Neoplasm, or NEN

A Phase 2 clinical trial (NCT05879055) is being conducted in China to evaluate pumitamig in combination with chemotherapy as a second-line treatment for patients with NEN.

Phase 2 Clinical Trial in First-Line PDAC

A Phase 2 clinical trial (NCT07255404) is being conducted in China to evaluate pumitamig in combination with chemotherapy as a first-line treatment for patients with metastatic PDAC.

Phase 2 Clinical Trial in Second-Line Glioblastoma

A Phase 2 clinical trial (NCT07297212) is being conducted in China to evaluate pumitamig alone or in combination with temozolomide as a second-line treatment for patients with recurrent glioblastoma.

ROSETTA RCC-208 Phase 1/2 Clinical Trial in RCC

A Phase 1/2 clinical trial (NCT07293351) to evaluate pumitamig alone or in combination with ipilimumab or cabozantinib in patients with advanced RCC is planned to start in 2026.

Phase 1/2 Clinical Trial in Advanced Solid Tumors

A Phase 1/2 clinical trial (NCT05918445) is being conducted in China to evaluate pumitamig as a monotherapy in patients with advanced solid tumors.

- Updated data from this trial are expected to be presented at the ELCC 2026 taking place on March 25-28, 2026 in Copenhagen, Denmark.

We have initiated several signal-seeking clinical trials to evaluate pumitamig with some of our proprietary novel assets in our portfolio:

Combination with Trastuzumab Pamirtecan (BNT323/DB-1303) Phase 1/2 Clinical Trial in Advanced/Metastatic Breast Cancer

A Phase 1/2 clinical trial (NCT06827236) is being conducted to evaluate trastuzumab pamirtecan in combination with pumitamig in patients with hormone receptor-positive (HR+) or hormone receptor-negative (HR-), human epidermal growth factor (HER)2-low, ultra-low, or null advanced metastatic breast cancer or TNBC.

- We expect data from this trial in 2026.

Combination with BNT324/DB-1311 Phase 1/2 Clinical Trial in Advanced Lung Cancers

A Phase 1/2 clinical trial (NCT06892548) is being conducted to evaluate BNT324/DB-1311 in combination with pumitamig in patients with advanced lung cancers.

- We expect data from this trial in 2026.

Combination with BNT324/DB-1311 Phase 2 Clinical Trial in Advanced/Metastatic Solid Tumors

A Phase 2 clinical trial (NCT06953089) is being conducted to evaluate BNT324/DB-1311 in combination with pumitamig or with TROP2 ADC candidate BNT325/DB-1305 in patients with advanced solid tumors.

- We expect data from this trial in 2026.

Combination with BNT325/DB-1305 Phase 1/2 Clinical Trial in Advanced Solid Tumors

A Phase 1/2 clinical trial (NCT05438329) is being conducted to evaluate BNT325/DB-1305 in patients with advanced solid tumors. As part of this clinical trial, pumitamig is being evaluated in combination with BNT325/DB-1305 in various solid tumor indications.

- In April 2025, at AACR 2025 Annual Meeting, we presented the first clinical data evaluating the combination of pumitamig plus BNT325/DB-1305. The interim data showed a manageable safety profile and early signs of anti-tumor activity in a cohort with patients with platinum-resistant ovarian cancer, or PROC. Across the 13 efficacy evaluable patients with PROC, seven patients achieved partial response and three stable disease. Responses were also observed in patients with NSCLC or TNBC.

- We expect data from the Phase 2 part of this trial in patients with TNBC in 2026.

Combination with BNT326/YL202 Phase 1/2 Clinical Trial in Advanced Solid Tumors

A Phase 1/2 clinical trial (NCT07070232) is being conducted to evaluate BNT326/YL202 as monotherapy and in combination with pumitamig in advanced solid tumors.

Combination with BNT326/YL202 Phase 1/2 Clinical Trial in Advanced NSCLC

A Phase 1/2 clinical trial (NCT07111520) is being conducted to evaluate BNT326/YL202 in combination with pumitamig in advanced NSCLC.

- We expect data from this trial in patients with NSCLC or 2L+ EGFRm NSCLC in 2026.

Combination with BNT314/GEN1059 Phase 1/2 Clinical Trial in Advanced/Metastatic colorectal cancer

A Phase 1/2 clinical trial (NCT07079631) is being conducted to evaluate BNT314/GEN1059 in combination with pumitamig and chemotherapy in patients with advanced colorectal cancer.

Combination with BNT3212 Phase 1/2 Clinical Trial in Advanced Solid Tumors

A Phase 1/2 clinical trial (NCT07147348) is being conducted to evaluate BNT3212, a novel bispecific antibody-drug conjugate candidate targeting EGFR and HER3, for use as monotherapy and in combination with pumitamig in patients with advanced solid tumors.

Combination with BNT3213 Phase 1/2 Clinical Trial in First-Line HCC

A Phase 1/2 clinical trial (NCT06584071) is being conducted in China to evaluate pumitamig in combination with BNT3213, a novel bispecific antibody candidate targeting TIGIT and PVRIG, as a first-line treatment for patients with locally advanced or metastatic HCC.

2. iNeST and FixVac

a) Autogene Cevumeran (RO7198457/BNT122), an Individualized Neoantigen Specific Immunotherapy, or iNeST

Autogene cevumeran is an investigational individualized mRNA cancer immunotherapy based on specific neoantigens that are present on a patient's tumor.

BNT122-01 Phase 2 Clinical Trial in Adjuvant Colorectal Cancer, or CRC

A randomized Phase 2 clinical trial (NCT04486378) is being conducted to evaluate autogene cevumeran as an adjuvant treatment of circulating tumor DNA, or ctDNA, positive, surgically resected Stage II (high risk)/Stage III CRC. The trial is expected to enroll about 327 patients to evaluate the efficacy of autogene cevumeran compared to watchful waiting after surgery and chemotherapy, which is the current standard of care for these high-risk patients. The primary endpoint for the trial is disease-free survival, or DFS. Secondary objectives include OS and safety.

- At the first pre-specified interim analysis of the ongoing BNT122-01 Phase 2 clinical trial, the futility boundary was crossed. The interim analysis was reviewed by an independent Data and Safety Monitoring Board, or DSMB, which is responsible for overseeing the safety and integrity of the trial. The DSMB considered autogene cevumeran to be generally well tolerated with no new safety signals identified, and also indicated that the data was not yet mature enough to draw reliable conclusions about efficacy, with a median follow-up time for participants at the time of the analysis of approximately nine months, which was deemed to be insufficient to evaluate the trial's primary endpoint. This assessment is consistent with recent data from a study published in Nature (Nakamura Y, et al., 2024), which showed that a majority of patients with ctDNA-positive colorectal cancer experience disease recurrence within 24 months after surgery. However, because the futility boundary was crossed, the DSMB was bound by its charter to make a non-binding recommendation to terminate the study. Based on this assessment that the data are not yet mature enough to draw reliable conclusions about efficacy, we have continued the trial in accordance with the protocol. The sponsor remains masked, and interim data will not be disclosed at this time ensuring the integrity of the ongoing trial and allowing for a comprehensive and mature assessment of the treatment's efficacy at the final analysis of the trial. The DSMB had no objections with the continuation of the study in the absence of safety concerns.

- An update from the ongoing Phase 2 trial in Stage II (high-risk)/ Stage III ctDNA+ adjuvant CRC is expected in early 2026. Timing of the data read-out from the final analysis of this trial has been updated from 2026 to 2027, given that events have accrued more slowly than projected.

IMCODE004 Phase 2 Clinical Trial in Adjuvant High-risk Muscle-invasive Urothelial Carcinoma, or MIUC

A Phase 2 clinical trial (NCT06534983) is being conducted to evaluate autogene cevumeran as an adjuvant treatment in combination with nivolumab compared to nivolumab alone in patients with high-risk MIUC. The trial aims to enroll approximately 362 patients. The primary endpoint for the trial is investigator-assessed DFS. Secondary endpoints include OS and safety.

We and our partner Roche have decided to discontinue the Phase 2 clinical trial (IMcode004; NCT06534983) evaluating autogene cevumeran as an adjuvant treatment in combination with nivolumab compared to nivolumab alone in patients with high-risk MIUC due to the rapidly emerging treatment landscape and shifting standard of care.

IMCODE003 Phase 2 Clinical Trial in Adjuvant Pancreatic Ductal Adenocarcinoma, or PDAC

A Phase 2 clinical trial (NCT05968326) is being conducted to evaluate autogene cevumeran in combination with atezolizumab followed by chemotherapy compared to chemotherapy alone as an adjuvant treatment for patients with resected PDAC who have not received prior systemic anti-cancer treatment and showed no evidence of

disease after surgery. The trial aims to enroll 260 patients. The primary endpoint is DFS. Secondary endpoints include OS and safety.

IMCODE001 Phase 2 Clinical Trial in First-line Advanced Melanoma

The IMCODE001 (NCT03815058) trial was the first randomized Phase 2 clinical trial with autogene cevumeran as part of the broader IMCODE study program. The trial evaluated the efficacy and safety of autogene cevumeran in combination with pembrolizumab versus pembrolizumab alone as a potential first-line treatment for patients with previously untreated advanced melanoma. The primary endpoint was progression free survival, or PFS, and was events-based. Secondary endpoints included OS, ORR, DOR and safety. In January 2025, the IMCODE001 trial was completed.

- In March 2025, topline results of the primary analysis were disclosed. While the initial data of the primary analysis support the findings across the broader autogene cevumeran study program demonstrating that autogene cevumeran can induce and expand high-magnitude and long-lived immune responses against the encoded neoantigens in this aggressive stage of melanoma, the trial did not meet its primary efficacy endpoint of statistically significant improvement of PFS in this advanced treatment setting. A numerical trend favoring the combination arm in OS was observed. The combination of autogene cevumeran with PD-L1 checkpoint blockade was well tolerated and adverse events were consistent with the known safety profiles of the individual trial treatments, with no new safety signals observed.

- In October 2025, data from this trial including exploratory endpoints and biomarker correlations were presented at the 2025 European Society For Medical Oncology, or ESMO, Congress. These data showed that autogene cevumeran can induce durable immune responses against the encoded neoantigens that persisted for up to 1.5 years after the last dose of autogene cevumeran. In the combination arm, the breadth of immune response correlated with a prolonged PFS. Further translational data showed a trend of improved OS in the combination arm compared to pembrolizumab monotherapy in patients with low tumor mutational burden, a population that usually responds poorly to checkpoint inhibitor treatment, and in tumors where immune-cell PD-L1 was high. These data support our therapeutic strategy to pursue autogene cevumeran to address the unmet medical need in the adjuvant or minimal residual disease treatment settings. These settings are characterized by lower tumor burden and heterogeneity, which aligns with the focus of our ongoing randomized Phase 2 trials in colorectal and pancreatic cancer.

b) FixVac

FixVac is our fully owned, systemic, off-the-shelf mRNA-based cancer immunotherapy approach. *FixVac* candidates are designed to target shared antigens that have been identified to be frequently expressed across patients with a specific cancer type.

i. BNT111

BNT111 is designed to elicit an immune response to four antigens (NY-ESO-1, MAGE-A3, tyrosinase, TPTE) that have each been found to be associated with cutaneous melanoma.

Phase 2 Clinical Trial in Anti-PD-(L)1 Refractory/Relapsed Unresectable Stage III or Stage IV Melanoma

A Phase 2 clinical trial (BNT111-01; NCT04526899) in collaboration with Regeneron Pharmaceuticals Inc., or Regeneron, to evaluate BNT111 in combination with cemiplimab in patients with anti-PD-(L)1 refractory/relapsed, unresectable Stage III or IV melanoma has been completed.

- In October 2025, data from this trial were presented at the 2025 ESMO Congress. As previously disclosed in August 2024, the trial met its primary efficacy outcome measure, demonstrating a statistically significant improvement in ORR in patients treated with BNT111 in combination with cemiplimab, as compared to a historical control. The data showed that the combination of BNT111 and cemiplimab induced anti-tumor responses that were deep and durable and a manageable safety profile for BNT111 as a single agent and in

combination. Follow-up data showed a positive trend towards improved long-term survival for the combination of BNT111 and cemiplimab. No further development of BNT111 in advanced melanoma is currently planned.

ii. BNT113

BNT113 contains two different RNAs encoding the two HPV16 oncoproteins E6 and E7, which are exclusively expressed in pre-malignant and malignant tissue.

AHEAD-MERIT Phase 2/3 Clinical Trial in Unresectable Recurrent or Metastatic, PD-L1+, HPV16+ Head and Neck Squamous Cell Carcinoma, or HNSCC

A Phase 2/3 clinical trial (AHEAD-MERIT; NCT04534205) is being conducted to evaluate BNT113 in combination with pembrolizumab versus pembrolizumab monotherapy as a first-line treatment for patients with unresectable recurrent or metastatic, PD-L1+, HPV16+ HNSCC.

- In December 2025, the FDA granted Fast Track designation to BNT113 for the treatment of patients with PD-L1+, HPV16+ HNSCC.

- Based on current event accrual projections, we expect data from the first interim analysis from the Phase 3 part of this trial in 2026.

iii. BNT116

BNT116 is comprised of six different NSCLC-associated tumor-associated antigens. BNT116 is being evaluated in two clinical trials as monotherapy and in combination with other immunotherapies, ADCs and chemotherapies in patients with advanced or metastasized NSCLC.

EMPOWERVAX Lung 1 Phase 2 Clinical Trial in PD-L1 ≥ 50% Advanced NSCLC

A Phase 2 clinical trial (NCT05557591) is being conducted in collaboration with Regeneron to evaluate BNT116 in combination with cemiplimab versus cemiplimab alone as a first-line treatment for patients with advanced NSCLC whose tumors express PD-L1 in ≥ 50% of their tumor cells. The primary objective of the Phase 2 trial is to assess the ORR per blinded-independent review committee.

LuCa-MERIT-1 Phase 1 Clinical Trial in NSCLC

A Phase 1 clinical trial (NCT05142189) is being conducted to evaluate the safety, tolerability and preliminary efficacy of BNT116 as monotherapy and in several combinations including with chemotherapy, cemiplimab, and some of our proprietary assets across various treatment lines and clinical settings in patients with NSCLC.

- In April 2025, at the 2025 Annual Meeting of the American Association for Cancer Research, or AACR, data from a cohort with frail patients from the Phase 1 trial were presented. The preliminary data showed anti-tumor activity, consistent immune response induction and a manageable safety profile in patients with PD-L1 positive (TPS≥1%) unresectable Stage III or metastatic Stage IV NSCLC who are not eligible for chemotherapy as first-line treatment.

- In September 2025, data were presented at the IASLC 2025 World Congress on Lung Cancer, or WCLC, from a cohort evaluating BNT116 in combination with cemiplimab as consolidation treatment in patients with NSCLC after receiving concurrent chemoradiotherapy. BNT116 in combination with cemiplimab demonstrated encouraging event-free and overall survival rates and a manageable safety profile.

3. Antibody-Drug Conjugates

i. Trastuzumab Pamirtecan (BNT323/DB-1303), an ADC in Development in Collaboration with DualityBio

Trastuzumab pamirtecan is a topoisomerase-1 inhibitor-based ADC directed against Human Epidermal Growth Factor Receptor 2, or HER2, a target that is over-expressed in a variety of cancers and contributes to the

aggressive growth and spread of cancer cells. The program received Fast Track Designation and Breakthrough Therapy designation from the FDA for advanced endometrial cancer.

DYNASTY-Breast02 Phase 3 Clinical Trial in Advanced or Metastatic HR+, HER2-low Breast Cancer

A Phase 3 clinical trial (NCT06018337) is being conducted to evaluate trastuzumab pamirtecan compared to investigator's choice of chemotherapy in advanced or metastatic HR+, HER2-low breast cancer subjects whose disease has progressed on at least two lines of prior endocrine therapy or within six months of first-line endocrine therapy and cyclin-dependent 4/6, or CDK4/6, inhibitor and no prior chemotherapy. The trial aims to enroll approximately 532 patients. The primary endpoint is PFS. Secondary endpoints include OS, ORR, DOR and safety, as well as patient-reported outcomes.

- Based on current event accrual projections, we expect interim data from this trial in 2026.

Phase 1/2 Clinical Trial in Advanced/Unresectable, Recurrent, or Metastatic HER2-Expressing Solid Tumors

A Phase 1/2 clinical trial (NCT05150691) is being conducted to evaluate trastuzumab pamirtecan in patients with advanced/unresectable, recurrent, or metastatic HER2-expressing solid tumors.

- A potentially registrational cohort with HER2-expressing (IHC3+, 2+, 1+) patients with advanced/recurrent endometrial cancer has completed enrollment.
- We expect data from this cohort in 2026.
- We and DualityBio are continuing discussions with the FDA and plan to file a biologics license application, or BLA, in second line endometrial cancer in 2026, subject to regulatory feedback.

Phase 3 Clinical Trial in Advanced Endometrial Cancer

A Phase 3 trial (NCT06340568) is being conducted to evaluate trastuzumab pamirtecan compared to investigator's choice of chemotherapy in patients with advanced and recurrent endometrial cancer. The trial aims to enroll approximately 480 patients. The primary endpoints are PFS and ORR. Secondary endpoints include OS, DOR and safety.

ii. BNT324/DB-1311, an ADC in Development in Collaboration with DualityBio

BNT324/DB-1311 is a topoisomerase-1 inhibitor-based ADC directed against B7H3. It has received Fast Track Designation from the FDA for the treatment of patients with advanced/unresectable, or metastatic CRPC, who have progressed on or after standard systemic regimens. It has also received Orphan Drug Designation from the FDA for the treatment of patients with advanced or metastatic esophageal squamous cell carcinoma and SCLC.

Phase 3 Clinical Trial in Metastatic CRPC

A Phase 3 clinical trial (NCT07365995) to evaluate BNT324/DB-1311 compared to docetaxel in patients with metastatic CRPC, is planned to start in 2026.

Phase 1/2 Clinical Trial in Advanced Solid Tumors

A Phase 1/2 clinical trial (NCT05914116) is being conducted to evaluate BNT324/DB-1311 in patients with advanced solid tumors.

- In June 2025 at the 2025 ASCO Annual Meeting, data from this trial were presented. In 73 patients with heavily pretreated metastatic CRPC, BNT324/DB-1311 was observed to have a manageable safety profile and showed encouraging preliminary clinical activity.

- In December 2025 at the 2025 ESMO Asia Congress, data from this trial were presented. In patients with previously treated cervical cancer or platinum resistant ovarian cancer BNT324/DB-1311 showed encouraging efficacy and a manageable safety profile.

- In February 2026, updated data from this trial were presented at the ASCO GU Cancers Symposium. BNT324/DB-1311 showed durable efficacy in heavily pretreated mCRPC patients with no new safety signals reported.

iii. BNT325/DB-1305, an ADC in Development in Collaboration with DualityBio

BNT325/DB-1305 is a topoisomerase-1 inhibitor-based ADC directed against TROP2.

Phase 1/2 Clinical Trial in Advanced Solid Tumors

A Phase 1/2 clinical trial (NCT05438329) is being conducted to evaluate BNT325/DB-1305 in patients with advanced solid tumors. As part of this clinical trial, BNT325/DB-1305 is being studied in combination with pumitamig in various solid tumor indications.

- In October 2025 at the 2025 ESMO Congress, data from this trial in patients with pretreated TNBC were presented. Data showed BNT325/DB-1305 to have encouraging durable antitumor activity and a manageable safety profile.

iv. BNT326/YL202, an ADC in Development in Collaboration with MediLink Therapeutics

BNT326/YL202 is a topoisomerase-1 inhibitor-based ADC directed against HER3.

Phase 1 Clinical Trial in Advanced or Metastatic EGFR-Mutated NSCLC or HR-Positive and HER2-Negative Breast Cancer

A Phase 1 clinical trial (NCT05653752) is being conducted to evaluate BNT326/YL202 as a later-line treatment in patients with locally advanced or metastatic EGFR-mutated NSCLC or HR-positive and HER2-negative breast cancer.

Phase 2 Clinical Trial in Advanced Solid Tumors

A Phase 2 clinical trial (NCT06107686) is being conducted in China to evaluate BNT326/YL202 in patients with advanced solid tumors.

- Data from this trial are expected to be presented at the ELCC 2026 taking place on March 25-28, 2026 in Copenhagen, Denmark.

Phase 2 Clinical Trial in Multiple Breast Cancers

A Phase 2 clinical trial (NCT06439771) is being conducted in China to evaluate BNT326/YL202 in patients with locally advanced or metastatic breast cancer with TNBC, HR-positive, HER2-zero-expression or HER2-low-expression.

- In December 2025, data from this trial in patients with HR+ breast cancer with HER2-null (including HER2-ultralow) or HER2-low expression were presented at the 2025 SABCS. Data showed BNT326/YL202 to have encouraging antitumor activity and a manageable safety profile.

v. BNT329, an ADC for the Treatment of Advanced Solid Tumors

BNT329 is a fully owned carbohydrate antigen 19-9, or CA19-9, targeting ADC. CA19-9 is expressed in pancreatic cancers and other solid tumors, plays a role in tumor adhesion and metastasis formation, and is a marker of an aggressive cancer phenotype.

Phase 1/2 Clinical Trial in Advanced Solid Tumors

A Phase 1/2 clinical trial (NCT07186842) is being conducted to evaluate BNT329 in patients with advanced solid tumors.

4. Other Antibody Product Candidates

i. Gotistobart (BNT316/ONC-392), a Selective Treg Modulator Antibody Candidate in Development in Collaboration with OncoC4

Gotistobart (BNT316/ONC-392) is a tumor microenvironment-selective regulatory T cell-depleting antibody targeting cytotoxic T-lymphocyte associated protein 4, or CTLA-4, candidate being developed in collaboration with OncoC4. The program received Fast Track Designation from the FDA in 2022, and Orphan Drug Designation for the treatment of sqNSCLC in January 2026.

PRESERVE-003 Phase 3 Clinical Trial in NSCLC

A two-stage global Phase 3 trial (NCT05671510) is being conducted to evaluate the efficacy and safety of gotistobart as monotherapy in patients with metastatic NSCLC that progressed under previous platinum-based chemotherapy and PD-(L)1-inhibitor treatment.

- In December 2025, at the IASLC ASCO 2025 North America Conference on Lung Cancer, data from the non-pivotal dose-confirmation stage of the two-stage global Phase 3 trial were presented. Gotistobart demonstrated a clinically meaningful OS benefit compared to standard of care chemotherapy and a manageable safety profile in sqNSCLC patients whose disease had progressed following anti-PD-(L)1 therapy and platinum-based chemotherapy.

- Based on current event accrual projections, we expect interim data from the pivotal stage of the two-stage Phase 3 trial in 2026.

PRESERVE-004 Phase 2 Clinical Trial in PROC

A Phase 2 clinical trial (NCT05446298) is being conducted to evaluate gotistobart in combination with pembrolizumab in patients with PROC. The clinical trial is designed to evaluate multiple doses of gotistobart in combination with a fixed dose of pembrolizumab in participants with ovarian cancer who are resistant to platinum-based chemotherapy. The primary endpoints are ORR and safety. Secondary endpoints include DOR, DCR, PFS and OS.

PRESERVE-006 Phase 1/2 Clinical Trial in Metastatic CRPC

A Phase 1/2 clinical trial (NCT05682443) is being conducted to evaluate the safety and efficacy of gotistobart in combination with lutetium Lu-177 vipivotide tetraxetan in patients with mCRPC who have disease progressed on androgen receptor pathway inhibition. The primary endpoints are PSA50 and safety.

- In June 2025, data from the Phase 1 part of this trial were presented at the ASCO Annual Meeting and in February 2026, updated data from the Phase 1 part were presented at the ASCO GU Cancers Symposium.. The data indicated a manageable safety profile and preliminary clinical activity for gotistobart in combination with Lu 177 in patients with mCRPC.

- We expect data from the Phase 2 part of this trial in 2026.

PRESERVE-001 Phase 1/2 Clinical Trial in Advanced or Metastatic Solid Tumors

A Phase 1/2 dose escalation clinical trial (NCT04140526) is being conducted to evaluate gotistobart as a single agent and in combination with pembrolizumab in patients with advanced or metastatic solid tumors.

- In June 2025, at the 2025 ASCO Annual Meeting, updated data from the melanoma cohorts of the ongoing trial were presented. The data suggested encouraging preliminary clinical activity and a manageable tolerability profile with no new safety signals observed.

ii. BNT314/GEN1059 is being developed in collaboration with Genmab. BNT314/GEN1059 is a potential first-in-class bispecific antibody product candidate designed to boost antitumor immune responses through epithelial cell adhesion molecule-, or EpCAM-, dependent 4-1BB agonistic activity.

Phase 1 Clinical Trial in Advanced or Metastatic Solid Tumors

A Phase 1 clinical trial (NCT06150183) is being conducted to evaluate the safety and preliminary antitumor activity of BNT314/GEN1059 in patients with advanced or metastatic solid tumors.

iii. BNT317, an Antibody for the Treatment of Advanced Solid Tumors

Phase 1 Clinical Trial in Advanced Solid Tumors

A Phase 1 clinical trial (NCT06750185) is being conducted to evaluate the safety, tolerability, pharmacokinetics, and immunogenicity of BNT317 in participants with advanced solid tumors.

5. Oncology Cell Therapy Product Candidates

i. BNT211, a chimeric antigen receptor, or CAR, T-cell therapy – CAR-T - in multiple solid tumors

BNT211 is a novel approach combining an autologous tumor-specific CAR-T cell therapy candidate targeting the oncofetal antigen Claudin-6 (CLDN6) with a CLDN6-encoding CAR-T cell amplifying RNA vaccine, or CARVac, that is based on BioNTech's FixVac platform in one regimen.

Phase 1 Clinical Trial in CLDN6-Positive Relapsed or Refractory Solid Tumors

A Phase 1 dose escalation clinical trial (NCT04503278) is being conducted to evaluate BNT211 as monotherapy or in combination with CARVac in patients with CLDN6-positive relapsed or refractory solid tumors, including non-small cell lung cancer, gastric cancer, ovarian cancer and testicular germ cell tumors.

B. Infectious Disease Programs

1. Next-Generation COVID-19 Vaccine

In collaboration with Pfizer, we are aiming to develop a vaccine candidate that enhances and broadens SARS-CoV-2 immunogenicity responses.

2. COVID-19 – Influenza Combination mRNA Vaccine Program – BNT162 + BNT161

In collaboration with Pfizer Phase 1/2 clinical trials are being conducted to evaluate the safety, tolerability and immunogenicity of the combination of the companies' mRNA vaccine candidates against influenza and COVID-19. We expect to provide updates as the program progresses.

3. Herpes Simplex Virus Vaccine Program – BNT163

A Phase 1 clinical trial (NCT05432583) is being conducted to evaluate the safety, tolerability, immunogenicity and preliminary efficacy of BNT163 for the prevention of genital lesions caused by HSV-2 and potentially HSV-1.

- In October 2025, data from this trial were presented at the 2025 Infectious Disease Week, or IDWeek, congress. The data showed BNT163 was well-tolerated with an acceptable safety profile and induced binding antibody and neutralizing titers to HSV-2 antigens.

4. Tuberculosis Vaccine Program - BNT164

In December 2025, a Phase 1a clinical trial (NCT05537038) to evaluate the safety, reactogenicity, and immunogenicity of BNT164 was completed.

A Phase 1b/2a clinical trial (NCT05547464) is being conducted to assess the safety, reactogenicity, and immunogenicity of mRNA vaccine candidates against tuberculosis disease.

5. Malaria Vaccine Program – BNT165

A Phase 1/2 trial (NCT06069544) to evaluate the safety, tolerability, immunogenicity and efficacy of a second investigational RNA-based vaccine candidate is on clinical hold by the FDA, as announced on March 4, 2025. BioNTech has complied with the hold by the FDA and, in accordance with the clinical trial protocol, had proactively paused the study. BioNTech is assessing next steps in the development of this vaccine candidate.

6. Mpox Vaccine Program – BNT166

A Phase 1/2 clinical trial (NCT05988203) is being conducted to evaluate the safety, tolerability, reactogenicity and immunogenicity of an mRNA-based multivalent vaccine candidate (BNT166a).

- In October 2025, data from the Phase 1 portion of this trial were presented at the 2025 IDWeek congress. The data showed that BNT166 was well-tolerated and induced multiantigen-directed antibodies with cross-mpox virus clade and cross-orthopoxvirus neutralization activity in vaccinia virus-naïve and experienced participants.

A randomized, placebo-controlled Phase 2 clinical trial (NCT07379580) is being conducted to evaluate the safety, reactogenicity, and immunogenicity of BNT166 in healthy participants.

7. Shingles Vaccine Program – BNT167

A Phase 1/2 clinical trial (NCT05703607) to evaluate the safety, tolerability, and immunogenicity of BNT167 in up to 900 healthy volunteers 50 through 69 years of age was terminated.

- Both we and Pfizer have decided to opt-out of the further development of BNT167.

8. HIV Antibody Program – BNT351

In February 2026, the first patient was dosed in a Phase 1 clinical trial (NCT07392372) to evaluate the safety, pharmacokinetics, and antiviral activity of BNT351 in adults living with and without HIV.

VI. Sales, Marketing and Distribution

Our commercial organization currently focuses on supporting sales of our COVID-19 vaccine in Germany and Türkiye. Our commercial organization is responsible for promoting our products to health care providers and providing information to stakeholders, including governmental organizations, in Germany and Türkiye.

As a result of our partnership with Pfizer, under which our commercialization responsibilities are limited to Germany and Türkiye, we maintain a lean fixed cost base for our COVID-19 vaccine business.

Our commercial organization is also responsible for preparing and obtaining reimbursement from third-party payors, including governmental organizations, for our COVID-19 vaccine.

We aim to build a specialized oncology sales force in major markets, including North America and Europe, while leveraging our commercial partners for co-commercialization. We are working towards being commercial-ready in anticipation of potential commercial oncology launches as soon as 2027, if approved.

VII. Manufacturing

We are building a fully integrated biotechnology company, with operations spanning from research through clinical development, manufacturing and sales and marketing. To successfully bring individualized immunotherapies and vaccines to people around the world, we believe that it is crucial to have in-house manufacturing capabilities that can be efficiently scaled for global clinical and commercial distribution. We have several manufacturing sites capable of developing automated production processes for on-demand production of our investigational therapies and vaccines. These can be classified into distinct GMP manufacturing capabilities.

We operate GMP-certified manufacturing facilities in Germany, where we manufacture mRNA therapeutics and engineered cell therapies for both our own pipeline, including a state-of-the art, multi-platform, GMP-certified manufacturing facility located in Marburg, Germany. We also operate a fifth facility in Germany where we manufacture custom peptides both to support our extensive immunomonitoring activities within our development programs and for third parties. Our subsidiary BioNTech Innovative Manufacturing Services GmbH, or BioNTech IMFS, has been manufacturing GMP-certified cellular products since 1999.

Outside of Germany, we operate manufacturing sites in Zhuhai and Nantong, China. The Zhuhai site serves as a local R&D and biotech hub, while the Nantong site serves as an industrial-scale antibody production (drug substance and drug product) facility for clinical programs. We are building a BioNTainer site in Kigali, Rwanda, with the intent to enable robust end-to-end manufacturing in Africa for mRNA-based medicines. Furthermore, we are advancing the development and commissioning of a state-of-the-art mRNA manufacturing facility at La Trobe University in Melbourne, Australia, and have established R&D mRNA manufacturing capabilities in leased laboratory space at the university.

Our approach has been to proactively build capacity in anticipation of demand from both internal research and development from our collaborators. We have done so by continuing to make significant investments in our manufacturing infrastructure, including our capacity to manufacture mRNA, viral vectors, cellular products and peptides. We believe that the development and optimization of our manufacturing processes in parallel to drug development is crucial to our success.

A. Manufacturing Operations

COVID-19 Vaccine. Our manufacturing site in Marburg was approved by the EMA for manufacturing of our COVID-19 drug product in March 2021. This approval made it one of the largest mRNA manufacturing sites worldwide. In addition, we have another GMP facility that currently produces our COVID-19 vaccine candidates for clinical trials. We have a network of sub-contractors established to provide drug products, and fill and finish services to enable production.

mRNA. We believe scaling up manufacturing for mRNA can best be executed as part of a proprietary manufacturing approach, rather than 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, our BioNTech East Wing facility, and our Marburg facility. The East Wing facility manufactures iNeST (finished product). BioNTech IMFS produces DS, formulated Drug Product as well as precursors (Liposomes) for early clinical supply. Our manufacturing facility in Marburg is one of the largest mRNA vaccine manufacturing sites worldwide with an annual capacity of up to three billion doses of mRNA drug substance and we believe we are well positioned to supply the quantities required by global market demand.

Cell Therapy Products. We have end-to-end capabilities and teams in Germany with over 20 years of experience in cell therapy manufacturing, quality control and release. Our cell therapy programs target novel and known tumor-specific antigens, including patient-specific mutant neoantigens. We also leverage our mRNA vaccine technology to further boost T-cell activation, expansion, and persistence. Our state-of-the-art manufacturing processes of cellular products involve the isolation of primary human blood cells and subpopulations, such as,

e.g., CD3+ T cells. At our BioNTech IMFS facility, cell products are cultured, expanded and genetically modified (e.g., CAR-T cells) in an aseptic automated production process in specialized cleanroom facilities with a turn-around time of below 35 days. We also have the capability for in-house mRNA production for the genetic modification of such innovative cell therapy products.

Peptides. Our custom peptide synthesis business has developed unique technologies to produce several million peptides over the past ten 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 peptides as starting materials in our engineered cell therapies as well as in some drug formulations and biomarker discovery studies. We have developed proprietary technologies to produce highly complex and purified peptide pools that consist of overlapping peptides spanning entire antigens or neoepitopes. In September 2025, we moved into a new manufacturing plant in Berlin, which approximately doubled our manufacturing capacity to produce peptides and diversified our peptide activities towards new fast-growing markets.

B. Manufacturing Facilities

The information included herein is as of the date of this Annual Report.

Manufacturing sites in Germany

Marburg

Marburg is one of our fully owned, state-of-the-art manufacturing facilities for just-in-time delivery and scalable production. Our Marburg manufacturing facility comprises eight large and small molecule production suites. It is one of the largest mRNA vaccine manufacturing sites globally. The facility has the capacity to produce up to three billion doses of mRNA drug substance vaccine annually.

Marburg is our central hub for innovation and development of novel manufacturing solutions. It is a center of excellence, not only in terms of facilities and devices, but as a know-how hub with appropriate and forward-looking staff training. We have about 450 employees on site. To ensure production, we work in flexible/different shift models up to 24/7 if required.

Idar-Oberstein

BioNTech IMFS: Our manufacturing operations for cell therapy products and clinical bulk mRNA are housed in our wholly owned subsidiary. 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 its first commercial supply contract for retroviral vectors. The BioNTech IMFS facility is located near Mainz. Around 500 staff members are employed at this facility, with collective expertise in molecular biology, cell biology and virology and a close working relationship with our R&D teams in Mainz. We consider BioNTech IMFS our powerhouse for early-stage mRNA material.

Mainz

BioNTech iNeST Clinical Manufacturing (East Wing): We utilize our GMP-certified manufacturing facility at our headquarters in Mainz, Germany for the production of iNeST immunotherapies. In 2015, our wholly owned subsidiary, BioNTech RNA Pharmaceuticals GmbH, or BioNTech RNA, and Siemens announced a collaboration for developing an automated, paperless and digitalized production site for individualized mRNA. We obtained our

GMP manufacturing authorization for iNeST production at our East Wing facility in June 2018 and manufactured our first drug product there the following month.

Over 300 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 manufactured and released more than 1,700 batches of mRNA since inception.

To perform our target identification process to feed into the iNeST downstream GMP manufacturing process, our headquarters also hold our core facility, which operates under Good Clinical Practice, or GCP, for labs. Incoming patients' materials (blood and tumor samples) are received and analyzed to identify characteristic mutations to generate the patient-specific target list used for individualized mRNA production.

BioNTech Clinical Manufacturing: Our GMP-certified manufacturing facility in Kupferbergterrasse, Mainz is authorized to conduct secondary packing, labeling, storage and batch release of primary packed investigational medicinal products.

Another GMP facility in Mainz for mRNA-based products was completed in 2025, with a target manufacturing license date of 2027. With advanced automation and streamlined processes, this new facility is designed to serve a high four-digit number of patients annually.

Tübingen

In January 2026, we became the sole owner of the German mRNA company CureVac's business operations. CureVac's Tübingen site is a GMP-compliant mRNA manufacturing hub primarily designed for clinical-stage supply. It includes multiple multi-product GMP suites and an upscaled facility planned for supporting late-stage trials and potentially commercial supply. A key asset is the automated "RNA Printer" enabling small-batch, end-to-end mRNA and LNP production suited for personalized oncology.

Berlin

JPT, our peptide manufacturing facility located in Berlin, was established in 2004 and became a wholly owned subsidiary of BioNTech in 2008. JPT has manufacturing capacity to produce up to 1 million peptides per year for research applications, including drug discovery and bioanalysis.

Global manufacturing sites

Outside of Europe, we maintain sites in China, Rwanda and Australia.

Nantong and Zhuhai, China

Biotheus, now a BioNTech subsidiary, operates two strategic Chinese sites linked to its biologics pipeline. Its Zhuhai location serves as a local R&D and biotech hub, with GMP production for early-phase clinical trials. The larger Nantong campus provides industrial-scale antibody production (drug substance and drug product) for clinical programs and is intended to support initial launches and ongoing commercial supply. Currently, Nantong operates a single drug substance line with three 2000-liter reactors and one filling line. A second drug substance line is under construction.

The BioNTainer: a platform for localized and sustainable mRNA production

The *BioNTainer* is an example of our innovative approach to establishing scalable vaccine production. It was developed to ensure sustainable, equitable access to our programs, particularly in low-income countries and regions with limited infrastructure. The *BioNTainer* allows scalable vaccine production by developing and delivering mRNA manufacturing facilities based on a containerized clean room solution with a modular design, standardized equipment, and software components. Each *BioNTainer* unit is a clean room, which we equip with state-of-the-art manufacturing solutions for the manufacture and formulation of mRNA-based vaccines. Each *BioNTainer* unit is built of six to eight ISO-sized containers. A *BioNTainer* unit can be equipped to manufacture a

range of mRNA-based vaccines targeted to regional needs: for example, our COVID-19 vaccine and our investigational malaria, tuberculosis, or mpox vaccines, if they are successfully developed, approved, and authorized by regulatory authorities and in line with regional demand. The BioNTainer units can also support clinical-scale manufacturing of investigational mRNA-based medicines.

Kigali, Rwanda Manufacturing Facility

Our first international BioNTainer site was the BioNTainer manufacturing facility in Kigali, Rwanda. The Kigali facility was planned to install two sets of *BioNTainer* units for commercial-scale bulk production of mRNA vaccines with the intent to enable robust end-to-end manufacturing in Africa for mRNA-based medicines. The first *BioNTainer* unit arrived in Kigali, Rwanda in 2023. We acknowledged this important milestone in progressing mRNA vaccine manufacturing capabilities in Africa with the inauguration of our site in Kigali, Rwanda.

In 2024, we announced that CEPI would be committing up to $145 million to support us to establish further mRNA clinical-scale manufacturing capabilities at the Kigali facility. The setup of clinical-scale manufacturing capabilities for mRNA-based vaccine candidates involves the installation of two additional *BioNTainer* units at the Kigali facility - one unit for clinical scale Drug Substance and bulk Drug Product production and one unit for vaccine filling. The clinical scale BioNTainer units are expected to be installed in 2026 and are intended to produce and fill up to 500,000 doses of clinical trial material and/or commercial vaccines per year. We plan to apply for a GMP manufacturing license in 2027. Under the terms of the agreement with CEPI, we intend to provide sustainable supply of our prophylactic vaccines manufactured at the Kigali facility if successfully developed and authorized, such as vaccines against malaria, mpox and tuberculosis, to low and lower middle-income countries, with priority supply to African countries.

The facility's manufacturing capacity will depend on the mRNA product being manufactured and various factors, such as dosage and formulation. For commercial vaccine production or in response to a pandemic, we may activate all installed BioNTainers on site and could potentially manufacture up to 50 million doses annually of a product, using an RNA process similar to that used for the COVID-19 vaccines by Pfizer and us.

The European Investment Bank, or EIB, and European Commission, or EC, are supporting the development of our mRNA manufacturing site in Rwanda. In October 2025, up to €95 million in blended EC and EIB financing was awarded to support site infrastructure and facility operations and to develop contract development manufacturing organization capabilities with the goal of enabling the manufacture of clinical trial materials for local partners. Our partnership with CEPI and the EC/EIB strengthens Africa's vaccine ecosystem.

By the end of 2025, BioNTech Rwanda employed approximately 40 people from eight different African countries and is expected to continue to grow in 2026.

Melbourne, Australia Manufacturing Facility

In 2023, we signed a multi-year strategic partnership with the State of Victoria, Australia, for an initiative to strengthen the local mRNA ecosystem with our BioNTainer technology. This partnership aims to provide high-tech manufacturing capabilities and our expertise to develop projects for further research and development.

We are advancing the development and commissioning of our state-of-the-art mRNA manufacturing facility on the Bundoora campus of La Trobe University in Melbourne. Having broken ground on the site in 2024, construction activities on the building structure have gained momentum. In November 2025, we celebrated the "topping-out" of the building, with the successful completion of the concrete superstructure. Once operationally ready, the facility is intended to support Australia's growing mRNA ecosystem by producing R&D and cGMP clinical-scale investigational mRNA-based medicines.

In advance of the completion of our R&D and clinical-scale mRNA manufacturing facility, in mid-2025, we established R&D mRNA manufacturing capabilities in leased laboratory space at La Trobe University. In October

2025, we celebrated the successful manufacture of mRNA on Australian soil. Our R&D mRNA manufacturing services are now available to the growing mRNA ecosystem, and we expect our capabilities to expand through 2026. Upon completion of construction, we expect to transfer our R&D processes and equipment trains into our own facility.

Following the opening of our Innovation Center in Melbourne's central business district in mid-2024, our local scientific and strategic leadership team made a concerted effort to engage with and integrate into the mRNA ecosystem in Australia and the broader region. We expect to continue to leverage our local and global expertise to assess and identify mRNA-focused research projects from academia and industry and facilitate their transition to clinical-stage development as potential future product candidates.

C. Other Certifications

BioNTech Diagnostics has a quality management system that is certified according to ISO 13485:2016 and JPT maintains an ISO 9001:2015 certified Quality Management System.

D. 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 an ISO 9001:2015 certified Quality Management System.

VIII. 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, without limitation:

- Bristol Myers Squibb to jointly develop, manufacture and commercialize pumitamig;
- DualityBio for the research and development of certain antibody drug conjugates;
- Genentech for our iNeST platform in our mRNA drug class;
- Genmab for our next-generation checkpoint immunomodulator platform in our protein-based therapeutics drug class;
- OncoC4 for the research and development of certain monoclonal anti-CTLA4 antibodies; and
- Pfizer for our COVID-19 vaccine program, which leverages technology from our infectious disease mRNA-based platform.

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.

A. BMS Collaboration

On June 2, 2025, we entered into a Global Co-Development and Co-Commercialization Agreement, which we refer to as the Original Agreement, with Bristol Myers Squibb Company, or BMS, to jointly develop, manufacture and commercialize our investigational bispecific antibody pumitamig across numerous solid tumor types.

Other than the right to receive upfront payment, non-contingent anniversary payments and development and regulatory approval milestones (which stay with BioNTech SE), we assigned our rights and obligations under the Original Agreement to our subsidiary BioNTech US Inc. pursuant to an Assignment and Assumption Agreement dated June 2, 2025 which was amended on August 15, 2025. In connection with the assignment, the parties also entered into a Parent Guarantee in favor of BMS dated June 2, 2025. The Original Agreement was amended and restated on August 15, 2025 to further define the performance-related rights and obligations of the collaboration, which, as so amended and restated, we refer to as the BMS Agreement.

Under the BMS Agreement, BMS paid us $1.5 billion in an upfront payment and agreed to pay $2 billion total in non-contingent anniversary payments through 2028. Furthermore, we will be eligible to receive up to $7.6 billion in additional development, regulatory and commercial milestones. The parties will equally share global profits and losses.

The parties have agreed to use commercially reasonable efforts to jointly develop pumitamig, as a monotherapy or in combination with other products, pursuant to a Joint Development Plan, or JDP. Development costs will generally be shared equally; provided, if a particular joint clinical trial involves pumitamig in combination with a proprietary or in-licensed asset of either party, cost sharing will be on an adjusted basis, subject to certain exceptions.

Each party may propose new clinical trials for additional indications or combinations to be added to the JDP. If the other party declines co-funding of a proposed new trial in the JDP, the proposing party may proceed independently at its own cost, under the oversight of the Joint Development Committee, subject to certain reimbursement rights against the other party.

The parties have also agreed to use commercially reasonable efforts to jointly commercialize pumitamig pursuant to a jointly-developed global commercialization strategy and certain co-commercialization and market access plans. The parties will equally share any profits and losses from the commercialization of pumitamig. A Joint Commercialization Committee will coordinate and allocate commercial responsibilities, including the “lead” role with respect to specific activities, in an equitable manner to maximize the success of pumitamig and to maximize the efficiencies of the collaboration and avoid duplication of efforts as much as possible. Each party has the right to contribute equally (on a market-by-market basis) to all strategic commercial planning and execution, subject to certain exceptions.

We will be solely responsible and will use commercially reasonable efforts for the global clinical supply of pumitamig initially before the completion of a manufacturing technology transfer from us to BMS. Following the completion of the manufacturing transfer, we will continue to be responsible and will use commercially reasonable efforts for the global clinical supply of pumitamig, but the parties may agree for BMS to manufacture certain quantities of the clinical supply. Following the completion of the manufacturing transfer and BMS being otherwise ready to manufacture and supply at scale, BMS will be responsible for the commercial supply of pumitamig, provided that we retain the right to contribute a certain percentage of global commercial supply, subject to certain conditions.

Each party has granted to the other party certain co-exclusive licenses under its intellectual property, or IP, including patents and know-how (including to each party’s share of any future jointly owned IP under the BMS Agreement), to perform development and medical affairs activities with respect to seek and obtain regulatory approvals of, and manufacture, commercialize and otherwise exploit pumitamig.

The parties have also agreed to a mutual right of first negotiation, effective from the date of the BMS Agreement through the fifth anniversary thereof, with respect to certain events related to next generation antibodies, where either party (a) receives a transaction proposal from a third party, (b) intends to enter into such a transaction with a third party, or (c) determines to initiate a registrational trial for such next generation antibody.

The term of the BMS Agreement commenced on June 2, 2025 and will remain in effect until and unless the parties mutually agree to permanently terminate and cease all exploitation of pumitamig, or the BMS Agreement is otherwise earlier terminated by the parties in accordance with its terms. BMS has the right to terminate for convenience by giving a specified period of prior notice. BMS may also terminate if BMS determines in good faith that there is unacceptable risk for harm in humans relating to pumitamig that is not resolved, or a Safety Issue. Each party may also terminate for uncured material breach or insolvency of the other party. In the event that the termination is by BMS for convenience or by us for uncured material breach, the parties will continue to co-fund certain ongoing clinical trials until the earlier of the completion or wind-down of such clinical trials or the conclusion of a specified period from the date of notice of termination. Upon termination, all licenses granted under the BMS Agreement will terminate, except that BMS will grant us a reversion license (other than where termination is by BMS for a Safety Issue) to BMS's interest in specified reversion IP to allow us to continue developing and commercializing licensed products in the form such licensed products existed as of the date of termination, subject to the parties agreeing on the financial payments for such reversion license. The grant of the reversion license is contingent on (i) the parties' agreement upon commercially reasonable financial payments and (ii) the parties entering into a reasonable license agreement for the reversion license. In the event that the parties cannot agree on commercially reasonable financial payments during a specified period, the parties will refer such matter for resolution by baseball arbitration. During the period between termination and entry into the reversion license (or a specified period following the termination date, if earlier), BMS may not bring any claim against us for infringement of any reversion IP in the conduct of any development activities ongoing as of the termination date.

B. DualityBio Global Strategic Partnership

In 2023, we entered into three License and Collaboration Agreements with DualityBio, which we refer to as the DualityBio Agreements. Each of the DualityBio Agreements relates to specific ADC assets. The first agreement, the HER2 Agreement, relates to the ADC asset targeting HER2 and was entered into on March 16, 2023. The second agreement, the B7H3 Agreement, relates to the ADC asset targeting B7H3 and was entered into on March 31, 2023. The third agreement, the TROP2 Agreement, relates to the ADC asset targeting TROP2 and was entered into on August 4, 2023.

Each of the three DualityBio Agreements relates to a license granted to us with respect to certain patents and know-how owned or otherwise controlled by DualityBio and our collaboration with DualityBio in the research and development of ADC therapeutics.

In each of the DualityBio Agreements, DualityBio granted us the exclusive, royalty-bearing and sublicensable right to exploit certain patents and know-how, which we refer to as the DualityBio IP, for the research, development, manufacture and commercialization of the respective ADC compound and pharmaceutical products comprising such compound, which we refer to as the DualityBio Products, in any field in the territory, which is all countries of the world except for mainland China, Hong Kong and Macau, which we refer to as the DualityBio Retained Territory. We were also granted the sole right to exploit the DualityBio IP to develop and manufacture the DualityBio Products in the DualityBio Retained Territory solely for the purpose of developing, manufacturing and commercializing the DualityBio Products in the territory.

Each party has final decision-making authority and is generally responsible for clinical trial supply costs and regulatory activities and costs with respect to their respective territory.

We are responsible for the commercialization of any DualityBio Products in the territory.

The B7H3 Agreement also grants DualityBio the option to share the development and commercialization costs and the profits and losses from the exploitation of the first original DualityBio Product in the United States. Under the B7H3 Agreement, we have further granted to DualityBio the option to assume a percentage of the total sales force of the first original DualityBio Product in the United States.

In partial consideration of DualityBio's granting of the licenses and rights to us under the DualityBio Agreements, we have made upfront payments to DualityBio in an aggregate amount of $220 million. In addition, we agreed to make potential payments upon the achievement of specified development, regulatory and commercial milestones. Such milestone payments could amount up to $2.6 billion in the aggregate (the TROP2 Agreement also provides for additional sales milestone payments in the event DualityBio works on, and we exercise, the option regarding the next-generation product). We further agreed to between single-digit to double-digit tiered royalties on net sales of all DualityBio Products, which also differ between the DualityBio Agreements. Royalties are subject to stacking provisions and will be reduced in case of respective biosimilar products entering the market. Furthermore, we agreed to reimburse DualityBio for certain development costs.

The DualityBio Agreements end on a country-by-country and DualityBio Product-by-DualityBio Product basis upon expiration of the respective last DualityBio royalty term for a DualityBio Product in that country. Thereafter, the licenses granted to us 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 or insolvency, we may terminate each DualityBio Agreement, in whole or in part, for convenience upon prior written notice.

On November 12, 2024, we and DualityBio entered into a side letter to the DualityBio Agreements to undertake certain development activities in the territory and DualityBio Retained Territory with DualityBio Products in combination with other product(s) that are proprietary to or owned or controlled by us or our affiliates.

C. Genentech iNeST Collaboration

Collaboration Agreement

On September 20, 2016, we entered into a Collaboration Agreement with Genentech and F. Hoffman-La Roche Ltd, together with all amendments thereto, collectively referred 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 continued certain clinical studies that were initiated prior to the execution of the Genentech Collaboration Agreement at our sole expense. Genentech may access and use any data generated in these 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 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 conducting 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).

D. Genmab Next-generation Immunomodulator Collaboration

On May 19, 2015, we entered into a License and Collaboration Agreement with Genmab, which was subsequently amended and supplemented by side letters, to jointly research, develop and commercialize polypeptide-based bispecific antibodies against certain target combinations for the treatment of cancer worldwide, or the Genmab Agreement Field, using certain Genmab technology. In connection with our entry into that License and Collaboration Agreement, Genmab paid us an upfront fee of $10 million. On July 18, 2022, this agreement was amended and restated by an Amended and Restated License and Collaboration Agreement (which, as amended, is referred to as the Genmab Agreement).

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 were governed by a research plan, which was subject to annual review and updates, and which specifies the clinical candidates to be developed. This research and evaluation phase expired on September 18, 2022.

We and Genmab must use commercially reasonable efforts to develop candidates selected by the joint research committee, or the LCA Products, through preclinical and clinical development. The preclinical and clinical development of the LCA 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 an LCA Product or of any of its components.

We and Genmab must use commercially reasonable efforts to jointly commercialize all LCA 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 an LCA 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-commercialize 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 LCA Products. Genmab is obligated to provide regular updates to us on regulatory activities.

Each party grants to the other party a worldwide, co-exclusive, sublicensable, royalty-free license under certain of such first party's intellectual property, including certain patents and know-how, to perform the research under this agreement and to research, develop, make, import, use and sell LCA 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 preclinical and clinical development phase for any LCA Product, engagement in research and development activities in the Genmab Agreement Field unilaterally by a party relating to an LCA Product or its Back-up Candidate or any bispecific antibody which targets the same target combination for which such LCA Product or 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 an LCA 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 other party may elect to continue the development and commercialization of the LCA Product or divest its interest in such LCA Product. If the other party elects to pursue development and commercialization of such LCA Product alone as a Unilateral Product, at its sole cost and subject to pre-defined milestone and royalty payments and certain additional pre-defined terms. If the other party wishes to not pursue such continued development and commercialization on such pre-defined payment and additional terms, then the parties will jointly divest their interest in such LCA Product to a third party, and if such divestiture fails, the parties will cease all development and commercialization of such LCA Product.

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 or (ii) the time when no LCA Products, Joint Combination Products or Proprietary Combination 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.

On August 5, 2022, we and Genmab expanded our global strategic collaboration to develop and commercialize novel immunotherapies for the treatment of cancer patients. Under this expansion, we and Genmab will jointly work to research, develop and commercialize novel monospecific antibody candidates for various cancer indications.

E. OncoC4 Collaboration

On March 17, 2023, we and OncoC4 entered into a License and Collaboration Agreement, or the OncoC4 Agreement, for the license, development and commercialization of ONC-392 and all other monoclonal anti-CTLA4 antibodies owned or controlled by OncoC4 (referred to as OncoC4 Licensed Compounds) as of the execution date, including development of combinations of such antibody with other products, for use in humans or animals, or the OncoC4 Field.

OncoC4 granted us an exclusive license under ONC-392 and OncoC4's interest in joint intellectual property to exploit OncoC4 Licensed Compounds and any pharmaceutical or biologic product containing OncoC4 Licensed Compound (referred to as OncoC4 Licensed Products) in the OncoC4 Field in the entire world, which we refer to as the OncoC4 Territory. Furthermore, OncoC4 granted us an exclusive option that ended June 30, 2024 to license AI-061, which is a biopharmaceutical composition containing as its sole active ingredients both ONC-392 and an anti-PD-1 antibody. OncoC4 retains all rights to the anti-PD-1 antibody outside of the combination with ONC-392.

We agreed to collaborate on research, development, and commercialization of ONC-392 in the OncoC4 Territory and to use commercially reasonable efforts to conduct development activities of OncoC4 Licensed Compounds and OncoC4 Licensed Products either as a monotherapy or in combination with an anti-PD-(L)1 antibody and/or standard of care product (which we refer to collectively as the Mono/PD-1/SOC Combinations) in accordance with a joint clinical development plan which is governed by a joint steering committee. All costs associated with the joint development responsibilities are shared equally between us and OncoC4.

We are solely responsible for all development activities for the OncoC4 Licensed Compounds and OncoC4 Licensed Products in any other form or combination other than the Mono/PD-1/SOC Combinations (we refer to such other combinations as OncoC4 Other Combinations) at our own expense and in accordance with a research and development plan prepared by us and shared with OncoC4 through the joint steering committee. We agreed to use commercially reasonable efforts to develop an OncoC4 Licensed Product in at least one indication for an OncoC4 Other Combination. We agreed to first offer OncoC4 the opportunity to co-fund any development of a PD-1 Combination prior to pursing such development independently or with a third party.

We agreed to be solely responsible, at our expense, for commercialization of OncoC4 Licensed Products worldwide and to use commercially reasonable efforts to commercialize OncoC4 Licensed Products for each approved indication in certain major markets.

In consideration for the rights granted to us by OncoC4, we made an upfront payment of $200 million, with a portion of the upfront payment to be used to fund OncoC4's share of the joint research and development costs related to ONC-392, and agreed to make potential payments upon the achievement of specified development and regulatory milestones and upon the achievement of specified sales milestones. We have further agreed to pay OncoC4 double digit, tiered royalties on annual net sales of OncoC4 Licensed Products during a certain royalty term starting from launch of product.

The OncoC4 Agreement shall continue until the last-to-expire royalty term in all countries in the OncoC4 Territory for all OncoC4 Licensed Products. Upon the expiration of the royalty term for an OncoC4 Licensed Product in a given country in the OncoC4 Territory, the exclusive license granted to us will become a perpetual, irrevocable, non-exclusive, fully paid-up, and royalty-free license with respect to such OncoC4 Licensed Product in such country. In addition to termination rights granted to each party in the case of the other party's uncured material breach or insolvency, we have the right to terminate the OncoC4 Agreement in its entirety for convenience with prior written notice to OncoC4.

F. Pfizer COVID-19 Vaccine 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. On January 29, 2021, effective as of March 17, 2020, we entered into an amended and restated Collaboration Agreement with Pfizer for the research, development and commercialization of immunogenic compositions comprising RNA in the Pfizer Corona Field, which we refer to as the Pfizer Agreement.

We and Pfizer agreed to collaborate on research, development and commercialization in the Pfizer Corona Field worldwide (excluding the Fosun collaboration territory), which we refer to as the Pfizer Collaboration 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 Agreement, Pfizer is leading clinical development of and is seeking regulatory approval for any candidates or products in the United States and we are leading clinical development of and are seeking regulatory approval for any candidates or products in the European Union, and we will agree on a strategy for all other countries in the Pfizer Collaboration Territory on an ongoing basis through the joint steering committees.

BioNTech can solely commercialize the vaccine in Germany and Türkiye (collectively referred to as the BioNTech Commercialization Territory, which is a subset of the Pfizer-Collaboration Territory). We have the option to opt-out of commercializing the vaccine in Germany and/or Türkiye, whereupon such countries will become part of the Pfizer Commercialization Territory of the Pfizer Collaboration Territory.

Pfizer has the right to commercialize any approved COVID-19 vaccine in the rest of the Pfizer Collaboration Territory. On a country-by-country basis in relation to the United Arab Emirates, Southeast Asia, and certain developing countries, if we obtain funding from a third-party 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 or distribute 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 Commercialization Territory.

If our Collaboration Agreement with Fosun expires or is otherwise terminated for any reason, as between us and any international pharmaceutical group headquartered outside of China, we have granted Pfizer a right of first negotiation to expand the Pfizer Commercialization Territory to include the Fosun Territory.

We and Pfizer share responsibilities for manufacturing and supplying our approved COVID-19 vaccines. If there is insufficient supply to satisfy the entire demand for vaccines in the Pfizer Collaboration 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, and taking into account any government supply obligations, or supply obligations included in any agreement reached with a third-party funding organization.

Under the Pfizer Agreement, we have granted Pfizer an exclusive, sublicensable license in the Pfizer Collaboration 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 Agreement. We undertake to maintain in full effect all intellectual property licenses held by us at the time we entered into the Pfizer 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 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. Under the Pfizer Agreement, we are obligated to indemnify Pfizer with respect to certain product liability and patent infringement claims.

During the term of the Pfizer 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 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 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. We and Pfizer will share the gross profits from commercializing a vaccine evenly, as well as the costs for shipping. The Pfizer Agreement continues for so long as either at least a vaccine is being developed for use in the Pfizer Collaboration Territory or a vaccine is being commercialized anywhere in the Pfizer Collaboration Territory. 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) on a country-by-country basis or in its entirety for convenience upon one (1) year's prior written notice provided that any such termination shall not become effective less than two (2) years from the first commercial sale of an approved vaccine.

IX. 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 other 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.

A. 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 are subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and 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 or marketing authorization (BLA/NDA) holder 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 GCP;
- 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 applicable regulations and GCP, 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 applicable regulations post approval, including any post-approval requirements, such as 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 product candidates and any future product candidates 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 patients 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 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 patients 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 patients. 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 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 receive periodic reports regarding the investigation from the investigators. 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, and particularly for rare diseases, 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 the 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/or 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 or to comply with post approval commitments 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 patients, 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 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 announced and 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, and/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 either an approval letter or a 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, and designation as a fast track product does not guarantee a decision by that goal date. 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.

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 additional 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). A designation of priority review does not guarantee a decision by the priority review date.

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 under expedited withdrawal procedures applicable to products approved under accelerated approval. 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 allogeneic 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 interactions 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, 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 or full approval is obtained. 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 manufacturing problems, or certain other events 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, including FDA statements regarding the safety of products;
- 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 the Food and Drug Administration Safety and Innovation Act. 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.

B. 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

Until recently, pursuant to the 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 had been implemented through national legislation of the member states. Under this system, a sponsor had to 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 could only start a clinical trial at a specific study site after an independent ethics committee had issued a favorable opinion.

In April 2014, the European Union adopted a new Clinical Trials Regulation (EU) No 536/2014, which took effect on January 31, 2022 and replaced the Clinical Trials Directive 2001/20/EC. Commission Implementing Regulation (EU) 2017/556 replaced the GCP Directive 2005/28/EC. The Clinical Trials Regulation has overhauled the former system of approvals. Specifically, the Regulation, which is directly applicable in all member states, aims to simplify and streamline the approval of clinical trials in the European Union. For instance, Regulation (EU) No 536/2014 enables sponsors to submit one online application via a single online platform known as the Clinical Trials Information System (CTIS) for approval to run a clinical trial in several European countries, making it more efficient to carry out such multinational trials. It provides for 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 limited involvement, although the clinical trial approval is still granted by each national competent authority. 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.

As of January 31, 2025, all new or ongoing clinical trials in the European Union are subject to the requirements of the Clinical Trials Regulation (and the Clinical Trial Directive no longer applies).

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, with a focus on traceability, apply to clinical trials of ATMPs. 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.

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 applicable legislation as 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.

The sponsor of a clinical trial must register the clinical trial in advance, and information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial will be made public as part of the registration. The results of the clinical trial must be submitted to the competent authorities and, with the exception of non-pediatric Phase 1 trials, will be made public at the latest within 12 months after the end of the trial.

During the development of a medicinal product, the European Medicines Agency, or EMA, and national medicines regulators within the European Union provide the opportunity for dialogue and guidance on the development program. At the EMA level, this is usually done in the form of scientific advice, which is given by the Scientific Advice Working Party of the Committee for Medicinal Products for Human Use, or CHMP. A fee is incurred with each scientific advice procedure. Advice from the EMA is typically provided based on questions concerning, for example, quality (chemistry, manufacturing and controls testing), nonclinical testing and clinical studies, and pharmacovigilance plans and risk-management programs. Advice is not legally binding with regard to any future marketing authorization application of the product concerned.

Marketing Authorization

To obtain a marketing authorization for a product under the European Union regulatory system, a sponsor must submit a marketing authorization application, or MAA, either under the centralized procedure administered by the EMA or one of the procedures administered by competent authorities in European Union member states (decentralized procedure, mutual recognition procedure, or if the product is to be approved in only one member state, the national 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 certain of the manufacturing or quality information is currently generally protected as commercially 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. The full operation of this policy has been suspended in recent years due to priorities. However, it continues to apply the policy to COVID-19 vaccines and therapeutics and any medicines with new active substances that received a CHMP opinion from September 2023 onwards or were

withdrawn before the opinion stage. A similar transparency requirement is contained in the Clinical Trials Regulation (EU) No 536/2014.

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 and European Economic Area member states. Pursuant to Regulation (EC) No. 726/2004, the centralized procedure is compulsory for specific products, including for medicines (including vaccines) 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 is 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 and vaccines) 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 will contain specific obligations to be fulfilled by the marketing authorization holder, including obligations with respect to the completion of ongoing or new studies, manufacturing information 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.

During the COVID-19 pandemic, the EMA followed a "rolling review" process for COVID-19 vaccines, which is an ad hoc procedure by which data is assessed as it becomes available with the aim of granting a conditional marketing authorization.

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 states. 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 (referred to as the "sunset" clause).

Emergency Use Distribution

The European Union medicines rules, as implemented into the national laws of the EU member states, permit national authorities to authorize temporarily the distribution of an unapproved medicinal product in certain emergency situations, including suspected or confirmed spread of pathogenic agents. Such an emergency use distribution, or EUD (sometimes referred to as a "temporary exemption," i.e., a temporary exemption from the requirement to obtain a marketing authorization), would apply for the duration of the emergency only and would be limited to the member state in which it has been issued. When considering whether to grant an EUD, the relevant member state decides, which data it requires for the grant of the EUD. COVID-19 vaccines to date have followed the centralized procedure, which was previously combined with a rolling review of data with a view to granting conditional marketing authorizations.

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 or efficacy 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 (including vaccines) 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 and the enforcement of these rules are governed by regulations in each member state and can differ from one country to another.

The enforcement actions and consequences for non-compliance with the EU legislation are similar to those listed above for the United States. For centrally approved products in the EU, there is the possibility of fines for regulatory non-compliance with certain of the legal requirements, including in relation to obligations regarding placing the product on the market, safety monitoring and pediatric compliance.

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 and Compassionate Use Programs

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.

Some member state laws also provide for compassionate use on a “cohort” basis, subject to review and approval of the cohort program based on the local laws in the member state.

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 orphan market exclusivity. During this orphan 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.

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.

C. 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 U.S. federal and state and other non-U.S. 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 or non-interventional study that compares the cost effectiveness of any product candidates we may develop to other available therapies. The conduct of such a clinical trial or study 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. The European Union recently adopted Regulation (EU) 2021/2282 on health technology assessment, which provides a framework for member states to cooperate on health technology assessments at the EU level. The Regulation is directly applicable in all EU member states which is in a phased period of applicability since January 12, 2025, although pricing will still be determined nationally. Moreover, at the national level, 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.

For COVID-19 vaccine candidates in the European Union, no pricing and reimbursement or health technology assessments discussions have taken place with the respective health insurances and competent bodies at a national member state level. Currently, COVID-19 vaccine candidates are supplied in the European Union based on vaccine supply agreements with the European Commission that is acting on behalf and in the name of the member states of the European Union.

D. United Kingdom

Following the UK's withdrawal from the European Union on January 31, 2020, the Trade and Cooperation Agreement, or the TCA, which formally entered into force on May 1, 2021, serves as the primary treaty defining the political and economic relationship between the UK and the European Union after such withdrawal. While the TCA governs tariff and quota free trade between the United Kingdom and the European Union markets, it does not provide for regulatory alignment. The regulatory framework for medicinal products in the United Kingdom is predominantly derived from European Union law. The UK currently offers different routes to obtain a marketing authorization: (a) a national application route with a 150-day assessment timeline, excluding clock stops or (b) an international recognition route by which a company relies on a positive CHMP opinion or an approval granted by another reference regulator, including the FDA and the Japanese PDMA. The international recognition procedure takes 60 days with no clock stops for simpler applications that were approved by the reference regulator within the past two years and 110 days with the possibility of a clock stop for all other eligible applications.

Clinical trial rules in the UK are based on the wording of the previous European Union Clinical Trials Directive 2001/20/EC, although the UK recently updated its legislation governing clinical trials pursuant to the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025. The reforms retain the core requirements of clinical trial regulation, including the need for both regulatory and ethics committee approval, but introduce procedural changes such as a combined regulatory and ethics committee review process, streamlined and accelerated assessments for low intervention clinical trials, and enhanced transparency obligations.

Domestic United Kingdom law provided that all existing European Union law in force on December 31, 2020 was retained in UK national law, subject to certain revisions that became necessary as a result of Brexit. However, the Retained EU Law (Revocation and Reform) Act 2023 came into force on January 1, 2024. This revoked some retained EU laws (although not any relating to medicines regulation). All other retained EU laws have been renamed as "assimilated laws" and are no longer subject to the EU principles of interpretation. Thus, while at

least initially the United Kingdom and the European Union laws relating to medicines are largely aligned, there is the potential for further divergence in the future.

Under the terms of the Northern Ireland Protocol to the Withdrawal Agreement, European Union law governing medicinal products continued to apply to and in Northern Ireland resulting in the potential for separate marketing authorizations in Great Britain and Northern Ireland. In March 2023, the Northern Ireland Protocol was adjusted by the Windsor Framework, which is another post-Brexit agreement between the EU and the UK. The Windsor Framework aims to make it easier to move certain goods, including medicines, from Great Britain to Northern Ireland. Beginning January 1, 2025, medicines for supply in the UK are now authorized UK-wide by the Medicines and Healthcare products Regulatory Agency (MHRA) only and companies can no longer apply for, or maintain, separate licenses for Great Britain and Northern Ireland to market new medicines. Other key changes introduced by the Windsor Framework include removing the requirements of the EU Falsified Medicines Directive (FMD) from products intended for Northern Ireland and a requirement that all medicines placed on the UK market be labeled “UK Only.”

E. Greater China

Mainland China

Similar to the United States and the European Union, Mainland China has rules governing the approval for development and commercialization of drugs, including specialized rules for vaccines. China’s drug law and regulations require that NMPA’s Center for Drug Evaluation, or CDE, approve a clinical trial application prior to initiating a study to support the safety and effectiveness of a drug, including a therapeutic or preventive biologic (i.e., a vaccine). This clinical trial application generally takes approximately 60 business days but may be expedited to 30 business days in the case of innovative drugs that meet certain conditions.

Once approved, vaccine clinical trials must be conducted at sites that are qualified disease prevention and control, or CDC, institutions and grade III hospitals, and the implementation of the trial must be in accordance with China’s general drug and specialized vaccine good clinical practice regulations and related guidelines. Other drug trials must be conducted at designated hospital sites in accordance with China’s general drug good clinical practice rules. Furthermore, prior to the commencement of the clinical trial in China each site’s ethics committee must approve the trial, and the National Health Commission must approve the collection and use of certain human samples containing genetic material and related genetic data. The human genetic resources, or HGR, approval requires a joint approval or record-filing application by the Chinese and foreign parties, setting forth the parties that will handle data and samples, the type and amount of samples that will be utilized during the study, the tests/analysis run, and the plans for storage or destruction, and potentially the intellectual property sharing arrangement among the parties, among other items. If the research is exploratory (i.e., not tied to a program designed to obtain registration in China), patentable IP arising from the use of the HGR samples and data must be jointly owned by the Chinese and foreign parties. Once approved, the HGR approval/filing may require updates and amendments and additional procedures to transfer data to foreign parties that are not on the approval. A final report is due at the end of the study.

Once a clinical trial in China is complete and/or foreign data is assembled, a company may submit an application for a marketing authorization, or MA, of the drug. This procedure will include submission of pre-clinical and clinical data, manufacturing information and test results, among other items, and may include an onsite pre-market verification by the Center for Food and Drug Inspections of NMPA. This application may be considered more quickly if the applicant qualifies for admission to various expedited programs, including breakthrough designation for drugs that are new to the world in some respect, treat life threatening or quality of life altering diseases and either have no comparator on the market or represent a significant clinical advantage over existing approved therapies. Conditional approval procedures permit approval of a drug based on earlier stage data, but subject continued marketing to the fulfillment of post-market conditions with a designation period of time, such as the completion of additional studies. Therapeutic biologics and small molecule drugs follow similar steps to approval for development and marketing. These steps are similar for drugs that are imported and those that are

produced domestically in China. However, domestically produced drugs must be produced at a facility that also obtains a drug manufacturing license based, in part, on a pre-marketing good manufacturing practice inspection.

At both the clinical trial and MA stages, applicants for imported drugs must list a regulatory agent on the application. The agent must be an entity in China. An imported drug MA holder must also make a filing to a provincial level government appointing a domestic responsible entity, which is an entity that assists the marketing authorization holder, or MAH, with fulfilling its post-market drug regulatory obligations in China. The domestic responsible entity of the MAH is jointly liable with the MAH for these drug regulatory obligations.

Once approved, vaccines may be procured by the CDC through platforms organized by the provincial governments. Vaccines in China must be sold and directly distributed by domestic manufacturers or general distributors appointed to represent overseas makers to municipal level CDCs, which handle allocation and distribution to points of vaccination in China. Distribution of other drugs occurs through procurement processes for sales at public hospitals or sales to private hospitals or pharmacies. Distributors of all drugs must possess a MA for the drug they are distributing for wholesale or a drug distribution license for wholesale or retail activities.

As is the case with all drugs, once on the market, MAHs will also have post-market obligations, including fulfillment of post-marketing commitments that were part of the grant of their MA. In the case of vaccines, MAHs must pay compensation for injuries caused adverse events following inoculation, or AEFIs, if the vaccine is not one required as part of the National Inoculation Program. The government bears the cost of NIP vaccines and related AEFIs. All drug MAHs are subject to other post-market obligations for drug marketing authorization holders, including recalls, adverse reaction reporting, annual reporting, and inspections. All drug MAs must be renewed every five years, and supplemental applications, notifications, or reports may need to be submitted for major, moderate and minor changes, respectively, to the original registration (e.g., significant manufacturing changes).

Advertisements of prescription drugs, including vaccines, must be pre-approved and may only be placed in approved medical journals. Other forms of “academic promotion” may be performed by medical representatives who are authorized in writing by MAHs (or their agents) and their information filed on government designated websites. Currently, medical representatives are permitted to provide information about the drug to health care professionals (in accordance with certain procedural rules) and collect feedback as to drug safety, although a proposed revision to this rule may further restrict the activities of the medical representatives.

Hong Kong and Macao

Mainland China’s drug regulatory system does not apply in Hong Kong or Macao. These administrative regions are governed by separate laws on the development, approval, manufacturing, distribution and advertising and promotion of drugs, including vaccines. Similar rules restricting advertising and promotional content and, in the case of Macao, government approved advertisements, also apply.

F. Türkiye

Other countries such as Türkiye and those in the Middle East have regulatory review processes and data requirements for medicinal products, including vaccines, similar to those described for the European Union. The regulatory licensing process in these countries may include local marketing authorization requirements, manufacturing/testing facility inspections, testing of drug product upon importation and other domestic requirements. Some countries, such as Türkiye, have introduced specific emergency authorization regimes for COVID-19 vaccines.

G. Rest of the World Regulation

The requirements governing the conduct of clinical trials, product (including vaccine) licensing, pricing, and reimbursement vary from country to country in markets outside the European Union and the United States. In many markets, clinical trials must be conducted in accordance with Good Clinical Practice and applicable

regulatory requirements. Ethical standards typically follow the Declaration of Helsinki principles. In response to the COVID-19 pandemic, some markets have granted or are considering the grant of emergency use authorizations for vaccine candidates instead of the otherwise available regulatory approval pathways. Supply of the COVID-19 vaccine to a number of countries outside of the United States and the European Union is similarly governed by vaccine supply agreements with local governments.

In Africa, there is limited harmonization of the regulation of drug and biological products across the continent, and the functionality and regulatory capacity of national medicines regulatory authorities varies between jurisdictions. For example, many regulators lack the technical expertise to independently assess marketing authorization applications and instead have adopted "reliance" procedures, whereby authorization by a foreign stringent regulatory authority or registration as a WHO pre-qualified product may be a condition for approval. The African Union ("AU") has issued several harmonization initiatives for medicines, including adopting the AU Model Law on Medical Products Regulation in 2016 and establishing the African Medicines Agency, or AMA, in 2019. The AMA's responsibilities will include evaluating medicines for the treatment of priority diseases, among other harmonization-related responsibilities, but has yet to issue any regulatory guidelines or procedures to date.

Failure to adhere to regulatory requirements may lead to, among others, fines, suspension or withdrawal of regulatory authorizations or approvals, product recalls, seizure of products, restrictions or suspensions of operations, or criminal prosecution.

H. 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 in the United States and elsewhere 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 U.S. 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 U.S. 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 U.S. 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;

- U.S. federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- U.S. 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 laws and regulations in U.S. states and other jurisdictions, such as U.S. 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 U.S. 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. Laws in U.S. states and other jurisdictions 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. U.S. 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.

I. Current and Future Healthcare Reform Legislation

In the United States and other 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 product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates 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 incoming new United States presidential administration may seek to pursue different or additional approaches to drug pricing and reimbursement or could seek additional legislation affecting drug pricing, either of which could affect future profitability.

Additionally, other federal health reform measures have been proposed and adopted in the United States in recent years:

- 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 in the United States and elsewhere 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 U.S. federal government, state legislatures, and other 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 U.S. 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.

J. Packaging and Distribution in the United States and Other Jurisdictions

If our products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply in the United States (and similar laws may apply in other jurisdictions). 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.

K. Other Environmental, Health and Safety Laws and Regulations

In the United States, the European Union and other jurisdictions, 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.

L. Regulation of Artificial Intelligence Systems and Models

Government authorities in the United States at the federal, state and local levels have been actively engaged in advancing policy frameworks, guidance documents, discussion papers, standards, and proposed legislation regarding the development and use of AI by life sciences companies and, where applicable, applying existing regulatory frameworks (e.g., FDA regulations) to particular uses of AI. Likewise, the EU and other countries and jurisdictions extensively regulate (or intend to extensively regulate) the development and use of AI systems and models. The processes for monitoring emerging regulatory frameworks, evaluating how current and emerging requirements for AI apply to our business, along with subsequent compliance with applicable requirements and best practices, require the expenditure of substantial time and financial resources.

A biotech company could use AI in a number of different contexts. For example, it may use AI in the medicines lifecycle for drug discovery, for non-clinical research and development, for data analysis in clinical trials and analysis of real world data, for precision medicine (e.g., clinical decision support), for supporting clinical trial design or assessing patient eligibility for clinical trials, for drafting medicinal product information documents, in the manufacturing of medicinal products and in machinery, or to assist with post-authorization safety monitoring, among other potential uses. If the AI is intended to perform a regulated activity (such as related to drug manufacturing, release testing, or producing clinical/diagnostic outputs) or otherwise be used in operations that are the subject of scrutiny by health authorities, the use of AI could trigger health authority oversight and, in some cases, application of existing laws and regulations relevant to healthcare, pharmaceuticals, and/or medical devices or sector-agnostic AI laws and regulations.

Outside the drug development and commercialization context, a biotech company may use AI for other operational reasons. For example, a company may have plans to use automated personnel recruitment tools, deploy facial recognition technology to ensure security of its services, use customer service chatbots, or allow its employees to use generative AI or general-purpose AI tools to increase the efficiencies of administrative tasks.

A company will need to identify how it uses AI in its business operations, and identify the relevant applicable regulatory regime that applies to ensure compliance. Failure to adhere to (or remain up to date with evolving) regulatory requirements may lead to compliance actions, penalties and other risks.

United States

In the United States, Congress, the White House, various federal agencies, and states have advanced proposed AI legislation, policy frameworks, guidance documents, whitepapers, and governing principles to address the use of AI, including when used in healthcare and life sciences. Of particular relevance to biotech companies, the FDA has been adapting and applying existing regulatory frameworks to account for AI and has issued guidance, discussion papers, and frameworks outlining FDA's approach to regulation and oversight of health-related uses of AI. To date, FDA has not issued a new regulatory framework specific to AI; rather, it has been applying its existing regulations for drug and biologic discovery, development, clinical testing and manufacturing to companies utilizing AI in these processes, such that companies seeking to incorporate AI into processes that are subject to FDA oversight need to demonstrate compliance with the existing regulations for drug and biologic sponsors. In this context, FDA issued two discussion papers on the use of AI in drug manufacturing (March 2023) and the development of drug and biological products (May 2023), and hosted a related public workshop in August 2024. Following feedback on the discussion papers and the workshop, in January 2025, FDA issued its first draft guidance document regarding uses of AI in drug development and other parts of the drug lifecycle, entitled "Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products." AI to support regulatory decision-making, within the scope of the draft guidance, includes AI intended to support regulatory determinations made by FDA (e.g., with respect to safety or effectiveness of a drug in a New Drug Application) *and* to support actions taken by sponsors in conformance with FDA's regulatory authority (e.g., current good manufacturing practices, post-marketing requirements, and INDs). The draft guidance proposes a seven-step risk-based framework for assessing the risk and credibility of AI models intended to support regulatory decision-making to determine whether the AI model is adequate for a specific use, and describes the associated documentation FDA may expect to review in an application or during an inspection.

FDA also actively regulates some health-related AI as "software as a medical device," or SaMD, under FDA's existing medical device frameworks and has issued guidance describing specific regulatory considerations that may apply to AI-based SaMD. Most recently, FDA issued draft guidance in January 2025 on lifecycle management and marketing submission recommendations for AI-enabled device software functions, and hosted its inaugural Digital Health Advisory Committee meeting in November 2024 to discuss total product lifecycle considerations for generative AI-enabled devices.

Additionally, at the executive level, the Trump Administration revoked a Biden Administration Executive Order on the Safe, Secure, and Trustworthy Development of Artificial Intelligence that Order contained a number of directives that would have impacted the life sciences sector, including directives to HHS to establish an AI "Task Force" responsible for issuing guidance on a number of AI topics (such as long-term safety and real-world performance monitoring, predictive and generative AI, equity principles, and privacy and security standards), develop a strategy for regulating the use of AI in drug development processes, develop an "AI assurance policy" to evaluate the performance of AI-enabled healthcare tools, and establish a common framework for capturing clinical errors resulting from AI deployed in healthcare settings. The Trump Administration issued a new Executive Order in January 2025 on Removing Barriers to American Leadership in Artificial Intelligence that established a policy of "global AI dominance" and directed entities to suspend, revise, or rescind any actions taken under the Biden Administration Executive Order that are inconsistent with this policy.

Members of Congress also have introduced a number of bills on AI regulation and frameworks for regulating AI. For example, the Bipartisan House AI Task Force released an AI report in December 2024 and the Bipartisan Senate AI Working Group released a roadmap for AI policy in May 2024, both of which included sections on policy recommendations for AI in health care. Senator Bill Cassidy (R-LA), who now chairs the Senate Health, Education, Labor, and Pensions Committee, also released a whitepaper on the "Framework for the Future of AI" in September 2023 that disfavored a "one-size-fits-all" approach to AI regulation and instead called for a flexible approach that takes into account the context of use and leverages existing frameworks.

U.S. state legislatures also have actively pursued AI legislation. For example, the Colorado AI Act imposes requirements for developers and deployers of certain high-risk AI systems, and other laws will require notice or disclosures for certain uses of generative AI or other AI systems. In addition to proposed and passed legislation, regulators have sought to apply existing legal authorities to AI systems, including in the life sciences sector. For example, the California Attorney General issued a legal advisory providing guidance to healthcare providers, vendors, investors, and other healthcare entities that develop, sell, and use AI systems and similar technologies. The advisory advised entities on their obligations under existing California law and described certain health-related uses of AI or marketing practices that might be unlawful.

We continue to monitor developments in the regulation of AI in drug and biologic development and commercialization, or for more general business practices, and to assess the applicability of these evolving frameworks and policies as well as existing legal frameworks that apply to our uses of AI. If we fail to meet regulator expectations or comply with applicable requirements, that could impact our ability to utilize AI-related processes or information in our development of product candidates or could subject us to delays, penalties or other risks.

European Union

The EU Artificial Intelligence Act, or the EU AI Act, entered into force on August 1, 2024. It establishes rules governing certain AI systems and general-purpose AI models that apply across the EU. It applies to various actors along the AI value chain, including "providers" and "deployers" of AI systems classified as "high-risk," "providers" of general-purpose AI models, and "providers" of general-purpose AI models with "systemic risk." It also prohibits certain AI practices and imposes transparency requirements in relation to certain AI systems and general-purpose AI models.

The EU AI Act sets out a transition period of two years (by August 2026) for most provisions, with the following exceptions: (i) the provisions relating to prohibited AI practices and AI literacy apply after six months (by February 2025); (ii) the provisions relating to general-purpose AI models and the AI Act's governance framework apply after one year (by August 2025); and (iii) the provisions relating to high-risk AI systems that are used as safety components of products or are themselves products regulated by certain EU harmonization legislation (e.g., machinery, medical devices) requiring third-party conformity assessments apply after three years (by August 2027).

The EU AI Act applies to providers, located in or outside the EU, that place on the market or put into service AI systems in the EU, or that place on the market general-purpose AI models in the EU. It also applies to deployers of AI systems located or established in the EU, and to providers or deployers located or established outside the EU where the output of the system is used in the EU. Whether a biotech company incurs obligations under the EU AI Act depends on whether it develops, offers, or uses any AI systems or general-purpose AI models; whether it qualifies as a "provider," "deployer," or other regulated actor; and the jurisdiction where the system is put into service, where the system or model is placed on the market, or where the output of a system is used.

Providers and deployers of "high-risk AI systems" will need to comply with numerous obligations that apply to such systems. The obligations for providers and deployers differ, with the majority of obligations falling to providers. The EU AI Act also contemplates circumstances where a deployer or other third-party must assume the obligations of the provider, e.g., where the third-party makes a substantial modification to a high-risk AI system that has already been placed on the market or put into service, but where the modified system remains high risk. The EU AI Act sets out an exhaustive list of "high-risk AI systems" in Annexes I and III. The categories of such systems that might be relevant to offerings of biotech companies include products that require a notified body conformity assessment under the EU Medical Devices Regulation 2017/745 or EU In Vitro Diagnostic Medical Devices Regulation 2017/746.

The EU AI Act imposes a separate set of obligations on providers of "general-purpose AI models" and an additional set of obligations on providers of "general-purpose AI models with systemic risk." The European Commission will designate general-purpose AI models that have "high-impact capabilities" as models with "systemic risk." Providers of general-purpose AI models—with or without "systemic risk"— must comply with certain obligations, including to draw up technical documentation about the general-purpose AI model, implement a copyright policy to comply with EU copyright laws, and make available a summary of the content used to train the model. Additional obligations apply to providers of general-purpose AI models with systemic risk, including, for example, to perform model evaluation (such as adversarial testing) and to report serious incidents to the European Commission's AI Office. Whether these obligations apply to a biotech company will depend on whether it develops any general-purpose AI models (or have them developed on its behalf) and places them on the market in the EU. If so, it will need to comply with the obligations that apply to all general-purpose AI models and assess whether any of these models could qualify as general-purpose AI models with systemic risk, which would require it to comply with additional obligations.

Of particular relevance to the biotech industry, the EMA has published a reflection paper on the use of AI (September 2024), which is aimed at biopharmaceutical companies intending to use AI in the lifecycle of their medicines, including for drug discovery, design, and development. It also covers the use of medical devices with AI/machine-learning (ML) technology that are used to generate data or other evidence to support an EU marketing authorization for a medicine (i.e., used within the context of clinical trials or combined with the use of a medicine). The EMA's view of "high patient risk" or "high regulatory impact" that AI can have differs from the classifications used in the EU AI Act. This requires biotech companies to assess whether the use of AI could affect patient safety ("high patient risk") or impact regulatory decision-making ("high regulatory impact") for the purpose of the EU medicines rules. This means that potentially, non-high-risk AI under the EU AI Act could still be relevant to the EMA if it impacts patient safety or evidence generation for a medicine subject to regulatory approval. The EMA guidance puts the onus on marketing authorization applicants/marketing authorization holders to ensure AI used during the medicines lifecycle is compliant with the medicines rules. If a biotech company intends to use AI in the context of its medicines it will need to carry out a regulatory impact and risk analysis and potentially discuss use cases with the EMA, including when there is no clearly written guidance available.

Failure to adhere to (or remain up to date with evolving) EU regulatory requirements may lead to delays, compliance risks, and penalties.

Rest of World

Outside the United States and EU, the requirements governing the use and deployment of AI may vary from country to country, though health regulators have taken some steps toward international harmonization on AI best practices. For example, FDA, UK MHRA, and Health Canada have issued joint guiding principles on topics such as good machine learning practices and transparency for ML-enabled devices. A company will need to identify how it uses AI in its business operations, and identify the relevant applicable regulatory regime that applies to ensure compliance. Failure to adhere to (or remain up to date with evolving) regulatory requirements may lead to delays, compliance risks, and penalties.

X. Intellectual Property

A. Introduction

We pursue a layered intellectual property strategy to protect our various technology platforms and their application to the treatment of serious diseases, such as cancer and infectious diseases including COVID-19. One focus of our intellectual property strategy is to provide protection for our platforms and products as they are developed. We also pursue intellectual property protection for assets that may be used in future development programs, may be of interest to our collaborators, and/or otherwise may prove valuable in the field.

Various aspects of our technology platforms and our product candidates are claimed in patent filings. We also pursue other modalities of intellectual property 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 and/or product candidates, as developments arise or are identified.

Regardless, 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 products as commercialized. As further variants of SARS-CoV-2 arise, and its impact and characteristics evolve, the composition, manufacture, and use (including, e.g., dosage regimen) of our COVID-19 vaccine products may be adjusted or modified and our filings may not protect them.

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 Intellectual Property” in this Annual Report.

As of January 1, 2026, our overall owned and in-licensed patent portfolio included more than 600 patent families, each of which includes, or can in the future include, 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 560 patent families

that are solely or jointly owned by BioNTech, including certain families acquired through our acquisitions and others 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. We did not extend any patent for our COVID-19 vaccine (*Comirnaty*) when it was approved by the FDA in the United States in 2021. 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 U.S. 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 patent terms for filings included in the portfolio that are directed to such aspects. Particularly given our pre-commercial state of development for many product candidates, we cannot be certain that any of the patent filings in our portfolio will provide meaningful protection for products that we do or 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 to the USPTO and similar authorities for examination 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 our COVID-19 vaccine and in current development candidates. Our patent portfolio also includes patent filings directed to mRNA formulations (including their production and use), including the lipoplex formulations currently utilized with our *FixVac* and iNeST platforms, and the lipid nanoparticles currently utilized with our mRNA, *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 and related features, 3' UTR structures, polyA tails, reduced-uracil content mRNAs, and modified nucleoside RNAs. Filings directed to each of these features, and/or to RNA constructs that include them (singly or in combination), or collectively, the mRNA Structure Filings, have been made in the United States and various other jurisdictions. Some such mRNA Structure Filings are owned solely by BioNTech SE, 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. We have non-exclusive rights to use certain U.S. and European patent filings owned by University of Pennsylvania and relating to RNA containing modified nucleosides through our sublicense agreements with mRNA RiboTherapeutics, Inc. (MRT) and CellScript, collectively, the MRT-CellScript Sublicenses, and 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 early-2040s.

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 and preparations thereof or collectively, the mRNA Lipoplex Filings. Issued mRNA Lipoplex Filing(s) has/have, and pending existing mRNA Lipoplex Filings, if issued, would have, 20-year terms that extend into the mid to late-2030s or early 2040s. Such mRNA Lipoplex Filings are solely owned by BioNTech or jointly owned by BioNTech and TRON.

In addition, our portfolio includes U.S. and other patent filings directed to lipid nanoparticles and polyplex technologies, which are solely owned by BioNTech or jointly owned by BioNTech 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 or early 2040s. Some of such mRNA Lipid Nanoparticle/Polyplex Filings were granted in certain foreign jurisdictions, and currently include 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 other patent filings relating to certain aspects of mRNA purification and production. These mRNA Manufacturing Filings are either solely owned by BioNTech, or jointly owned by BioNTech and TRON and, if issued, would have 20-year terms that would extend into the mid- 2030s to early 2040s; there are patents granted in certain foreign jurisdictions including EP and U.S..

mRNA Commercial Products and Product Candidates

Our COVID-19 vaccine (BNT162b2), marketed as *Comirnaty*, is our most advanced mRNA product. Additional COVID-19 vaccine candidates, as well as various dosing regimens and use in patient populations with certain medical conditions are being tested in clinical trials.

Comirnaty and Other COVID-19 Vaccine mRNA Product Candidates

Both our current and previously-marketed monovalent and bivalent COVID-19 vaccines utilize modified-nucleoside mRNA formulated in lipid nanoparticles.

Our platform patent filings relevant to our COVID-19 vaccines, collectively, the "BNT162b2 Platform Filings", include certain mRNA Structure Filings relating to features for increasing translation efficiency and/or stability of mRNA constructs (e.g., certain 3' UTR structures containing a specific sequence element, interrupted polyA tails, and certain 5' cap/cap proximal sequence combinations), including filings that are jointly owned by BioNTech and TRON; also relevant are certain mRNA Manufacturing Filings. Issued BNT162b2 Platform Filings have, and pending BNT162b2 Platform Filings, if issued, would have 20-year terms extending into the late-2020s to the

early-2040s. We also have undertaken various patent filings specifically related to the BNT162b2 structure (including as may be tailored based on particular SARS-CoV-2 variants), composition, formulation, packaging, use and/or manufacture, collectively the BNT162b2 Filings, including filings that have arisen through collaboration with third parties such as Pfizer. Such filings relevant to our COVID-19 vaccines, if issued, would have 20-year terms that would extend into the early 2040s.

As noted above, our MRT-CellScript Sublicenses grant us rights to use certain U.S. and European patents and applications relating to mRNA containing modified nucleosides, including as used in BNT162b2. We also have a non-exclusive license from the National Institutes of Health granting us a right to use certain technology described in U.S. and European patent filings that may relate to SARS-CoV-2 spike (S) protein mutations that lock the S protein in an antigenically preferred prefusion conformation; such a variant is utilized in BNT162b2.

Additionally, we have obtained third-party licenses to technologies relating to certain lipids and/or lipid nanoparticles and formulations used in BNT162b2, including a non-exclusive license from Acuitas granting use rights relevant to proprietary lipid nanoparticles and formulations used in BNT162b2.

Additional COVID-19 vaccine mRNA product candidates are being developed and tested in clinical trials, which share with BNT162b2 certain structural elements, and/or features of the composition, formulation, packaging, use and/or method of manufacture. Thus, some or all of the BNT162b2 Platform Filings and/or BNT162b2 Filings, as well as the in-licensed rights discussed above with respect to BNT162b2, may be relevant to certain of these candidates.

Moreover, we are currently studying safety and efficacy of our COVID-19 vaccines and vaccine candidates in various dosing regimens (including booster doses) and/or in different age groups and/or individuals with various medical conditions, and also in combination with other vaccines or therapies. Certain of our patent filings, including certain BNT162b2 Filings, cover such uses being tested in clinical trials.

Oncology mRNA Product Candidates

Certain mRNA oncology product candidates are also in clinical development and involve various platforms.. Some of our most advanced clinical oncology programs involve our iNeST immunotherapy product candidates being developed with our collaborator, Genentech. We also have *FixVac* product candidates in clinical trials.

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 and mRNA Lipoplex Filings relevant to our iNeST product candidates and discussed below 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 other 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 and TRON.

Our current clinical trials for *FixVac* product candidates are studying such product candidates in treatment of various cancers. 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 these indications, and if issued, would have 20-year terms extending into the mid-2030s.

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 other 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. Many of the Neoantigen Filings are solely owned by BioNTech, or jointly owned by BioNTech and TRON; our acquisition of Neon Therapeutics, Inc., or Neon, added various Neoantigen Filings, including both BioNTech U.S.-owned and in-licensed filings. BioNTech and TRON jointly own issued EP patent number 2714071, whose claims recite steps relating to neoantigen selection, that were unsuccessfully opposed by multiple third parties. Said third parties have unsuccessfully appealed the decision to reject such opposition and the patent was maintained as granted. In addition, related EP patent number 3473267 with claims reciting steps relating to neoantigen selection for an RNA vaccine encoding a recombinant polyepitopic polypeptide was unsuccessfully opposed by a single third party. Said third party has unsuccessfully appealed the decision to reject such opposition and the patent was maintained as granted. Related EP patent number 3892295 from the same patent family with claims reciting steps relating to neoantigen selection for an RNA vaccine encoding a recombinant polyepitopic polypeptide was opposed by a third party; the opposition was rejected, no appeal was filed and the patent is maintained as granted; claims in related U.S. cases are granted. If we are unsuccessful in any future opposition/appeal proceedings, 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 Intellectual Property" in this Annual Report.

We are currently studying our iNeST product candidates in several 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.

RiboMab and RiboCytokine

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 that are also relevant to our iNeST and/or *FixVac* product candidates, including certain patent filings relating to 3' UTR structures containing a specific sequence element, and interrupted polyA tail structures; and patent filings under the MRT-CellScript Sublicenses relating to nucleoside-modified mRNAs as well as certain patent filings we have licensed from Acuitas and Genevant relating to lipid or non-liposomal formulations.

Infectious Diseases beyond COVID-19

Certain patent filings that might be useful to our infectious disease mRNA vaccines beyond our COVID-19 vaccine program 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 and/or trans-amplifying RNAs may also be relevant, including filings jointly owned by BioNTech SE and TRON; such filings are collectively referred herein as Amplifying RNA Filings. Such Amplifying RNA Filings, if issued, would have 20-year terms that extend into the late-2030s to early-2040s. These Amplifying RNA Filings currently include granted patents in Europe and the United States. We have also undertaken and continue to undertake filings specific to particular product candidates.

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.

2. Cell Therapy

Engineered Cell Therapy

Our engineered cell therapy product class features the use of chimeric antigen receptor, or CAR-, T cell or individualized T-cell receptors (TCRs) for oncology therapy. Our patent filings relevant to these platforms and product candidates, or the CAR-T/TCR Filings, are generally solely owned by BioNTech SE or co-owned by BioNTech SE 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 compositions of matter comprising individualized T-cell receptors. The CAR-T/TCR Filings, if issued, would have patent terms that would extend into the mid-2030s to mid-2040s.

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 SE and TRON, 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. The terms of our co-ownership of such patent filings with TRON are summarized below in "—C. In-Licensing."

3. Antibodies

Our antibodies product class features bispecific checkpoint immunomodulators for oncology therapy, which are developed through collaboration with Genmab. Our development candidates include bispecific antibodies that are designed to activate 4-1BB upon simultaneous binding to CD-40 or EpCAM. 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.

Our collaboration with Genmab also includes development of monospecific antibody candidates to address malignant solid tumors. For example, BNT313 is a CD27 antibody based on Genmab's proprietary HexaBody technology platform, specifically engineered to form an antibody hexamer (a formation of six antibodies) upon binding its target on the cell membrane of the T cells. We have also undertaken and continue to undertake filings specific to particular product candidates.

Our patent portfolio also includes certain patent filings relevant to the structure of pumitamig, a bispecific antibody targeting PD-L1 and VEGF-A, collectively the Pumitamig Filings. Such Pumitamig Filings, if issued, would have 20-year terms into the early 2040s.

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. Certain of these filings are directed to substituted imidazoquinolines, and, if issued, would have 20-year terms that would extend into the late 2030s.

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. In addition to the agreements described in the section "—B.VIII. Third-Party Collaborations" above, we have entered into material intellectual property licensing or option arrangements with Acuitas, MRT-CellScript, the NIH, and TRON.

The key terms of these arrangements are summarized below.

Acuitas License Agreement

In April 2020, we entered into a Non-Exclusive License Agreement with Acuitas, or the Acuitas License Agreement. Under the Acuitas License Agreement, Acuitas grants us a non-exclusive worldwide license, with the right to sublicense (subject to certain conditions) under Acuitas' LNP technology to develop, manufacture and commercialize licensed products directed to the SARS-CoV-2 surface glycoprotein. We have the option to convert the non-exclusive licenses to exclusive licenses subject to certain additional financial obligations.

Under the Acuitas License Agreement, we must pay Acuitas up to between approximately $1.6 million and $2.45 million in development milestone payments, $2.5 million and $3.75 million in regulatory milestone payments and $2.5 million and $3.75 million in commercial milestone payments upon the occurrence of certain milestone events. We are further required to pay Acuitas a low single-digit tiered percentage royalty on net sales of licensed products, subject to certain potential customary reductions. Our royalty obligations continue under the Acuitas License Agreement on a country-by-country and product-by-product basis until the later of (i) the expiration of the last-to-expire licensed valid patent claim covering such licensed product in such country, (ii) expiration of any data exclusivity, market exclusivity or supplemental protection certificates period for such product in such country, and (iii) certain years following the first commercial sale of such product in such country.

The Acuitas License Agreement will continue on a product-by-product and a country-by-country basis until there are no more payments owed to Acuitas for such product in such country. Upon expiration of the Acuitas License Agreement, the license will become fully paid up and will remain in effect. We have the right to terminate the Acuitas License Agreement for convenience following a certain notice period. Either party may terminate the Acuitas License Agreement in the event of a material breach by the other party following a cure period. Alternatively, instead of exercising our right to terminate in the event of Acuitas' material breach, we may elect to instead continue the license but reduce our milestone and royalty payment obligations to Acuitas by a certain percentage. In the event of termination of the Acuitas License Agreement by us for convenience or by Acuitas for our material breach, the licenses granted under such agreement will terminate, except that we will have the right to sell off any remaining inventories of licensed products for a certain period of time.

CellScript and mRNA Ribotherapeutics License Agreement

BioNTech RNA (now merged into BioNTech SE) 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.

NIH License Agreement

On May 27, 2020, we and the HHS, as represented by the National Institute of Allergy and Infectious Diseases, or NIAID, of the NIH, entered into a patent license agreement to facilitate the development of a vaccine against COVID-19, or, as amended and restated on December 20, 2024, the NIH License Agreement. Pursuant to the NIH License Agreement, our royalty obligation on Net Sales (as defined in the NIH License Agreement) of Licensed Products (as defined in the NIH License Agreement, and which includes our and Pfizer's COVID-19 vaccine) is an amount of up to a low single-digit percentage of Net Sales of Licensed Products. The NIH License Agreement also provides a framework for a license for use in Combination Products (as defined in the NIH License Agreement, and which would include the COVID-19 vaccine used in combination with other active pharmaceutical ingredients).

The NIH License Agreement remains in effect until expiration of the licensed patents. We have the right to terminate the NIH License Agreement for convenience with 60 days' prior notice, and NIAID may terminate for our uncured material breach.

TRON Agreements

In 2015, we and our subsidiaries BioNTech RNA (now merged into BioNTech SE), 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 Pharmaceuticals AG, or Ganymed, TRON, Johannes Gutenberg-Universität Mainz and Universitätsmedizin der Johannes Gutenberg-Universität Mainz, or the TRON License Agreement. The TRON Research Agreement and TRON License Agreement together replaced and superseded our 2008 Cooperation, Purchase and Licensing Agreement with the University Mainz, or the 2008 Cooperation Agreement. In 2015, we and our subsidiaries BioNTech RNA (now merged into BioNTech SE), 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.

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, small interfering RNA (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 antigen 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, 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. 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; or (b) the prophylaxis, diagnosis and treatment of oncological diseases, infectious diseases and rare genetic diseases. 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.

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, *BioNTech*, *Comirnaty*, *BioNTainer*, *FixVac*, *RiboCytokine*, and *RiboMab*, including logo versions of some of these trademarks.

Brand names appearing in italics throughout this report are trademarks owned by BioNTech. All other trademarks are the property of their respective owners.

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.

XI. 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.

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 and Pfizer, 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, ease of distribution, storage and administration, 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.

Specifically, our marketed monovalent and bivalent COVID-19 vaccines and any other COVID-19 vaccines we and Pfizer develop compete with other COVID-19 vaccines that have been approved or authorized for temporary or emergency use and a number of vaccine manufacturers, academic institutions and other organizations currently have programs to develop COVID-19 vaccine candidates.

XII. Legal Proceedings

We are and may be involved in various legal proceedings, including patent litigation, product liability and other product-related litigation, as well as other legal proceedings that arise from time to time in the ordinary course of business, including, but not limited to, personal injury, consumer, off-label promotion, securities, antitrust, employment law, tax, environmental, and/or other claims or investigations.

We currently do not believe that any of these matters will have a material adverse effect on our financial position, and will continue to monitor the status of these and other claims that may arise. However, we could incur judgments, enter into settlements or revise our expectations regarding the outcome of matters, which could have a material adverse effect on our results of operations and/or our cash flows in the period in which the amounts are accrued or paid. Our assessments, which result from a complex series of judgments about future events and uncertainties, are based on estimates and assumptions that have been deemed reasonable by management, but that may prove to be incomplete or inaccurate, and unanticipated events and circumstances may occur that might cause us to change those estimates and assumptions.

Certain pending matters to which we are a party are discussed below.

For a description of the risks relating to these and other legal proceedings we face and may in the future face and our assessments thereof, see “Risk Factors” in this Annual Report.

Moderna Proceedings

Germany

Infringement Proceedings – EP'949 and EP'565

In August 2022, Moderna filed a lawsuit against us and Pfizer and our wholly owned subsidiaries, BioNTech Manufacturing GmbH, BioNTech Europe GmbH and BioNTech Manufacturing Marburg GmbH, Pfizer Manufacturing Belgium NV, Pfizer Ireland Pharmaceuticals and Pfizer Inc. in the Düsseldorf Regional Court alleging Comirnaty's infringement of two European patents, 3590949B1, or EP'949, and 3718565B1, or EP'565. With respect to EP'565, on November 7, 2023, the Opposition Division of the EPO revoked EP'565 after a one-day oral hearing held in the co-pending opposition proceeding, and on December 7, 2023, it issued the written decision revoking EP'565. On February 7, 2024, Moderna appealed the Opposition Division's revocation decision on EP'565. An oral hearing on Moderna's appeal was held on January 27, 2026, and at the conclusion of this hearing, the Technical Boards of Appeal affirmed the revocation of EP'565. With respect to EP'949, on December 8, 2023, the Opposition Division issued a preliminary opinion noting that it believes EP'949 is likely invalid. As a result of those developments in the EPO proceedings, the Düsseldorf Regional Court postponed its hearing on infringement with respect to EP'949, originally scheduled for December 12, 2023, to January 21, 2025. On May 16, 2024, the EPO Opposition Division decided that EP'949 is valid, in amended form, and issued its written decision regarding the same on July 8, 2024. We appealed this decision, and the appeal is currently pending, with an oral hearing scheduled for September 2026. The Düsseldorf Regional Court held an infringement hearing on January 21, 2025, and on March 5, 2025, the Düsseldorf Regional Court issued a first-instance decision declining to stay the infringement proceedings and finding infringement of EP'949 by us and Pfizer. We and Pfizer have appealed the Düsseldorf Regional Court's infringement decision, and the appeal is currently pending. The court has not ruled on the invalidity of EP'949, which will be decided in a next step by the EPO in the opposition appeal proceedings. Moderna has not yet taken steps to enforce the Düsseldorf Regional Court's first-instance decision on infringement.

United Kingdom

In August 2022, Moderna filed a lawsuit asserting Comirnaty's infringement of EP'949 and EP'565 against us and our wholly owned subsidiaries, BioNTech Manufacturing GmbH, BioNTech Europe GmbH and BioNTech Manufacturing Marburg GmbH, and Pfizer Limited, Pfizer Manufacturing Belgium NV and Pfizer Inc. in the Business and Property Courts of England and Wales, in the UK High Court. In September 2022, we and Pfizer filed a revocation action in the Business and Property Courts of England and Wales requesting revocation of EP'949 and EP'565.

The UK High Court held a trial between April 22, 2024, and May 21, 2024. On July 2, 2024, the UK High Court released two judgments. The first judgment concerns the validity of EP'949 and EP'565. In this first judgment, the UK High Court found that EP'565 is invalid and therefore not infringed, while EP'949 is valid and infringed. The second judgment concerns whether Moderna's October 2020 commitment not to "enforce [its] COVID-19 related patents against those making vaccines intended to combat the pandemic," or the Patent Pledge, amounted to a consent under UK law to carry out any acts that would otherwise amount to patent infringement. With respect to this judgment, the UK High Court found that Moderna's Patent Pledge amounted to consent to carry out activities that might otherwise infringe its patents prior to March 2022, but not after March 2022.

The UK High Court held a hearing on September 25, 2024, during which the Court granted Pfizer and BioNTech permission to appeal its judgment regarding the validity of EP'949, and declined Moderna's permission to appeal its judgment regarding validity of EP'565. On October 16, 2024, Moderna sought permission from the UK Appeals Court to appeal the EP'565 judgment. On November 11, 2024, the UK Appeals Court denied Moderna's

application to appeal; accordingly, the UK designation of EP'565 is finally revoked with no further opportunity to appeal in UK. No party sought permission to appeal the UK High Court's judgment on the patent pledge.
The UK Court of Appeal held an oral hearing on the appeal of EP'949 on July 10-11, 2025. On August 1, 2025, the UK Court of Appeal issued a judgment agreeing with the UK High Court that EP '949 is valid, and dismissed our appeal. We applied for permission to appeal this decision to the UK Supreme Court, and on December 8, 2025, the UK Supreme Court denied permission to appeal. Accordingly, the UK designation of EP '949 is valid and infringed. However, Moderna has not yet taken steps to enforce this final judgment on infringement. Additionally, EP '949 is currently subject to opposition proceedings at the EPO. The Opposition Division initially issued a preliminary opinion noting that EP '949 is invalid, but in May 2024, issued a first-instance decision finding EP '949 valid. BioNTech and Pfizer appealed this first-instance decision, which is currently pending. The oral hearing in this appeal is scheduled for September 2026.

United States

U.S. District Court Litigation

In August 2022, Moderna filed a lawsuit in the U.S. District Court for the District of Massachusetts against us and our wholly owned subsidiaries BioNTech Manufacturing GmbH and BioNTech US Inc. and Pfizer Inc. alleging Comirnaty's infringement of U.S. Patent Nos. 10,898,574; 10,702,600 and 10,933,127 and seeking monetary relief. On April 12, 2024, the U.S. District Court for the District of Massachusetts stayed the litigation pending resolution of the inter partes review of U.S. Patent Nos. 10,702,600 and 10,933,127.

Inter Partes Review

In August 2023, Pfizer and we filed petitions seeking inter partes review of U.S. Patent Nos. 10,702,600 and 10,933,127 before the United States Patent Trial and Appeal Board, or the PTAB. On March 6, 2024, the PTAB issued decisions instituting *inter partes* review proceedings on all challenged claims of U.S. Patent Nos. 10,702,600 and 10,933,127. An oral hearing on the merits occurred on December 10, 2024. On March 5, 2025, the PTAB found all challenged claims of Moderna's U.S. Patent Nos. 10,933,127 and 10,702,600 to be unpatentable and thus invalid. Moderna appealed this decision on May 6, 2025.

Netherlands

In September 2022, Moderna filed a lawsuit against us and our wholly owned subsidiary BioNTech Manufacturing GmbH and Pfizer B.V., Pfizer Export B.V., C.P. Pharmaceuticals International C.V. and Pfizer Inc. in the District Court of The Hague alleging Comirnaty's infringement of EP'949 and EP'565. The District Court of the Hague held a hearing on October 6, 2023, on infringement and validity with respect to EP'949. On December 6, 2023, the Court found EP'949 to be invalid. On March 5, 2024, Moderna appealed this decision, and the appeal is pending. A hearing on the EP'949 appeal has been set for September 22, 2025, with a decision expected on or around March 31, 2026. The EP'565 case has been stayed pending the outcome of Moderna's appeal of the Opposition Division's revocation of EP'565.

Ireland

In May 2023, Moderna filed a lawsuit against us and our wholly owned subsidiary BioNTech Manufacturing GmbH, Pfizer Inc., Pfizer Healthcare Ireland, Pfizer Ireland Pharmaceuticals, and C.P. Pharmaceuticals International C.V. alleging Comirnaty's infringement of EP'949 and EP'565 in the High Court of Ireland. On February 26, 2024, the High Court of Ireland stayed the lawsuit pending the final determination of the EPO opposition proceedings for EP'949 and EP'565 (in each case including any appeals).

Belgium

In May 2023, Moderna filed a lawsuit against us, our wholly owned subsidiary BioNTech Manufacturing GmbH, Pfizer Inc. and Pfizer Manufacturing Belgium alleging Comirnaty's infringement of EP'949 and EP'565 in the

Brussels Dutch-speaking Enterprise Court. On May 29, 2024, the parties filed a joint request to stay the proceedings, which was entered by the Enterprise Court.

All of the above proceedings are currently pending.

We believe we have strong defenses against the allegations claimed relative to each of the patents and intend to vigorously defend ourselves in the proceedings mentioned above. However, our analysis of Moderna's claims is ongoing and complex, and we believe the outcome of the suit remains substantially uncertain. Taking into account discussions with our external lawyers, we do not consider the probability of an outflow of resources to be sufficient to recognize a provision at the balance sheet date. In our opinion, these matters constitute contingent liabilities as of the balance sheet date. However, it is currently impractical for us to estimate with sufficient reliability the respective contingent liabilities.

Arbutus and Genevant Proceedings

In April 2023, Arbutus Biopharma Corp., or Arbutus, and Genevant Sciences GmbH, or Genevant, filed a lawsuit against Pfizer and us in the U.S. District Court for the District of New Jersey alleging that Pfizer and we have infringed the following patents owned by Arbutus: U.S. Patent Nos. 9,504,651; 8,492,359; 11,141,378; 11,298,320; and 11,318,098, through the use of Genevant's lipid nanoparticle technology and methods for producing such lipids in Comirnaty, and seeking monetary relief. This proceeding is currently pending.

We believe we have strong defenses against the allegations claimed relative to each of the patents and intend to vigorously defend ourselves in the lawsuit mentioned above. However, our analysis of Arbutus and Genevant's claims is ongoing and complex, and we believe the outcome of the suit remains substantially uncertain. Taking into account discussions with our external lawyers, we do not consider the probability of an outflow of resources to be sufficient to recognize a provision at the balance sheet date. In our opinion, these matters constitute contingent liabilities as of the balance sheet date. However, it is currently impractical for us to estimate with sufficient reliability the respective contingent liabilities.

GlaxoSmithKline Proceedings

In April 2024, GlaxoSmithKline Biologicals SA and GlaxoSmithKline LLC, or GSK, filed a lawsuit against Pfizer and us and our wholly owned subsidiaries BioNTech Manufacturing GmbH and BioNTech US Inc. in the U.S. District Court for the District of Delaware alleging that the cationic lipid used in Comirnaty infringes U.S. Patent Nos. 11,638,693; 11,638,694; 11,666,534; 11,766,401; and 11,786,467; and seeking monetary relief. On August 14, 2024, GSK filed an amended complaint to assert infringement of three additional patents, U.S. Patent Nos. 11,759,422; 11,655,475; and 11,851,660. A trial is scheduled to occur in June 2027. This proceeding is currently pending.

Ireland

In July 2025, GlaxoSmithKline Biologicals SA filed a lawsuit against our wholly owned subsidiary BioNTech Manufacturing GmbH, Pfizer Ireland Pharmaceuticals Unlimited Company, and Pfizer Healthcare Ireland Unlimited Company, alleging Comirnaty's infringement of European Patent Nos. 2,590,626, 4,066,856, and 4,226,941 in the High Court of Ireland. This proceeding is currently pending.

Unified Patent Court

In July 2025, GlaxoSmithKline Biologicals SA filed two lawsuits against BioNTech SE, BioNTech Europe GmbH, BioNTech Manufacturing GmbH, and BioNTech Manufacturing Marburg GmbH, as well as 26 Pfizer entities, in the Unified Patent Court (Hague Division). In the first lawsuit, GSK alleges Comirnaty's infringement of European Patent No. 2,590,626 ("EP 626"), and in the second lawsuit, GSK alleges Comirnaty's infringement of European Patent Nos. 4,066,856 ("EP 856") and 4,226,941 ("EP 941"). Oral hearings wherein the UPC will hear the parties'

arguments regarding infringement and invalidity of EP 626, EP 856, and EP 941 have been scheduled for September/October 2026. This proceeding is currently pending.

United Kingdom

In September 2025, we and Pfizer filed a revocation action against GlaxoSmithKline Biologics S.A. in the Business and Property Courts of England and Wales, in the U.K. High Court, requesting revocation of European Patent Nos. 2,590,626, 4,066,856, and 4,226,941. On October 7, 2025, GSK filed a defense and counterclaim for infringement against BioNTech SE and BioNTech Manufacturing GmbH, alleging Comirnaty's infringement of European Patent Nos. 2,590,626, 4,066,856, and 4,226,941. A trial has been scheduled for February 2027. This proceeding is currently pending.

We believe we have strong defenses against the allegations claimed relative to each of the patents and intend to vigorously defend ourselves in the lawsuit mentioned above. However, our analysis of GlaxoSmithKline's claims is ongoing and complex, and we believe the outcome of the suit remains substantially uncertain. Taking into account discussions with our external lawyers, we do not consider the probability of an outflow of resources to be sufficient to recognize a provision at the balance sheet date. In our opinion, these matters constitute contingent liabilities as of the balance sheet date. However, it is currently impractical for us to estimate with sufficient reliability the respective contingent liabilities.

Promosome Proceedings

In January 2025, Promosome LLC, or Promosome, filed a lawsuit against us and Pfizer in the Unified Patent Court, or UPC, Munich Division, alleging that Comirnaty infringes EP 2 401 365 and seeking monetary relief. An oral hearing wherein the UPC will hear the parties' arguments regarding infringement and invalidity has been scheduled for May 12-13, 2026. This proceeding is currently pending.

We believe we have strong defenses against the allegations claimed relative to the patent and intend to vigorously defend ourselves in the lawsuit mentioned above. However, our analysis of Promosome's claim is ongoing and complex, and we believe the outcome of the suit remains substantially uncertain. Taking into account discussions with our external lawyers, we do not consider the probability of an outflow of resources to be sufficient to recognize a provision at the balance sheet date. In our opinion, this matter constitute a contingent liabilities as of the balance sheet date. However, it is currently impractical for us to estimate with sufficient reliability the respective contingent liability.

CureVac Proceedings

Although the CureVac proceedings no longer qualify as contingent liabilities in accordance with IAS 37 as of December 31, 2025, we summarize below the current status of the CureVac proceedings to enhance comparability with our prior-year disclosure.

Infringement Proceedings – EP'122, DE'961, DE'974, DE'575, and EP'668

In July 2022, CureVac AG, or CureVac, filed a lawsuit against us and our wholly owned subsidiaries, BioNTech Manufacturing GmbH and BioNTech Manufacturing Marburg GmbH, in the Düsseldorf Regional Court, alleging Comirnaty's infringement of one European patent, EP1857122B1, or EP'122, and three Utility Models DE202015009961U1, DE202015009974U1, and DE202021003575U1. In August 2022, CureVac added European Patent EP3708668B1, or EP'668, to its German lawsuit.

On August 15, 2023, the Düsseldorf Regional Court held a hearing on infringement with respect to all five IP rights. At the hearing, the Court stated it would render its infringement ruling with respect to EP'122 on December 28, 2023. On September 28, 2023, the Court issued orders suspending its infringement rulings with respect to the remaining four IP rights (DE'961, DE'974, DE'575, and EP'668) pending validity decisions in the DE'961, DE'974, and DE'575 cancellation proceedings before the German Patent and Trademark Office and in

the EP'668 opposition proceedings before the Opposition Division of the European Patent Office, or the EPO. In the September 28th orders, the Court explained that it was suspending its infringement rulings until validity decisions are reached, while contemporaneously noting concerns regarding the validity of DE'961, DE'974, DE'575, and EP'668. After EP'122 was declared invalid in the first-instance nullity proceedings by the Federal Patent Court on December 19, 2023 (see below), on December 27, 2023, the Düsseldorf Regional Court canceled the December 28, 2023 decision date and stayed the infringement proceedings as to EP'122 until a final appellate decision is rendered as to the validity of EP'122 by the Federal Court of Justice. On June 7, 2024, CureVac waived DE'575 and withdrew this utility model from the infringement proceedings.

On July 1, 2024, the EPO Opposition Division issued a preliminary opinion noting that it believes EP'668 is likely invalid. The EPO Opposition Division held an oral hearing regarding the validity of EP'668 between March 25-27, 2025. At the conclusion of this hearing, the Opposition Division upheld EP'668 in amended form, but only after finding that the alleged technical effect – increased protein expression – was not achieved across the broad scope of the amended claim. The written decision by the Opposition Division to uphold EP'668 in amended form was issued on July 11, 2025, and we and Pfizer appealed this written decision. An oral hearing with respect to infringement of EP'668 was scheduled by the Düsseldorf Regional Court for July 1, 2025, but it was rescheduled for January 27, 2026. On July 3, 2025, GlaxoSmithKline Biologicals SA filed a request seeking to intervene in the EP'668 infringement proceedings. This request to intervene was to be heard at the January 27, 2026 hearing. On December 15, 2025, we completed our acquisition of CureVac. On December 19, 2025, CureVac withdrew its claims of infringement with respect to EP '122, DE '961, DE '974, and EP '668. As a result of CureVac's withdrawal of its claims of infringement, the January 27, 2026 hearing is cancelled and these infringement cases have been dismissed.

Infringement Proceedings – EP'755, DE'123, and DE'130

In July 2023, CureVac SE filed a second lawsuit against us and our wholly owned subsidiaries, BioNTech Manufacturing GmbH and BioNTech Manufacturing Marburg GmbH, in the Düsseldorf Regional Court, alleging Comirnaty's infringement of one European patent, EP4023755B1, or EP'755, and two Utility Models DE202021004123U1, and DE202021004130U1. On June 7, 2024, CureVac waived DE'123 and withdrew this utility model from the infringement proceedings. The Court has stayed the infringement proceedings with respect to DE'130 pending a validity decision in the co-pending cancellation proceeding before the German Patent and Trademark Office. On July 24, 2024, the EPO Opposition Division issued a preliminary opinion noting that it believes EP'755 is likely invalid, and held a three-day oral hearing beginning on May 13, 2025. At the conclusion of the hearing, the EPO Opposition Division upheld EP'755 in amended form. We appealed the Opposition Division's written decision upon its issuance. A hearing on infringement with respect to EP'755 was to occur in the Düsseldorf Regional Court on July 1, 2025, but this was rescheduled to January 27, 2026. On July 3, 2025, GlaxoSmithKline Biologicals SA filed a request to intervene in the EP'755 infringement proceedings. This request to intervene was to be heard at the January 27, 2026 hearing. On December 15, 2025, we completed our acquisition of CureVac. On December 19, 2025, CureVac withdrew its claims of infringement with respect to EP '755 and DE '130. As a result of CureVac's withdrawal of its claims of infringement, the January 27, 2026 hearing has been cancelled and these infringement cases have been dismissed.

Nullity Proceedings – EP'122

In September 2022, we filed a nullity action in the Federal Patent Court of Germany seeking a declaration that EP'122 is invalid. In April 2023, the Federal Patent Court of Germany issued a preliminary opinion in the EP'122 nullity action in support of the validity of EP'122. The preliminary opinion does not address any infringement of EP'122. The preliminary opinion is a preliminary assessment by the court of the merits of a claim, and is non-binding. On December 19, 2023, the Federal Patent Court held an oral hearing, after which it nullified EP'122. On April 25, 2024, the Federal Patent Court issued a judgment containing its written reasons for nullifying EP'122. On May 6, 2024, CureVac appealed the judgment, which is currently pending. On December 15, 2025, we completed our acquisition of CureVac. As of this date, CureVac became a wholly-owned subsidiary of

BioNTech. As a result, the parties to these proceedings are no longer adverse. An oral hearing on this appeal is scheduled for July 2026.

Cancellation Proceedings – DE'961, DE'974, and DE'575

In November 2022, we filed cancellation actions seeking the cancellation of the three German Utility Models in the German Patent and Trademark Office. On December 20, 2023, the German Patent and Trademark Office issued a preliminary opinion that DE'974 is likely to be cancelled. On January 23, 2024, the German Patent and Trademark Office issued a preliminary opinion that DE'961 is likely to be cancelled. Both preliminary opinions are based on invalidity pursuant to para. 1 (2) no. 5 Utility Model Act. On March 7, 2024, the German Patent and Trademark Office issued a preliminary opinion that DE'575 is likely to be cancelled. On June 6, 2024, CureVac submitted a written statement to the German Patent and Trademark Office waiving DE'575. On June 12, 2024, we withdrew our request for cancellation of DE'575. On June 25 and 26, 2024, the German Patent and Trademark Office heard oral arguments regarding DE'961 and DE'974, and at the conclusion of the hearing on June 26, 2024, confirmed that both DE'961 and DE'974 were cancelled. In November 2024, the German Patent and Trademark Office issued its written decisions cancelling DE'961 and DE'974. CureVac has filed an appeal in both cancellation proceedings, which are currently pending.

Cancellation Proceedings– DE'123 and DE'130

In November 2023, we filed cancellation actions seeking the cancellation of German Utility Models DE'123 and DE'130 in the German Patent and Trademark Office. On June 6, 2024, CureVac submitted a written statement to the German Patent and Trademark Office waiving DE'123. On June 12, 2024, we withdrew our request for cancellation of DE'123. On December 5, 2024, the German Patent and Trademark Office issued a preliminary opinion that DE'130 is likely to be cancelled. An oral hearing regarding the validity of DE'130 before the German Patent and Trademark Office was scheduled for March 10, 2026, but a postponement has been requested. As a result, the March 10, 2026 hearing will not go forward. For additional information about events and developments since the end of the calendar year ended December 31, 2025, please see Note 18 to our consolidated financial statements included elsewhere in this Annual Report.

C. Organizational Structure

See Item 18.

D. Property, Plant and Equipment

The following is a summary of our principal owned and leased real estate. We also lease other properties in the ordinary course of business as part of our global operations.

Germany

- Our headquarters are located in Mainz, where we own and lease over 105,000 square meters of office, laboratory, GMP manufacturing, and research and development space, including our wholly-owned laboratory, GMP manufacturing, storage, and office space at An der Goldgrube 12, 55131 and a GMP-compliant production facility for which we expect a manufacturing license in 2027.

- We also have manufacturing facilities in Marburg, where we lease over 23,000 square meters of GMP, technical, warehouse, laboratory, and office space, Idar-Oberstein, where we own a facility of over 13,000 square meters consisting of storage, development, laboratory, clean room, and office space and also lease additional office and warehouse space, and Tübingen, where we occupy 37,000 square meters of laboratory and office space, most of which is leased.

- Elsewhere in Germany, we occupy over 25,000 square meters of laboratory, office, freezer farm, and handling space, including a wholly-owned laboratory and office space in Berlin and other leased properties in Munich, Fussgoenheim, Mutterstadt and Wiesbaden.

Global locations

- In China, we occupy a freehold manufacturing facility in Nantong of approximately 62,000 square meters, and also lease additional office, laboratory, and pilot manufacturing space in Zhuhai. While most of the Nantong site is currently in a shell and core condition, it is intended to be developed further to support additional capacity.

- In the United States, we principally occupy over 9,000 square meters of leased laboratory and office space in Cambridge, Massachusetts and Gaithersburg, Maryland.

- In the United Kingdom, we lease over 7,000 square meters of shell and core laboratory and office space in Cambridge.

- We are also developing modular mRNA vaccine manufacturing facilities on leased sites in Kigali, Rwanda and Melbourne, Australia, with construction expected to be complete in 2026. The Kigali site is expected to have over 9,900 square meters of manufacturing, laboratory, office, warehouse, canteen, guardhouse, and supporting utility spaces. The Melbourne site is expected to have over 8,000 square meters of manufacturing, laboratory, office, and warehouse space.

- We also lease office and laboratory space in Vienna, Austria and office space in London, England, Paris, France, and Amsterdam, the Netherlands, and own a production site in Singapore.

For additional information regarding plans to construct, expand or improve facilities, including expenditures and financing, see Item 4.B.VII and Item 5 to this Annual Report.

Item 4A. Unresolved Staff Comments

None.

Item 5. Operating and Financial Review and Prospects

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

A. Operating Results

Financial Operations Overview

The following table shows our consolidated statements of profit or loss for each period presented:

	Years ended December 31,		
(in millions €, except per share data)	**2025**	**2024**	**2023**
Revenues	2,869.9	2,751.1	3,819.0
Cost of sales	(641.8)	(541.3)	(599.8)
Research and development expenses	(2,104.9)	(2,254.2)	(1,783.1)
Sales and marketing expenses	(110.0)	(67.9)	(62.7)
General and administrative expenses	(514.4)	(531.1)	(495.0)
Other operating expenses	(1,088.3)	(811.5)	(293.0)
Other operating income	184.6	140.6	105.0
Operating profit / (loss)	**(1,404.9)**	**(1,314.3)**	**690.4**
Finance income	423.9	664.0	519.6
Finance expenses	(69.8)	(27.4)	(23.9)
Profit / (Loss) before tax	**(1,050.8)**	**(677.7)**	**1,186.1**
Income taxes	(85.3)	12.4	(255.8)
Net profit / (loss)	**(1,136.1)**	**(665.3)**	**930.3**
Earnings / (Loss) per share			
Basic earnings / (loss) per share	(4.70)	(2.77)	3.87
Diluted earnings / (loss) per share	(4.70)	(2.77)	3.83

Non-IFRS Measures as Defined by BioNTech

In addition to our results determined in accordance with IFRS Accounting Standards, or IFRS results, we report certain adjusted, non-IFRS, measures used internally as a supplemental measure of our business performance. We believe that reporting these adjustments, and the non-IFRS measures that result, together with our IFRS results provides helpful complementary information to better understand our business performance and to facilitate comparability of business performance across different periods. These non-IFRS measures are also used by management for financial forecast and internal reporting purposes. Non-IFRS measures are intended to and may also provide useful information in evaluating performance relative to peer companies, many of which use similar non-IFRS measures to supplement their IFRS results.

While non-IFRS measures may offer additional insights, our non-IFRS measures are not, and should not be viewed as, a substitute for their most directly comparable IFRS Accounting Standards measures, and should always be considered alongside our financial statements prepared in accordance with IFRS Accounting Standards.

Non-IFRS adjustments include certain items that are associated with discrete events or matters and that management does not consider indicative of our performance for the period, and thus are excluded from the measures based on IFRS Accounting Standards. Non-IFRS measures are also aligned with the financial forecast of our management, which do not include these events or matters given their nature.

Our non-IFRS measures exclude the following items in relation to our measures based on IFRS Accounting Standards:

- **Expenses and income from legal proceedings**, defined as:

  Expenses (net of insurance recoveries) and income arising from certain legal proceedings (e.g., contractual-disputes, litigations, and government investigations), resulting from past events, that would result generally in a provision in accordance with IAS 37, an accrual, or outflow of resources (such as cash) recorded in our other operating result (other operating income or expense) in the period, which management does not consider indicative of the Company's performance for the period and exceeds a minimum threshold of €10.0 million per matter. These expenses and income do not include expenses from obligations or income from receivables arising from agreements following the settlements or conclusions for future transactions and operations, or expenses for external legal advisory services or internal legal costs. The Company describes the key facts of the matter such as involved parties, dispute, jurisdiction, terms of a settlement or court-ordered judgment in the respective sections in the Notes to the Consolidated Financial Statements.

- **Impairment and reversal**, defined as:

  Expenses in accordance with IAS 36 impairment of goodwill and impairment and reversals of impairments of intangible assets (IAS 38), property, plant and equipment (IAS 16) and right-of-use assets (IFRS 16) that relate to matters which management does not consider indicative of the Company's performance for the period and that exceed a minimum threshold of €10.0 million per asset or group of assets. Write-downs of inventories (IAS 2) or impairments of other assets not covered by IAS 16, IAS 38 and IFRS 16 are not adjusted.

- **Employee-related expenses from restructuring**, defined as:

  Major restructuring costs recognized in accordance with IAS 37 for streamlining operations and improving overall efficiency under specific Board approved programs that are of a significant scale and result in a structural change but do not relate to matters which management considers indicative of the Company's performance for the period, where the costs of individual or related projects, including employee-related costs such as severance or outplacement, exceed a minimum threshold of €10.0 million. This does not include training or relocating continuing staff, marketing, investment in new systems and distribution networks, or consulting costs related to the restructuring.

- **Income from bargain purchase and income and expenses from divestiture related items**, defined as:

  Income from a bargain purchase resulting from a business combination according to IFRS 3/IFRS 10 and income and expenses from valuation of non-current assets as held for sale according to IFRS 5, above a minimum threshold of €10.0 million per item are adjusted, where management does not consider such income or expenses to be indicative of the Company's performance for the period.

These non-IFRS adjustments result in the following adjusted measures based on IFRS Accounting Standards: adjusted expenses, adjusted operating profit/loss, adjusted profit/loss before tax, adjusted net profit/loss, and adjusted earnings/loss per share on both a basic and diluted basis (each referred to with the prefix "Adjusted" or as a whole "Adjusted Results"). The calculation of these and the adjusted results as a whole is based on the concepts of the applicable IFRS Accounting Standards, but includes the above described adjustments.

Due to their non-standardized nature, our adjusted results may not be directly comparable to those of other companies, unlike measures based on IFRS Accounting Standards.

The following tables provide a reconciliation of our adjusted results to our measures based on IFRS Accounting Standards for the years ended December 31, 2025, 2024 and 2023:

Non-IFRS Reconciliation for the year ended December 31, 2025

		non-IFRS adjustments				
(in millions €, except per share data)	IFRS Results	Expenses and income from legal proceedings	Impairment and reversal	Employee-related expenses from restructuring	Income from bargain purchase and income and expenses from divestiture related items	Adjusted Results
Cost of sales	(641.8)	—	30.5	—	—	(611.3)
Research and development expenses	(2,104.9)	—	85.4	—	—	(2,019.5)
Other operating expenses	(1,088.3)	789.5	71.6	57.0	—	(170.2)
Other operating income	184.6	—	—	—	(15.0)	169.6
Operating loss	**(1,404.9)**	**789.5**	**187.5**	**57.0**	**(15.0)**	**(385.9)**
Loss before tax	**(1,050.8)**	**789.5**	**187.5**	**57.0**	**(15.0)**	**(31.8)**
Net loss[1]	**(1,136.1)**	**789.5**	**187.5**	**57.0**	**(15.0)**	**(117.1)**
Loss per share						
Basic loss per share	(4.70)					(0.48)
Diluted loss per share	(4.70)					(0.48)

(1) Tax effects are not considered as part of our non-IFRS adjustments.

Non-IFRS Reconciliation for the year ended December 31, 2024

		non-IFRS adjustments				
(in millions €, except per share data)	IFRS Results	Expenses and income from legal proceedings	Impairment and reversal	Employee-related expenses from restructuring	Income from bargain purchase and income and expenses from divestiture related items	Adjusted Results
Cost of sales	(541.3)	—	48.1	—	—	(493.2)
Research and development expenses	(2,254.2)	—	81.5	—	—	(2,172.7)
Other operating expenses	(811.5)	657.4	—	—	—	(154.1)
Operating loss	**(1,314.3)**	**657.4**	**129.6**	**—**	**—**	**(527.3)**
Profit / (Loss) before tax	**(677.7)**	**657.4**	**129.6**	**—**	**—**	**109.3**
Net profit / (loss)[1]	**(665.3)**	**657.4**	**129.6**	**—**	**—**	**121.7**
Earnings / (Loss) per share						
Basic earnings / (loss) per share	(2.77)					0.51
Diluted earnings / (loss) per share	(2.77)					0.50

(1) Tax effects are not considered as part of our non-IFRS adjustments.

For the year ended December 31, 2023, our adjusted results were identical to our results under IFRS Accounting Standards.

The following table shows our condensed adjusted results for each period presented:

Adjusted Results (non-IFRS measures)[1]	Years ended December 31,		
(in millions €, except per share data)	**2025**	**2024**	**2023**
Adjusted cost of sales	(611.3)	(493.2)	(599.8)
Adjusted research and development expenses	(2,019.5)	(2,172.7)	(1,783.1)
Adjusted other operating expenses	(170.2)	(154.1)	(293.0)
Adjusted other operating income	169.6	140.6	105.0
Adjusted operating profit / (loss)	**(385.9)**	**(527.3)**	**690.4**
Adjusted profit / (loss) before tax	**(31.8)**	**109.3**	**1,186.1**
Adjusted net profit / (loss)[2]	**(117.1)**	**121.7**	**930.3**
Adjusted earnings / (loss) per share			
Adjusted basic earnings / (loss) per share	(0.48)	0.51	3.87
Adjusted diluted earnings / (loss) per share	(0.48)	0.50	3.83

(1) Certain adjusted results presented in this table are identical to our results under IFRS Accounting Standards. A reconciliation of the adjusted results to our measures based on IFRS Accounting Standards can be found above in this section.

(2) Tax effects are not considered as part of our non-IFRS adjustments.

Comparison of the year ended December 31, 2025 and the year ended December 31, 2024

Revenues

The following is a summary of revenues recognized for the periods indicated:

	Years ended December 31,		Change	
(in millions €)	**2025**	**2024**	**€**	**%**
COVID-19 vaccine revenues	1,995.3	2,432.1	(436.8)	(18)
Revenues from out-licensing	613.0	—	613.0	n.m.
Other revenues	261.6	319.0	(57.4)	(18)
Total revenues	**2,869.9**	**2,751.1**	**118.8**	**4**

COVID-19 Vaccine Revenues

Our COVID-19 vaccine revenues were recognized from the supply and sales of our COVID-19 vaccine worldwide during the years ended December 31, 2025 and 2024, mainly comprising our share of the collaboration partner's gross profit derived from sales in the collaboration partner's territory. Overall, our COVID-19 vaccine revenues amounted to €1,995.3 million and €2,432.1 million during the years ended December 31, 2025 and 2024, respectively and decreased as compared to the year ended December 31, 2024, in line with a lower COVID-19 vaccine market demand. Our COVID-19 vaccine revenues are subject to seasonal effects in the fall and winter of the northern hemisphere.

Revenues from Out-Licensing

On June 2, 2025, we and BMS announced a global strategic partnership to co-develop and co-commercialize our next-generation bispecific antibody candidate, pumitamig (BNT327 / BMS986545), broadly for multiple solid tumor types. Under the terms of the agreement, we granted BMS a worldwide, co-exclusive license to use the licensed intellectual property, or IP, for the development, manufacturing and commercialization of our

investigational bispecific antibody pumitamig as monotherapy or in combination with other products. We and BMS will jointly share development and manufacturing costs on a 50:50 basis, subject to certain exceptions. Global profits and losses will be equally shared as well. We received an upfront payment amounting to $1.5 billion during the year ended December 31, 2025, and are eligible to receive $2.0 billion total in non-contingent anniversary payments through 2028 as well as up to $7.6 billion in additional development, regulatory and commercial milestone payments contingent on achievement of certain development, regulatory and commercial milestones.

On August 15, 2025, we and BMS entered into an amended and restated agreement that replaced the original agreement. The new agreement governs the collaboration, including in particular the performance-related rights and obligations, without affecting the financial terms agreed in the original agreement. The license granted in respect of our IP was determined to be a separate unit of account from the other promises, which we refer to as development activities, and accounted for under IFRS 15 as the granting of a license to our IP is an output of our ordinary activities. Based on the terms of the contract, we have identified material rights relating to options to cancel the contract. In allocating revenues to the material rights throughout the development period, management determined an expected consideration of $3.5 billion, consisting of the upfront payment and the anniversary payments. The expected consideration is attributed to each option to cancel the contract using the practical alternative under IFRS 15.B43. Each material right is recognized as revenues at the point in time BMS makes use of its option or when such right expires. The upfront payment was recorded as contract liability (€1,313.6 million, converted as of the contract date of the initial agreement, June 2, 2025). We determined that the criteria in IFRS 15.9 were subsequently met with the conclusion of the amended and restated agreement as of August 15, 2025. During the year ended December 31, 2025, revenues in the amount of €613.0 million were recognized on a cumulative catch-up basis as of June 2, 2025, the date the initial agreement was effective, and €700.6 million have been deferred and will be recognized upon BMS makes use of its option or when such right expires. All milestone payments are considered to be constrained, as the achievement of the milestone events depends on the success of the underlying research and development activities, which is outside our control. Sales-based milestone payments will be recognized when the underlying sale transactions have occurred.

Other revenues

Our remaining other revenues were mainly derived from a pandemic preparedness contract with the German government, during the year ended December 31, 2025. The change was mainly due to the catch-up of revenues associated with the pandemic preparedness contract in the amount of €103.1 million in previous year, partly compensated by a one-time effect associated with Pfizer´s opt-out from the further development of our shingles program, BNT167, in the amount of €60.0 million in the year ended December 31, 2025.

Cost of Sales

Our cost of sales increased by €100.5 million, or 19%, from €541.3 million during the year ended December 31, 2024 to €641.8 million during the year ended December 31, 2025. This increase was mainly driven by higher COVID-19 vaccine sales in our commercialization territory, which included the share of gross profit we owe our collaboration partner Pfizer, higher expenses from inventory scrapping and write-downs to net realizable value and impairments on property, plant and equipment from the analysis on CGU External Product Sales JPT of €30.5 million. Expenses arising from inventory write-downs to net realizable value amounted to €162.8 million during the year ended December 31, 2025 compared to €125.8 million for year ended December 31, 2024 (€94.5 million for year ended December 31, 2023). In addition, our cost of sales during the fiscal year 2024 have been impacted by multiple positive extraordinary effects, including from inventory valuation effects.

Our adjusted cost of sales increased by €118.1 million, or 24%, from €493.2 million during the year ended December 31, 2024 to €611.3 million during the year ended December 31, 2025. During the years ended December 31, 2025 and 2024, our adjusted cost of sales exclude impairments on property, plant and equipment from the analysis on CGU External Product Sales JPT, and impairments on property, plant and equipment in Germany and worldwide, respectively.

Research and Development Expenses

Our research and development expenses decreased by €149.3 million, or 7%, from €2,254.2 million during the year ended December 31, 2024 to €2,104.9 million during the year ended December 31, 2025. This development was mainly driven by cost savings resulting from active portfolio management and positive effects resulting from our cost share with our collaboration partner BMS, partly offset by the acceleration of late-stage trials for our immuno-oncology, or IO, and antibody-drug conjugate, or ADC, programs.

Our adjusted research and development expenses decreased by €153.2 million, or 7%, from €2,172.7 million during the year ended December 31, 2024 to €2,019.5 million during the year ended December 31, 2025. During the years ended December 31, 2025 and 2024, our adjusted research and development expenses exclude impairments related to the product candidates due to revision of our commercial forecast assumptions, and impairments from revised prioritization of product candidates in the overall portfolio, respectively.

Sales and Marketing Expenses

Our sales and marketing expenses increased by €42.1 million, or 62%, from €67.9 million during the year ended December 31, 2024 to €110.0 million during the year ended December 31, 2025, mainly due to our ongoing commercial build-up.

General and Administrative Expenses

Our general and administrative expenses decreased by €16.7 million, or 3%, from €531.1 million during the year ended December 31, 2024 to €514.4 million during the year ended December 31, 2025. The decrease was primarily driven by a reduction in external services and our continued cost discipline.

Other Operating Result

Our total other operating result decreased by €232.8 million, or 35%, from a negative operating result of €670.9 million during the year ended December 31, 2024 to a negative operating result of €903.7 million during the year ended December 31, 2025. The change was mainly related to higher expenses for settlements in the amount of €132.1 million and to expenses in connection with our pipeline prioritization, which included impairments of €71.6 million and employee-related costs of €57.0 million. The impairments comprise €57.8 million on property, plant and equipment (see Note 11 of our consolidated financial statements included elsewhere in this Annual Report) and €13.8 million on right-of-use assets (see Note 20 of our consolidated financial statements included elsewhere in this Annual Report), all located outside of Europe.

Our adjusted total other operating result decreased by €12.9 million, or 96%, from a negative adjusted operating result of €13.5 million during the year ended December 31, 2024 to a negative adjusted operating result of €0.6 million during the year ended December 31, 2025. During the years ended December 31, 2025 and 2024, our adjusted other operating result exclude primarily expenses in connection with the settlements of legal proceedings (contractual and non contractual). In addition, our adjusted other operating result during the year ended December 31, 2025 excludes expenses in connection with our pipeline prioritization, comprising impairments of €71.6 million and employee-related costs of €57.0 million and a bargain purchase of €15.0 million.

Finance Result

Our finance result during the years ended December 31, 2025 and 2024 was mainly derived from returns, such as interest, resulting from our financial investments as well as fair value adjustments of our money market funds. Our total finance result decreased by €282.5 million, or 44%, from a positive finance result of €636.6 million during the year ended December 31, 2024 to a positive finance result of €354.1 million during the year ended December 31, 2025. This change was mainly due to lower interest income and negative impacts from foreign exchange differences, primarily derived from our security investments disclosed as cash equivalents and bank accounts held in foreign currency.

Income Taxes

The following table summarizes our income taxes for the periods indicated:

	Years ended December 31,		Change	
(in millions €)	**2025**	**2024**	**€**	**%**
Current income taxes	11.4	(2.3)	13.7	(596)
Deferred taxes	73.9	(10.1)	84.0	(832)
Income taxes expenses / (income)	**85.3**	**(12.4)**	**97.7**	**(788)**

Our current income taxes for the year ended December 31, 2025 were mainly determined by BioNTech Australia (€7.2 million) and the Biotheus Group (€4.7 million). In addition, there is the current tax income at BioNTech SE resulting from the tax assessment for the year 2024 amounting to €1.1 million.

As of December 31, 2025, our accumulated tax losses comprised tax losses of German entities that were incurred within and prior to the establishment of a tax group with BioNTech SE or by entities that are not within the tax group or U.S. tax group.

The amount of deductible temporary differences, unused tax losses, and unused tax credits for which no deferred tax asset is recognized in the statement of financial position as of December 31, 2025, is €4,220.6 million (December 31, 2024: €2,028.8 million). Thus, as of December 31, 2025, we have not recognized deferred tax assets for unused tax losses and temporary differences in an amount of €609.0 million (December 31, 2024: €332.4 million) as the criteria of the recognition guidance for IAS 12, which requires that no reliance should be placed on future events that cannot be controlled and are uncertain, are not met. Unrecognized deferred tax assets are re-assessed at each reporting date and are recognized to the extent that it has become probable that future taxable profits will allow the deferred tax asset to be recovered.

As of December 31, 2025, all previously recognized deferred tax assets for unused U.S. federal and state tax losses and tax credits, and deductible temporary differences were derecognized, resulting in deferred tax expense of €68.4 million, as there is not sufficient probability in terms of IAS 12 that future taxable income will be available against which these unused deferred tax assets can be utilized. The material unrecognized U.S. federal and state tax losses and tax credits will begin to expire in 2036.

The realization of deferred tax assets is dependent upon the generation of future taxable income, the amount and timing of which are subject to uncertainties. The assessments of the recoverability of deferred tax assets and the nature of uncertain tax positions are subject to significant judgment by management and subject to change. We may become subject to income tax audits and adjustments by local tax authorities.

The group does not recognize deferred tax liabilities for taxable temporary differences associated with investments in subsidiaries, in cases where the group is able to control the timing of the reversal of the temporary difference and it is probable that the temporary differences will not reverse in the foreseeable future. The aggregate amount of temporary differences associated with investments in subsidiaries, for which deferred tax liabilities have not been recognized, is €34.3 million (December 31, 2024: €14.5 million).

Information about Our Operating Segments

Decisions with respect to business operations and resource allocations are made by our Management Board, as the chief operating decision maker based on BioNTech as a whole. Accordingly, we operate and make decisions as a single operating segment, which is also our reporting segment.

Related Party Transactions

Related party transactions that occurred during the years ended December 31, 2025 and 2024 are explained in Item 7 of this Annual Report as well as in Note 21 of our consolidated financial statements included elsewhere in this Annual Report.

B. Liquidity and Capital Resources

Given our strong financial, scientific and operational accomplishments, we believe we have the resources to diligently allocate our current capital to drive a multi-platform strategy and deliver a fully integrated global biotechnology company. We focus our R&D on rapidly advancing our diversified clinical oncology pipeline with synergistic potential and maintaining leadership position in COVID-19 vaccine business. We plan to continue investing in the acceleration of late-stage trial execution for our immuno-oncology, or IO, and antibody-drug-conjugates, or ADCs, programs. In addition, we plan to enhance capabilities through complementary acquisitions, technologies, infrastructure and manufacturing. As a science and innovation driven company, we will continue to focus investments on R&D and scaling the business for commercial readiness in oncology in 2026.

As of December 31, 2025, we had cash and cash equivalents of €7,675.4 million, current security investments disclosed as financial assets of €7,158.5 million and non-current security investments disclosed as financial assets of €2,401.7 million accumulating to €17,235.6 million in cash, cash equivalents and security investments. In general, the aim is to protect and maximize the financial resources available for further research and development projects.

Cash and cash equivalents and financial securities are invested in accordance with our asset management and investment policy, primarily with a focus on liquidity and capital preservation, and consist primarily of cash in bank accounts and on hand as well as long- and short-term financial investments.

Cash Flow

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

	Years ended December 31,		
(in millions €)	**2025**	**2024**	**2023**
Net cash flows from / (used in):			
Operating activities	456.0	207.7	5,371.4
Investing activities	(2,468.5)	(2,081.2)	(6,954.5)
Financing activities	(52.9)	(45.9)	(778.6)
Total cash outflow before change in cash and cash equivalents resulting from exchange rate differences and other valuation effects	**(2,065.4)**	**(1,919.4)**	**(2,361.7)**

Operating Activities

We derive cash flows from operations primarily from the sale of products and services rendered. Our cash flows from operating activities are significantly influenced by cash we generate from our COVID-19 vaccine collaboration under which we receive a share of our collaboration partner's gross profit as well as cash received from out-licensing and our use of cash for operating expenses and working capital to support the business.

Our net cash flows from operating activities during the year ended December 31, 2025 were €456.0 million. Cash received from our revenue streams exceeded the cash payments for our operating business, resulting in a cash inflow of €76.4 million for the year ended December 31, 2025. In addition, we generated positive cash

contributions mainly from interest and other payments related to the security investments of €337.0 million and grants of €75.1 million, which were partly offset by share based payment programs of €25.3 million.

Cash received from our revenue streams exceeded the cash payments for our operating activities for the year ended December 31, 2024, resulting in a positive cash contribution of €184.0 million. Additionally, the positive cash contribution from interest and other payments related to the security investments of €474.9 million and grants of €106.0 million were offset mainly by exercised share-based payment programs and related wage tax payments of €154.5 million as well as by tax payments of €389.2 million. In total, the cash inflow from operating activities was €207.7 million.

Net cash generated in operating activities for the year ended December 31, 2023, was €5,371.4 million, comprising a profit before tax of €1,186.1 million, negative non-cash adjustments of €393.2 million, and a net positive change in assets and liabilities of €5,574.8 million. Non-cash items primarily included net foreign exchange differences as well as share-based payment expenses without cash-effect. The net positive change in assets and liabilities was primarily due to a decrease in trade receivables related to our COVID-19 collaboration with Pfizer.

Investing Activities

Our net cash flows used in investing activities during the year ended December 31, 2025 were €2,468.5 million. This amount includes €1,910.3 million mainly representing net payments in security investments. The payments for intangible assets were mainly driven by a payment of €565.1 million for the settlement of our pre-existing relationship in connection with the License and Collaboration Agreement with Biotheus entered into in November 2023, which is separate from the remaining purchase price to be transferred for the acquired business of Biotheus. Since the consideration for the CureVac business combination was mainly settled in ADSs, a positive cash contribution of €264.4 million was generated, which was partly offset by the remaining net cash outflow for the Biotheus business combination of €78.5 million (see Note 5 of our consolidated financial statements included elsewhere in this Annual Report). The net payments in property, plant and equipment €175.1 million related to investments in building our laboratory and office facilities in Mainz, Germany and elsewhere.

Net cash used in investing activities for the year ended December 31, 2024, was €2,081.2 million. The amount includes net investments of €1,400.1 million spend into security investments, €188.9 million in equity instruments and €165.8 million in intangibles, mainly driven from in-licensing arrangements. In addition, the amount for capital expenditures supporting our operating activities amounts to €307.1 million whereof the majority was related to investments in building our laboratory and office facilities in Mainz, Germany as well as the sites in Singapore and Kigali, Rwanda.

Net cash used in investing activities for the year ended December 31, 2023, was €6,954.5 million. The amount includes €5,912.1 million spend into security investments, €330.6 million caused by or driven from in-licensing arrangements as well as €336.9 million for collaborations or M&A transactions. In addition, the amount for capital expenditures supporting our operating activities amounts to €275.5 million whereof the majority was related to investments in building our laboratory and office facilities in Mainz, Germany.

Financing Activities

Our net cash flows used in financing activities during the year ended December 31, 2025 were €52.9 million and mainly related to our lease payments of €39.6 million and net repayments of loans and borrowings of €11.3 million.

Our net cash flows used in financing activities during the year ended December 31, 2024 were €45.9 million and mainly related to our lease payments of €43.6 million.

Our net cash flows used in financing activities during the year ended December 31, 2023 were €778.6 million and mainly related to our share repurchase programs of ADS amounting to €738.5 million.

Operation and Funding Requirements

As part of our capital allocation strategy, we expect to continue to incur significant and increasing operating expenses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we and our collaborators:

- continue or expand our research or development of our programs in preclinical development;
- continue or expand the scope of our clinical trials for our product candidates;
- initiate additional preclinical, clinical, or other trials for our product candidates, including under our collaboration agreements;
- continue to invest in our immunotherapy platforms to conduct research to identify novel technologies;
- change or increase our manufacturing capacity or capability;
- change or add additional suppliers;
- add additional infrastructure to our quality control, quality assurance, legal, compliance and other groups to support our operations as a public company and our product development and commercialization efforts, including new and expanded sites globally;
- attract and retain skilled personnel;
- seek marketing approvals and reimbursement for our product candidates;
- enhance our commercial infrastructure for other product candidates for which we are seeking to obtain marketing approval;
- seek to identify and validate additional product candidates;
- acquire or in-license other product candidates and technologies;
- acquire other companies;
- make milestone or other payments under any in-license agreements;
- maintain, protect, defend, enforce and expand our intellectual property portfolio; and
- experience any delays or encounter issues with any of the above.

We are a party to license and research and development agreements with universities and other third parties, as well as patent assignment agreements, under which we have obtained rights to patents, patent applications and know-how. We enter into contracts in the normal course of business with CROs for clinical trials and clinical and commercial supply manufacturing, and with vendors for preclinical research studies and for other services and products for operating purposes. We work together with CMOs who manufacture our product candidates and products, and enter into lease agreements to lease laboratory, GMP manufacturing, storage and office spaces. Purchase obligations under our agreements, to the extent that they are quantifiable and not cancellable, have

been considered when defining our guidance for future cash commitments. The following table shows our significant committed cash outflow within one year and for the years 2027 and beyond.

Year ended December 31, 2025

(in millions €)	Less than 1 year	1 to 5 years	More than 5 years	Total
Commitments under purchase agreements for property, plant and equipment	101.6	64.0	—	165.6
Contractual obligation to acquire intangible assets	114.5	396.3	340.4	851.2
Total	**216.1**	**460.3**	**340.4**	**1,016.8**

Year ended December 31, 2025

(in millions €)	Less than 1 year	1 to 5 years	More than 5 years	Total
Loans and borrowings	7.2	24.5	5.4	37.1
Trade and other payables	534.9	—	—	534.9
Lease liabilities	53.1	144.0	64.0	261.1
Contingent consideration	51.3	47.0	50.0	148.3
Foreign exchange forward contracts	0.4	—	—	0.4
Other financial liabilities	307.9	19.6	—	327.5
Total	**954.8**	**235.1**	**119.4**	**1,309.3**

We are subject to all of the risks related to the development and commercialization of pharmaceutical products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business.

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

- the initiation, progress, timing, costs, and results of preclinical or nonclinical studies and clinical trials for our product candidates;
- the amount and timing of revenues and associated costs from sales of our COVID-19 vaccine;
- the results of research and our other platform activities;
- the clinical development plans we establish for our product candidates;
- the terms of any agreements with our current or future collaborators, and the achievement of any milestone payments under such agreements to be paid to us or our collaborators;
- the number and characteristics of product candidates that we develop or may in-license;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, the EMA and other comparable regulatory authorities;
- the cost of filing, prosecuting, obtaining, maintaining, protecting, defending and enforcing our patent claims and other intellectual property rights, including actions for patent and other intellectual property infringement,

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

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

C. Research and Development, Patents and Licenses, etc.

Full details of our research and development activities and expenditures are given in Item 4 and under the description of the “Operating Results” in this Item 5 within this Annual Report.

D. Trend Information

See the description of “Operating Results” as well as ”Liquidity and Capital Resources” in this Item 5, “Business Overview” in Item 4 and “Risk Factors” in Item 3 within this Annual Report.

E. Critical Accounting Estimates

For a discussion of our Significant Accounting Judgments, Estimates and Assumption please refer to Note 3 to our consolidated financial statements included elsewhere in this Annual Report.

F. Comparison of the year ended December 31, 2024 and the year ended December 31, 2023

For a discussion of our operating results for the year ended December 31, 2023, and a comparison of the years ended December 31, 2024 and 2023, please refer to Item 5 of our Annual Report on Form 20-F for the year ended December 31, 2024.

Item 6. Directors, Senior Management and Employees

A. Directors and Senior Management

Management Board (Vorstand)

The following changes to the Management Board took place in 2025 and 2026:

- Ramón Zapata succeeded Jens Holstein as our Chief Financial Officer on July 1, 2025.
- Ryan Richardson concluded his service as our Chief Strategy Officer on September 30, 2025.
- Kylie Jimenez joined the Management Board as our Chief People Officer on March 1, 2026.

The following table sets forth the names and functions of the current members of our Management Board, their ages as of December 31, 2025, and their terms:

Name	Age	Term Expires	Position
Prof. Ugur Sahin, M.D.	60	December 31, 2026	Chief Executive Officer
Annemarie Hanekamp	45	June 30, 2028	Chief Commercial Officer
Kylie Jimenez	49	February 28, 2030[2]	Chief People Officer
Sierk Poetting, Ph.D.	53	November 30, 2026	Chief Operating Officer
James Ryan, Ph.D.	50	August 31, 2027	Chief Legal Officer and Chief Business Officer
Prof. Özlem Türeci, M.D.	59	December 31, 2026	Chief Medical Officer
Ramón Zapata	52	June 30, 2028[1]	Chief Financial Officer

(1) Appointed on July 1, 2025.

(2) Appointed on March 1, 2026.

The business address of the members of our Management Board is the same as our business address: An der Goldgrube 12, D-55131 Mainz, Germany.

The following is a brief summary of the business experience of all our Management Board members:

Prof. Ugur Sahin, M.D., co-founded BioNTech in 2008 and has served as our Chief Executive Officer since that time. He is a physician, immunologist and leader in the development of novel approaches to fight cancer and infectious diseases. Ugur Sahin is one of the world's foremost experts on messenger ribonucleic acid (mRNA) medicines. He has pioneered several fundamental breakthroughs enabling the development of mRNA vaccines and other types of immunotherapies. He initiated and oversaw "Project Lightspeed", the historic development of the first mRNA vaccine for COVID-19, moving from lab and clinical testing to conditional approval within an unprecedented 11-month period. He also leads BioNTech's research and development of neoantigen specific as well as non-neoantigen specific mRNA cancer immunotherapies, which can be individually tailored and produced on demand according to the profile of non-synonymous mutations identified by next-generation sequencing in patients' tumors. Ugur Sahin is co-inventor of more than 500 filed patents applications and patents. His academic credentials include serving as a Full Professor in Translational Oncology & Immunology at Johannes Gutenberg University in Mainz, Germany, where he was the supervisor of more than 50 Ph.D. students. He also holds the role of Chairman of the Scientific Management Board of the Helmholtz Institute for Translational Oncology (HI-TRON). Based on his contributions to scientific discovery, Ugur Sahin has received numerous awards and recognitions, including the German Sustainability Award, the Mustafa Prize, and the German Cancer Award. He is married to Özlem Türeci.

Annemarie Hanekamp is our Chief Commercial Officer. She joined BioNTech in 2024 and has more than 20 years of experience in the healthcare industry, including 15 years of commercial experience in companies ranging from early-stage biotechnology companies to full-scale pharmaceutical companies. She successfully delivered significant value in a broad range of roles: at Novartis, she led the U.S. and global teams through a time of strategic opportunities and operational headwinds following an unprecedented strong launch uptake of their novel treatment for prostate cancer. She was also responsible for building a new global oncology organization following a company-wide transformation. At Bristol Myers Squibb Co., she held a pivotal role in evolving the company's U.S. oncology strategy, resulting in significant and sustainable growth including an expanded market access as well as product launches. Annemarie Hanekamp holds degrees in biomedical sciences as well as organizational leadership.

Sierk Poetting, Ph.D., is our Chief Operating Officer. He joined us in September 2014 from Novartis, where he had held various roles since 2006, most recently serving as Vice President and Chief Financial Officer of the

Sandoz Division in North America from 2012 to 2014. Sierk Poetting started his career as a consultant with McKinsey & Company. A German citizen, he holds a Master of Science in Optical Sciences from the University of Arizona and a Ph.D. in Physics from the Ludwig-Maximilians University in Munich.

James Ryan, Ph.D., is our Chief Legal Officer and Chief Business Officer. He has guided BioNTech through a wide range of key business, IP and transactional activities, mergers and acquisitions, strategic collaborations and equity capital markets transactions including the Company's IPO in 2019. James Ryan and his teams played a pivotal role in the successful development of the Pfizer-BioNTech COVID-19 Vaccine, supporting every legal aspect of the program, its launch and commercialization, and was also instrumental in the strategic collaboration with Bristol Myers Squibb. James Ryan joined BioNTech in 2018 and was appointed as a Member of the Management Board in 2023. He brings over 20 years of global legal and IP expertise in the pharmaceutical industry to the Company. In his prior role, he established the legal group of GW Pharmaceuticals (NASDAQ: GWPH), where he also served as Head of Legal Affairs. James Ryan also worked for a number of UK and US law firms, including Special Counsel at Covington & Burling LLP, where he specialized in commercial and strategic transactions with a focus on companies in the life sciences sector. James Ryan has a Ph.D. in epigenetics from the University of St Andrews, is a member of the Law Society of England & Wales, and a member of the Law Society of Ireland.

Prof. Özlem Türeci, M.D., Co-founder and Chief Medical Officer of BioNTech, is a physician, immunologist, and cancer researcher with translational and clinical experience. She has helped lead the discovery of cancer antigens, the development of mRNA-based individualized and off-the-shelf immunotherapy candidates and other types of immunotherapies which are currently in clinical development. Özlem Türeci leads the clinical development of BioNTech's "Project Lightspeed", the company's successful effort to develop and distribute an mRNA-based vaccine against COVID-19, a historic achievement completed in less than one year. Özlem Türeci previously served as CEO and Chief Medical Officer of Ganymed Pharmaceuticals AG, which she co-founded with Ugur Sahin and Christoph Huber. She is also a professor for Personalized Immunotherapy at the University Medical Center Mainz and the Helmholtz Institute for Translational Oncology Mainz (HI-TRON) and currently serves as President of the Association for Cancer Immunotherapy (CIMT) in Germany. She is a recipient of the German Sustainability Award, among other notable recognitions. Özlem Türeci is married to Ugur Sahin.

Ramón Zapata is our Chief Financial Officer. He joined BioNTech in 2025 and is a seasoned global finance executive with more than 25 years of experience in the pharmaceutical and consumer goods industries. He has held leadership roles at leading global companies including Novartis, Sandoz, and Mondelēz International, and has worked across Europe, North America, Latin America, and the Middle East. Throughout his career, he has led finance functions enabling seamless execution from drug discovery through commercialization, including overseeing M&A transactions and successful integrations as well as driving digital finance transformations. Prior to joining BioNTech, he served as Chief Financial Officer and Head of Scientific Operations of BioMedical Research at Novartis, where he was responsible for the overall leadership of the division's finance strategy and operations, portfolio realignment, cross-functional integration, and strategic external collaborations. He holds dual citizenship of the United States and Mexico. He is a Certified Public Accountant (CPA) from Universidad Panamericana. He holds an MBA from IPADE Business School, with academic credits earned at IESE Business School as part of the program. He also earned a postgraduate diploma in Tax Legislation from ITAM and is currently pursuing a Master's degree in Industrial-Organizational Psychology at Harvard University.

Kylie Jimenez is our Chief People Officer. She is responsible for the company's global people strategy and its execution in support of BioNTech's long-term objectives. Her remit includes leadership and succession, organizational effectiveness, culture, and people governance across the enterprise. Kylie Jimenez has held HR leadership roles across North America, Europe, and Latin America. Her experience spans multinational organizations in the pharmaceutical, industrial, consumer goods, and automotive sectors. She has overseen people and organizational transformation initiatives that aim to strengthen culture, improve effectiveness, and enable employees to perform at their best. Through her role, she supports an environment where people can grow, lead, and contribute meaningfully to BioNTech's purpose. She holds a degree from the University of

Waterloo, the Certified Human Resources Professional (CHRP) designation (Canada), and the INSEAD Certificate in Corporate Governance.

Supervisory Board (Aufsichtsrat)

The following table sets forth the names and functions of the members of our Supervisory Board during 2025, their ages as of December 31, 2025, their terms (which expire on the date of the relevant year's general shareholders' meeting) and their principal occupations outside of our Company:

Name	Age	Term Expires[1]	Principal Occupation
Helmut Jeggle (Chair Supervisory Board)	55	2026	Managing partner and entrepreneurial venture capital investor of Salvia GmbH (Supervisory Board member of 4SC AG, AiCuris AG and Tonies SE, Board Director at Bambusa Therapeutics Inc.)
Ulrich Wandschneider, Ph.D. (Deputy Chair Supervisory Board)	64	2027	Managing director of beebusy capital GmbH and independent consultant to companies in the lifescience and healthcare sector (Deputy Chair of the Supervisory Board Marienhaus GmbH and Chair of the Supervisory Board fischerAppelt AG)
Baroness Nicola Blackwood	46	2027	Chair of Oxford University Innovations Limited (Equity Partner, ReCode Health Ventures LLC, Chair of Genomics England Limited, Chair of Health Data Research Service, Senior Independent NED on the RTW Biotech Opportunities Ltd.)
Prof. Anja Morawietz, Ph.D.	48	2026	Certified Public Accountant and Management Consultant, Professor of External Accounting and General Business Administration at the Nuremberg University of Applied Sciences Georg Simon Ohm
Michael Motschmann	68	2027	Member of the Management Board and head of equity investments of MIG Capital AG (Supervisory Board member AFFiRiS AG and HMW-Emissionshaus AG)
Prof. Rudolf Staudigl, Ph.D.	71	2026	Independent consultant (member of the Supervisory Board of Groz-Beckert KG (Deputy Chair), Chairman of the Supervisory Board of Zadient Technologies SAS)

[1] Term expires as of the AGM during the years indicated.

The business address of the members of our Supervisory Board is the same as our business address: An der Goldgrube 12, D-55131 Mainz, Germany.

The following is a brief summary of the prior business experience of the members of our Supervisory Board:

Helmut Jeggle has been Chair of our Supervisory Board since its foundation in 2008. He has a degree in business administration from the University of Applied Sciences in Neu-Ulm and an MBA (Master of Business Administration) from the Stuttgart Institute of Management and Technology. From 2000 to 2007, Helmut Jeggle held various positions at Hexal AG. From 2007 onwards, he was, among other things, in charge of Direct Investments at ATHOS KG, the family office of the Strüngmann family, from which he resigned as general partner (Komplementär) in April 2021. Since 2014, Helmut Jeggle has been Managing Director of Salvia GmbH, where he acts as an entrepreneurial venture capital investor. He is currently a member of two other supervisory boards of listed companies, including 4SC AG and Tonies SE.

Ulrich Wandschneider, Ph.D., has served as a member of our Supervisory Board since 2018. He has more than 20 years of experience in the healthcare sector as a manager in the operative business and as a member of boards and committees. He was a Partner at Arthur Andersen until 2002 and at Deloitte from 2002 to 2004 in the healthcare and life science sector for many years. From 2004 to 2016 Ulrich Wandschneider served as Chief Executive Officer first of Mediclin AG later of Asklepios Kliniken GmbH & Co. KGaA. In addition to BioNTech SE, he is deputy chairman of the Supervisory Board of Marienhaus GmbH, chairman of the Supervisory Board of

fischerAppelt AG, chairman of the Board of Trustees of Oberberg GmbH and he serves as chairman or member of various Advisory Boards, such as chairman of the Advisory Board of Argentum Pflege Holding GmbH and Panorama Fachklinik GmbH and member of the Advisory Board of Creative Balloons GmbH.

Baroness Nicola Blackwood has served as a member of our Supervisory Board since May 25, 2023. She has been Chair of Genomics England since 2020 and Chair of Oxford University Innovation since 2021. She is a member of the House of Lords, the upper chamber of the Parliament of the United Kingdom (UK). Blackwood was elected Member of Parliament for Oxford West and Abingdon 2010 to 2017 and served as Minister for Innovation at the UK Department of Health and Social Care from 2016 to 2017 and 2019 to 2020 where she led on life sciences, NHS data and digital transformation and global health security. Among other roles, she was Chair of the technical regulator, the Human Tissue Authority, as well as a Chair of the UK House of Commons Science and Technology Select Committee and a member of the House of Lords Science and Technology Select Committee. Nicola Blackwood was educated at Trinity College of Music, London, St Anne's College, Oxford, and Emmanuel College, Cambridge.

Prof. Anja Morawietz, Ph.D., has served as a member of our Supervisory Board since 2022. She has been a professor of external accounting and general business administration at the Nuremberg University of Applied Sciences Georg Simon Ohm since 2015. Her research areas are international and national accounting, current developments in corporate governance and sustainability reporting. She also works as a freelance auditor, particularly in audit-related consulting. Previously, she worked for ten years for auditing company KPMG AG, where she conducted audits of annual and consolidated financial statements and advised clients on accounting and regulatory issues. After training as a bank clerk at Norddeutsche Landesbank in Hanover, Anja Morawietz studied business administration at Goethe University in Frankfurt am Main, where she also completed her doctorate as an external doctoral candidate.

Michael Motschmann has served as a member of our Supervisory Board since 2008. He co-founded MIG Verwaltungs AG, or MIG, in 2004, where he serves on the Management Board and as Head of Equity Investments. In his role with MIG, Michael Motschmann currently serves on the supervisory boards of several private portfolio companies.

Prof. Rudolf Staudigl, Ph.D., has served as a member of our Supervisory Board since 2022. He studied chemistry at Ludwig Maximilian University of Munich, obtaining his Ph.D. (Dr. rer. nat) in 1981. After postdoctoral research at Harvard University (Cambridge, USA) and Ludwig Maximilian University, he joined Wacker Chemitronic in 1983. Mr. Staudigl became Vice President of Operations at Wacker Siltronic Corporation (Portland, Oregon, USA) in 1989 and President a year later. He joined the Executive Board of Wacker Chemitronic in 1993. In 1995, Rudolf Staudigl was appointed to the Executive Board of Wacker Chemie. In May 2008, Rudolf Staudigl was appointed President & CEO of Wacker Chemie AG. Until July 2024, he was a member of the Supervisory Board of TÜV Süd Aktiengesellschaft. He currently serves as Deputy Chairman of the Supervisory Board of Groz-Beckert and Chairman of the Supervisory Board of Zadient Technologies SAS.

B. Compensation

Amount of Compensation of Our Supervisory Board and Management Board Members

The compensation of the members of our Supervisory Board and Management Board is disclosed below in accordance with Section 162 Paragraph 1 of the German Stock Corporation Act, or AktG, and in line with our Compensation Report published on our website at *www.biontech.de*.

Compensation is considered granted if it either has been actually received or the activities to which it relates have been performed. Compensation is considered owed if the compensation components are legally due, but have not yet been received. Where the preceding definition applies, compensation is referred to only as being "granted and owed". The Institute of Public Auditors in Germany, Incorporated Association (Institut der

Wirtschaftsprüfer, IDW) has provided two interpretations for the presentation. According to interpretation 1, compensation is only shown as granted and owed in the year in which it is received (inflow principle; "Zuflussprinzip"). According to interpretation 2, compensation may also be disclosed in the compensation report for the financial year in which the activity underlying the compensation was performed (vesting principle; "Erdienungsprinzip"). The Supervisory Board and the Management Board have decided to apply interpretation 2 to short-term compensation components such as fixed compensation, fringe benefits, short-term incentives (STI), cash-settled sign-on or other cash-settled one-time payments, and interpretation 1 to long-term compensation components such as share-based payments relating to long-term incentives (LTI) (even if ultimately settled in cash), share-based sign-on bonuses or other share-based one-time payments. An approach which deviates from interpretation 1 was chosen because it allows a fair presentation of the actual benefits, which are, for example, subject to final underlying share price developments. That is, the benefits from our share-based payment arrangements are considered granted and owed when the awards are settled.

The total compensation granted or owed according to Section 162 Paragraph 1 AktG to all members of the Supervisory Board and the Management Board for the years ended December 31, 2025 and 2024 is presented in the following sections. The 2025 financial year reflected the first full year after the shareholders adopted the revised compensation system at the AGM on May 17, 2024, or the Compensation System 2024. Compensation for the Management and Supervisory Board was previously determined under the compensation system approved by the AGM on June 22, 2021, and June 1, 2022, or the Compensation System 2021/2022. Both compensation systems are published on our website at *www.biontech.de*.

Since Kylie Jimenez joined the Management Board on March 1, 2026, no compensation or other items related to Management Board compensation are reportable as of December 31, 2025.

Compensation of Our Supervisory Board Members

Our Supervisory Board's compensation is designed to promote the Company's long-term development and business strategy and reflects the duties, time commitment and demands of the role, the Company's market position, and the need to be able to attract suitably qualified candidates. Supervisory Board members receive 100% fixed compensation under article 9 of the Company's Articles of Association and they are also reimbursed for their expenses.

Under article 9 of the Company's Articles of Association, our Supervisory Board receives 100% fixed compensation. All members of the Supervisory Board are also reimbursed for their expenses incurred in connection with their service on the Supervisory Board. While retaining this system for the compensation of Supervisory Board members, the compensation of the Supervisory Board and its committee members was adjusted during the year ended December 31, 2024, to take into account the increasing time commitment required from them in terms of their activities, responsibilities and necessary qualifications and competencies under German stock corporation and European laws and the life sciences industry. The new system was approved by the Annual General Meeting, or AGM, on May 17, 2024, and was applied on a pro rata basis for the year ended December 31, 2024 upon the entry of the revised Articles of Association in our Commercial Register on August 30, 2024. Pursuant to Section 113 Paragraph 3 AktG, as amended by the Act Implementing the Second Shareholder Rights Directive, a listed company's AGM must pass a resolution on the compensation of its Supervisory Board members at least every four years.

Until August 30, 2024, each member of the Supervisory Board received annual base compensation of €70,000 (the Chair and Vice Chair received €210,000 and €105,000, respectively). The Chair of the Audit Committee received an additional €30,000 per year. Other committee Chairs each received an additional €15,000 per year. Each ordinary committee member received an additional €5,000 per committee. As of August 30, 2024, the members of the Supervisory Board receive annual base compensation of €120,000 (the Chair and Vice Chair receive €360,000 and €180,000, respectively). The Chair of the Audit Committee receives an additional €50,000

per year. Other committee Chairs each receive an additional €30,000 per year. Each ordinary committee member receives an additional €10,000 per committee.

Compensation is provided on a pro rata basis for individuals who are members of the Supervisory Board or a committee for part of the financial year. No pro rata payments were made in 2025 and 2024.

BioNTech also covers any value-added tax applicable to compensation or expense reimbursement. Supervisory Board members are included in our D&O liability insurance and are co-insured at our expense.

The compensation granted and owed to our Supervisory Board members during the years ended December 31, 2025 and 2024, is presented in the following table:

in thousands €[1]	**Helmut Jeggle** *Chair*	**Ulrich Wandschneider, Ph.D.** *Vice Chair*	**Baroness Nicola Blackwood**	**Prof. Anja Morawietz, Ph.D.**	**Michael Motschmann**	**Prof. Rudolf Staudigl, Ph.D.**
Base Compensation						
2025	360	180	120	120	120	120
2024	261	130	87	87	87	87
Committee Compensation						
2025	40	40	20	60	20	40
2024	27	27	13	43	13	27
Total						
2025	**400**	**220**	**140**	**180**	**140**	**160**
2024	**288**	**157**	**100**	**130**	**100**	**114**

(1) The concept of compensation being granted or owed is described in the above section “Amount of Compensation of Our Supervisory Board and Management Board Members”.

Compensation of Our Management Board Members

We have entered into service agreements with all current members of our Management Board. We believe that the agreements between us and the members of our Management Board provide for payments and benefits (including upon termination of service) that are in line with customary market practice.

The total compensation granted or owed to all members of the Management Board for the years ended December 31, 2025 and 2024 is presented in the table below.

Serving members of the Management Board as of December 31, 2025

in thousands €	Prof. Ugur Sahin, M.D.	Annemarie Hanekamp[2]	Sierk Poetting, Ph.D.	James Ryan, Ph.D.	Prof. Özlem Türeci, M.D.	Ramón Zapata[7]
Fixed compensation[1]						
2025	700	550	550	550	469	310
2024	700	275	550	550	550	—
Fringe benefits[3]						
2025	5	47	18	39	22	38
2024	5	64	19	109	—	—
Short-term incentive – first installment[4]						
2025	350	300	300	300	350	175
2024	130	69	111	111	111	—
Short-term incentive – second installment[4]						
2025	—	—	—	—	—	—
2024	130	69	111	111	111	—
Other variable compensation[5]						
2025	—	—	—	—	—	500
2024	—	1,250	—	—	—	—
Share-based payments (incl. long-term incentive)[6]						
2025						
Management Board Grant – LTI	—	275	—	92	—	—
2024						
Management Board Grant – LTI	4,386	—	1,774	—	1,754	—
CEO Grant 2019	259,531	—	—	—	—	—
Total						
2025	**1,055**	**1,172**	**868**	**981**	**841**	**1,023**
2024	**264,882**	**1,727**	**2,565**	**881**	**2,526**	**—**

Continued on next page

Members of the Management Board who stepped down in 2025

in thousands €	Jens Holstein[8]	Ryan Richardson[9]
Fixed compensation		
2025	275	413
2024	550	550
Fringe benefits[3]		
2025	17	122
2024	5	27
Short-term incentive – first installment[4]		
2025	150	167
2024	111	111
Short-term incentive – second installment[4]		
2025	—	—
2024	111	111
Other variable compensation[5]		
2025	—	688
2024	—	—
Share-based payments (incl. long-term incentive)[6]		
2025		
Management Board Grant – LTI	—	—
Other share-based payment arrangements	387	—
2024		
Management Board Grant – LTI	—	1,785
Total		
2025	**829**	**1,390**
2024	**777**	**2,584**

(1) For James Ryan, a part of the fixed compensation was paid by BioNTech UK Limited, a subsidiary of BioNTech SE. Approximately 30% of his total compensation is attributable to his position as a member of the Management Board and approximately 70% is attributable to his position as a director of BioNTech UK Limited.

(2) Annemarie Hanekamp was appointed to the Management Board as Chief Commercial Officer (CCO) with effect as of July 1, 2024. Her compensation for the year ended December 31, 2024 was granted on a pro-rata basis. For the year ended December 31, 2024, she was granted a guaranteed pro rata STI bonus in the amount of 50% of the maximum amount, i.e., €137,500. The first half of the corresponding net amount was paid out in April 2025 and the second in January 2026, irrespective of the share price performance. The Supervisory Board granted her a one-time sign-on bonus of €1,750,000 as of her appointment (see below section “Other Payments”). Out of this amount, €1,250,000 was paid as a cash bonus in July 2024 subject to repayment in reducing amounts if the service agreement ends other than for good cause before June 30, 2027 (resolutory condition considered granted and owed fully in 2024). The remainder of €500,000 will be granted in shares in July 2028 or, at the earliest possible date after a potential blackout period, provided she is still a Management Board member on June 30, 2028. Annemarie Hanekamp received a guaranteed pro rata LTI grant of €275,000 for the period from July 1 to December 31, 2024 due to her appointment to the Management Board during 2024. This amount reflected 50% of the annual target value and was settled in cash in 2025.

(3) Includes social security, health and additional insurance, company bike and travel expenses. Other fringe benefits which are integral to the performance of business duties, such as costs for security services, are not included in the amount.

(4) The structure of the STI payout was changed with the adoption of the Compensation System 2024. Under the Compensation System 2024, 100% of the STI relating to the year ended December 31, 2025 will be paid out in the month after the approval of the 2025 consolidated financial statements. In contrast, under the Compensation System 2021 / 2022, 50% of the STI relating to the year ended December 31, 2024 was paid out in the month after the approval of the 2024 consolidated financial statements and the remaining 50% will be paid out (and adjusted) in March 2026 (see below section “Short-Term Incentive (STI) Compensation”).The amounts ultimately determined were as follows: Ugur Sahin €116 thousand, Jens Holstein €100 thousand, Sierk Poetting €100 thousand, Ryan Richardson €100 thousand, James Ryan €100 thousand and Özlem Türeci €100 thousand.

(5) One-time sign-on bonuses are reported under other variable compensation in this table for transparency purposes, even though the Compensation System 2024 classifies them as fringe benefits.

(6) Explanations of our share-based payment arrangements are given in section “Share-Based Payments (incl. Long-Term Incentive (LTI) and Other One-Time Awards)” below and include the LTI arrangements and the CEO Grant 2019.

(7) Ramón Zapata was appointed to the Management Board as Chief Financial Officer (CFO) with effect as of July 1, 2025. His compensation for the year ended December 31, 2025 was granted on a pro-rata basis. The Supervisory Board granted him a one-time cash sign-on bonus of €900,000

as part of his appointment (see below section "Other Payments"). Out of this amount, €500,000 was paid in cash in January 2026. The remaining €400,000 will be due in cash in January 2027, provided he is still a Management Board member on July 31, 2026.

(8) Served through June 30, 2025.

(9) Served through September 30, 2025.

Fixed Compensation

	Years ended December 31,	
in thousands €	**2025**	**2024**
Serving members of the Management Board as of December 31, 2025		
Prof. Ugur Sahin, M.D.	700	700
Annemarie Hanekamp[1]	550	275
Sierk Poetting, Ph.D.	550	550
James Ryan, Ph.D.[2]	550	550
Prof. Özlem Türeci, M.D.	469	550
Ramón Zapata[3]	310	—
Members of the Management Board who stepped down in 2025		
Jens Holstein[4]	275	550
Ryan Richardson[5]	413	550

(1) Appointed on July 1, 2024.

(2) James Ryan's compensation is partly paid in the U.K. (in GBP) by the Company's subsidiary BioNTech UK Limited, and partly in Germany (in Euro).

(3) Appointed on July 1, 2025.

(4) Served through June 30, 2025.

(5) Served through September 30, 2025.

Fixed compensation is primarily paid out as a salary in twelve monthly installments within a calendar year. Özlem Türeci's annual fixed compensation was increased from May 2025 from €550,000 to €620,000 to reflect her increased time commitment and responsibilities. As part of her unpaid sabbatical in December 2025, she did not receive a fixed compensation during her leave.

Fringe Benefits

The Management Board also receives fringe benefits. These mainly comprise allowances for health and long-term care insurance and supplementary insurance, non-cash benefits for bicycles, travel allowances and relocation costs. Management Board members may also be reimbursed for individual tax advice expenses. In general, Management Board members do not receive pension benefits. James Ryan receives certain fringe benefits under his service agreement with BioNTech UK Limited, including a matching pension contribution to a defined benefit pension scheme subject to payments he makes into the scheme, group income protection, life assurance, private medical healthcare and occupational sick pay.

The Company maintains Directors and Officers, or D&O, insurance for Management Board members, which provides coverage for legal defense costs and any damages arising from claims against a Management Board member for breach of their duties. The D&O insurance includes an AktG-compliant deductible for the Management Board members. D&O insurance expenses are not classified as compensation, as they are incurred in the Company's own interests to cover risks faced by our Management Board, Supervisory Board, and other senior executives and managing directors of BioNTech Group entities.

Short-Term Incentive, or STI, Compensation

Under the Compensation System 2024, the Management Board is entitled to receive a short-term performance-related cash bonus with a one-year assessment period. The STI payment is capped at 60% of the annual fixed

compensation and is contingent upon the achievement of certain financial and non-financial performance criteria of the Group.

At its first meeting after the end of the relevant financial year, the Supervisory Board determines the Management Board's actual STI target achievement.

The Supervisory Board determined that the 2025 Company Goals and ESG Targets were fully achieved.

The following table summarizes the overall target achievement and the resulting annual bonus payout amount per Management Board member for the year ended December 31, 2025.

Short-Term Incentive (STI) Compensation for the year ended December 31, 2025	Relative to fixed compensation (in %)	Compensation Corridor		Overall Target Achievement (in %)	STI Payment (in thousands)
		Lower Limit (0%)	Upper Limit (100%)		
Serving members of the Management Board as of December 31, 2025					
Prof. Ugur Sahin, M.D.	50	—	350	100	350
Annemarie Hanekamp	55	—	300	100	300
Sierk Poetting, Ph.D.	55	—	300	100	300
James Ryan, Ph.D.	55	—	300	100	300
Prof. Özlem Türeci, M.D.	75	—	350	100	350
Ramón Zapata[1]	56	—	175	100	175
Members of the Management Board who stepped down in 2025					
Jens Holstein[2]	55	—	150	100	150
Ryan Richardson[3]	55	—	225	n / a	167

(1) Appointed on July 1, 2025.

(2) Served through June 30, 2025.

(3) Served through September 30, 2025. Ryan Richardson was granted a guaranteed STI payment relating to the year ended December 31, 2025 in the amount of €166,500, which was paid out during the third quarter of 2025.

Under the Compensation System 2024, 100% of the STI relating to the year ended December 31, 2025 will be paid out in April 2026, the month after the approval of the 2025 consolidated financial statements. The STI relating to the year ended December 31, 2024 was structured into two installments under the Compensation System 2021/2022. The first STI installment for the year ended December 31, 2024 amounting to 50% of the total STI was paid out in April 2025, the month after the approval of the 2024 consolidated financial statements. The second STI installment is subject to adjustments in relation to the development of the Company's share price between the determination date (when the STI achievement is determined) and the respective anniversary of that date. If the share price (based on the market price of our ADSs) increases or decreases, the payment amount is multiplied by the factor price development. The second STI installment for the year ended December 31, 2024 will be paid out (and adjusted) in March 2026.

The STI payment for the year ended December 31, 2025, is considered granted and owed in 2025, when the Management Board completed the compensation-related activity. The same approach applied to both STI installments for the year ended December 31, 2024.

Other Payments

Due to the highly competitive biotech environment and the need to attract qualified candidates, the Supervisory Board may agree to compensate new Management Board members with a one-time sign-on bonus. Such bonus payments are designed to compensate for the variable compensation the individual may have forfeited by leaving another company for BioNTech. During the 2025 financial year, Ramón Zapata was granted a one-time cash sign-on bonus of €900,000 (gross) as part of his appointment. Out of this amount, €500,000 was paid in

cash in January 2026. The remaining €400,000 will be due in cash in January 2027, provided he is still a Management Board member on July 31, 2026.

During the 2024 financial year, Annemarie Hanekamp received a one-time payment of €1,750,000 as part of her appointment. Out of this amount, €1,250,000 was paid as a cash bonus in July 2024 and is subject to repayment in reducing amounts if the service agreement ends other than for good cause before June 30, 2027. The remaining €500,000 will be granted in ADSs in July 2028 or at the earliest possible date after a potential blackout period, provided she is still a Management Board member on June 30, 2028.

In 2021, the Supervisory Board granted Jens Holstein, who retired from the Management Board during 2025, a one-time signing bonus of 4,246 phantom shares valued at €800,000. The phantom shares vested in four equal installments on July 1 of 2022, 2023 and 2024 and June 30, 2025 and were settled in cash on July 1, 2025. The cash payment was subject to caps based on the settlement closing price (no more than 800% of the closing price at grant) and the total payout (which could not exceed €6.4 million). Neither cap was invoked, and the final gross payout was €386,526.

In connection with Ryan Richardson's separation from the Management Board effective September 30, 2025, he received a one-time payment of €687,500 (gross).

Share-Based Payments (incl. Long-Term Incentive, or LTI, and Other One-Time Awards)

Our Management Board's service agreements provide for long-term, four-year incentive compensation (Management Board Grant – LTI) through an annual grant of options to acquire BioNTech shares and, as of the Compensation System 2024, performance share units, or PSUs (described further below), as determined by the Supervisory Board. These LTI awards are in line with the Compensation System 2021/2022 and the Compensation System 2024 and are subject to the terms and conditions of the respective authorizations of the AGM creating our ESOP and the applicable option and PSU agreements.

During the year ended December 31, 2025, the number of options and PSUs granted were calculated based on a target value of €3,500,000 for Ugur Sahin, €1,800,000 for Özlem Türeci and €1,650,000 for each other Management Board member. The unvested portions of Ryan Richardson's and Jens Holstein's LTI awards granted for the years 2022 to 2024 were forfeited upon their departure from the Management Board in 2025.

During the year ended December 31, 2024, the number of options granted was calculated based on a target value of €1,150,000 for Ugur Sahin and €550,000 for each other Management Board member. Annemarie Hanekamp received a guaranteed pro rata LTI grant of €275,000 for the period from July 1 to December 31, 2024 due to her appointment to the Management Board during 2024. This amount reflected 50% of the annual target value and was settled in cash in 2025.

We also entered into a one-time share-based payment arrangement with our CEO Ugur Sahin, the Chief Executive Officer Grant granted in 2019, or the CEO Grant 2019, which is explained below. Following the vesting of 25% on an annual basis since 2019, the CEO Grant 2019 vested and became exercisable on October 9, 2023. Ugur Sahin exercised the CEO Grant 2019 during the year ended December 31, 2024.

The various LTI awards vest at a rate of 25% annually over four years. The annual vesting dates starting the year after the options were awarded are as follows:

Name of the Program	Annual vesting dates
LTI 2021	May 12 (May 17 for Jens Holstein)
LTI 2022	May 31
LTI 2023	May 22
LTI 2024	August 26
LTI 2025	May 27 (PSUs), May 28 (ESOP)

While vesting, the LTI awards continue to be subject to performance and waiting conditions.

The benefits from our share-based payment arrangements (including long-term incentive) are considered granted and owed when the awards are settled (see further section 6.B). During the years ended December 31, 2024 and 2025, this principle applied to the awards granted under the CEO Grant 2019, LTI 2020 Program, LTI 2020 (EEP) Program and the one-time signing bonus of Jens Holstein as a result of their exercise and settlement. With respect to these Programs, the table ”Compensation Granted and Owed” in section 6.B shows the implied market value calculated using the closing price of an ADS of BioNTech on Nasdaq on the respective last trading day preceding each exercise date converted from USD to Euro using the exchange rates published by the German Central Bank (Deutsche Bundesbank) on the same days, as well as applying the effective exercise price and maximum cap mechanism. The implied market value may vary from the benefit in kind.

In accordance with Section 162 Paragraph 1 No. 3 AktG, the table below provides an overview of share options and other share-based payment instruments granted to our Management Board and outstanding as of December 31, 2025.

Overview of ongoing LTI awards of serving members of the Management Board as of December 31, 2025

Program Name and Grant Date	Management Board Member	Target Value (€)	Initial Number of Options (O), Phantom Options (PO), Restricted Stock Unit (RSU) or Performance Share Units (PSU)	Award Exercise Price (€)[1]	Earliest Award Exercise Date[2]	Award Expiration Date	Number of Awards Granted (G), Exercised (E), or Forfeited (F) during the year	Number of Awards Outstanding
LTI 2021[5] 5/12/2021	Prof. Ugur Sahin, M.D.	750,000	17,780 (PO)	157.64	5/12/2025	5/12/2031	—	17,780
	Sierk Poetting, Ph.D.	550,000	7,112 (PO)				—	7,112
	Prof. Özlem Türeci, M.D.	550,000	7,112 (PO)				—	7,112
LTI 2022[6] 5/31/2022	Prof. Ugur Sahin, M.D.	750,000	19,997 (PO)	129.45	5/31/2026	5/31/2032	—	19,997
	Sierk Poetting, Ph.D.	550,000	14,664 (PO)				—	14,664
	Prof. Özlem Türeci, M.D.	550,000	14,664 (PO)				—	14,664
LTI 2023[7] 5/22/2023	Prof. Ugur Sahin, M.D.	1,150,000	38,506 (O)	96.97	5/22/2027	5/22/2033	—	38,506
	Sierk Poetting, Ph.D.	550,000	18,416 (O)				—	18,416
	Prof. Özlem Türeci, M.D.	550,000	18,416 (O)				—	18,416
LTI 2024[8] 8/26/2024	Prof. Ugur Sahin, M.D.	1,150,000	53,233 (O)	75.91	8/26/2028	8/26/2034	—	53,233
	Sierk Poetting, Ph.D.	550,000	25,459 (O)				—	25,459
	James Ryan, Ph.D.	550,000	25,459 (O)				—	25,459
	Prof. Özlem Türeci, M.D.	550,000	25,459 (O)				—	25,459
LTI 2025[9] 5/27/2025	Prof. Ugur Sahin, M.D.	3,500,000	23,434 (PSU)	n / a	5/27/2029	5/27/2035	23,434 (G)	23,434
			18,747 (O)	93.35	5/28/2029	5/28/2035	18,747 (G)	18,747
	Annemarie Hanekamp	1,650,000	11,047 (PSU)	n / a	5/27/2029	5/27/2035	11,047 (G)	11,047
			8,838 (O)	93.35	5/28/2029	5/28/2035	8,838 (G)	8,838
	Sierk Poetting, Ph.D.	1,650,000	11,047 (PSU)	n / a	5/27/2029	5/27/2035	11,047 (G)	11,047
			8,838 (O)	93.35	5/28/2029	5/28/2035	8,838 (G)	8,838
	James Ryan, Ph.D.	1,650,000	11,047 (PSU)	n / a	5/27/2029	5/27/2035	11,047 (G)	11,047
			8,838 (O)	93.35	5/28/2029	5/28/2035	8,838 (G)	8,838
	Prof. Özlem Türeci, M.D.	1,800,000	11,633 (PSU)	n / a	5/27/2029	5/27/2035	11,633 (G)	11,047
			9,306 (O)	93.35	5/28/2029	5/28/2035	9,306 (G)	8,838
LTI 2020 (EEP)[10] 12/15/2020	James Ryan, Ph.D.	n/a	1,163 (RSU)	n / a	12/15/2024	n / a	1,163 (E)	—
LTI 2021 (EEP)[10] 12/10/2021	James Ryan, Ph.D.	n/a	313 (RSU)	n / a	12/10/2025	n / a	—	313
LTI 2022 (EEP)[10] 12/9/2022	James Ryan, Ph.D.	n/a	740 (RSU)	n / a	12/9/2026	n / a	—	740
LTI 2023 (EEP)[10] 12/8/2023	James Ryan, Ph.D.	n/a	750 (RSU)	n / a	12/8/2027	n / a	—	750

Overview of ongoing LTI awards of Members of the Management Board who stepped down in 2025

Program Name and Grant Date	Management Board Member	Target Value (€)	Initial Number of Options (O), Phantom Options (PO), Restricted Stock Unit (RSU) or Performance Share Units (PSU)	Award Exercise Price (€)[1]	Earliest Award Exercise Date[2]	Award Expiration Date	Number of Awards Granted (G), Exercised (E), or Forfeited (F) during the year	Number of Awards Outstanding
LTI 2021[5] 5/12/2021 - 5/17/2021	Jens Holstein [3]	275,000	6,463 (PO)	159.00	5/17/2025	5/17/2031	—	6,463
	Ryan Richardson [4]	260,000	6,163 (PO)	157.64	5/12/2025	5/12/2031	—	6,163
Signing Bonus 7/1/2021	Jens Holstein [3]	n/a	4,246 (PO)	n / a	7/1/2025	n / a	4,246 (E)	—
LTI 2022[6] 5/31/2022	Jens Holstein [3]	550,000	14,664 (PO)	129.45	5/31/2026	5/31/2032	3,666 (F)	10,998
	Ryan Richardson [4]	280,000	7,465 (PO)				1,867 (F)	5,598
LTI 2023[7] 5/22/2023	Jens Holstein [3]	550,000	18,416 (O)	96.97	5/22/2027	5/22/2033	9,208 (F)	9,208
	Ryan Richardson [4]	550,000	18,416 (O)				9,208 (F)	9,208
LTI 2024[8] 8/26/2024	Jens Holstein [3]	550,000	25,459 (O)	75.91	8/26/2028	8/26/2034	19,094 (F)	6,365
	Ryan Richardson [4]	550,000	25,459 (O)				19,094 (F)	6,365

(1) All options are subject to an exercise price cap (see above).

(2) Indicates the end of the respective waiting periods.

(3) Served through June 30, 2025.

(4) Served through September 30, 2025.

(5) Management Board Grant (Long-Term Incentive) in the respective year. Phantom options were issued which vested in four equal installments on May 12 of 2022, 2023, 2024 and 2025 for all Management Board members except Jens Holstein, and in the case of Jens Holstein, vested in four equal installments on May 17 of the same years. The options became exercisable on May 12, 2025 and May 17, 2025, respectively.

(6) Management Board Grant (Long-Term Incentive) in the respective year. Phantom options were issued which vest in four equal installments on May 31 of 2023, 2024, 2025 and 2026 for all Management Board members. These phantom options will not become exercisable before the expiry of the waiting period on May 31, 2026.

(7) Management Board Grant (Long-Term Incentive) in the respective year. Options vest in four equal installments on May 22 of 2024, 2025, 2026 and 2027 but may not be exercised before May 22, 2027.

(8) Management Board Grant (Long-Term Incentive) in the respective year. Options vest in four equal installments on August 26 of 2025, 2026, 2027 and 2028 but may not be exercised before August 26, 2028.

(9) Management Board Grant (Long-Term Incentive) in the respective year. PSUs vest in four equal installments on May 27 of 2026, 2027, 2028 and 2029 but may not be exercised before May 28, 2029. Options vest in four equal installments on May 28 of 2026, 2027, 2028 and 2029 but may not be exercised before May 28, 2029.

(10) James Ryan's 2020, 2021, 2022 and 2023 awards were granted under the BioNTech 2020 Employee Equity Plan (EEP). These awards vest in equal annual installments over four years and are subject to a four-year waiting period.

Management Board Grant (Long-Term Incentive)

As noted above, the Management Board's long-term, incentive compensation (Management Board Grant – LTI) is comprised of an annual grant of a combination of PSUs and options to acquire BioNTech shares, all of which are subject to a four-year waiting period from grant. The grants are subject to the terms and conditions of the respective authorizations of the AGM creating our Employee Stock Ownership Plan, or ESOP, and the applicable option and PSU agreements. Management Board members were awarded phantom options in May 2021 and 2022, options in May 2023 and August 2024, and a combination of options and PSUs in May 2025.

Stock Options

Grant Date	Exercise Price(1)
May 12, 2021	$185.23 (€157.64)
May 17, 2021	$186.83 (€159.00)
May 31, 2022	$152.10 (€129.45)
May 22, 2023	$113.94 (€96.97)
August 26, 2024	€75.91
May 28, 2025	€93.35

(1) All conversions from USD to EUR are calculated using the foreign exchange rate as published by the German Central Bank (Deutsche Bundesbank) as of December 31, 2025.

All options are subject to an exercise price cap, which means that the exercise price shall be adjusted to ensure that the current price of an ADS as of the exercise date does not exceed 800% of the exercise price. For the phantom share options issued under the LTI 2021 and 2022 programs and the options issued under the LTI 2023, 2024 and 2025 programs, as well as the PSUs under the LTI 2025 program, the maximum compensation that each member is entitled to receive, together with other compensation components received in the respective grant year, shall not exceed €20.0 million for Ugur Sahin and €10.0 million for all others. The options vest annually in equal installments over four years commencing on the first anniversary of the grant date and become exercisable four years after the grant date.

In the case of options granted under the Compensation System 2021/2022, vested options can only be exercised if both of the following performance criteria are met:

- Threshold Amount: At the time of exercise, the current share price must be equal to or greater than the threshold amount. The threshold amount is the exercise price, which increases by seven percentage points on each anniversary of the grant date.
- Target Price: At the time of exercise, the current share price must be at least equal to the target price, defined as:
  - for the twelve-month period starting on the fourth anniversary of the grant date, $8.5 billion divided by the total number of ordinary shares outstanding immediately following the initial public offering (excluding shares owned by BioNTech); and
  - for each twelve-month period starting on the fifth or subsequent anniversary, 107% of the target share price applicable for the prior twelve-month period.
- Index Performance: The closing price for the fifth trading day prior to the start of the relevant exercise window must be higher than the exercise price by at least the same percentage by which the Nasdaq Biotechnology Index (or a comparable successor index) has increased since the last trading day before the grant date.

In the case of options granted under the Compensation System 2024 and from the 2025 financial year onwards, vested options can only be exercised if all of the following performance criteria are met:

- Threshold Amount: At the time of exercise, the current share price must be at least 180% of the exercise price, which increases by an additional twenty percentage points from the fifth and each subsequent anniversary of the approval date.
- Index Performance: The closing price for the fifth trading day prior to the start of the relevant exercise date must be higher than the exercise price by at least the same percentage by which the Nasdaq Biotechnology Index (or a comparable successor index) has increased since the last trading day before the grant date.
- Additional Terms:
  - After the waiting period expires, option rights may be exercised only during the exercise windows specified in the ESOP agreement.
  - Option rights can be exercised up to ten years after the grant date; after this period, any unexercised options will be forfeited without compensation.

Performance Share Units (PSUs)

PSUs have a performance period of four years beginning with the grant of the PSUs by the Supervisory Board. The initial size of the PSU award is determined by dividing an individually-agreed amount in each Management Board's service contract by a reference price, which is the average closing price of the last 90 trading days prior to the date of the Supervisory Board's resolution on the issue of the PSUs, or the PSU Issue Date, except that it may not fall below $105.16.

Performance Targets and Determination of Target Achievement

PSUs can only be settled if the share price has performed as well or better in percentage terms than the Nasdaq Biotechnology Index (or a comparable successor index) in the period from the last trading day before the PSU Issue Date to the fifth trading day before the start of the relevant exercise period. If the share price performs as

well or better than the index, the target is achieved and the PSUs can be settled. If the share price underperforms the index, the PSUs cannot be settled and expire without compensation.

- Waiting Period: The PSUs granted vest 100% after a vesting period of four years from the grant date, subject to achieving the performance target. If the target is achieved, the PSUs can be converted into a cash payment, shares or ADSs.

- Vesting Conditions: One quarter of the PSUs vest each year from the grant date. Early termination of the Management Board service contract leads to a corresponding reduction in the vested PSUs. The unvested portion lapses without compensation.

- Settlement Closing Price: The Settlement Closing Price for the PSUs is the closing price of our ADSs on the last trading day prior to the day on which the PSUs are settled in the trading system with the highest total trading volume on the ten trading days prior to the date of settlement.

- Cash Settlement: To settle the PSUs, we may choose to grant (1) our own existing shares, (2) our own ADSs, (3) shares or rights or certificates representing them in another listed company, (4) a cash payment or (5) another form of settlement instead of new shares from authorized capital. The amount of the cash payment is calculated by multiplying the vested PSUs by the Settlement Closing Price.

Chief Executive Officer Grant (CEO Grant 2019)

In September 2019, we granted Prof. Ugur Sahin, M.D., an option to purchase 4,374,963 of our shares under the ESOP 2017 / 2019 program. All of these option rights vested and became exercisable in 2023, and were exercised on August 9, 2024, with an exercise price for each option of €13.74 ($15.00) calculated using the foreign exchange rate published by the German Central Bank (Deutsche Bundesbank) on the day before the exercise date and by applying the effective exercise cap (but not increasing above a Euro amount equivalent to USD 30) and the maximum cap mechanism as disclosed above. The closing price of one ADS on Nasdaq on the settlement date converted from U.S. Dollars to Euro using the exchange rate published by the German Central Bank (Deutsche Bundesbank) on the same day was €73.68 and led to an intrinsic value of the exercised options of €259.5 million.

Share Ownership Guideline

The Supervisory Board believes that the Management Board should maintain a significant stake in the Company to promote its long-term interests and achieve its long-term strategic goals, and align the Management Board's personal interests with those of the Company. As a result, the Supervisory Board adopted share ownership guidelines effective January 1, 2025 as part of the new compensation system for the Management Board pursuant to Section 87a AktG.

Management Board members are required to achieve the applicable ownership level within four years after first becoming subject to the Guidelines. The ownership level must be maintained for so long as they remain a Management Board member. In the event of non-compliance, the Compensation, Nominating, and Corporate Governance Committee of the Supervisory Board may deduct the missing difference in value from variable remuneration (STI and LTI) components to be granted or determined. Target ownership levels and progress towards compliance for each Management Board member serving as of December 31, 2025 are detailed below:

Member of Management Board	Target (% of fixed compensation)	Beginning of the position-building	End of the position-building phase	Status as of Dec. 31, 2025
Prof. Ugur Sahin, M.D. (since 2008)	200%	January 1, 2025	January 1, 2029	100% of investment target achieved
Sierk Poetting, Ph.D. (since Sept. 01, 2014)	100%	January 1, 2025	January 1, 2029	100% of investment target achieved
Prof. Özlem Türeci, M.D. (since 2019)	100%	January 1, 2025	January 1, 2029	100% of investment target achieved
James Ryan, Ph.D. (since Sept. 01, 2023)	100%	January 1, 2025	January 1, 2029	14% of investment target achieved
Annemarie Hanekamp (since July 01, 2024)	100%	January 1, 2025	January 1, 2029	0% of investment target achieved
Ramón Zapata (since July 01, 2025)	100%	July 1, 2025	July 1, 2029	0% of investment target achieved

Compensation of Former Management Board Members

This section outlines the compensation entitlements to Management Board members who served in prior periods but did not serve during the current fiscal year 2025.

Sean Marett left the Management Board by mutual agreement with effect as of June 30, 2024. To ensure a smooth transition of services, Sean Marett entered into a 12-month consultancy agreement with the Company on July 1, 2024, which was extended in 2025 to June 30, 2026.

The following table discloses the options granted to former Management Board members, which are outstanding as of December 31, 2025:

Former members of the Board of Management who served in prior periods but did not serve during the current fiscal year 2025

Program Name and Grant Date	Management Board Member	Target Value (€)	Initial Number of Options (O), Phantom Options (PO), Restricted Stock Unit (RSU) or Performance Share Units (PSU)	Award Exercise Price (€)[1]	Earliest Award Exercise Date[2]	Award Expiration Date	Number of Awards Granted (G), Exercised (E), or Forfeited (F) during the year	Number of Awards Outstanding
LTI 2020[4] 2/13/2020	Sean Marett[3]	300,000	38,968 (O)	26.20	2/13/2024	2/13/2030	—	38,968
LTI 2021[5] 5/12/2021	Sean Marett[3]	300,000	7,112 (PO)	157.64	5/12/2025	5/12/2031	—	5,334
LTI 2022[6] 5/31/2022	Sean Marett[3]	550,000	14,664 (PO)	129.45	5/31/2026	5/31/2032	—	7,332
LTI 2023[7] 5/22/2023	Sean Marett[3]	550,000	18,416 (O)	96.97	5/22/2027	5/22/2033	—	4,604
Separation Agreement[8] 8/26/2024	Sean Marett[3]	n/a	5,760 (PO)	75.91	8/26/2028	8/26/2034	—	5,760

(1) All options are subject to an exercise price cap (see above).

(2) Indicates the end of the respective waiting periods.

(3) Served through June 30, 2024.

(4) Management Board Grant (Long-Term Incentive) in the respective year. Options vested in four equal installments on February 13 of 2021, 2022, 2023 and 2024, are now exercisable following the expiry of the waiting period on February 13, 2024.

(5) Management Board Grant (Long-Term Incentive) in the respective year. Phantom options vested in four equal installments on May 12 of 2022, 2023, 2024 and 2025, are now exercisable following the expiry of the waiting period on May 12, 2025.

(6) Management Board Grant (Long-Term Incentive) in the respective year. Phantom options were issued which vest in four equal installments on May 31 of 2023, 2024, 2025 and 2026. These phantom options will not become exercisable before the expiry of the waiting period on May 31, 2026.

(7) Management Board Grant (Long-Term Incentive) in the respective year. Options vest in four equal installments on May 22 of 2024, 2025, 2026 and 2027 but may not be exercised before May 22, 2027.

(8) Pursuant to Sean Marett's separation agreement, he was granted 5,760 phantom options representing one-quarter of the 2024 LTI award, which are subject to the same conditions and waiting period that apply to the 2024 LTI awards granted to the Management Board (see above).

C. Board Practices

Two-Tiered Board Structure

We are a European public company with limited liability (Societas Europaea or SE) (also referred to as European stock corporation, and in the official terminology of the European legislation referred to as European public limited-liability company), having its seat in Germany. We have chosen to have a two-tiered SE structure. Hence, our corporate bodies are the Management Board (*Vorstand*), the Supervisory Board (*Aufsichtsrat*) and the shareholders' meeting (*Hauptversammlung*). Our Management and Supervisory Boards are entirely separate, and, as a rule, no individual may simultaneously be a member of both boards.

Our Management Board is responsible for the day-to-day management of our business in accordance with applicable laws, our Articles of Association (*Satzung*) and the Management Board's internal rules of procedure (*Geschäftsordnung*). Our Management Board represents us in our dealings with third parties.

The principal function of our Supervisory Board is to supervise our Management Board. The Supervisory Board is also responsible for appointing and removing the members of our Management Board, representing us in connection with transactions between a current or former member of the Management Board and us, and granting approvals for certain significant matters.

Our Management Board and our Supervisory Board are solely responsible for and manage their own areas of competency (*Kompetenztrennung*); therefore, neither board may make decisions that, pursuant to applicable law, our Articles of Association or the internal rules of procedure are the responsibility of the other board. Members of both boards owe a duty of loyalty and care to us. In carrying out their duties, they are required to exercise the standard of care of a prudent and diligent businessperson. If they fail to observe the appropriate standard of care, they may become liable to us.

In carrying out their duties, the members of both boards must take into account a broad range of considerations when making decisions, including our interests and the interests of our shareholders, employees, creditors and, to a limited extent, the general public, while respecting the rights of our shareholders to be treated on equal terms. Additionally, the Management Board is responsible for implementing an appropriate and effective internal control system and risk management system with regard to the scope of business activities and the risk situation of the Company.

Our Supervisory Board has comprehensive monitoring responsibilities. To ensure that our Supervisory Board can carry out these functions properly, our Management Board must, among other duties, regularly report to our Supervisory Board regarding our current business operations and future business planning (including financial, investment and personnel planning). In addition, our Supervisory Board or any of its members is entitled to request special reports from the Management Board on all matters regarding the Company, our legal and business relations with affiliated companies and any business transactions and matters at such affiliated companies that may have a significant impact on our position at any time.

Under German law, our shareholders have, as a general rule, no direct recourse against the members of our Management Board or the members of our Supervisory Board in the event that they are believed to have breached their duty of loyalty and care to us. Apart from when we are unable to fulfill our third party obligations, tortious conduct to board members or other special circumstances, only we have the right to claim damages against the members of our two boards.

We may waive these claims to damages or settle these claims only if at least three years have passed since a claim associated with any violation of a duty has arisen and only if our shareholders approve the waiver or settlement at a shareholders' meeting with a simple majority of the votes cast, provided that no shareholders who in the aggregate hold one-tenth or more of our share capital oppose the waiver or settlement and have their opposition formally recorded in the meeting's minutes.

Supervisory Board

German law requires that the Supervisory Board consists of at least three members, while a company's articles of association may stipulate a certain higher number. Our Supervisory Board currently consists of six members.

As we are not subject to co-determination, the members of our Supervisory Board are all elected by the shareholders' meeting in accordance with the provisions of the SE Regulation and the German Stock Corporation Act (*Aktiengesetz*). German law does not require the majority of our Supervisory Board members to be independent and neither our Articles of Association (*Satzung*) nor the rules of procedure for our Supervisory Board provide otherwise. As per our Supervisory Board's assessment, an appropriate number of shareholder representatives on the Supervisory Board (i.e. the entire Supervisory Board) are independent if the Supervisory Board has two independent members. The Supervisory Board considers Helmut Jeggle and Michael Motschmann to be independent irrespective of the fact that they have been members of the Supervisory Board since 2008. As stated in the declaration to the German Corporate Governance Code, or the Corporate Governance Code, (*Entsprechenserklärung*) published by the Company on February 25, 2026 pursuant to Section 161 para. 1 of the German Stock Corporation Act (*Aktiengesetz*), which in accordance with the Corporate Governance Code is issued in connection with the Declaration pursuant to Section 315d in conjunction with Section 289f of the German Commercial Code (*HGB*), the length of membership does not give rise to any fears of material conflicts of interest on the part of the members of the Supervisory Board and therefore does not stand in the way of their independence. However, the rules of procedure for our Supervisory Board provide that the Supervisory Board should have an independent member with expertise in the field of accounting, internal control processes and auditing. Ulrich Wandschneider, Anja Morawietz, Michael Motschmann and Rudolf Staudigl fulfill this role.

Under European law, a member of a supervisory board of an SE may be elected for a maximum term to be specified in the articles of association, which must not exceed six years. Re-election, including repeated re-election, is permissible. The shareholders' meeting may specify a term of office for individual members or all of the members of our Supervisory Board which is shorter than the standard term of office and, subject to statutory limits, may set different start and end dates for the terms of members of our Supervisory Board. Our Articles of Association provide for a term of approximately five years, depending on the date of the annual general shareholders' meeting in the year in which the term of the relevant member is to expire.

The shareholders' meeting may, at the same time as it elects the members of the Supervisory Board, elect one or more substitute members. The substitute members replace members who cease to be members of our Supervisory Board and take their place for the remainder of their respective terms of office. Currently, no substitute members have been elected or have been proposed to be elected.

Members of our Supervisory Board may be dismissed at any time during their term of office by a resolution of the shareholders' meeting adopted by at least a simple majority of the votes cast. In addition, any member of our Supervisory Board may resign at any time by giving one month's written notice – or, in the event of cause, giving written notice with immediate effect – of his or her resignation to the Management Board.

Our Supervisory Board elects a chairperson and a deputy chairperson from its members. The deputy chairperson exercises the chairperson's rights and obligations whenever the chairperson is unable to do so. The members of our Supervisory Board have elected Helmut Jeggle as chairperson and Ulrich Wandschneider as deputy chairperson, each for the term of their respective membership on our Supervisory Board.

The Supervisory Board meets at least twice each calendar half-year. Our Articles of Association provide that a quorum of the Supervisory Board members is present if at least three of its members participate in the vote. Members of our Supervisory Board are deemed present if they attend the meeting via telephone or other (electronic) means of communication (including via video conference) or submit their written vote through

another member. Additionally, our Articles of Association allow for resolutions to be taken via telephone or other (electronic) means of communications (including via video conference).

Resolutions of our Supervisory Board are passed by the vote of a simple majority of the votes cast unless otherwise required by law, our Articles of Association or the rules of procedure of our Supervisory Board. In the event of a tie, the chairperson of the Supervisory Board has the casting vote. Our Supervisory Board is not permitted to make management decisions, but in accordance with European and German law and in addition to its statutory responsibilities, it has determined that certain matters require its prior consent, including:

- entering into certain large transactions;
- acquiring any material interests in businesses of third parties (except group companies) or disposing of material assets or shares of the Group (other than in relation to an internal reorganization);
- issuing shares from authorized capital, unless the shares are issued pursuant to a redemption of stock appreciation rights; and
- acquiring treasury shares in return for valuable consideration.

Each member of the Supervisory Board shall disclose any conflicts of interest to the Supervisory Board, especially those that may arise from providing advice or holding any offices or board positions at customers, suppliers, creditors or other third parties. Material conflicts of interest that are not merely temporary and that are specific to a particular Supervisory Board member shall result in this particular member leaving office. Our Supervisory Board also puts in place adequate measures to limit, prevent or resolve conflicts of interest in accordance with applicable legal requirements and the Company's Conflicts of Interest Policy.

Our Supervisory Board conducted a self-assessment for the year ended December 31, 2025. It covered all key aspects of the Supervisory Board's work, including its committees, its composition, its competence profile, its main topics and its relationship with the Management Board. The results of the self-assessment have been evaluated and will subsequently be presented to the Supervisory Board. Based on the self-assessment, the Supervisory Board believes that it, its committees and the Management Board continue to operate at a professional and cooperative level. No fundamental need for change was identified.

Supervisory Board Practices

Decisions are generally made by our Supervisory Board as a whole, however decisions on certain matters may be delegated to committees of our Supervisory Board to the extent permitted by law. The chairperson, or if he or she is prevented from doing so, the deputy chairperson, chairs the meetings of the Supervisory Board and determines the order in which the agenda items are discussed, the method and order of voting, as well as any adjournment of the discussion and passing of resolutions on individual agenda items after a due assessment of the circumstances. Our Supervisory Board may designate further types of actions as requiring its approval.

In addition, each member of the Supervisory Board is obliged to carry out his or her duties and responsibilities personally, and such duties and responsibilities cannot be generally and permanently delegated to third parties. However, the Supervisory Board and its committees have the right to appoint independent experts for the review and analysis of specific circumstances in accordance with its control and supervision duties under applicable European and German law. We would bear the costs of any such independent experts that are retained by the Supervisory Board or any of its committees.

Pursuant to Section 107 para. 3 of the German Stock Corporation Act (*Aktiengesetz*), the Supervisory Board may form committees from among its members and charge them with the performance of specific tasks. The committees' tasks, authorizations and processes are determined by the Supervisory Board. Where permissible by law, important powers of the Supervisory Board may also be transferred to committees.

The Supervisory Board has established an Audit Committee, a Compensation, Nominating, Governance Committee, a Capital Markets Committee and a Product Committee by resolution. Set forth in the table below are the members of the respective committees during the year ended December 31, 2025.

Name of Committee	Members
Audit Committee	Prof. Anja Morawietz, Ph.D. (Chair), Prof. Rudolf Staudigl, Ph.D and Ulrich Wandschneider, Ph.D.
Compensation, Nominating and Corporate Governance Committee	Prof. Rudolf Staudigl, Ph.D. (Chair), Baroness Nicola Blackwood and Michael Motschmann.
Capital Markets Committee	Helmut Jeggle (Chair), Prof. Anja Morawietz, Ph.D. and Michael Motschmann
Product Committee	Ulrich Wandschneider, Ph.D. (Chair), Baroness Nicola Blackwood and Helmut Jeggle

Audit Committee

Our Audit Committee for the year ended December 31, 2025 consisted of Anja Morawietz. (Chair), Rudolf Staudigl and Ulrich Wandschneider. The Audit Committee assists the Supervisory Board in overseeing the accuracy and integrity of our financial statements, our accounting and financial reporting processes and audits of our financial statements, the effective functioning of our internal control system, our risk management system, our compliance with legal and regulatory requirements, our independent auditor's qualifications and independence, the performance of the independent auditor and the effective functioning of our internal audit functions, and, subject to certain limitations, adopts and implements pertinent decisions on behalf of the Supervisory Board. The Audit Committee's duties and responsibilities to carry out its purpose, include, among others:

- oversight of the Company's accounting, sustainability reporting, financial reporting processes, sustainability reporting processes and the audit of the annual financial statements and the consolidated financial statements and the (group) management reports and sustainability report and the effectiveness of the internal control system;
- oversight of the effectiveness of the Risk Management System and the internal Audit System;
- monitoring the independent audit, in particular the selection and independence of the auditor, the quality of the audit and the additional services provided by the auditor;
- making a recommendation to the Supervisory Board with respect to the proposal for the appointment of the auditors;
- considering the commissioning of the audit engagement, as well as the compensation, retention and oversight of the independent auditor;
- evaluating the qualifications, independence and quality of performance of the independent auditor;
- reviewing and pre-approving the audit and non-audit services to be performed by the independent auditor;
- reviewing and discussing with the independent auditor the annual audit plan and overall auditing strategy, the independent auditor's responsibilities and the management's responsibilities under the auditing process, and reviewing with the independent auditor and management the critical accounting policies and practices to be applied;

- reviewing of alternative treatments of financial information discussed by the independent auditor and the board, the implications of using such alternative disclosures and treatments, and the independent auditor's preferred treatment;

- reviewing and discussing with the independent auditor and management the adequacy and effectiveness of our internal accounting controls and critical accounting policies;

- reviewing and discussing with the independent auditor and management the results of our annual audit;

- reviewing non-financial reporting;

- reviewing the effectiveness of the compliance management system;

- reviewing, approving and monitoring any related party transactions in accordance with SEC regulations or German law and reviewing and monitoring potential conflict of interest situations on an ongoing basis for compliance with our policies and procedures; and

- overseeing procedures for the receipt, retention and treatment of complaints received regarding accounting, internal accounting controls or auditing matters or other matters of compliance.

Within the limits of applicable European and German law, the Audit Committee shall have the resources and authority appropriate to discharge its duties and responsibilities, including the authority to select, retain, terminate, and approve the fees and other engagement terms of special or independent counsel, accountants or other experts and advisors, as it deems necessary or appropriate for so discharging its duties and responsibilities, without seeking approval of the Management Board or Supervisory Board.

All members of the Audit Committee qualify as “independent directors” as such term is defined in Rule 10A-3 under the Exchange Act and Nasdaq Rule 5605. Additionally, our Supervisory Board has determined that Anja Morawietz, Rudolf Staudigl and Ulrich Wandschneider qualify as “audit committee financial expert” as that term is defined under the Exchange Act. In addition, Anja Morawietz as Chair of the Audit Committee, Rudolf Staudigl and Ulrich Wandschneider have the special knowledge and experience required by the German Corporate Governance Code in the field of accounting and expertise in the field of auditing.

Compensation, Nominating and Corporate Governance Committee

Our Compensation, Nominating and Corporate Governance Committee for the year ended December 31, 2025 consisted of Rudolf Staudigl (Chair), Nicola Blackwood and Michael Motschmann. The Compensation, Nominating and Corporate Governance Committee’s duties and responsibilities to carry out its purpose include, among others:

- preparing and discussing with management policies relating to the remuneration of the members of our Management Board;

- reviewing and supervising corporate goals and objectives for the remuneration of the members of the Management Board, including evaluation of the performance of the members of the Management Board in light of these goals and proposals to the Supervisory Board for remuneration based on such evaluations;

- reviewing all equity-based compensation plans and arrangements and making recommendations to the Supervisory Board regarding such plans;

- assisting with identifying and recruiting candidates to fill positions on the Management Board and the Supervisory Board;

- considering any corporate governance issue that arises and developing appropriate recommendations for the Supervisory Board; and

- overseeing the evaluation of the Supervisory Board and reporting on its performance and effectiveness.

Capital Markets Committee

Our Capital Markets Committee for the year ended December 31, 2025 consisted of Helmut Jeggle (Chair), Anja Morawietz and Michael Motschmann. The Capital Markets Committee advises and makes recommendations to the Supervisory Board on issues in connection with capital measures and takeover, merger and acquisition activities. Its responsibilities include the following tasks:

- overseeing the activities of the Company relating to its capital structure and capital raising, including preparation for and implementation of public offerings and share issuances; and

- overseeing the activities of the Company relating to takeovers, mergers and acquisitions activities.

Product Committee

Our Product Committee for the year ended December 31, 2025 consisted of Ulrich Wandschneider (Chair), Nicola Blackwood and Helmut Jeggle. The Product Committee advises and makes recommendations to the Supervisory Board with respect to our strategy and investment in research and development programs and product launch preparations including commercialization. Its responsibilities include the following tasks:

- advising on strategy, execution and communication regarding relevant go-to-market efforts;

- overseeing the activities relating to (a) product development, (b) launch plans and (c) their execution; and

- advising on market potential for products in clinical development.

Management Board

Our Supervisory Board determines the exact number of members of our Management Board, which must consist of at least two members. Pursuant to the Articles, the Supervisory Board may also appoint a chairperson or a spokesman of the Management Board. Ugur Sahin has been appointed the chair of the Management Board.

The members of our Management Board are appointed by our Supervisory Board for a term of up to five years. They are eligible for reappointment or extension, including repeated re-appointment and extension, after the completion of their term in office, in each case again for up to an additional five years. Under certain circumstances, such as a serious breach of duty or a vote of no confidence by the shareholders in a shareholders' meeting, a member of the Management Board may be removed from office by our Supervisory Board prior to the expiration of his or her term.

The members of our Management Board conduct the daily business of the Company in accordance with applicable laws, our Articles of Association and the rules of procedure for the Management Board adopted by our Supervisory Board. They are generally responsible for the management of our company and for handling our daily business relations with third parties, the internal organization of our business and communications with our shareholders.

A member of the management board of an SE governed by German law may not deal with or vote on matters relating to proposals, arrangements or contractual agreements between himself or herself and the Company, and a member of our Management Board may be liable to us if he or she has a material interest in any contractual agreement between the Company and a third party which is not disclosed to and approved by our Supervisory Board.

The rules of procedure for our Management Board provide that certain matters require a resolution of the entire Management Board, in addition to transactions for which a resolution adopted by the entire Management Board is required by law or required by our Articles of Association. In particular, the entire Management Board shall decide on, among others:

- the budget plan for the following year, which is to be presented by the Management Board to the Supervisory Board by December 10 of each year;
- presentation of the Company's financial statements and consolidated financial statements and reviews of operations of the Company and the Group;
- reporting to the Supervisory Board;
- all measures and transactions that require the Supervisory Board's approval;
- all measures and transactions that are of fundamental importance or involve an extraordinary economic risk to us, including without limitation, establishing new lines of business or discontinuing existing ones, acquisitions or sales of material business assets, material interests, holdings and investments and material contracts or transactions;
- convening the Company's shareholders' meetings and proposals for resolutions by the Company's shareholders' general meetings; and
- appointment and termination of key managers in the Group.

Code of Ethics and Conflicts of Interest Policy

We have adopted a Code of Ethics & Business Integrity, or Code of Ethics, which outlines the principles of legal and ethical business conduct under which we do business. The Code of Ethics applies to all of our Supervisory Board members, Management Board members, directors of our subsidiaries and employees. The full text of the Code of Ethics is available on our website at https://www.biontech.de. The information and other content appearing on our website are not incorporated by reference into this Annual Report and our website address is included in this report as an inactive textual reference only. Any amendments or waivers from the provisions of the Code of Ethics for members of our Supervisory or Management Boards will be made only after approval by our Supervisory Board and will be disclosed on our website promptly following the date of such amendment or waiver.

We have also adopted a Conflicts of Interest Policy which sets forth the procedures by which we manage potential and actual conflicts of interest. Under the Conflicts of Interest Policy, which applies to all of our Supervisory Board members, Management Board members, directors of our subsidiaries and employees, an actual, potential or perceived conflict of interest must be disclosed when it first arises. If the conflict is transactional in nature and involves a member of the Management Board or the Supervisory Board, the Management or Supervisory Board, as the case may be, with the abstention of the conflicted member, shall decide whether to approve the transaction.

In addition, we have implemented compliance policies that describe the compliance management systems that have been implemented for us and our subsidiaries. Our compliance policies are designed to ensure compliance with applicable legal requirements, while at the same time implementing high ethical standards that are mandatory for both management and each employee. The overall responsibility for the compliance management system lies with the Management Board. The Audit Committee will receive regular reports on the operation of the compliance management system.

D. Employees

As of December 31, 2025, we had 7,807 full-time equivalent employees working for us, of whom 1,310 hold a doctoral degree or higher. The following tables provides an overview of employee full-time equivalent broken down by function and by the regions of Europe, North America, Asia and Australia and Africa. The calculation of full-time equivalent employees is based on BioNTech Group employees, excluding Board Members, interns, Ph.D. or working students, apprentices and employees on unpaid leave.

Full-time equivalents	Clinical Research & Development	Scientific / Pre-Clinical Research & Development	Operations	Commercial & Business Development	Enabling Functions	Other Services Businesses	CureVac[1]	∑
Europe	529	1,304	2,264	67	1,118	369	666	6,317
North America	294	135	76	68	92	15	8	688
Asia and Australia	227	58	260	2	75	—	—	622
Africa	—	—	34	—	3	143	—	180
Total as of December 31, 2025	**1,050**	**1,497**	**2,634**	**137**	**1,288**	**527**	**674**	**7,807**
Europe	565	1,345	2,051	125	1,194	391	—	5,671
North America	324	217	141	20	94	16	—	812
Asia and Australia	12	3	76	1	8	—	—	100
Africa	—	—	32	—	4	153	—	189
Total as of December 31, 2024	**901**	**1,565**	**2,300**	**146**	**1,300**	**560**	**—**	**6,772**
Europe	494	1,321	1,911	109	1,135	328	—	5,298
North America	245	198	117	4	83	14	—	661
Asia	—	2	24	—	1	1	—	28
Total as of December 31, 2023	**739**	**1,521**	**2,069**	**113**	**1,222**	**469**	**—**	**6,133**

(1) This overview lists full-time equivalent employees of CureVac entities on which control was gained in December 2025 separately, as their allocation by function is still in progress.

During the year ended December 31, 2025, we revised our methodology for allocating employees in order to better reflect their operational activities within the reported functions. To improve comparability, this revision also resulted in an adjustment of prior-year figures. The increase in full-time equivalent employees compared with the previous year is primarily attributable to the acquisitions of Biotheus and CureVac in fiscal year 2025.

None of our employees has engaged in any labor strikes. We apply the collective labor agreements of the chemical industry and related industries at our Marburg site. We have works councils at our Idar-Oberstein, Mainz, Marburg, Martinsried/Neuried and Berlin (JPT Peptide Technologies GmbH) sites as well as a group works council (*Konzernbetriebsrat*). Further, we maintain a couple of works agreements (*Betriebsvereinbarungen*) and group works agreements (*Konzernbetriebsvereinbarungen*) with respect to certain topics at our Idar-Oberstein, Mainz, Marburg, Martinsried/Neuried and Berlin (JPT Peptide Technologies GmbH) sites or the group. We consider our relationship with our employees to be positive and have not experienced any major labor disputes.

E. Share Ownership

The share ownership information with respect to Management Board and Supervisory Board members is presented in Item 7 below.

F. Disclosure of a Registrant's Action to Recover Erroneously Awarded Compensation

Not applicable.

Item 7. Major Shareholders and Related Party Transactions

A. Major Shareholders

The following table presents information, as of December 31, 2025, regarding the beneficial ownership of our ordinary shares for:

- each person, or group of affiliated persons, known by us to own beneficially 5% or more of our outstanding shares;
- each member of our Supervisory Board;
- each member of our Management Board; and
- all members of our Supervisory Board and Management Board as a group.

The number of ordinary shares beneficially owned by each entity, person, and member of our Supervisory Board and our Management Board is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any ordinary shares over which the individual has sole or shared voting power or investment power as well as any ordinary shares that the individual has the right to acquire within 60 days of December 31, 2025, 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. All of our ordinary shares and ADSs representing our ordinary shares vote on an equal basis.

The percentage of outstanding ordinary shares is computed on the basis of 251,325,340 ordinary shares outstanding as of December 31, 2025. This amount excludes 7,702,147 shares held in treasury. Amounts presented in this section include ordinary shares held in the form of ADSs. Unless otherwise indicated, the address for each beneficial owner is An der Goldgrube 12, 55131 Mainz, Germany.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage Beneficially Owned
5% shareholders		
AT Impf GmbH[1]	101,279,878	40.3%
Medine GmbH [2]	40,132,788	16.0%
All 5% shareholders, as a group	**141,412,666**	**56.3%**
Members of the Supervisory Board and the Management Board		
Prof. Ugur Sahin, M.D. [3]	41,246,918	16.4%
Annemarie Hanekamp	—	—
Kylie Jimenez	—	—
Sierk Poetting, Ph.D.[4]	692,539	<1.0 %
James Ryan, Ph.D.	1,426	<1.0 %
Prof. Özlem Türeci, M.D.	123,331	<1.0 %
Ramón Zapata	—	—
Helmut Jeggle [5]	975,967	<1.0 %
Ulrich Wandschneider, Ph.D.[6]	1,480	<1.0 %
Baroness Nicola Blackwood	—	—
Prof. Anja Morawietz, Ph.D.[7]	240	<1.0 %
Michael Motschmann	—	—
Prof. Rudolf Staudigl, Ph.D.	400	<1.0 %
All members of our Supervisory Board and Management Board, as a group	**43,042,301**	**17.1%**

(1) Consists of 101,279,878 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. ATHOS KG via AT Impf GmbH has de facto control over BioNTech based on its substantial shareholding, which practically enables it to exercise the majority of voting rights to pass resolutions at our Annual General Meeting, or AGM. As of December 31, 2025 Thomas Maier is a general partner (*Komplementär*) of ATHOS KG and may be deemed to be beneficial owners of the securities held by AT Impf KG. Mr. Maier disclaims beneficial ownership of such shares except to the extent of their pecuniary interest therein.

(2) The sole shareholder of Medine GmbH is Ugur Sahin, and, as a result, Ugur Sahin is deemed to be the beneficial owner of the securities held by Medine GmbH. Consists of 40,132,788 ordinary shares held by Medine GmbH, 1,021,398 of which are held for the benefit of a former colleague pursuant to a trust arrangement. Pursuant to this arrangement, Medine GmbH retains voting power, but not dispositive power, over such shares for so long as such shares are held in trust and accordingly Medine GmbH and Ugur Sahin each may be deemed beneficially to own such shares.

(3) Consists of the shares described in footnote 2 above, plus 1,114,130 ordinary shares held directly by Ugur Sahin. He is the sole shareholder of Medine GmbH.

(4) Consists of (a) 549,387 ordinary shares held by Tofino GmbH (Sierk Poetting is sole shareholder of Tofino GmbH), (b) 141,514 ordinary shares held directly by Sierk Poetting and (c) 1,638 ordinary shares held by his immediate family. Mr. Poetting disclaims beneficial ownership of the 1,638 ordinary shares held by his immediate family except to the extent of his pecuniary interest therein.

(5) Consists of (a) 332,316 ordinary shares held directly by Helmut Jeggle and (b) 643,651 ordinary shares held by Salvia GmbH.

(6) Consists of 1,480 ordinary shares held by beebusy Capital GmbH. Ulrich Wandschneider is sole shareholder of beebusy Capital GmbH.

(7) Consists of (a) 200 ordinary shares held directly by Anja Morawietz and (b) 40 ordinary shares held by her immediate family.

Holdings by U.S. Shareholders

Our share capital consists of ordinary shares, some of which are traded in the United States by means of American Depositary Shares (ADSs), each representing one ordinary share. Our depositary, The Bank of New York Mellon, is the holder of the ordinary shares underlying the ADSs. Based on the limited information available to us and the depositary, we generally cannot determine with certainty the number of U.S. shareholders or how many shares such shareholders own.

B. Related Party Transactions

See Item 18.

C. Interests of Experts and Counsel

Not applicable.

Item 8. Financial Information

A. Consolidated Statements and Other Financial Information

See Item 18.

B. Significant Changes

Not applicable.

Item 9. The Offer and Listing

A. Offer and Listing Details

ADSs representing our ordinary shares have been listed on the Nasdaq Global Select Market under the symbol “BNTX” since October 10, 2019. Prior to that date, there was no public trading market for our ADSs.

B. Plan of Distribution

Not applicable.

C. Markets

ADSs representing our ordinary shares have been listed on the Nasdaq Global Select Market under the symbol “BNTX” since October 10, 2019.

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

Item 10. Additional Information

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

General

We were incorporated as a German stock corporation (Aktiengesellschaft) with the legal name Petersberg 91. 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*) are publicly available from the commercial register (*Handelsregister*) at the local court of Mainz, Germany, electronically at www.unternehmensregister.de and as an exhibit to this Annual Report.

Share Capital

We have share capital registered in the commercial register (*Handelsregister*) in the amount of €259,027,487.00 which is divided into 259,027,487 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 Financial Years

Our share capital as registered with the commercial register (Handelsregister) amounts to 259,027,487, including an amount of €7,702,147 relating to 7,702,147 ordinary shares held in treasury as of December 31, 2025. Since January 1, 2023, our share capital has changed as follows:

- On December 10, 2025, our share capital as registered with the commercial register (Handelsregister) was increased by issuing 9,871,086 shares.

- On December 29, 2025, our share capital as registered with the commercial register (Handelsregister) was increased by issuing 604,201 shares and now amounts to 259,027,487.

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, with the consent of the Supervisory Board, to 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 is valid for a maximum period of five years. 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 € 113,800,813 by issuing, on one or more occasions, up to 113,800,813 new, registered shares with no par value (*Genehmigtes Kapital 2025*) in return for cash contributions or contributions in kind, in each case with consent of the Supervisory Board. This authorization expires on May 15, 2030.

Any new shares issued from the authorized capital will participate in the profits starting with the financial 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 €4,943,452 through issuance of new registered shares with no par value, or Conditional Capital ESOP 2017/2019 (*Bedingtes Kapital ESOP 2017/2019*). The Conditional Capital ESOP 2017/2019 may only be used to issue shares to the holders of option rights granted under the authorization for the Conditional Capital ESOP 2017/2019, or the Authorization 2017/2019.

The conditional capital increase will only be implemented to the extent that stock options under the Authorization 2017/2019 are exercised and such stock options are not serviced by our providing treasury shares or through cash payments. Any new shares issued under the Conditional Capital ESOP 2017/2019 pursuant to § 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 €24,855,220 through issuance of new registered shares with no par value, or Conditional Capital WSV 2024 (*Bedingtes Kapital WSV 2024*). 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 WSV 2024 pursuant to § 4(7) of our Articles of Association (*Satzung*) 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.

Pursuant to § 4(8) of our Articles of Association (*Satzung*), our share capital is conditionally increased by €1,300,000 through issuance of new, registered shares with no par value, or Conditional Capital ESOP 2021 (*Bedingtes Kapital ESOP 2021*). The Conditional Capital ESOP 2021 serves exclusively to grant rights to the

holders of stock options issued by the Company in accordance with the authorization granted by the Annual General Meeting on June 22, 2021 under agenda item 6 letter d) also as amended by the resolution of the Annual General Meeting on May 17, 2024 under agenda items 12 and 13, or the Authorization 2021.

The conditional capital increase will only be implemented to the extent that stock options under our ESOP are exercised by the holders of the stock options issued by the Company on the basis of Authorization 2021 and such stock options are not settled by the Company with treasury shares or through cash payments. Any new shares issued under the Conditional Capital ESOP 2021 pursuant to § 4(8) of our Articles of Association (*Satzung*) shall participate in profits from the beginning of the preceding 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.

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 Bezugsrecht*).

Further, it is possible for a shareholder resolution approved by three-quarters of the share capital voting on the resolution to exclude preemptive rights both where the general meeting itself resolves that the new securities are to be issued and in relation to the authorized capital, i.e., an authorization for the Management Board, with the consent of the Supervisory Board, to resolve on the issuance of new securities; provided, however, that in each case, the exclusion or the authorization to 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 during the authorization period 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 a scrip 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. Additional restrictions with regard to the shares issued may be agreed upon; 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 2025 and under exclusion of subscription rights pursuant to bullets one through three above may not exceed 10% of the share capital, either at the time that the amendment to the Articles of Association (*Satzung*), resolved upon by the general meeting of May 17, 2024, came into effect or, if lower, at the time of utilization of the authorization. To be counted against the aforementioned 10% 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. 10 and 11 of the general meeting of May 17, 2024).

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 the 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.

Shareholders' Meetings and Voting Rights

Pursuant to our Articles of Association (*Satzung*), shareholders' meetings may be held in person or virtually at our seat or in any municipality in Germany with more than 500,000 inhabitants. Generally, shareholders' meetings are convened by our Management Board, or our Supervisory Board. Shareholders representing in the aggregate at least five percent of our ordinary shares may, subject to certain formal prerequisites, request that a shareholders' meeting be convened. Shareholders representing in the aggregate at least five percent of our ordinary shares or owning shares with an aggregate nominal value of at least €500,000 may request the addition of one or several items to the agenda of any shareholders' meeting. Shareholders' meetings may be summoned either via publication in the German Federal Gazette (*Bundesanzeiger*) or via mail or email, in each case generally at least 30 days before the meeting.

Shareholders may participate 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 €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 financial 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 financial 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 AktG. The Company's shareholders' meeting held on May 17, 2024 authorized the Management Board until May 16, 2029, 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.

C. Material Contracts

Except as otherwise disclosed in this Annual Report (including the exhibits thereto), we are not currently, and have not been in the last two years, party to any material contract, other than contracts entered into in the ordinary course of our business.

D. Exchange Controls

There are currently no legal restrictions in the Federal Republic of Germany on international capital movements and foreign exchange transactions, except in limited embargo circumstances (*Teilembargo*) relating to certain areas, entities or persons as a result of applicable resolutions adopted by the United Nations and the European Union. Restrictions currently exist with respect to, among others, Belarus, Bosnia & Herzegovina, Burundi, Central African Republic, China, D.R. Congo, Guinea, Guinea-Bissau, Haiti, Iran, Iraq, Lebanon, Libya, Mali, Moldova and the Transnistria region, Myanmar, Nicaragua, Niger, North Korea, Russia, Serbia, Somalia, South Sudan, Sudan, Syria, Tunisia, Türkiye, Ukraine, Venezuela, Yemen and Zimbabwe.

For statistical purposes, there are, however, limited notification requirements regarding transactions involving cross-border monetary transfers. With some exceptions, every corporation or individual residing in the Federal Republic of Germany must report to the German Central Bank (*Deutsche Bundesbank*) (i) any payment received from, or made to, a non-resident corporation or individual that exceeds €50,000 (or the equivalent in a foreign currency) and (ii) (with the exception of individuals residing in the Federal Republic of Germany) in case the sum

of claims against, or liabilities payable to, non-resident corporations or individuals exceeds €6,000,000 (or the equivalent in a foreign currency) at the end of any calendar month. Payments include cash payments made by means of direct debit, checks and bills, remittances denominated in euros and other currencies made through financial institutions, as well as netting and clearing arrangements.

E. 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 the ADSs representing our ordinary shares.

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 report. 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 introduced, may also be applicable on sales and/or transfer of 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 report 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, in light of the ADR Tax Circular, represent a beneficial ownership interest in the underlying shares of BioNTech and qualify as ADRs for the purpose of the ADR Tax Circular. If the ADSs qualify as ADRs under the ADR Tax Circular, dividends would accordingly be attributable to holders of the ADSs for German tax purposes, and not to the legal owner of the ordinary shares (i.e., the financial institution on behalf of which the ordinary shares are stored at a domestic depository for the ADS holders). Furthermore, holders of the ADSs should be treated as beneficial owners of the capital of BioNTech with respect to capital gains (see below in section "—German Taxation of Capital Gains of the U.S. Treaty Beneficiaries of the ADSs"). However, investors should note that circulars published by the German tax authorities (including the ADR Tax Circular) are not, 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 the ADSs, owning the ADSs 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 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 generally 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*), subject to certain prerequisites, do not 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). A U.S. treaty beneficiary other than a company holding ADSs which represent 10% or more of the voting shares in BioNTech 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 qualify as a 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 generally only to be adhered to by the German tax authorities but are, for example, not binding 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*) within four years after the end of the calendar year in which the capital gains or dividends have been received (*bezogen*).

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 German 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 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-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 refund process 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 in connection with a withholding of tax amounts may no longer be issued by the domestic depositary of the shares upon request of the foreign depositary agents. Rather, individual tax certificates need to be issued which might delay a potential refund procedure. Moreover, the simplified refund procedure based on electronic data exchange (*Datenträgerverfahren*) for claims for reimbursement based on ADRs has been suspended temporarily 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 ADSs held as business assets (*Betriebsvermögen*).

ADSs as Private Assets (*Privatvermögen*)

If the ADSs are held as private assets by a German tax resident, dividends and capital gains (other than capital gains from the disposition of a 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*), subject to certain prerequisites, do not form part of the taxable dividend income but should 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 €1,000 for an individual or €2,000 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.

Since 2021, the basis for the calculation of the solidarity surcharge (*Solidaritätszuschlag*) has been reduced for certain individual persons being subject to tax assessments (other than withholding taxes), and in certain cases, the solidarity surcharge has been abolished. However, the abolition or reduction of the solidarity surcharge is not applicable to corporations. In addition, the abolition or reduction of the solidarity surcharge will not affect withholding taxes. Solidarity surcharge will still be levied at 5.5% on the full withholding tax amount and withheld

accordingly. There will not be any separate refund of such withheld solidarity surcharge (regardless of the aforementioned exemption limits) in case the withholding tax cannot be refunded either.

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, has to file withholding tax returns for a withholding tax of 15% in accordance with statutory formal requirements 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 (and the corresponding notification and payment obligations) 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 income tax (and solidarity surcharge thereon) at a rate of 15.825% and also subject to trade tax of between 7.0% and 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.

Capital gains and dividend income of a German tax resident corporation are generally subject to German trade tax of between 7.0% and 19.0% depending on the multiplier applied by the relevant municipality. 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 this 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. Since 2021, the basis for the calculation of the solidarity surcharge (*Solidaritätszuschlag*) has been reduced for certain individual persons being subject to tax assessments (other than withholding taxes), and in certain cases, the solidarity surcharge has been abolished, subject to the limitations described above in "—ADSs as Private Assets (*Privatvermögen*)". 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 dividend payments.

Material United States Federal Income Tax Considerations

The following discussion describes material U.S. federal income tax considerations relating to the acquisition, ownership and disposition of ADSs by a U.S. Holder (as defined below) that acquires our ADSs and holds them as a capital asset. This discussion is based on the tax laws of the United States, including the Internal Revenue Code of 1986, as amended, or the Code, Treasury regulations promulgated or proposed thereunder, and administrative and judicial interpretations thereof, all as in effect on the date hereof. These tax laws are subject to change, possibly with retroactive effect, and subject to differing interpretations that could affect the tax consequences described herein. This section does not address the treatment of a non-U.S. holder, nor does it address the tax treatment under the laws of any state, local or foreign taxing jurisdiction.

For purposes of this discussion, a "U.S. Holder" is a beneficial owner of our ADSs that, for U.S. federal income tax purposes, is:

- an individual who is a citizen or resident of the United States;
- a domestic corporation (or other entity taxable as a corporation);
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust if (i) a court within the United States is able to exercise primary supervision over the trust's administration and one or more U.S. persons have the authority to control all substantial decisions of the trust or (ii) a valid election under the Treasury regulations is in effect for the trust to be treated as a U.S. person.

This discussion does not address all aspects of U.S. federal income taxation that may be applicable to U.S. Holders in light of their particular circumstances or status (including, for example, banks and other financial institutions, insurance companies, broker and dealers in securities or currencies, traders that have elected to mark securities to market, regulated investment companies, real estate investment trusts, partnerships or other pass- through entities, corporations that accumulate earnings to avoid U.S. federal income tax, tax-exempt organizations, pension plans, persons that hold our shares as part of a straddle, hedge or other integrated investment, persons subject to alternative minimum tax or whose "functional currency" is not the U.S. dollar).

If a partnership (including any entity or arrangement treated as a partnership for U.S. federal income tax purposes) holds our ADSs, the tax treatment of a person treated as a partner in the partnership for U.S. federal income tax purposes generally will depend on the status of the partner and the activities of the partnership. Partnerships (and other entities or arrangements so treated for U.S. federal income tax purposes) and their partners should consult their own tax advisors.

In general, and taking into account the earlier assumptions, for U.S. federal income and German tax purposes, a holder of ADSs will be treated as the owner of the shares represented by those ADSs. Exchanges of shares for ADSs, and ADSs for shares, generally will not be subject to U.S. federal income or to German tax.

This discussion addresses only U.S. Holders and does not discuss any tax considerations other than U.S. federal income tax considerations. Prospective investors are urged to consult their own tax advisors regarding the U.S. federal, state and local, and foreign tax consequences of the purchase, ownership, and disposition of ADSs.

Dividends

Under the U.S. federal income tax laws, and subject to the passive foreign investment company, or PFIC, rules discussed below, the gross amount of any dividend we pay out of our current or accumulated earnings and profits (as determined for U.S. federal income tax purposes) is includible in income for a U.S. Holder and subject to U.S. federal income taxation. Dividends paid to a noncorporate U.S. Holder that constitute qualified dividend income will be taxable at a preferential tax rate applicable to long-term capital gains, provided that the U.S. Holder holds the ADSs for more than 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 as part of the gross dividend payment, as described above under "—German Taxation—General Rules for the Taxation of Holders Not Tax Resident in Germany," 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 taxed generally 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 believe that we were a PFIC for our 2025 taxable year. Because the determination of our PFIC status is made annually based on the factual tests described below, however, we cannot estimate with certainty at this stage whether or not we are likely to be treated as a PFIC in the current taxable year or any future taxable years. In particular, the total value of our asset test generally will be calculated taking into account the market price of our ADSs or ordinary shares. This value has fluctuated considerably in the past, and may fluctuate considerably in the future. Even if we determine that we are not a PFIC for a taxable year, there can be no assurance that the IRS will agree with our conclusion regarding our PFIC status.

We are 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. In addition, cash and short-term investment are treated as passive assets regardless of the fact that they may not produce any income. 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 are classified as a PFIC in any taxable year, a U.S. Holder will be subject to special rules with respect to distributions on and sales, exchanges and other dispositions of the ADSs. In addition, a U.S. Holder that holds the ADSs at any time during a taxable year in which we are classified as a PFIC generally will continue to have 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 described below as if such ADSs had been sold on the last day of the last taxable year for which we were a PFIC.

Certain elections by a U.S. Holder, described below, generally alleviate some of the adverse consequences of the excess distribution rules and would result in an alternative treatment of the ADSs, as described below.

A U.S. Holder of PFIC shares must generally file an annual information return on IRS Form 8621 (Information Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund) and will make any of the elections described below such Form attached to a timely filed U.S. federal income tax return (including available extensions). The failure to file IRS Form 8621 could result in an extension of the statute of limitations with respect to U.S. federal income tax.

Excess Distribution Rules. If we are 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 will 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 is treated as ordinary income and is 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 is subject to tax at the U.S. Holder's regular ordinary income rate for the current year and is not 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 are a PFIC, this tax

treatment for U.S. Holders applies 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 do not qualify for the lower rates of taxation applicable to long-term capital gains discussed above under "—Taxation of Dividends."

Elective Alternative Treatment. If we are a PFIC, the rules above do not apply to a U.S. Holder that makes an election to treat ADSs as stock of a "qualified electing fund" or QEF. We intend to provide to U.S. Holders the required information to make a valid QEF election and expect to provide that information after April 15, 2026 and before August 15, 2026 on our corporate website. As a result, a U.S. Holder is expected to be able to make the QEF election with respect to its ADSs with an extension to file its U.S. federal income tax return. A U.S. Holder that makes a QEF election is required to include in income its pro rata share of our ordinary earnings and net capital gain as ordinary income and long-term capital gain, respectively, subject to a separate election to defer payment of taxes, which deferral is subject to an interest charge. A U.S. Holder makes a QEF election generally by attaching a completed IRS Form 8621 to a timely filed United States federal income tax return for the year beginning with which the QEF election is to be effective (taking into account any extensions). A QEF election can be revoked only with the consent of the IRS. We intend to annually provide or make available the information required for a U.S. Holder to make a valid QEF election.

The rules above also do not apply to a U.S. Holder that makes a "mark-to-market" election with respect to the ADSs. This election is available with respect to the ADSs only if they meet certain minimum trading requirements to be considered "marketable stock" for purposes of the PFIC rules. Generally, shares or ADSs are treated as marketable stock if they are "regularly traded" on a "qualified exchange" within the meaning of applicable U.S. Treasury Regulations. ADSs generally will be considered regularly traded during any calendar year during which they are traded, other than in de minimis quantities, on at least 15 days during each calendar quarter. Any trades that have as their principal purpose meeting this requirement will be disregarded. Our ADSs will be marketable stock as long as they remain listed on the Nasdaq Global Select Market and are traded regularly.

A U.S. Holder that makes a valid mark-to-market election for the first tax year in which the holder holds (or is deemed to hold) ADSs and for which we are a PFIC will be required to include each year an amount equal to the excess, if any, of the fair market value of such ADSs the holder owns as of the close of the taxable year over the holder's adjusted tax basis in such ADSs. The U.S. Holder will be entitled to a deduction for the excess, if any, of the holder's adjusted tax basis in the ADSs over the fair market value of such ADSs as of the close of the taxable year, but only to the extent of any net mark-to-market gains with respect to such ADSs included by the U.S. Holder under the election for prior taxable years. The U.S. Holder's basis in such ADSs will be adjusted to reflect the amounts included or deducted pursuant to the election. Amounts included in income pursuant to a mark-to-market election, as well as gain on the sale, exchange or other taxable disposition of such ADSs, will be treated as ordinary income. The deductible portion of any mark-to-market loss, as well as loss on a sale, exchange or other disposition of ADSs to the extent that the amount of such loss does not exceed net mark-to-market gains previously included in income, will be treated as ordinary loss.

The mark-to-market election applies to the taxable year for which the election is made and all subsequent taxable years, unless the shares cease to be treated as marketable stock for purposes of the PFIC rules or the IRS consents to its revocation. The excess distribution rules described above generally will not apply to a U.S. Holder for tax years for which a mark-to-market election is in effect. However, if we are a PFIC for any year in which the U.S. Holder owns the ADSs but before a mark-to-market election is made, the interest charge rules described above applies to any mark-to-market gain recognized in the year the election is made.

U.S. Holders are urged to consult their tax advisors as to our status as a PFIC, and the tax consequences to them if we were a PFIC, including the reporting requirements and the desirability of making, and the availability of, a QEF election or a mark-to-market election with respect to the ADSs.

Medicare Tax

Non-corporate U.S. Holders that are individuals, estates or trusts and whose income exceeds certain thresholds generally are subject to a 3.8% tax on all or a portion of their net investment income, which may include their gross dividend income and net gains from the disposition of ADSs. A U.S. person that is an individual, estate or trust is encouraged to consult its tax advisors regarding the applicability of this Medicare tax to its income and gains in respect of any investment in ADSs.

Information Reporting with Respect to Foreign Financial Assets

Individual U.S. Holders may be subject to certain reporting obligations on IRS Form 8938 (Statement of Specified Foreign Financial Assets) with respect to the ADSs for any taxable year during which the U.S. Holder's aggregate value of these and certain other "specified foreign financial assets" exceed a threshold amount that varies with the filing status of the individual. This reporting obligation also applies to domestic entities formed or availed of to hold, directly or indirectly, specified foreign financial assets, including the ADSs. Significant penalties can apply if U.S. Holders are required to make this disclosure and fail to do so.

U.S. Holders who acquire ADSs for cash may be required to file IRS Form 926 (Return by a U.S. Transferor of Property to a Foreign Corporation) with the IRS and to supply certain additional information to the IRS if (i) immediately after the transfer, the U.S. Holder owns directly or indirectly (or by attribution) at least 10% of our total voting power or value or (ii) the amount of cash transferred to us in exchange for ADSs, when aggregated with all related transfers under applicable regulations, exceeds $100,000. Substantial penalties may be imposed on a U.S. Holder that fails to comply with this reporting requirement.

Information Reporting and Backup Withholding

In general, information reporting, on IRS Form 1099, will apply to dividends in respect of ADSs and the proceeds from the sale, exchange or redemption of ADSs that are paid to a holder of ADSs within the United States (and in certain cases, outside the United States), unless such holder is an exempt recipient such as a corporation. Backup withholding (currently at a 24% rate) may apply to such payments if a holder of ADSs fails to provide a taxpayer identification number (generally on an IRS Form W-9) or certification of other exempt status or fails to report in full dividend and interest income.

Backup withholding is not an additional tax. A U.S. Holder generally may obtain a refund of any amounts withheld under the backup withholding rules that exceed the U.S. Holder's income tax liability by filing a refund claim with the IRS.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

We are subject to the informational requirements of the Exchange Act. 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 an Internet website that contains reports and other information about issuers, like us, that file electronically with the SEC. The address of that website is www.sec.gov.

We also make available on our website, free of charge, our Annual Report and the text of our reports on Form 6-K, including any amendments to these reports, as well as certain other SEC filings, as soon as reasonably practicable after they are electronically filed with or furnished to the SEC. Our website address is www.biontech.de. The information contained on our website is not incorporated by reference in this Annual Report and our website address is included in this Annual Report as an inactive textual reference only.

Statements contained in this Annual Report regarding the contents of any contract or other document are not necessarily complete, and, where the contract or other document is an exhibit to the Annual Report, each of these statements is qualified in all respects by the provisions of the actual contract or other documents.

I. Subsidiary Information

Not applicable.

J. Annual Report to Security Holders

Not applicable.

Item 11. Quantitative and Qualitative Disclosures About Market Risk

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

Counterparty Risk

In order to mitigate default risks within our asset management portfolio, we diversify our cash investments among various counterparties and instruments that have an investment grade rating. Transactions are carried out within the limits approved by the treasury committee.

Foreign Currency Risk

We publish our consolidated financial statements in Euro. Revenue and expenses incurred in U.S. dollars will be translated into Euro when they are reported in our consolidated financial statements. We are subject to currency risks as the majority of our income and expenditures are denominated in Euro and the U.S. dollar. As such, we are mainly exposed to exchange rate fluctuations between these currencies. Cash inflows denominated in U.S. dollar mainly result from generating proceeds under our collaboration agreements. Our revenues from contracts with customers are primarily from the sale of COVID-19 vaccines as well as from out-licensing of pumitamig (BNT327 / BMS986545) to BMS and represents payments we receive mainly in U.S. dollar. Within the collaboration agreement with BMS we received an upfront payment amounting to $1.5 billion during the year ended December 31, 2025 and are eligible to receive $2.0 billion total in non-contingent anniversary payments through 2028 as well as up to $7.6 billion in additional development, regulatory and commercial milestone payments contingent on achievement of certain development, regulatory and commercial milestones. Cash outflows dominated in U.S. dollar mainly result from amounts spent on research and development activities, license obligations and settlement payments as well as expanding our global footprint further. With the aim of preserving capital, surplus liquidity is mainly invested in domestic currency investments as exchange rate fluctuations can reduce the value of our financial positions. We limit the effects of the identified risks by means of a coordinated and consistently implemented risk strategy. Besides applying natural hedging relationships where

possible, foreign exchange forward contracts are concluded, as a matter of principle, as instruments to mitigate foreign currency exchange risk associated with foreign currency-denominated payments.

For further disclosures relating to foreign exchange forward contracts, see Note 12 to our consolidated financial statements included elsewhere in this Annual Report.

Notwithstanding our efforts to mitigate some foreign currency exchange risks, there can be no assurance that our hedging activities will adequately protect us against the risks associated with foreign currency fluctuations. We believe the counterparties to our foreign currency forward contracts are creditworthy multinational commercial banks. While we believe the risk of counterparty nonperformance is not material, a sustained decline in the financial stability of financial institutions as a result of disruption in the financial markets could affect our ability to secure creditworthy counterparties for our foreign currency hedging programs. Therefore, developments on the financial markets are continuously monitored to enable us to respond to exceptional events at short notice.

As a result, any substantial future appreciation or decline of the U.S. dollar against the Euro could have a material effect on our revenue and profitability. As an example, if the U.S. dollar weakens by 5% against the Euro, monetary assets and liabilities denominated in U.S. dollar as of December 31, 2025 would have an effect of €38.2 million on our profit before tax.

For additional information about our quantitative and qualitative market risks, see Note 12 to the consolidated financial statements.

Item 12. Description of Securities other than Equity Securities

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable.

C. Other Securities

Not applicable.

D. American Depositary Shares

Fees and Expenses

Persons depositing or withdrawing shares or ADS holders must pay:	For:
$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)	Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates
$.05 (or less) per ADS	Any cash distribution to ADS holders
A fee equivalent to the fee that would be payable if securities distributed to an ADS holder had been shares and the shares had been deposited for issuance of ADSs	Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depositary to ADS holders
$.05 (or less) per ADS per calendar year	Depositary services
Registration or transfer fees	Transfer and registration of shares on our share register to or from the name of the depositary or its agent when an ADS holder deposits or withdraws shares
Expenses of the depositary	Cable and facsimile transmissions (when expressly provided in the deposit agreement) Converting foreign currency to U.S. dollars
Taxes and other governmental charges the depositary or the custodian has to pay on any ADSs or shares underlying ADSs, such as stock transfer taxes, stamp duty or withholding taxes	As necessary
Any charges incurred by the depositary or its agents for servicing the deposited securities	As necessary

The depositary collects its fees for delivery and surrender of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depositary may collect any of its fees by deduction from any cash distribution payable (or by selling a portion of securities or other property distributable) to ADS holders that are obligated to pay those fees. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the depositary may make payments to us to reimburse us for costs and expenses generally arising out of establishment and maintenance of the ADS program, waive fees and expenses for services provided to us by the depositary or share revenue from the fees collected from ADS holders. In performing its duties under the deposit agreement, the depositary may use brokers, dealers, foreign currency dealers or other service providers that are owned by, or affiliated with, the depositary and that may earn or share fees, spreads or commissions.

The depositary may convert currency itself or through any of its affiliates and, in those cases, acts as principal for its own account and not as agent, advisor, broker or fiduciary on behalf of any other person and earns revenue, including, without limitation, transaction spreads, that it will retain for its own account. The revenue is based on, among other things, the difference between the exchange rate assigned to the currency conversion made under the deposit agreement and the rate that the depositary or its affiliate receives when buying or selling foreign currency for its own account. The depositary makes no representation that the exchange rate used or obtained in any currency conversion under the deposit agreement will be the most favorable rate that could be obtained at the time or that the method by which that rate will be determined will be the most favorable to ADS holders,

subject to the depositary's obligations under the deposit agreement. The methodology used to determine exchange rates used in currency conversions is available upon request.

Payment of Taxes

ADS holders will be responsible for any taxes or other governmental charges payable on their ADSs or on the deposited securities represented by any of their ADSs. The depositary may refuse to register any transfer of ADS holders ADSs or allow him or her to withdraw the deposited securities represented by his or her ADSs until those taxes or other charges are paid. It may apply payments owed to you or sell deposited securities represented by his or her ADSs to pay any taxes owed and you will remain liable for any deficiency. If the depositary sells deposited securities, if appropriate, it will 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.

PART II

Item 13. Defaults, Dividend Arrearages and Delinquencies

Not applicable.

Item 14. Material Modifications to the Rights of Security Holders and Use of Proceeds

Not applicable.

Item 15. Controls and Procedures

Disclosure Controls and Procedures

As required by Rule 13a-15 under the Exchange Act, management, including our Chief Executive Officer and our Chief Financial Officer, has performed an evaluation of the effectiveness of our disclosure controls and procedures. Disclosure controls and procedures refer to controls and other procedures designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. Disclosure controls and procedures include, without limitations, controls and procedures designed to ensure that information required to be disclosed by us in our reports that we file or submit under the Exchange Act is accumulated and communicated to management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding our required disclosures.

Based on the foregoing, our CEO and CFO have concluded that, as of the end of the period covered by this annual report, our disclosure controls and procedures were effective in ensuring that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in by the SEC's rules and forms, and that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management to allow timely decisions regarding required disclosure.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f). Our internal control over financial reporting is a process designed by or under the supervision of the Chief Financial Officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external reporting purposes in accordance with International Financial Reporting Standards as issued by the IASB.

No system of internal control over financial reporting, including one determined to be effective, may prevent or detect all misstatements. It can provide only reasonable assurance regarding financial statement preparation and presentation. Also, projections of the results of any evaluation of the effectiveness of internal control over financial reporting into future periods are subject to inherent risk. The relevant controls may become inadequate due to changes in circumstances or the degree of compliance with the underlying policies or procedures may deteriorate.

Our management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2025. In making this assessment, it used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in "Internal Control - Integrated Framework (2013)".

Based on this assessment, our management has determined that the Company's internal control over financial reporting as of December 31, 2025 is effective.

As permitted by the SEC, the Company has elected to exclude an assessment of the internal controls of acquisitions made during the year ended December 31, 2025, namely the acquisition of CureVac B.V. and Biotheus Inc. In the aggregate, both acquisitions accounted for 0% of revenue and 6% of total assets in the Company's consolidated financial statements.

Attestation Report of the Registered Public Accounting Firm

The effectiveness of our internal control over financial reporting as of December 31, 2025 has been audited by EY GmbH & Co. KG Wirtschaftsprüfungsgesellschaft, an independent registered public accounting firm. Their report is included on page F-2. EY GmbH & Co. KG Wirtschaftsprüfungsgesellschaft is a member of the Chamber of Public Accountants (*Wirtschaftsprüferkammer*), Berlin, Germany.

Changes in Control over Financial Reporting

There has been no change in our internal control over financial reporting during the year ended December 31, 2025 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 16. [Reserved]

Item 16A. Audit Committee Financial Expert

Our Audit Committee for the year ended December 31, 2025 consisted of Anja Morawietz. (Chair), Rudolf Staudigl and Ulrich Wandschneider. All members of the Audit Committee qualify as "independent directors" as such term is defined in Rule 10A-3 under the Exchange Act and Nasdaq Rule 5605. Additionally, our Supervisory Board has determined that Anja Morawietz, Rudolf Staudigl and Ulrich Wandschneider qualify as "audit committee financial expert" as that term is defined under the Exchange Act.

Item 16B. Code of Ethics

We have adopted a Code of Ethics & Business Integrity, or Code of Ethics, which outlines the principles of legal and ethical business conduct under which we do business. The Code of Ethics applies to all of our Supervisory Board members, Management Board members, directors of our subsidiaries and employees. The full text of the Code of Ethics is available on our website at https://www.biontech.de. The information and other content appearing on our website are not part of this Annual Report and our website address is included in this Annual Report as an inactive textual reference only. Any amendments or waivers from the provisions of the Code of Ethics for members of our Supervisory or Management Boards will be made only after approval by our Supervisory Board and will be disclosed on our website promptly following the date of such amendment or waiver.

Item 16C. Principal Accountant Fees and Services

EY GmbH & Co. KG Wirtschaftsprüfungsgesellschaft, or EY, has served as our independent registered public accounting firm for the years ended December 31, 2025, December 31, 2024, and December 31, 2023 for which audited financial statements appear in this Annual Report.

The following table sets out the aggregate fees for professional audit services and other services rendered by EY in the periods indicated:

	Years ended December 31,	
(in millions €)	**2025**	**2024**
Audit fees	3.7	2.8
Audit-related fees	0.5	—
Tax fees	0.7	0.6
Total fees for professional audit services and other services	**4.9**	**3.4**

In the year ended December 31, 2025, audit fees related to professional services associated with the integrated audit of our consolidated financial statements and our internal control over financial reporting as set out in this Annual Report, professional services associated with interim reviews, audit fees related to the remuneration report and professional services related to our statutory and regulatory filings for our subsidiaries. Due to additional procedures related to the acquisition of Biotheus and CureVac and to our internal controls over financial reporting in the year ended December 31, 2025, expenses increased compared to the year ended December 31, 2024. In the year ended December 31, 2024, audit fees related to professional services associated with the integrated audit of our consolidated financial statements and our internal control over financial reporting as set out in this Annual Report, professional services associated with interim reviews, audit fees related to the remuneration report and professional services related to our statutory and regulatory filings for our subsidiaries.

In the year ended December 31, 2025, audit-related services for SEC filings have been received. In the year ended December 31, 2024, no audit-related services have been received.

In the year ended December 31, 2025 and year ended December 31, 2024, tax service fees were billed for services in conjunction with transactions, especially with our financing and deal transactions.

The Audit Committee evaluates the qualifications, independence and performance of the independent auditor as well as pre-approves and reviews the audit and non-audit services to be performed by the independent auditor. The external audit plan and fees for professional audit services and other services rendered by EY for the years ended December 31, 2025 and 2024, were approved by the Audit Committee. The Audit Committee monitors compliance with the German and U.S. rules on non-audit services provided by an independent registered public accounting firm.

Item 16D. Exemptions from the Listing Standards for Audit Committees

Please see “Board Practices—Supervisory Board Practices—Audit Committee” in Item 6C of this Annual Report for the information required by this Item 16D.

Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers

Not applicable.

Item 16F. Change in Registrant’s Certifying Accountant

Not applicable.

Item 16G. Corporate Governance

German Corporate Governance Code

The German Corporate Governance Code, or the Corporate Governance Code, was originally published by the German Federal Ministry of Justice (*Bundesministerium der Justiz*) in 2002. The version currently in effect, dated April 28, 2022, was published in the German Federal Gazette (*Bundesanzeiger*) on June 27, 2022. The Corporate Governance Code contains principles (*Grundsätze*), recommendations (*Empfehlungen*) and suggestions (*Anregungen*) relating to the management and supervision of German companies that are listed on a stock exchange. It follows internationally and nationally recognized standards for good and responsible corporate governance. The purpose of the Corporate Governance Code is to make the German system of corporate governance transparent for investors. The Corporate Governance Code includes corporate governance principles, recommendations and suggestions with respect to shareholders and shareholders' meetings, the management and supervisory boards, transparency, accounting policies and auditing.

There is no obligation to comply with the recommendations or suggestions of the Corporate Governance Code. The German Stock Corporation Act (*Aktiengesetz*) requires only that the management board and supervisory board of a German company listed on a trading facility (such as a stock exchange) which is regulated and supervised by government authorities issue an annual declaration that either (i) states that the company has complied with the recommendations of the Corporate Governance Code or (ii) lists the recommendations that the company has not complied with and explains its reasons for deviating from the recommendations of the Corporate Governance Code (*Entsprechenserklärung*). In addition, a listed company is also required to state in this annual declaration whether it intends to comply with the recommendations or list the recommendations it does not plan to comply with in the future. These declarations must be made accessible to shareholders at all times. If the company changes its policy on certain recommendations between such annual declarations, it must disclose this fact and explain its reasons for deviating from the recommendations. Non-compliance with suggestions contained in the Corporate Governance Code need not be disclosed.

As a listed company, our Management Board and Supervisory Board comply with the Corporate Governance Code except for such provisions which are listed explicitly in the annual declaration and for which they provide an explanation of non-compliance.

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.

	European Union/Federal Republic of Germany	Delaware
Board System	A European stock corporation may choose to have a two-tier board structure composed of the Management Board (Vorstand) and the Supervisory Board (Aufsichtsrat). We have chosen this structure. 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 Delaware law, a corporation has a unitary board structure, and it is the responsibility of the board of directors to appoint and oversee the management of the corporation on behalf of and in the best interests of the stockholders of the corporation. Management is responsible for running the corporation and overseeing its day-to-day operations.
Appointment and Number of Directors	Under applicable European and German law, a European stock corporation governed by German law with a share capital of at least €3 million 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.	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.

Removal of Directors	Members of the Management Board of a European stock corporation are appointed by the Supervisory Board for a maximum period of six years with an opportunity to be reelected. The articles of association may provide for a shorter term which in our case is up to five years. The members of the Management Board may be reelected, even repeatedly. The Supervisory Board may remove a member of the Management Board prior to the expiration of his or her term only for cause, such as gross breach of duties (*grobe Pflichtverletzung*), the inability to manage the business properly (*Unfähigkeit zur ordnungsgemäßen Pflichtausübung*) or a vote of no-confidence during the shareholders' meeting (*Vertrauensentzug*). The shareholders themselves are not entitled to appoint or dismiss the members of the Management Board. Under European law, a member of the Supervisory Board of a company may be elected for a term of up to six years. The articles of association may provide for a shorter term. Our Supervisory Board members are, if the general meeting does not resolve on a shorter term, elected for a period up to the end of the general meeting deciding on the discharge for the fourth financial year after the election. Reelection, including repeated reelection, is permissible. Members of the Supervisory Board may be removed with or without cause by way of a general meeting resolution, with the applicable majority requirement depending on the relevant company's articles of association.	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 such director's removal would be sufficient to elect such director 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 such director is a part.
Vacancies on the Board of Directors	Under the law, vacant positions on the Management Board are filled by the Supervisory Board in accordance with the general rules of appointment, which provide that vacancies are filled by the simple majority of votes of Supervisory Board members present or represented by proxy at the vote (with, under certain circumstances, the chairman having a casting vote), unless otherwise provided by the company's articles of association. In case of emergencies, a vacant position on the Management Board may be filled by an individual appointed by the court. Vacant positions on the Supervisory Board are filled in accordance with the general rules of appointment.	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 bylaws of the corporation or (ii) the certificate of incorporation directs that a particular class of stock is to elect such director, in which case a majority of the other directors elected by such class, or a sole remaining director elected by such class, will fill such vacancy.
Annual General Meeting	A European stock corporation, which is governed by German law, must hold an annual shareholders' meeting within six months of the end of its fiscal year. The annual shareholders' meeting must be held at a location determined by the articles of association. If the articles of association do not provide for a specific location, the shareholders' meeting shall be held at the company's seat or, if applicable, at the venue (in Germany) where its shares are listed. Under the articles of association, the Management Board is authorized to provide for the Annual General Meeting to be held without the physical presence of the shareholders or their proxies at the location of the Annual General Meeting (virtual Annual General Meeting).	Under Delaware law, the annual meeting of stockholders shall be held at such place, on such date and at such time as may be designated from time to time by the board of directors or as provided in the certificate of incorporation or by the bylaws.

General Meeting	Under the law, extraordinary shareholders' meetings, in addition to the annual shareholders' meetings, may be called either by the Management Board, or the Supervisory Board. Shareholders holding at least 5% of the company's share capital are entitled to request that an extraordinary shareholders' meeting be convened. In the event that the meeting is not then so convened, a competent court may order that the meeting be convened or authorize the shareholders or their representative to convene the meeting themselves.	Under Delaware law, special meetings of the stockholders may be called by the board of directors or by such person or persons as may be authorized by the certificate of incorporation or by the bylaws.
Notice of General Meetings	Under applicable European and German law, unless a longer period is otherwise provided for in the articles of association or applies because of registration requirements stipulated in the articles of association, the shareholders must be given at least 30 days' advance notice of the shareholders' meeting. Such notices must at least specify the name of the company, the statutory seat of the company, and the location, date and time of the shareholders' meeting. In addition, the invitation must contain the agenda items as well as the Management Board's and the Supervisory Board's voting proposal for each agenda item and, depending on the circumstances, certain further information. If all shareholders entitled to attend the shareholders' meeting are present or represented and do not object to the meeting being held, the formalities of calling and holding of a shareholders' meeting do not apply.	Under Delaware law, unless otherwise provided in the certificate of incorporation or bylaws, written notice of any meeting of the stockholders must be given to each stockholder entitled to vote at the meeting not less than ten nor more than 60 days before the date of the meeting and shall specify the place, date, hour, and purpose or purposes of the meeting.
Proxy	A shareholder may designate another person to attend, speak and vote at a shareholders' meeting of the company on such shareholder's behalf by proxy. With respect to Management Board meetings, a Management Board member may transmit its (written or verbal) vote via another Management Board member. With respect to Supervisory Board meetings, a Supervisory Board member may participate in voting by issuing a written vote to another Supervisory Board member or any third party entitled to attend the Supervisory Board meeting.	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	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 or settle claims for damages against a negligent Management or Supervisory Board member only after the expiry of three years and only if the company's shareholder meeting approves thereof and no minority holding at least 10% of the capital stock raises an objection. In case a third party raises claims directly against members of the Management Board or of the Supervisory Board, such members may claim from the company under additional requirements indemnification regarding liabilities arising out of or in connection with their services to the company.	Under Delaware law, a corporation's certificate of incorporation may include a provision eliminating or limiting the personal liability of a director or officer to the corporation and its stockholders for damages arising from a breach of fiduciary duty as a director or officer. However, no provision can limit the liability of a director or officer for: • any breach of the director's or officer's duty of loyalty to the corporation or its stockholders; • acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law; • intentional or negligent payment of unlawful dividends or stock purchases or redemptions; or • any transaction from which the director derives an improper personal benefit.
Voting Rights	Under the relevant European and German law, each share, except for statutory non-voting preferred shares (*nicht stimmberechtigte Vorzugsaktien*), entitles its holder to vote at the shareholders' meeting with, in the case of no-par value shares, each share conferring one vote. While German law does not provide for a minimum attendance quorum for 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.	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.

Shareholder Vote on Certain Transactions	Under applicable European and German law, certain shareholders' resolutions of fundamental importance require the vote of at least three-quarters of the share capital present or represented in the voting at the time of adoption of the resolution. Resolutions of fundamental importance include, in particular, capital increases with exclusion of subscription rights, capital decreases, the creation of authorized or conditional share capital, the dissolution of a company, a merger into or with another company, split-offs and split-ups, the conclusion of inter-company agreements (*Unternehmensverträge*), in particular domination agreements (*Beherrschungsverträge*) and profit and loss transfer agreements (*Ergebnisabführungsverträge*).	Generally, under Delaware law, unless the certificate of incorporation provides for the vote of a larger portion of the stock, completion of a merger, consolidation, sale, lease or exchange of all or substantially all of a corporation's assets or dissolution requires: • the approval of the board of directors; and • approval by the vote of the holders of a majority of the outstanding stock or, if the certificate of incorporation provides for more or less than one vote per share, a majority of the votes of the outstanding stock of a corporation entitled to vote on the matter.
Standard of Conduct for Directors	Under applicable European and German law, both Management and Supervisory Board members must conduct their affairs with "the care and diligence of a prudent business man" and act in the best interest of the company. The scope of the fiduciary duties of Management and Supervisory Board members is generally determined by European and German legislation and by the courts. 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; • to evaluate and issue a resolution on certain transactions which can only be conducted by the Management Board after approval of the Supervisory Board; • to approve the company's financial statements; • to appoint the Management Board members and to represent the company in transactions between the company and members of the Management Board; and • to approve service contracts between individual members of the Management Board and the company.	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 themselves of all material information reasonably available regarding a significant transaction. The duty of loyalty requires that a director act in a manner such director reasonably believes to be in the best interests of the corporation. A director must not use such director's 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 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.

Stockholder 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. Additionally, pursuant to German case law, the Supervisory Board is obliged to pursue the company's claims against the Management Board, unless the interest of the company keeps them from doing so. The Management Board, or, if a claim is against a member of the Management Board, the Supervisory Board, is obliged to pursue the company's claims against the designated individuals if so resolved by a simple majority of votes cast during a shareholders' meeting. With a simple majority of votes, shareholders can request that a representative pursues the claim on behalf of the company. If the company is unable to fulfill its third- party obligations, the company's creditors may pursue the company's damage claims against members of the Management Board for certain wrongdoings. Under certain circumstances, shareholders can bring forward damage claims of the company against its management on their own behalf. In order to bring forward such a claim one shareholder alone or together with other shareholders needs to hold at least one percent of the company's share capital or a participation of €100,000 in the share capital. Additionally, the claimant(s) need(s) to pass through special claim approval procedures.	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 plaintiff's shares thereafter devolved on the plaintiff by operation of law; and • either (i) allege with particularity the efforts made by the plaintiff to obtain the action the plaintiff desires from the directors and the reasons for the plaintiff's failure to obtain the action, or (ii) or state the reasons for not making the effort. Additionally, the plaintiff must remain a stockholder through the duration of the derivative suit. The action will not be dismissed or compromised without the approval of the Delaware Court of Chancery.

Foreign Private Issuer Exemptions

As a "foreign private issuer," as defined by the SEC, although we are permitted to follow certain corporate governance practices of the Federal Republic of Germany, instead of those otherwise required under the rules of the Nasdaq Stock Market LLC, or Nasdaq, for domestic issuers, we follow the Nasdaq corporate governance rules applicable to foreign private issuers. While we voluntarily follow most Nasdaq corporate governance rules, we intend to take advantage of the following limited exemptions:

- exemption from filing quarterly reports on Form 10-Q and providing current reports on Form 8-K disclosing significant events within four days of their occurrence (however, we intend to furnish quarterly financial information under cover of Form 6-K);

- exemption from compliance with Regulation FD, which generally requires that when a company intentionally discloses material non-public information, it do so through a public disclosure that is broadly available to all members of the public at the same time. However, we do furnish quarterly financial information and other information on a more frequent basis under cover of Form 6-K, and intend to continue doing so. Moreover, we comply with other securities laws, such as rule 10b-5 (rule targeting securities fraud), among others;

- exemption from Section 16 rules regarding short-swing profit liability and short sale prohibitions for sales of ordinary shares by insiders; and

- exemption from the Nasdaq rules applicable to domestic issuers requiring disclosure within four business days of any determination to grant a waiver of the code of business conduct and ethics to directors and officers. Although we will require board approval of any such waiver, we may choose not to disclose the waiver in the manner set forth in the Nasdaq rules, as permitted by the foreign private issuer exemption.

Furthermore, Nasdaq Rule 5615(a)(3) provides that, as a foreign private issuer, we may rely on home country corporate governance practices in lieu of certain of the rules in the Nasdaq Rule 5600 Series and Rule 5250(d), provided that we nevertheless comply with Nasdaq's Notification of Noncompliance requirement (Rule 5625) and the Voting Rights requirement (Rule 5640) and that we have an audit committee that satisfies Rule 5605(c)(3), consisting of committee members that meet the independence requirements of Rule 5605(c)(2)(A)(ii). Although we are permitted to follow certain corporate governance rules that conform to German requirements in lieu of many of the Nasdaq corporate governance rules, we comply with the Nasdaq corporate governance rules applicable to foreign private issuers. We may utilize these exemptions for as long as we continue to qualify as a foreign private issuer.

Item 16H. Mine Safety Disclosure

Not applicable.

Item 16I. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

Item 16J. Insider Trading Policies

We have adopted an insider trading policy that is reasonably designed to promote compliance with applicable insider trading laws, rules and regulations, and any listing standards applicable to us. A copy is included as an exhibit to this Annual Report.

Item 16K. Cybersecurity

Risk Management and Strategy

Our cybersecurity approach aims for comprehensive protection of our information, systems, assets, physical locations, and people. From a business perspective, this means protecting key information assets and complying with applicable international and national privacy laws, information security policies and contractual obligations.

Our Information Security Policy, adopted in 2023, defines our information security management objectives and principles, and our Data Privacy Policy, effective since 2021, provides for a consistent level of company-wide data privacy and data protection. In addition, our Information Classification Policy, introduced internally during the year ended December 31, 2023, provides a system for classifying and protecting our physical and digital assets. These policies are applicable to BioNTech SE and its affiliates, including all Supervisory Board and Management Board members, as well as all other officers and employees, and are part of our overall Information Security Management System, or ISMS. We successfully completed the ISO/IEC 27001:2022 certification process for our ISMS in February 2025.

The ISMS enables us to systematically manage information security through defined processes and structures. This helps to reduce the risks of business interruptions, disclosure of sensitive data or intellectual property, and other damages caused by IT security incidents. Additionally, as an operator of an essential service, we are regulated by the IT Security Act and must comply with legislative requirements, including the implementation of security measures to reduce information security risks.

We aim to prevent the implementation of overly complicated and time-consuming procedures that may lead to an unnecessary increase in effort. We are striving to align the protection of data and the provision of essential service with our organizational context and economic approach. We aim to create an ISMS that is not limited to documentation but is fully integrated into daily practice.

Our processes for assessing, identifying, and managing material risks from cybersecurity threats are integrated into our overall enterprise risk management system, which was developed with input from internal and external experts.

To achieve and preserve information security, we strive for the orderly planning, implementation, control, and optimization of all activities required for the protection of data privacy and the detection, response and recovery of data privacy risks. We are committed to the continual improvement of our ISMS based on the results of the performance evaluation. We will initially seek certifications for our main manufacturing facility and an R&D site in addition to the cybersecurity organization.

We take responsibility for the transparent communication and proper processing of personal data. This includes the storage, access, retention, and security of all personal data when engaging with patients, employees, customers, business partners, and vendors. We communicate our practices in a data privacy statement on our corporate website. We require the third parties with which we contract to adhere to contractual privacy and security provisions, and we request specific information from major vendors about their practices in protecting data privacy.

When processing personal data, we are responsible for ensuring that we comply with applicable data protection laws. These include the European Union's General Data Protection Regulation (*GDPR*), the German Commercial Code (*HGB*), the German Federal Data Protection Act (*BDSG*), the German IT Security Act 2.0 (IT-SiG 2.0), the German Federal Office for Information Security Act (*BSIG*), and other privacy and data security laws in the jurisdictions where we operate. In April 2023, we were designated as a part of Germany's critical infrastructure (*KRITIS*) under the BSIG, which has resulted in heightened reporting and verification obligations. In 2025, we implemented a global data privacy framework that sets out the requirements and standards applicable to processing personal data. The framework is designed to foster compliance with the applicable regulations and sets minimum standards for the Company. As part of our global strategy, privacy-related documents, such as informed consent forms for clinical trials, are being standardized company-wide. The forms facilitate the user-friendly implementation of the standards we have established and provide transparency on how and why we process personal data.

In 2025, there were no substantiated complaints concerning material data breaches, including leaks, thefts, or losses of personal data such as patient or customer data. Contracts and confidentiality agreements with clinical trial sites were compliant with relevant regulations. We do not believe that any cybersecurity threats in 2025, including as a result of any previous cybersecurity incidents, have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition. For a discussion of cybersecurity and data privacy-related risks and uncertainties, see Item 3.D, "Risk Factors," of this Annual Report on Form 20-F.

Governance

We take a centralized approach to managing cyber and information security to facilitate consistent compliance across entities and locations. Our overarching strategy was developed in 2021 by the Chief Operating Officer, or COO, and Chief Information Security Officer, or CISO, in alignment with the Data Protection Officer and Head of Global Security and Protection, and is regularly updated. The ISMS was implemented in 2024.

- The ISMS audit committee (the Committee) is comprised of three people from the supervisory board and the CFO. The Committee supports the ISMS and approves related policies and IT security protection measures.

They are informed about the implementation progress and functioning of the ISMS and determine the risk appetite as well as our risk strategy. The progress of the ISMS, along with related Key Performance Indicators, is presented to the Committee on an annual basis. The Committee also informs the entire Management Board about the outcome of its review.

Our COO and Management Board member, Sierk Poetting, is responsible for assessing and managing our material risks from cybersecurity threats. His ambit includes reviewing our information security capabilities, reporting data privacy issues to the Management Board, and supporting our Information Security Organization, or ISO, in obtaining the resources it needs. The COO's extensive experience in risk management, operations and corporate governance, with over 11 years of experience in the pharmaceutical industry in particular, are critical to the management of cyber and information security at the Company.

- The COO is supported by the CISO, who leads the ISO and is accountable for security strategy, operations, and policy development and implementation. In November 2025, the CISO role was formalized as an independent, consolidated leadership role, integrating the responsibilities of both the Head of IT and the Head of Cyber and Information Security. The CISO functionally reports to the COO while maintaining operational alignment with the Head of IT, ensuring focused leadership and strengthening operational synergies in cyber and information security. The CISO's responsibilities include reporting on cyber and information security to the Management Board, allocating resources for the ISO, and informing the Supervisory Board's Audit Committee of any key security aspects and ISMS improvements. The CISO also oversees our cyber and information security strategy, global policy development, security operations, and the implementation of the ISMS. The role extends across BioNTech's subsidiaries, which either manage their own ISMS (such as InstaDeep) or are in the process of being integrated into the global ISMS (such as Biotheus). Our CISO, Dominik Stihl, has over two decades of experience in Cybersecurity, IT Risk Management, and Identity & Access Governance. Mr. Stihl is a CISSP-certified professional who has successfully led global security organizations and driven compliance strategies for critical infrastructure protection. Our Head of IT, Head of Cyber and Information Security, Data Protection Officer, and Head of Global Security and Protection each bring in additional expertise.

- Data privacy matters fall under the purview of our Chief Legal Officer, or CLO, and Management Board member, James Ryan, who is supported by our Senior Director, Data Privacy. Dr. Ryan's qualifications include twenty years of expertise in legal and intellectual property matters, both within the pharmaceutical industry as well as as an outside counsel with a focus on strategic life sciences transactions. Together with his deep familiarity with the Company's history, operations, and processes, James Ryan is uniquely positioned to advise on data privacy matters.

For additional information on Sierk Poetting's and James Ryan's experience, see Item 6.A, "Directors and Senior Management".

PART III

Item 17. Financial Statements

See Item 18.

Item 18. Financial Statements

The financial statements are filed as part of this Annual Report beginning on page F-1.

Item 19. Exhibits

Exhibit Number	Description
1.1	Articles of Association of the Registrant (incorporated herein by reference to Exhibit 99.1 to the Registrant's Report on Form 6-K (File No. 001-39081), filed with the SEC on January 6, 2026)
2.1	Form of Specimen American Depositary Receipt (included in Exhibit 2.3)
2.2	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)
2.3	Form of Deposit Agreement among the Registrant, the depositary and holders and beneficial owners of the American Depositary Shares (incorporated herein by reference to Exhibit 1 to the Registration Statement on Form F-6 (File No. 333-233898), filed with the SEC on September 23, 2019)
2.4*	Description of Securities of the Registrant
4.1†	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)
4.2†	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)
4.3†	Supplementary Agreement for [***] 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)
4.4†	License Agreement by and among the Registrant, TRON-Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH, Johannes Gutenberg-Universität Mainz, Universitätsmedizin der Johannes Gutenberg-Universität and Ganymed Pharmaceuticals AG, dated January 1, 2015 (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)
4.5†	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)
4.6†	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)

4.7†	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 (File No. 001-39081), filed with the SEC on March 31, 2020)
4.8†	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 (File No. 001-39081), filed with the SEC on March 31, 2020)
4.9	Joinder and Third Amendment to the Collaboration Agreement by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH, BioNTech Manufacturing GmbH, Genentech, Inc. and F. Hoffman-La Roche Ltd, effective as of October 1, 2020 (incorporated herein by reference to Exhibit 4.16 to the Registrant's Annual Report on Form 20-F (File No. 001-39081) filed with the SEC on March 30, 2022)
4.10†	Fourth Amendment to the Collaboration Agreement by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH, BioNTech Manufacturing GmbH, Genentech, Inc. and F. Hoffman-La Roche Ltd, effective as of October 26, 2020 (incorporated herein by reference to Exhibit 4.17 to the Registrant's Annual Report on Form 20-F (File No. 001-39081) filed with the SEC on March 30, 2022)
4.11†	Patent Sublicense Agreement by and between CellScript, LLC and BioNTech RNA Pharmaceuticals GmbH, dated July 14, 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)
4.12†	Second Amendment to Patent Sublicense Agreement by and between CellScript, LLC and BioNTech RNA Pharmaceuticals GmbH, effective as of August 1, 2020 (incorporated herein by reference to Exhibit 4.19 to the Registrant's Annual Report on Form 20-F (File No. 001-39081) filed with the SEC on March 30, 2022)
4.13†	Patent Sublicense Agreement by and between mRNA RiboTherapeutics, Inc. and BioNTech RNA Pharmaceuticals GmbH, dated July 14, 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)
4.14†	Second Amendment to Patent Sublicense Agreement by and between mRNA RiboTherapeutics, Inc. and BioNTech RNA Pharmaceuticals GmbH, effective as of August 1, 2020 (incorporated herein by reference to Exhibit 4.21 to the Registrant's Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 30, 2022)
4.15†	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)
4.16†	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)
4.17†	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)
4.18†	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)
4.19†	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)
4.20†	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)
4.21†	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)
4.22†	Lease Agreement by and among the Registrant and Wista-Management GmbH, dated April 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)
4.23†	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)
4.24†	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 (File No. 001-39081) filed with the SEC on March 31, 2020)
4.25†	Amendment to Lease Agreement by and among the Registrant and Wista-Management GmbH, dated June 1, 2020 (incorporated herein by reference to Exhibit 10.38 to the Registrant's Registration Statement on Form F-1 (File No. 333-233970), filed with the SEC on July 21, 2020)
4.26†	Amended and Restated Collaboration Agreement by and between the Registrant and Pfizer Inc., dated March 17, 2020 (incorporated herein by reference to Exhibit 4.44 to the Registrant's Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 30, 2021)

4.27†	Advance Purchase Agreement by and among BioNTech Manufacturing GmbH, Pfizer Inc., and the European Commission, dated November 20, 2020 (incorporated herein by reference to Exhibit 4.51 to the Registrant's Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 30, 2021)
4.28†	Purchase Agreement by and among BioNTech Manufacturing GmbH, Pfizer Inc., and the European Commission, dated February 17, 2021 (incorporated herein by reference to Exhibit 4.52 to the Registrant's Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 30, 2021)
4.29†	Lease for Buildings H028 and H30 by and between the Pharmaserv GmbH and Novartis Manufacturing GmbH (incorporated herein by reference to Exhibit 4.53 to the Registrant's Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 30, 2021)
4.30†	Lease Agreement by and between the Registrant, as successor-in-interest to Kite Pharma, Inc., and Tech Park 270 III, LLC, dated as of December 1, 2017 (incorporated herein by reference to Exhibit 4.34 to the Registrant's Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 27, 2023)
4.31†	Amendment No. 3 to Lease Agreement by and between the Registrant, as successor-in-interest to Kite Pharma, Inc., and Tech Park 270 III, LLC, dated as of July 24, 2018 (incorporated herein by reference to Exhibit 4.35 to the Registrant's Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 27, 2023)
4.32†	Amendment No. 4 to Lease Agreement by and between the Registrant, as successor-in-interest to Kite Pharma, Inc., and Tech Park 270 III, LLC, dated as of May 23, 2019 (incorporated herein by reference to Exhibit 4.36 to the Registrant's Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 27, 2023)
4.33†	License Agreement by and between the Registrant and Acuitas Therapeutics, Inc., dated as of April 7, 2020 (incorporated herein by reference to Exhibit 4.37 to the Registrant's Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 27, 2023)
4.34†	Advanced Purchase Agreement by and among the Registrant, Pfizer Inc. and European Commission, dated as of May 20, 2021 (incorporated herein by reference to Exhibit 4.38 to the Registrant's Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 27, 2023)
4.35†	Transfer of Source Code for MyMUT Software Versions by and between the Registrant and TRON gGmbH, dated as of May 5, 2021 (incorporated herein by reference to Exhibit 4.39 to the Registrant's Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 27, 2023)
4.36†	Amendment No. 6 to Lease Agreement by and between the Registrant and Tech Park 270, LLC, dated as of August 2, 2021 (incorporated herein by reference to Exhibit 4.40 to the Registrant's Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 27, 2023)
4.37†	Side Letter No. 5 to License and Collaboration Agreement by and between Registrant and Genmab A/S, dated August 12, 2021 (incorporated herein by reference to Exhibit 4.41 to the Registrant's Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 27, 2023)
4.38†	Transfer of Source Code MyMUT Software Versions by and between the Registrant and TRON gGmbH, dated as of September 10, 2021 (incorporated herein by reference to Exhibit 4.43 to the Registrant's Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 27, 2023)
4.39†	Lease for Areas and Rooms in Building 536 and 537 by and between the Pharmaserv GmbH and Novartis Manufacturing GmbH, dated as of January 19, 2022 (incorporated herein by reference to Exhibit 4.45 to the Registrant's Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 27, 2023)
4.40†	Amended and Restated License and Collaboration Agreement, by and between BioNTech SE and Genmab A/S, entered into July 18, 2022, effective as of May 19, 2015 (incorporated herein by reference to Exhibit 4.46 to the Registrant's Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 27, 2023)
4.41†	Real Estate Purchase Contract with Conveyance Together with Inventory Purchase Contract by and between Santo Service GmbH, BioNTech Real Estate An der Goldgrube 12 GmbH & Co. KG and BioNTech Manufacturing GmbH, dated as of December 12, 2022 (incorporated herein by reference to Exhibit 4.47 to the Registrant's Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 27, 2023)
4.42†	License and Collaboration Agreement, by and between the Registrant and OncoC4, Inc., dated as of March 17, 2023 (incorporated herein by reference to Exhibit 4.48 to the Registrant's Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 20, 2024)
4.43†	Amendment No. 1 to the License and Collaboration Agreement, by and between the Registrant and OncoC4, Inc., dated as of February 14, 2024 (incorporated herein by reference to Exhibit 4.49 to the Registrant's Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 20, 2024)
4.44†	License and Collaboration Agreement (HER2), by and between the Registrant and Duality Biologics (Suzhou) Co. Ltd., dated as of March 16, 2023 (incorporated herein by reference to Exhibit 4.50 to the Registrant's Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 20, 2024)
4.45†	License and Collaboration Agreement (B7H3), by and between the Registrant and Duality Biologics (Suzhou) Co. Ltd., dated as of March 31, 2023 (incorporated herein by reference to Exhibit 4.51 to the Registrant's Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 20, 2024)
4.46†	License and Collaboration Agreement (TROP2), by and between the Registrant and Duality Biologics (Suzhou) Co. Ltd., dated as of August 4, 2023 (incorporated herein by reference to Exhibit 4.52 to the Registrant's Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 20, 2024)

4.47†	Letter Re: Combination trials under License and Collaboration Agreements (HER2, B7H3 and TROP2), by and between the Registrant and Duality Biologics (Suzhou) Co. Ltd., dated as of November 13, 2024 (incorporated herein by reference to Exhibit 4.54 to the Registrant's Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 10, 2025)
4.48†	Amended and Restated Agreement, by and between the Registrant and the U.S. Department of Health and Human Services, as represented by the National Institute of Allergy and Infectious Diseases, an Institute or Center of the National Institutes of Health, dated as of December 20, 2024 (incorporated herein by reference to Exhibit 4.56 to the Registrant's Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 10, 2025)
4.49†	Amended and Restated Global Co-Development and Co-Commercialization Agreement, by and between BioNTech US, Inc. and Bristol-Myers Squibb Company, and, solely for the purposes of Section 10.1 through Section 10.4, the Registrant, dated as of August 15, 2025 (incorporated herein by reference to Exhibit 99.1 to the Registrant's Report on Form 6-K (File No. 001-39081), filed with the SEC on September 8, 2025)
8*	List of Subsidiaries of the Registrant
11.1†	Insider Trading Policy of the Company (incorporated herein by reference to Exhibit 11.1 to the Registrant's Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 10, 2025)
12.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
12.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
13.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
13.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
15.1*	Consent of EY GmbH & Co. KG Wirtschaftsprüfungsgesellschaft
97	Compensation Clawback Policy (incorporated herein by reference to Exhibit 97 to the Registrant's Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 20, 2024)
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

† Certain information has been excluded from the exhibit because it is both (i) not material and (ii) the type of information that the Registrant treats as private or confidential.

SIGNATURES

The Registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this Annual Report on Form 20-F on its behalf.

BioNTech SE

Date: March 10, 2026

By: /s/ Prof. Ugur Sahin, M.D.
Prof. Ugur Sahin, M.D.
Chief Executive Officer

Date: March 10, 2026

By: /s/ Ramón Zapata Gomez
Ramón Zapata Gomez
Chief Financial Officer

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Supervisory Board of BioNTech SE.

Opinion on the Financial Statements

We have audited the accompanying consolidated statements of financial position of BioNTech SE (the Company) as of December 31, 2025 and 2024, the related consolidated statements of profit or loss, comprehensive income, changes in stockholders' equity and cash flows for each of the three years in the period ended December 31, 2025, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2025, in conformity with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standard Board and in conformity with IFRS as adopted by the European Union.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2025, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated March 10, 2026, expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating

the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Revenue recognition from collaboration partner's COVID-19 vaccine sales

Description of the Matter

As described in more detail in Note 6 to the consolidated financial statements, the Company recognized revenues associated with COVID-19 vaccine sales of €2.0 billion, mainly comprising the Company's share of its collaboration partner´s gross profit. The Company was contractually eligible to receive a share of the collaboration partner's gross profit from vaccine sales in the collaboration partner's territories. Such gross profit share was recognized as collaboration revenue. In order to determine the gross profit share, the Company used certain information from the collaboration partner, including vaccine sales outside of the United States and associated production costs, some of which was based on preliminary data shared by the partner and might differ once final data is available.

Auditing revenue recognition specific to the gross profit share was complex due to the significant estimation uncertainty in inputs to the calculation. Specifically, the collaboration partner's vaccine sales outside of the United States and associated manufacturing and shipping costs are partially estimated for the last month in the period based on historical information and could change based on the actual vaccine sales and costs incurred.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of the Company's controls related to revenue recognition from the collaboration partner's vaccine sales outside of the United States. For example, we tested controls over management's review of the significant assumptions used to determine the gross profit share the Company is eligible to receive.

Our audit procedures included, among others, reading the contract with the collaboration partner to understand key terms and obtaining an understanding of management's methodology and assumptions used to calculate the estimated gross profit share. We performed a hindsight analysis to assess management's accuracy in estimating the collaboration partner's vaccine sales outside of the United States and manufacturing and shipping costs. We obtained a confirmation directly from the collaboration partner regarding vaccine sales and cost inputs used to estimate the profit share and tested the completeness and accuracy of the Company's gross profit share calculation. We performed a sensitivity analysis of the significant assumptions to evaluate the change in the gross profit share resulting from changing the assumptions, as well as an analysis of previous estimation compared to the actual payments obtained to date. We evaluated the Company's related disclosures in the consolidated financial statements.

Revenue recognition from out-licensing to collaboration partner

Description of the Matter

The Company recorded €0.6 billion in revenues from a collaboration agreement with Bristol-Myers Squibb (the BMS Collaboration Agreement) for the year ended December 31, 2025. As discussed in Note 6 to the consolidated financial statements, the terms of the BMS Collaboration Agreement include a license for the Company's intellectual property. Amounts received under such arrangement include a non-refundable upfront payment, non-contingent anniversary payments and other contingent payments for the achievement of certain development, regulatory and commercial milestones. Based on the terms of the contract, the Company identified material rights relating to options to cancel the contract. Each material right is recognized as revenue at the point in time the collaboration partner makes use of its option or when such right expires.

Auditing the Company's revenue recognition for the BMS Collaboration Agreement was complex because it required significant judgement in determining the nature of the license and the appropriate timing of revenue recognition, including assessing whether the license is distinct from the development activities, how consideration should be allocated to performance obligations, and when material rights associated with cancellation options should be recognized as revenue. These judgements had a significant impact on the amount and timing of revenue recognized.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of controls over the Company's process for revenue recognition from the collaboration partner, including controls assessing the accounting treatment of the BMS Collaboration Agreement.

Our audit procedures included, among others, reading the relevant contracts related to the BMS Collaboration Agreement to understand key terms and purpose and design of the collaboration arrangement, evaluating management's application of IFRS 15 to determine the timing of revenue recognition, including the treatment of the license and the allocation of consideration to material rights. We assessed the reasonableness of management's judgments by comparing the underlying inputs and analyses of those judgements to the terms of the BMS Collaboration Agreement, relevant accounting guidance and the Company's historical practices for collaboration arrangements. We also evaluated the Company's related disclosures in the consolidated financial statements.

Claims and legal contingencies

Description of the Matter

As described in more detail in Note 18 to the consolidated financial statements, the Company is involved in various claims and litigation specifically related to patent infringements matters. The Company, assisted by their internal and external legal counsel, assesses the need to record a provision or disclose a contingency on a case-by-case basis considering the underlying facts of each matter. The Company discloses contingent liabilities in circumstances where a cash outflow is probable, but management is unable to make a reasonable estimate of the expected financial effect that will result from ultimate resolution of the proceeding, or a cash outflow is reasonably possible. A provision is recorded when a cash outflow is deemed probable and reasonably estimable.

Auditing management's determination of whether a loss of such patent liability matters is probable and reasonably estimable, reasonably possible or remote, and the related disclosures, is highly subjective and requires significant judgement.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of the Company’s controls in assessing the completeness, valuation, presentation and disclosures with respect to such claims and legal proceedings. For example, this included testing controls related to the Company’s process for identification, recognition, measurement and disclosure of claims and legal contingencies.

Our substantive procedures included, among others, assessing the completeness of the claims and legal proceedings subject to evaluation by the Company and the determination of the probability of their outcomes through review of presentations for board meetings and inspection of letters addressing the matters from both internal and external legal counsel. Further, we held discussions with internal counsel to confirm our understanding of the allegations, reviewed legal expenses incurred, evaluated resolutions of claims concluded against management’s historical assessments and obtained written representations from executives of the Company confirming the completeness and accuracy of the information provided. We evaluated the adequacy of the Company’s disclosures in relation to these matters.

Acquisition of Biotheus – Accounting and Valuation of the Settlement of Pre-Existing Relationships and Valuation of Intangible Assets

Description of the Matter

As described in Note 5 to the consolidated financial statements, in 2025 the Company completed its acquisitions of Biotheus for total consideration of €280.1 million (the Biotheus Acquisition). The acquisition was accounted for as business combination, and the Company recorded intangible assets, primarily consisting of in-process research and development, of €172.8 million. The Biotheus Acquisition also included the settlement of a pre-existing relationship of €567.3 million which has been accounted for outside of the business combination and purchase price allocation.

Auditing management's accounting for the Biotheus Acquisition was subjective and complex given the high degree of judgement and significant estimation uncertainty applied in determining the total consideration from the purchase price net of amounts attributable to the settlement of the pre existing relationship, as well as the fair value of the intangible assets acquired. The significant estimation uncertainty was primarily due to the sensitivity of the respective fair values of the intangible assets acquired and measurement of the pre-existing relationship to underlying assumptions, including estimated probabilities of successful development, revenue projections, and discount rates. These significant assumptions were forward-looking and could be affected by future market and economic conditions.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of controls over the Company's business combination process including controls over the accounting conclusions reached and the development and approval of the significant assumptions used in the discounted cash-flow models to determine the valuation for the settlement of the pre-existing relationship and the intangible assets acquired.

To audit the accounting for the Biotheus Acquisition, our procedures included, among others, assessing management's documentation on the accounting treatment, reading the relevant purchase agreement and assessing the settlement of the identified pre-existing relationship. We evaluated the reasonableness of estimated probabilities of successful development and revenue projections by comparing them to observable industry and economic trends and standards, external data sources, and historical product trends, including those of similar products, where applicable. With the assistance of our valuation specialists, we evaluated the methodologies utilized by the Company and tested the discount rates by comparing to independently developed ranges and assessing underlying data against external sources. We also performed sensitivity analyses of the significant assumptions to evaluate the change in the fair values resulting from changes in the assumptions and assessed the adequacy of the Company's disclosures.

Acquisition of CureVac N.V. – Valuation of Intangible Assets

Description of the Matter

As described in Note 5 to the consolidated financial statements, in 2025 the Company completed its acquisition of CureVac N.V. for total consideration of €400.1 million ("the CureVac Acquisition"). The CureVac Acquisition was accounted for as business combination, and the Company recorded intangible assets, primarily consisting of intellectual property rights, licenses and similar rights, of €240.3 million.

Auditing the valuation of acquired intangible assets was complex due to the significant estimation uncertainty, primarily attributable to the sensitivity of fair values of the intangible assets to underlying assumptions, including estimated probabilities of successful development, revenue projections, and discount rates. These significant assumptions were forward-looking and could be affected by future market and economic conditions.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of controls over the Company's business combination process including controls over the accounting conclusions reached and the development and approval of the significant assumptions used in the discounted cash-flow models to determine the valuation of the intangible assets acquired.

To audit the valuation for acquired intangible, our procedures included, among others, assessing the reasonableness of estimated probabilities of successful development and revenue projections by comparing them to observable industry and economic trends and standards, external data sources, and historical product trends, including those of similar products, where applicable. With the assistance of our valuation specialists, we evaluated the methodologies utilized by the Company and tested the discount rates by comparing to independently developed ranges and assessing underlying data against external sources. We also performed sensitivity analyses of the significant assumptions to evaluate the change in the fair values resulting from changes in the assumptions and assessed the adequacy of the Company's disclosures.

/s/ EY GmbH & Co. KG Wirtschaftsprüfungsgesellschaft

We have served as the Company's auditor since 2018

Cologne, Germany

March 10, 2026

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Supervisory Board of BioNTech SE.

Opinion on Internal Control Over Financial Reporting

We have audited BioNTech SE's internal control over financial reporting as of December 31, 2025, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission "(2013 framework)," (the COSO criteria). In our opinion, BioNTech SE (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2025, based on the COSO criteria.

As indicated in the accompanying Management's Annual Report on Internal Control over Financial Reporting, management's assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of Biotheus Inc. and Curevac B.V., which are included in the 2025 consolidated financial statements of the Company and constituted approximately 6% of total assets as of December 31, 2025 and 0% of revenues for the year then ended. Our audit of internal control over financial reporting of the Company also did not include an evaluation of the internal control over financial reporting of Biotheus Inc. and Curevac B.V.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated statements of financial position of the Company as of December 31, 2025 and 2024, the related consolidated statements of profit or loss, comprehensive income, changes in stockholders' equity and cash flows for each of the three years in the period ended December 31, 2025, and the related notes and our report dated March 10, 2026 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ EY GmbH & Co. KG Wirtschaftsprüfungsgesellschaft

Cologne, Germany

March 10, 2026

Consolidated Statements of Profit or Loss

		Years ended December 31,		
(in millions €, except per share data)	**Note**	**2025**	**2024**	**2023**
Revenues	6	2,869.9	2,751.1	3,819.0
Cost of sales	7.1	(641.8)	(541.3)	(599.8)
Research and development expenses	7.1	(2,104.9)	(2,254.2)	(1,783.1)
Sales and marketing expenses	7.1	(110.0)	(67.9)	(62.7)
General and administrative expenses	7.1	(514.4)	(531.1)	(495.0)
Other operating expenses	7.2	(1,088.3)	(811.5)	(293.0)
Other operating income	7.2	184.6	140.6	105.0
Operating profit / (loss)		**(1,404.9)**	**(1,314.3)**	**690.4**
Finance income	7.3	423.9	664.0	519.6
Finance expenses	7.3	(69.8)	(27.4)	(23.9)
Profit / (Loss) before tax		**(1,050.8)**	**(677.7)**	**1,186.1**
Income taxes	8	(85.3)	12.4	(255.8)
Net profit / (loss)		**(1,136.1)**	**(665.3)**	**930.3**
Earnings / (Loss) per share				
Basic earnings / (loss) per share	9	(4.70)	(2.77)	3.87
Diluted earnings / (loss) per share	9	(4.70)	(2.77)	3.83

The accompanying notes form an integral part of these consolidated financial statements.

Consolidated Statements of Comprehensive Income

		Years ended December 31,		
(in millions €)	**Note**	**2025**	**2024**	**2023**
Net profit / (loss)		**(1,136.1)**	**(665.3)**	**930.3**
Other comprehensive income				
Other comprehensive income that may be reclassified to profit or loss in subsequent periods, net of tax				
Exchange differences on translation of foreign operations		(99.3)	43.5	(19.8)
Net other comprehensive income / (loss) that may be reclassified to profit or loss in subsequent periods		**(99.3)**	**43.5**	**(19.8)**
Other comprehensive loss that will not be reclassified to profit or loss in subsequent periods, net of tax				
Net gain / (loss) on equity instruments designated at fair value through other comprehensive income	12	(15.9)	(146.6)	3.7
Remeasurement gain / (loss) on defined benefit plans		0.4	—	0.3
Net other comprehensive income / (loss) that will not be reclassified to profit or loss in subsequent periods		**(15.5)**	**(146.6)**	**4.0**
Other comprehensive loss, net of tax		**(114.8)**	**(103.1)**	**(15.8)**
Comprehensive income / (loss), net of tax		**(1,250.9)**	**(768.4)**	**914.5**

The accompanying notes form an integral part of these consolidated financial statements.

Consolidated Statements of Financial Position

(in millions €)		December 31,	December 31,
Assets	**Note**	**2025**	**2024**
Non-current assets			
Goodwill	10	367.9	380.6
Other intangible assets	10	1,606.0	790.4
Property, plant and equipment	11	1,080.9	935.3
Right-of-use assets	20	210.2	248.1
Contract assets	6	2.0	9.8
Other financial assets	12	2,554.2	1,254.0
Other non-financial assets	14	7.3	26.3
Deferred tax assets	8	13.5	81.7
Total non-current assets		**5,842.0**	**3,726.2**
Current assets			
Inventories	13	110.7	283.3
Trade and other receivables	12	924.2	1,463.9
Contract assets	6	8.1	10.0
Other financial assets	12	7,201.8	7,021.7
Other non-financial assets	14	173.8	212.7
Income tax assets	8	52.6	50.0
Cash and cash equivalents	12	7,675.4	9,761.9
Total current assets		**16,146.6**	**18,803.5**
Total assets		**21,988.6**	**22,529.7**
Equity and liabilities			
Equity			
Share capital	15	259.0	248.6
Capital reserve	5, 16	2,473.3	1,398.6
Treasury shares	15	(7.7)	(8.6)
Retained earnings		17,961.9	19,098.0
Other reserves	16	(1,462.3)	(1,325.5)
Total equity		**19,224.2**	**19,411.1**
Non-current liabilities			
Lease liabilities, loans and borrowings	12, 20	215.2	214.7
Other financial liabilities	12	94.9	46.9
Provisions	17	35.5	20.9
Contract liabilities	6	88.0	183.0
Other non-financial liabilities	19	104.2	87.5
Deferred tax liabilities	8	84.3	42.4
Total non-current liabilities		**622.1**	**595.4**
Current liabilities			
Lease liabilities, loans and borrowings	12, 20	52.2	39.5
Trade payables and other payables	12	534.9	426.7
Other financial liabilities	12	351.7	1,443.4
Income tax liabilities	8	65.6	4.5
Provisions	17	145.3	144.8
Contract liabilities	6	754.9	294.9
Other non-financial liabilities	19	237.7	169.4
Total current liabilities		**2,142.3**	**2,523.2**
Total liabilities		**2,764.4**	**3,118.6**
Total equity and liabilities		**21,988.6**	**22,529.7**

The accompanying notes form an integral part of these consolidated financial statements.

Consolidated Statements of Changes in Stockholders' Equity

		Equity attributable to equity holders of the parent					
(in millions €)	Note	Share capital	Capital reserve	Treasury shares	Retained earnings	Other reserves	Total equity
As of January 1, 2023		**248.6**	**1,828.2**	**(5.3)**	**18,833.0**	**(848.9)**	**20,055.6**
Net profit		—	—	—	930.3	—	**930.3**
Other comprehensive loss		—	—	—	—	(15.8)	**(15.8)**
Total comprehensive income / (loss)		**—**	**—**	**—**	**930.3**	**(15.8)**	**914.5**
Treasury shares used for acquisition of business combination		—	102.6	1.1	—	—	**103.7**
Share repurchase program		—	(731.6)	(6.9)	—	—	**(738.5)**
Share-based payments	16	—	30.2	0.3	—	(15.1)	**15.4**
Current and deferred taxes		—	—	—	—	(104.8)	**(104.8)**
As of December 31, 2023		**248.6**	**1,229.4**	**(10.8)**	**19,763.3**	**(984.6)**	**20,245.9**
Net loss		—	—	—	(665.3)	—	**(665.3)**
Other comprehensive loss		—	—	—	—	(103.1)	**(103.1)**
Total comprehensive loss		**—**	**—**	**—**	**(665.3)**	**(103.1)**	**(768.4)**
Share-based payments	16	—	169.2	2.2	—	(237.8)	**(66.4)**
As of December 31, 2024		**248.6**	**1,398.6**	**(8.6)**	**19,098.0**	**(1,325.5)**	**19,411.1**
Net loss		—	—	—	(1,136.1)	—	**(1,136.1)**
Other comprehensive loss		—	—	—	—	(114.8)	**(114.8)**
Total comprehensive loss		**—**	**—**	**—**	**(1,136.1)**	**(114.8)**	**(1,250.9)**
Issuance of share capital, net of transaction costs	15	10.4	856.0	—	—	—	**866.4**
Obligation to issue share capital	5	—	132.6	—	—	—	**132.6**
Share-based payments	16	—	86.1	0.9	—	(22.0)	**65.0**
As of December 31, 2025		**259.0**	**2,473.3**	**(7.7)**	**17,961.9**	**(1,462.3)**	**19,224.2**

Consolidated Statements of Cash Flows

		Years ended December 31,		
(in millions €)	**Note**	**2025**	**2024**	**2023**
Operating activities				
Net profit / (loss)		(1,136.1)	(665.3)	930.3
Income taxes	8	85.3	(12.4)	255.8
Profit / (Loss) before tax		**(1,050.8)**	**(677.7)**	**1,186.1**
Adjustments to reconcile loss before tax to net cash flows:				
Depreciation, amortization and impairment of property, plant, equipment, intangible assets and right-of-use assets	10, 11, 20	382.8	298.0	183.4
Share-based payment expenses	16	106.2	100.9	51.4
Net foreign exchange differences		(6.6)	(109.5)	(298.0)
(Gain) / Loss on disposal of property, plant and equipment		(2.5)	(0.3)	3.8
Finance income excluding foreign exchange differences	7.3	(423.9)	(648.5)	(519.6)
Finance expense excluding foreign exchange differences	7.3	21.4	27.4	7.9
Government grants	7.2	(63.0)	(31.5)	2.4
Other non-cash (income) / loss	5	585.4	—	—
Unrealized (gain) / loss on derivative instruments at fair value through profit or loss		(10.4)	4.6	175.5
Working capital adjustments:				
Decrease in trade and other receivables, contract assets and other assets		1,083.7	387.7	5,374.0
Decrease in inventories		177.9	74.5	81.9
(Decrease) / Increase in trade payables, other financial liabilities, other liabilities, contract liabilities, refund liabilities and provisions		(723.8)	758.4	118.9
Interest received and realized gains from cash and cash equivalents		337.0	474.9	258.2
Interest paid and realized losses from cash and cash equivalents		(11.0)	(13.5)	(5.4)
Income tax received / (paid), net		3.8	(389.2)	(482.9)
Share-based payments	16.2	(25.3)	(154.5)	(766.2)
Government grants received		75.1	106.0	—
Net cash flows from operating activities		**456.0**	**207.7**	**5,371.4**
Investing activities				
Purchase of property, plant and equipment		(175.1)	(286.5)	(249.4)
Proceeds from sale of property, plant and equipment		4.5	1.2	(0.7)
Purchase of intangible assets		(573.9)	(165.8)	(455.4)
Acquisition of subsidiaries and businesses, net of cash acquired	5	186.3	—	(336.9)
Investment in other financial assets		(11,422.5)	(12,370.3)	(7,128.4)
Proceeds from maturity of other financial assets		9,512.2	10,740.2	1,216.3
Net cash flows used in investing activities		**(2,468.5)**	**(2,081.2)**	**(6,954.5)**
Financing activities				
Proceeds from loans and borrowings	12	6.7	—	0.3
Repayment of loans and borrowings	12	(18.0)	(2.3)	(0.1)
Payments related to lease liabilities	20	(39.6)	(43.6)	(40.3)
Share repurchase program		—	—	(738.5)
Transaction costs related to issuance of share capital	5	(2.0)	—	—
Net cash flows used in financing activities		**(52.9)**	**(45.9)**	**(778.6)**
Net decrease in cash and cash equivalents		(2,065.4)	(1,919.4)	(2,361.7)
Change in cash and cash equivalents resulting from exchange rate differences		(27.0)	14.8	(14.5)
Change in cash and cash equivalents resulting from other valuation effects		5.9	2.8	164.8
Cash and cash equivalents at the beginning of the period		9,761.9	11,663.7	13,875.1
Cash and cash equivalents as of December 31		**7,675.4**	**9,761.9**	**11,663.7**

The accompanying notes form an integral part of these consolidated financial statements.

Notes to the Consolidated Financial Statements

1 Corporate Information

BioNTech SE is a limited company incorporated and domiciled in Germany. American Depositary Shares (ADS) representing BioNTech SE's ordinary shares have been publicly traded on the Nasdaq Global Select Market since October 10, 2019. The registered office is located in Mainz, Germany (An der Goldgrube 12, 55131 Mainz). BioNTech SE is registered in the commercial register B of the Mainz Local Court under the number HRB 48720. The accompanying consolidated financial statements present the financial position and the results of operation of BioNTech SE and its subsidiaries and have been prepared on a going concern basis in accordance with the IFRS Accounting Standards as issued by the International Accounting Standards Board. References to the "Company", "BioNTech", "Group", "we", "us" and "our" refer to BioNTech SE and its consolidated subsidiaries, except where the context otherwise requires.

Our consolidated financial statements for the year ended December 31, 2025, were authorized for issue in accordance with a resolution of the Supervisory Board on March 9, 2026.

2 Significant Accounting Policies

2.1 Basis of Preparation

General

The consolidated financial statements have been prepared in accordance with the IFRS Accounting Standards as issued by the International Accounting Standards Board. We have applied all IFRS standards and interpretations that were effective on and endorsed by the European Union (EU) as at December 31, 2025. There were no standards or interpretations as at December 31, 2025, impacting our Consolidated Financial Statements for the years ended December 31, 2025, 2024, and 2023, that were effective but not yet endorsed. Therefore, our Consolidated Financial Statements comply with both, IFRS as issued by the International Accounting Standards Board (IASB) and IFRS as endorsed by the EU.

We prepare and publish our consolidated financial statements in Euros and round numbers to thousands or millions of Euros, respectively. Accordingly, numerical figures shown as totals in some tables may not be exact arithmetic aggregations of the figures that preceded them and figures presented in the explanatory notes may not add up to the rounded arithmetic aggregations. Rounding applied may differ from rounding published in different units in the previous years.

Segment Information

Decisions with respect to business operations and resource allocations are made by our Management Board, as the chief operating decision maker based on BioNTech as a whole. Accordingly, we operate and make decisions as a single operating segment, which is also our reporting segment.

2.2 Basis of Consolidation

The consolidated financial statements comprise the financial statements of BioNTech SE and its controlled investees (subsidiaries).

The Group controls an investee if, and only if, the Group has

- power over the investee (i.e., existing rights that give it the current ability to direct the relevant activities of the investee);
- exposure, or rights, to variable returns from its involvement with the investee; and
- the ability to use its power over the investee to affect its returns.

Generally, there is a presumption that a majority of voting rights results in control.

Whether an investee is controlled is re-assessed if facts and circumstances indicate that there are changes to one or more of the three elements of control. Consolidation of a subsidiary begins when control is obtained over the subsidiary and ceases when control over the subsidiary is lost.

The profit / (loss) and each component of other comprehensive income / (loss) for the period are attributed to the equity holders of the parent of the Group and to the non-controlling interests, even if this results in the non-controlling interests having a deficit balance. When necessary, adjustments are made to the consolidated financial statements of subsidiaries to bring their accounting policies in line with the Group's accounting policies. All intra-group assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated on consolidation.

A change in the ownership interest of a subsidiary, without a loss of control, is accounted for as an equity transaction.

If control over a subsidiary is lost, the related assets (including goodwill), liabilities, non-controlling interests and other components of equity are derecognized, while any resultant gain or loss is recognized in the consolidated statements of profit or loss. Any investment retained is recognized at fair value.

In accordance with IFRS 11 (Joint Arrangements), we classify our joint arrangements (i.e. arrangements in which we exercise joint control with one or more parties) either as a joint operation or as joint venture. We exercise joint control over a joint arrangement when decisions relating to the relevant activities of the arrangement require unanimous consent of us and the other parties with whom control is shared.

2.3 Summary of Material Accounting Policies

2.3.1 Foreign Currencies

Our consolidated financial statements are presented in Euros, which is also our functional currency. For each entity, the Group determines the functional currency, and items included in the consolidated financial statements of such entities are measured using that functional currency. We use the direct method of consolidation and, on disposal of a foreign operation, the gain or loss that is reclassified to the consolidated statements of profit or loss reflects the amount that arises from using this method.

Transactions and Balances

Transactions in foreign currencies are initially recorded by the Group's entities at their respective functional currency spot rates at the date the transaction first qualifies for recognition.

Monetary assets and liabilities denominated in foreign currencies are translated at the functional currency spot rates of exchange at the reporting date.

Non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rates at the dates of the initial transactions.

In determining the spot exchange rate to use on initial recognition of the related asset, expense or income (or part of it) on the derecognition of a non-monetary asset or non-monetary liability relating to advance consideration, the date of the transaction is the date on which the Group initially recognizes the non-monetary asset or non-monetary liability arising from the advance consideration. If there are multiple payments or receipts in advance, the Group determines the transaction date for each payment or receipt of advance consideration.

Foreign Currency Translation

Foreign currency translation effects from the translation of operating activities include foreign exchange differences arising on operating items such as trade receivables and trade payables and are either shown as other operating income or expenses on a cumulative basis. Foreign currency translation effects presented within finance income and expenses include foreign exchange differences arising on financing items such as loans and borrowings as well as foreign exchange differences arising on cash and cash equivalents and are either shown as finance income or expenses on a cumulative basis.

Foreign Currency Translation on Consolidation

Upon consolidation, the assets and liabilities of foreign operations are translated into Euros at the rate of exchange prevailing at the reporting date and the transactions recorded in their consolidated statements of profit or loss are translated at exchange rates prevailing at the dates of the transactions.

The exchange differences arising on translation for consolidation are recognized in other comprehensive income. On disposal of a foreign operation, the component of other comprehensive income relating to that particular foreign operation is reclassified to profit or loss.

Any goodwill arising on the acquisition of a foreign operation and any fair value adjustments to the carrying amounts of assets and liabilities arising upon the acquisition are treated as assets and liabilities of the foreign operation and translated at the spot rate of exchange at the reporting date.

2.3.2 Current versus Non-Current Classifications

Assets and liabilities in the consolidated statements of financial position are presented based on current or non-current classification.

An asset is current when it is either: (i) expected to be realized or intended to be sold or consumed in the normal operating cycle, (ii) held primarily for the purpose of trading, (iii) expected to be realized within twelve months after the reporting period, or (iv) cash or cash equivalents, unless it is restricted from being exchanged or used to settle a liability for at least twelve months after the reporting period. All other assets are classified as non-current.

A liability is current when it is either: (i) expected to be settled in the normal operating cycle, (ii) held primarily for the purpose of trading, (iii) due to be settled within twelve months after the reporting period, or (iv) there is no unconditional right to defer the settlement of the liability for at least twelve months after the reporting period. The terms of the liability that could, at the option of the counterparty, result in its settlement by the issue of equity instruments do not affect its classification. The Group classifies all other liabilities as non-current.

Deferred tax assets and liabilities are classified as non-current assets and liabilities, respectively.

2.3.3 Revenue from Contracts with Customers

Revenue

Identification of the Contract

We generate revenues from collaboration and license agreements, which contain multiple elements, including licenses to use, research, develop, manufacture and commercialize candidates and products, research and

development services as well as obligations to develop and manufacture preclinical and clinical material and products. We determined that those collaboration and license agreements qualify as contracts with customers. A contract is an agreement between two or more parties that establishes enforceable rights and obligations.

Identification of Performance Obligations

Our customer contracts often include bundles of licenses, goods and services. If the granting of a license is bundled together with delivering of goods and or the rendering of services, it is assessed whether these agreements are comprised of more than one performance obligation. A performance obligation is only accounted for as the grant of a license if the grant of a license is the sole or the predominant promise of the performance obligation.

A customer contract may provide a customer with an unilateral option to cancel the contract. We determine whether such right indicates that the customer has a material right that would need to be accounted for as a performance obligation (e.g., there is a discount for goods or services provided during the cancellable period that provides the customer with a material right).

Determining Transaction Prices

We apply judgment when determining the consideration that is expected to be received. If the consideration in an agreement includes a variable amount, we estimate the amount of consideration to which we will be entitled in exchange for transferring the goods to the customer. At contract inception, the variable consideration is estimated based on the most likely amount of consideration expected from the transaction and constrained until it is highly probable that a significant revenues reversal in the amount of cumulative revenues recognized will not occur when the associated uncertainty with respect to the variable consideration is subsequently resolved. The estimated revenues are updated at each reporting date to reflect the current facts and circumstances.

Allocation of Transaction Prices

If a contract with a customer contains more than one performance obligation, the transaction price is allocated to each performance obligation based on relative standalone selling prices. If an option to cancel the contract provides a customer with a material right, a portion of the transaction price is allocated to such material right at contract inception and recognized when or as the option is exercised or expires. We have established the following hierarchy to determine the standalone selling prices.

- Where standalone selling prices for offered licenses, goods or services are observable and reasonably consistent across customers, our standalone selling price estimates are derived from our respective pricing history. However, due to the limited number of customers and the limited company history, this approach can rarely be used.

- Where sales prices for an offering are not directly observable or highly variable across customers, we follow a cost-plus-margin approach.

- For offerings that have highly variable pricing and lack substantial direct costs to estimate based on a cost-plus-margin approach, we allocate the transaction price by applying a residual approach.

Judgment is required when estimating standalone selling prices.

Recognition of Revenues

For each separate performance obligation, it is evaluated whether control is transferred either at a point in time or over time. For performance obligations that are satisfied over time, revenues are recognized based on a measure of progress, which depicts the performance in transferring control to the customer. With regard to our licensing arrangements, we distinguish between whether the license granted is considered to be a right to access our intellectual property or a right to use our intellectual property. When we provide the licensee with a

research and development license, which represents a right to access our intellectual property as it exists throughout the license period (as our intellectual property is still subject to further research), the promise to grant a license is accounted for as a performance obligation satisfied over time as our customers simultaneously receive and consume the benefits from our performance. In other cases, when we provide the licensee with a right to use our intellectual property as it exists at the point in time the license is granted, revenue is recognized at a point in time when the customer can first use and benefit from the license.

Revenues based on the collaboration partners' gross profit, which is shared under the respective collaboration agreements, are recognized based on the sales-based or usage-based royalty exemption; i.e., when the underlying sales occur, which is when the performance obligation has been satisfied. As described further in Note 3, judgment is applied to certain aspects when accounting for the collaboration agreements.

Revenue arrangements that involve two or more partners who contribute to the provision of a specific good or service to a customer are assessed in terms of principal-agent considerations in order to determine the appropriate treatment for the transactions between us and the collaborator and the transactions between us and other third parties. The classification of transactions under such arrangements is determined based on the nature and contractual terms of the arrangement along with the nature of the operations of the participants. Any consideration related to activities in which we are considered the principal, which includes being in control of the good or service before such good or service is transferred to the customer, is accounted for as gross revenues. Any consideration related to activities in which we are considered the agent is accounted for as net revenues.

Revenues from the sale of pharmaceutical and medical products (e.g., COVID-19 vaccine sales and other sales of peptides and retroviral vectors for clinical supply) are recognized when we transfer control of the product to the customer. Control of the product normally transfers when the customer gains physical possession and we have not retained any significant risks of ownership or future obligations with respect to the product. In general, payments from customers are due within 30 days after invoice. However, with respect to our collaboration with Pfizer Inc., or Pfizer, there is a significant time lag between when revenues are recognized and the payments are received. The contractual settlement of the gross profit share has a temporal offset of more than one calendar quarter. As Pfizer's financial quarter for subsidiaries outside the United States differs from ours, it creates an additional time lag between the recognition of revenues and the payment receipt.

For certain contracts, the finished product may temporarily be stored at our location under a bill-and-hold arrangement. Revenues from bill-and-hold arrangements are recognized at the point in time when the customer obtains control of the product and all of the following criteria have been met: (i) the arrangement is substantive; (ii) the product is identified separately as belonging to the customer; (iii) the product is ready for physical transfer to the customer; and (iv) we do not have the ability to use the product or direct it to another customer. In determining when the customer obtains control of the product, we consider certain indicators, including whether title and significant risks and rewards of ownership have transferred to the customer and whether customer acceptance has been received.

Contract Balances

Contract Assets

A contract asset is the right to consideration in exchange for goods or services transferred to the customer. If we transfer goods or services to a customer before the customer pays the respective consideration or before payment is due, a contract asset is recognized for the earned consideration that is conditional.

Trade Receivables

A receivable represents our right to an amount of consideration that is unconditional (i.e., only the passage of time is required before payment of the consideration is due).

Contract Liabilities

A contract liability is the obligation to transfer goods or services to a customer for which we have received consideration (or an amount of consideration is due) from the customer. If a customer pays consideration before we transfer goods or services to the customer, a contract liability is recognized when the payment is made or when the payment is due (whichever is earlier). Contract liabilities are recognized as revenue when we fulfill our performance obligations under the contract.

2.3.9 Intangible Assets

Intangible assets acquired separately are measured on initial recognition at cost. The cost of intangible assets acquired in a business combination is their fair value at the date of acquisition. Following initial recognition, intangible assets are carried at cost less any accumulated amortization and accumulated impairment losses.

The portion of the consideration paid by us in in-licensing agreements to acquire rights to intellectual property is recognized as an intangible asset, referred to as In-process R&D. If an in-licensing agreement includes research and development services, the share of consideration attributable to these services is deferred and recognized in research and development expenses as goods or services are received. Payments depending on the achievement of specific milestones as part of the purchase of intangible assets, except for intangible assets acquired in a business combination, are recognized as subsequent acquisition cost of the intangible asset and as a financial liability once the milestone is reached.

The useful lives of intangible assets are assessed as either finite or indefinite.

Intangible assets with finite lives are amortized generally on a straight-line basis over the useful life and assessed for impairment whenever there is an indication that the intangible asset may be impaired. The amortization period and the amortization method for an intangible asset with a finite useful life are reviewed at the end of each reporting period at the least. The amortization expense on intangible assets with finite lives is recognized in the consolidated statements of profit or loss in the expense category that is consistent with the function of the intangible assets.

A summary of the useful lives applied to the Group’s intangible assets is as follows:

Intangible assets	Useful life (years)
Intellectual property rights	8-20
Licenses	3-20
Software	3-8

Intangible assets with indefinite useful lives are tested for impairment at least annually, or when there is an indication for impairment, either individually or at the level of a cash-generating unit (see Note 2.3.11 for further details). In the case of intangible assets not yet available for use, the point in time from which a capitalized asset can be expected to generate economic benefit for the Group cannot be determined. Such assets are not amortized, and therefore classified as having an indefinite useful life. The intangible assets not yet available for use are tested for impairment annually, or when there is an indication for impairment on an individual basis. The assessment of indefinite life is reviewed annually to determine whether the indefinite life continues to be supportable. If not, the change in useful life from indefinite to finite is made on a prospective basis. In the case an intangible asset not yet available for use is out-licensed to a third party and such license is determined to be a right to use our intellectual property, the intangible asset which is not derecognized shall be reclassified from indefinite to finite at the earlier date of (a) the out-licensing to such third party or (b) obtaining marketing approval from a regulatory authority.

We have classified advanced payments on intangible assets as intangible assets that are not yet ready for use. Advanced payments on intangible assets are tested for impairment on an annual basis.

An intangible asset is derecognized upon disposal (i.e., at the date the recipient obtains control) or when no future economic benefits are expected from its use or disposal. Any gain or loss arising upon derecognition of the asset (calculated as the difference between the net disposal proceeds and the carrying amount of the asset) is included in the consolidated statements of profit or loss.

See Note 2.3.4 for further details in connection with our accounting of internally generated intangible assets.

2.3.4 Research and Development Expenses

Research and development costs are expensed in the period in which they are incurred. Regarding internal projects, we consider that regulatory approval and other uncertainties inherent in the development of new products preclude the capitalization of internal development expenses as an intangible asset until marketing approval from a regulatory authority is obtained. Payments made to third parties, such as contract research and development organizations as compensation for subcontracted research and development, that are deemed not to transfer intellectual property are expensed as internal research and development expenses in the period in which they are incurred. Such payments are only capitalized if they meet the criteria for recognition of an internally generated intangible asset, usually when marketing approval has been received from a regulatory authority. We have entered into agreements under which third parties grant licenses to us, which are known as in-license agreements. If in-licensing results in consideration for the acquisition of intellectual property that meets the definition of an identifiable asset, this is capitalized as an intangible asset unless the respective intellectual property is mainly used as part of our general ongoing research and development activities without any intent to market the respective product as such. If the transaction also includes research and development services to be provided by the licensor, the share of consideration attributable to these services is recognized in research and development expenses in line with the performance of the services. Sales-based milestone or royalty payments incurred under license agreements after the approval date of the respective pharmaceutical product are recognized as expenses in cost of sales as incurred.

Subsequent internal research and development costs in relation to intellectual property rights are expensed because the technical feasibility of the internal research and development activity can only be demonstrated by the receipt of marketing approval for a related product from a regulatory authority in a major market.

Reimbursements for research and development in connection with collaboration agreements are offset against research and development expenses (see also Note 2.3.8).

Prior to the second quarter of 2023, we had assessed that inventory produced prior to successful regulatory approval did not meet the criteria for capitalization as an asset, and accordingly expensed the costs of pre-launch inventory as research and development costs. Based on the experience of the past years and the developments since our COVID-19 vaccine was first authorized or approved for emergency or temporary use, our assessment regarding the potential to produce economic benefits changed. Beginning with the second quarter of 2023, pre-launch products from the *Comirnaty* product family with their potential for economic benefit fulfill the recognition criteria for an asset under the IFRS Conceptual Framework. At each reporting date, the respective inventory is measured at the lower of cost and net realizable value. Reaching market authorization in the pharmaceutical industry is associated with uncertainty. We consider the net realizable value to be zero until regulatory approval is obtained, as this is the probable amount expected to be realized from its sale until approval is obtained. The write-down is recognized in the statements of profit or loss as research and development expenses. If regulatory approval for a product candidate is obtained, the relevant write-down would be reversed to a maximum of the original cost. Subsequently, inventory is recognized as cost of sales.

2.3.5 Government Grants

Government grants and similar grants which are accounted for in accordance with IAS 20 are recognized where there is reasonable assurance that the grant will be received and all attached conditions will be complied with. When the grant relates to an expense item, it is recognized as other income on a systematic basis over the periods that the related costs for which the grant is intended to compensate are expensed. When the grant relates to an asset, it is recognized as deferred income within the consolidated statements of financial position. Other income is subsequently recognized in our consolidated statements of profit or loss over the useful life of the underlying asset subject to funding.

2.3.6 Taxes

Current Income Tax

Current income tax assets and liabilities are measured at the amount expected to be recovered from or paid to the taxation authorities. The tax rates and tax laws used to compute the amount are those that are enacted or substantively enacted at the reporting date in the countries where the Group operates and generates taxable income.

In addition, current income taxes presented for the period include adjustments for uncertain tax payments or tax refunds for periods not yet finally assessed by tax authorities, excluding interest expenses and penalties on the underpayment of taxes. In the event that amounts included in the tax return are considered unlikely to be accepted by the tax authorities (uncertain tax positions), a provision for income taxes is recognized.

Management periodically evaluates positions taken in the tax returns with respect to situations in which applicable tax regulations are subject to interpretation and establishes provisions where appropriate.

Deferred Tax

Deferred tax is provided using the liability method on temporary differences between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes at the reporting date.

Deferred tax liabilities are recognized for all taxable temporary differences, except:

- when the deferred tax liability arises from the initial recognition of goodwill or an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss; or
- in respect of taxable temporary differences associated with investments in subsidiaries, when the timing of the reversal of the temporary differences can be controlled and it is probable that the temporary differences will not reverse in the foreseeable future.

Deferred tax assets are recognized for all deductible temporary differences, the carry forward of unused tax credits and any unused tax losses. Deferred tax assets are recognized to the extent that it is probable that taxable profit will be available against which the deductible temporary differences, the carry forward of unused tax credits and unused tax losses can be utilized, except:

- when the deferred tax asset relating to the deductible temporary difference arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss; or
- in respect of deductible temporary differences associated with investments in subsidiaries, deferred tax assets are recognized only to the extent that it is probable that the temporary differences will reverse in the foreseeable future and taxable profit will be available against which the temporary differences can be utilized.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply in the year in which the asset is realized, or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted at the reporting date.

Unrecognized deferred tax assets are re-assessed at each reporting date and are recognized to the extent that it has become probable that future taxable profits will allow the deferred tax asset to be recovered.

Recognition of Taxes

Current and deferred tax items are recognized similarly to the underlying transaction either in profit or loss, other comprehensive income or directly in equity.

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

Sales Tax

Expenses and assets are recognized net of sales tax, except when the sales tax incurred on a purchase of assets or services is not recoverable from the taxation authority.

The net amount of sales tax recoverable from, or payable to, the taxation authority is included as part of receivables or payables in the consolidated statements of financial position.

Global Minimum Taxation

Based on the Organisation for Economic Co-operation and Development (OECD) Base Erosion and Profit Shifting (BEPS) project to tackle tax avoidance, the OECD/G20 Inclusive Framework (an association of about 140 countries) decided to introduce a global minimum taxation for large multinational groups (known as Pillar 2). The Global Anti-Base Erosion Rules are intended to ensure that large multinational groups pay a minimum level of tax on the income arising in each jurisdiction where they operate. In December 2021, the OECD published its Model Rules, which serve as a draft bill for implementation into national domestic law, followed by guidelines and commentaries published in March 2022. In December 2022, the EU adopted a corresponding directive (EU 2022/2523) that obliges EU member states to transpose the rules into national domestic law. If the effective tax rate in any jurisdiction is below the minimum rate (15%), the Group may be subject to the so-called top-up tax or a so-called qualified domestic minimum top-up tax.

Several jurisdictions in which the Group operates have transposed the OECD Model Rules into national domestic law and brought them into force. In addition, the Group is closely following the progress of the legislative process in each country in which the Group operates. As of the balance sheet date, the BEPS Pillar 2 regulations (*MinBestRL UmsG*) had already been transposed into German law (*MinStG*). The date of application of the law in Germany is for financial years beginning after December 30, 2023. Subsequently, as the OECD Model Rules have entered into force in Germany, the Group is obliged to file top-up tax information returns for all entities which are part of the Group, beginning in financial year 2024. The Group falls within the scope of these regulations. The Group carried out an analysis as of the reporting date to determine the fundamental impact and the jurisdictions in which the Group is exposed to possible effects in connection with a Pillar 2 top-up tax.

2.3.7 Business Combinations and Goodwill

Business combinations are accounted for using the acquisition method. The cost of an acquisition is measured as the aggregate of the consideration transferred, which is measured at acquisition date fair value, and the amount of any non-controlling interests in the acquiree.

Goodwill is initially measured at cost as the excess of the aggregate of the consideration transferred and the amount recognized for non-controlling interests and any previous interest held over the net identifiable assets acquired and liabilities assumed.

Costs related to executing business combinations are recognized when they are incurred and are classified as general and administrative expenses.

After initial recognition, goodwill is tested at least annually or when there is an indication for impairment. See Note 2.3.11. For the purpose of impairment testing, goodwill acquired in a business combination is, from the acquisition date, allocated to each of the cash-generating units that are expected to benefit from the combination, irrespective of whether other assets or liabilities of the acquiree are assigned to those units.

2.3.8 Joint Arrangements

Joint arrangements are either classified as a joint operation or as joint venture. Provided that we exercise joint control over a joint arrangement that is not structured through a separate vehicle, those activities are classified as a joint operation. The assets, liabilities, revenues and expenses in relation to such a joint operation are accounted for in accordance with the IFRS Accounting standards applicable to the particular assets, liabilities, revenues and expenses.

2.3.10 Property, Plant and Equipment

Construction in progress is stated at cost. Property, plant and equipment are stated at cost, net of accumulated depreciation and accumulated impairment losses, if any. Such cost includes the cost of replacing part of the property, plant and equipment if the recognition criteria are met. All other repair and maintenance costs are expensed as incurred.

Depreciation is calculated on a straight-line basis over the estimated useful lives of the assets, generally applicable as follows:

Property, plant and equipment	Useful life (years)
Buildings	10-33
Equipment, tools and installations	7-18

Operating and business equipment has a useful life of 1-10 years and is reported under equipment, tools and installations due to immateriality. Leasehold improvements disclosed in buildings have a useful life of the shorter period of the underlying lease term or the economic useful live (see Note 2.3.17).

An item of property, plant and equipment initially recognized is derecognized upon disposal (i.e., at the date the recipient obtains control) or when no future economic benefits are expected from its use or disposal. Any gain or loss arising on derecognition of the asset (calculated as the difference between the net disposal proceeds and the carrying amount of the asset) is included in the consolidated statements of profit or loss when the asset is derecognized.

The residual values, useful lives and methods of depreciation of property, plant and equipment are reviewed at each financial year-end and adjusted prospectively, if appropriate.

2.3.11 Impairment of Non-Financial Assets

At each reporting date, we assess whether there is an indication that a non-financial asset may be impaired. Goodwill is tested for impairment at least annually. Impairment is determined for goodwill by assessing the recoverable amount of each cash-generating unit (or group of CGUs) to which the goodwill relates. If any indication exists, or when annual impairment testing is performed, we estimate the asset's or CGU's recoverable amount. The recoverable amount is the higher of an asset's or CGU's fair value less costs of disposal and its value in use. The recoverable amount is determined for an individual asset, unless the asset does not generate cash inflows that are largely independent of those from other assets or groups of assets. If the asset does not generate independent cash inflows, the impairment test is performed for the smallest group of assets that generate largely independent cash inflows from other assets (CGU). When the carrying amount of an asset or cash-generating unit exceeds its recoverable amount, the asset or the non-current assets of the CGU are considered impaired and written down to their recoverable amount.

Impairment losses are recognized in the consolidated statements of profit or loss in expense categories consistent with the function of the impaired asset.

As long as intangible assets are classified as intangible assets with an indefinite useful life, they are tested for impairment annually at the CGU level, as appropriate, and when circumstances indicate that the carrying value may be impaired.

Intangible assets not yet available for use are not amortized, but rather tested for impairment when a triggering event arises or at least once a year. The identification of triggering events takes place on a quarterly or on an ad hoc basis with the involvement of the responsible departments, taking internal and external information sources into consideration. The impairment test is performed annually or if there are indications of impairment by determining the asset's value in use. In assessing value in use, the estimated discounted future cash flows are based on long-term forecast calculations reflecting the asset's estimated product life cycles. The assumptions are based on internal estimates along with external market studies. The result of the valuation depends to a large extent on the estimates by the management of the future cash flows of the assets and the discount rate applied, and is therefore subject to uncertainty. Any expense resulting from an impairment of intangible assets with finite lives is recognized in the consolidated statements of profit or loss in the expense category that is consistent with the function of the respective intangible assets.

2.3.12 Financial Instruments

A financial instrument is any contract that gives rise to a financial asset of one entity and a financial liability or equity instrument of another entity.

i) Financial Assets

Initial Recognition and Measurement

Financial assets are initially measured at fair value as of the trade date and – depending on their classification – subsequently measured at amortized cost, fair value through other comprehensive income (OCI) or fair value through profit or loss.

Subsequent Measurement

The measurement of financial assets depends on their classification, as described below.

Financial Assets Measured at Amortized Cost

Financial assets measured at amortized cost include trade receivables and other financial assets that are generally measured using the effective interest rate (EIR) method. With respect to trade receivables, we applied the practical expedient, which means that they are measured at the transaction price determined in accordance with IFRS 15. Refer to the accounting policies in Note 2.3.3. Other financial assets measured at amortized cost are held to collect contractual cash flows, which are solely payments of principal and interest. Gains and losses

are recognized in our consolidated statements of profit or loss when the financial asset is derecognized, modified or impaired.

Financial Assets Designated at Fair Value through OCI (Equity Instruments)

Upon initial recognition, we can irrevocably elect to classify equity investments as equity instruments designated at fair value through OCI if they meet the definition of equity under IAS 32 and are not held for trading. The classification is determined on an instrument-by-instrument basis. Gains and losses on these financial assets are never recycled to profit or loss. Dividends are recognized as other income in the consolidated statements of profit or loss when the right of payment has been established. If dividends clearly represent a recovery of part of the cost of the investment they are recognized in the OCI. Equity instruments designated at fair value through OCI are not subject to impairment assessment. We elected to irrevocably classify our non-listed and listed equity investments under this category. They are recognized using trade date accounting.

Financial Assets at Fair Value through Profit or Loss

When we acquire contractual rights to cash flows from the sale of patent-protected biopharmaceutical products by unrelated biopharmaceutical companies as royalty assets and do not own the intellectual property or have the right to commercialize the underlying products, royalty assets are recognized as financial assets measured at fair value through profit and loss. We recognize day one gains and losses only when the fair value is evidenced by a quoted price in an active market for the same instrument or is based on a valuation technique that only uses data from observable markets. In all other cases, we defer the difference between the fair value at initial recognition and the transaction price. After initial recognition, we recognize that deferred difference as a gain or loss only to the extent that it arises from a change in a factor that market participants would take into account when pricing the asset or liability.

Derivatives not designated as hedging instruments are measured at fair value through profit or loss. A financial asset exists if the derivative has a positive fair value.

Derecognition

A financial asset (or, where applicable, a part of a financial asset or part of a group of similar financial assets) is primarily derecognized (i.e., removed from the consolidated statements of financial position) when the rights to receive cash flows from the asset have expired or have been transferred in terms of fulfilling the derecognition criteria.

Impairment of Financial Assets

An allowance for expected credit losses (ECLs) is considered for all non-derivative financial debt investments, including cash, time deposits and debt securities of the Group. ECLs are based on the difference between the contractual cash flows due in accordance with the contract and all of the cash flows that the Group expects to receive, discounted at an approximation of the original effective interest rate. Included in the projected cash inflows are amounts generated from selling the collateral on hand and from additional credit support measures that are fundamental to the terms of the contract. For the credit risk of non-derivative financial debt investments, including cash, time deposits and dept securities, we use the probability weighted model.

For trade receivables and contract assets the Group applies a simplified approach in calculating ECLs. This means that the Group does not track changes in credit risk, but instead recognizes a loss allowance based on lifetime ECLs at each reporting date. We have established an ECL model that is based on the probability of default (PD), considers the respective country default probabilities and takes the maturities into account. In order to determine the PD of companies, we use the maturities of the trade receivables and the score of the companies.

If there is objective evidence that certain trade receivables or contract assets are fully or partially impaired, additional loss allowances are recognized to account for expected credit losses. A debtor's creditworthiness is assumed to be impaired if there are objective indications that the debtor is in financial difficulties, such as the disappearance of an active market for its products or impending insolvency.

ii) Financial Liabilities

Financial liabilities are generally measured at amortized cost using the effective interest rate (EIR) method. Derivatives with negative fair values not designated as hedging instruments and liabilities for contingent consideration in business combinations are measured at fair value.

All financial liabilities are recognized initially at fair value and, in the case of loans and borrowings and payables, net of directly attributable transaction costs.

Financial liabilities measured at amortized cost include loans and borrowings, trade payables and other financial liabilities. They are measured at amortized cost using the EIR method. Gains and losses are recognized in the consolidated statements of profit or loss when the liabilities are derecognized as well as through the EIR amortization process.

Amortized cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the EIR. The EIR amortization is included as finance costs in the consolidated statements of profit or loss.

Derecognition

A financial liability is derecognized when the obligation under the liability is discharged or cancelled or expires. When an existing financial liability is replaced by another from the same lender on substantially different terms, or the terms of an existing liability are substantially modified, such an exchange or modification is treated as the derecognition of the original liability and the recognition of a new liability. The difference in the respective carrying amounts is recognized in the consolidated statements of profit or loss.

iii) Expenses and Income from Exchange Forward Contracts

Effects from foreign exchange forward contracts, which are measured at fair value through profit or loss, are shown as either other operating income or other operating expenses on a cumulative basis and might switch between those two items during the year-to-date reporting periods.

2.3.13 Fair Value Measurement

Fair value is a market-based measurement. For some assets and liabilities, observable market transactions or market information is available. For other assets and liabilities, observable market transactions or market information might not be available. When a price for an identical asset or liability is not observable, another valuation technique is used. To increase consistency and comparability in fair value measurements, there are three levels of the fair value hierarchy:

- Level 1 contains the use of quoted prices in active markets for identical assets or liabilities.
- Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability either directly or indirectly.
- Level 3 inputs are unobservable.

Within this hierarchy, estimated values are made by management based on reasonable assumptions, including other fair value methods.

For assets and liabilities that are recognized in the financial statements at fair value on a recurring basis, we determine whether transfers have occurred between levels in the fair value hierarchy by re-assessing categorization (based on the lowest level input that is significant to the fair value measurement as a whole) at the end of each reporting period.

For the purpose of fair value disclosures, classes of assets and liabilities have been determined on the basis of the nature, characteristics and risks of the asset or liability and the level of the fair value hierarchy, as explained above.

2.3.14 Inventories

Inventories are valued at the lower of cost and net realizable value.

Costs incurred in bringing each product to its present location and condition are accounted for as follows:

- raw materials and supplies: purchase cost on a first-in / first-out basis;
- unfinished goods and finished goods: cost of direct materials and labor, including both internal manufacturing and third-party contract manufacturing organizations, or CMOs, and a proportion of manufacturing overheads based on the normal operating capacity, but excluding borrowing costs.

Net realizable value is the estimated selling price in the ordinary course of business less estimated costs of completion and the estimated costs necessary to make the sale. Write-offs are recorded if inventories are expected to be unsaleable, do not fulfill the specification defined by our quality standards or if their shelf-life has expired. For our inventories subject to the collaboration partners' gross profit share mechanism, we consider the contractual compensation payments in the estimate of the net realizable value.

Beginning with the second quarter of 2023, pre-launch products from the *Comirnaty* product family with their potential for economic benefit fulfill the recognition criteria for an asset under the IFRS Conceptual Framework. At each reporting date, the respective inventory is measured at the lower of cost and net realizable value. However, because is not probable until regulatory approval is obtained, we consider the net realizable value to be zero, as this is the probable amount expected to be realized from its sale until approval is obtained.

2.3.15 Cash and Cash Equivalents

Cash and cash equivalents comprise cash at banks and on hand and short-term investments that we consider to be highly liquid (including deposits, money market funds and reverse repos) with an original maturity of three months or less that are readily convertible to a known amount of cash and subject to an insignificant risk of changes in value. Deposits with an original maturity of more than three months are recognized as other financial assets.

2.3.16 Treasury Shares

We apply the par value method to our repurchases of outstanding American Depositary Shares, or ADSs. Accordingly, the nominal value of acquired treasury shares is deducted from equity and shown in the separate item "Treasury shares". Any premium paid in excess of the nominal value of a repurchased ADS is deducted from the capital reserve. On the trade date, we recognize a liability, and on the settlement date, we settle in cash. We recognize the foreign exchange differences that may occur between the trade and settlement date as profit or loss.

2.3.17 Leases

At the inception of a contract, we assess whether the contract is, or contains, a lease. A contract is, or contains, a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

At inception or on reassessment of a contract that contains a lease component, the consideration in the contract is allocated to each lease component on the basis of their relative standalone prices. However, for leases of land and buildings in which we are a lessee, we have elected not to separate non-lease components, and instead account for the lease and non-lease components as a single lease component.

We recognize a right-of-use asset and a lease liability at the lease commencement date.

The right-of-use asset is initially measured at cost.

The depreciation of the right-of-use asset is calculated on a straight-line basis over the estimated useful lives of the assets or shorter lease term, as follows:

Right-of-use assets	Useful life or shorter lease term (years)
Buildings	2-25
Equipment, tools and installations	2-5
Production facilities	2-3
Automobiles	3-4

The lease liability is initially measured at the present value of the lease payments that are not paid at the commencement date, discounted using the incremental borrowing interest rate implicit in the lease or, if that rate cannot be readily determined, the Group's incremental borrowing rate. Generally, the incremental borrowing rate is used as the discount rate.

The lease liability is subsequently measured at amortized cost using the EIR method. It is remeasured when there is a change in future lease payments arising from a change in an index or rate, if there is a change in the estimate of the amount expected to be payable under a residual value guarantee, or if we change our assessment of whether we will exercise a purchase, extension or termination option. When the lease liability is remeasured, a corresponding adjustment is made to the carrying amount of the right-of-use asset or is recorded in the consolidated statements of profit or loss if the carrying amount of the right-of-use asset has been reduced to zero.

Right-of-use assets are presented separately and lease liabilities are presented under "Financial liabilities" in the consolidated statements of financial position.

Short-Term Leases and Leases of Low-Value Assets

We have elected not to recognize right-of-use assets and lease liabilities for short-term leases of machinery that have a lease term of 12 months or less or leases of low-value assets. We recognize the lease payments associated with these leases as an expense in the consolidated statements of profit or loss on a straight-line basis over the lease term.

2.3.18 Provisions

Provisions are recognized when there is a present obligation (legal or constructive) as a result of a past event, it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation

and a reliable estimate can be made of the amount of the obligation. When we expect some or all of a provision to be reimbursed, for example, under an insurance contract, the reimbursement is recognized as a separate asset, but only when the reimbursement is virtually certain.

A provision is also recognized for certain contracts with suppliers for which the unavoidable costs of meeting the obligations exceed the economic benefits expected to be received. The economic benefits considered in the assessment comprise the future benefits we are directly entitled to under the contract as well as the anticipated future benefits that are the economic consequence of the contract if these benefits can be reliably determined.

The expense relating to a provision is presented in the consolidated statements of profit or loss net of any reimbursement if reimbursement is considered to be virtually certain.

2.3.19 Share-Based Payments

Employees (and others providing similar services) receive remuneration in the form of share-based payments, which are settled in equity instruments (equity-settled transactions) or in cash (cash-settled transactions).

In accordance with IFRS 2, share-based payments are generally divided into cash-settled and equity-settled. Both types of payment transactions are measured initially at their fair value as of the grant date. The fair value is determined using an appropriate valuation model, further details of which are given in Note 16. Rights granted under cash-settled transactions are remeasured at fair value at the end of each reporting period until the settlement date. The cost of share-based payment awards is recognized over the relevant service period, applying either the straight-line method or the graded vesting method, where applicable.

These costs are recognized in cost of sales, research and development expenses, sales and marketing expenses or general and administrative expenses, together with a corresponding increase in equity (other reserves) or other liabilities, over the period in which the service is provided (the vesting period). The cumulative expense recognized for cash- and equity-settled transactions at each reporting date until the vesting date reflects the extent to which the vesting period has expired, and also reflects the best estimate of the number of equity instruments expected to ultimately vest.

Service and non-market performance conditions are not taken into account when determining the grant date fair value of awards, but the likelihood of the conditions being met is assessed as part of our best estimate of the number of equity instruments that will ultimately vest. Market performance conditions are reflected within the grant date fair value. Any other conditions attached to an award, but without an associated service requirement, are considered to be non-vesting conditions. Non-vesting conditions are reflected in the fair value of an award and lead to an immediate expensing of an award unless there are also service and/or performance conditions.

If we have a choice of settling either in cash or by providing equity instruments, the rights granted are accounted for as an equity-settled transaction, unless there is a present obligation to settle in cash.

If, due to local tax regulations, an amount is withheld for the employee's tax obligations and paid directly to the tax authorities in cash on the employee's behalf, the entire share-based payment program remains an equity-settled plan based on the IFRS 2 classification. Accordingly, the amount withheld for the employee's tax obligations expected to be paid directly to the tax authorities is reclassified from "Other reserves" to "Other non-financial liabilities".

2.3.20 Cash Dividend

We recognize a liability to pay a dividend when the distribution is authorized. As per the corporate laws of Germany, a distribution is authorized when it is approved by the general shareholder meeting. A corresponding amount is recognized directly in equity.

2.4 Standards Applied for the First Time

In 2025, the following potentially relevant new and amended standards and interpretations became effective, but did not have a material impact on our consolidated financial statements:

Standards / Interpretations	Date of application
Amendments to IAS 21 The Effects of Changes in Foreign Exchange Rates: Lack of Exchangeability	January 1, 2025

2.5 Standards Issued but Not Yet Effective

The new and amended standards and interpretations that are issued but not yet effective by the date of issuance of the financial statements and that might have an impact on our financial statements are disclosed below. We have not adopted any standards early and intend to adopt these new and amended standards and interpretations, if applicable, when they become effective.

Standards / Interpretations	Date of application
Amendments to the Classification and Measurement of Financial Instruments – Amendments to IFRS 9 and IFRS 7	January 1, 2026
Annual Improvements Volume 11	January 1, 2026
Contracts Referencing Nature-dependent Electricity – Amendments to IFRS 9 and IFRS 7	January 1, 2026
IFRS 18 Presentation and Disclosure in Financial Statements	January 1, 2027
IFRS 19 Subsidiaries without Public Accountability: Disclosures	January 1, 2027
Amendments to IAS 21 The Effects of Changes in Foreign Exchange Rates: Translation to a Hyperinflationary Presentation Currency	January 1, 2027
Amendments to IFRS 19 Subsidiaries without Public Accountability: Disclosures	January 1, 2027

An analysis of the effects of IFRS 18 on our financial statement presentation and disclosures has been initiated and is currently ongoing. IFRS 18 requires additional defined (sub)totals in the consolidated statement of profit or loss, disclosures about management performance measures and introduces new principles for aggregating and disaggregating information to help determine items in the primary financial statements, particularly in profit or loss statement, and appropriate location of material information. Since the beginning of 2025, we have been analyzing the effects of implementing IFRS 18 by performing both qualitative and quantitative assessments. The following overview summarizes the key subject areas and their estimated impact on our financial statements:

– Structure of consolidated statements of profit or loss: The consolidated statement of profit or loss will be classified in specified totals and subtotals by defining five categories: “Operating”, “Investing”, “Financing”, “Income Taxes” and “Discontinued Operations”. The first three categories are new and supplemented by the requirement to present subtotals for operating profit/loss and profit/loss before financing and income taxes, identifying the main business activity has to be identified. This determination is based on an assessment of facts and circumstances and requires a certain degree of judgment and is relevant for the definition of operating profit. The operating category should include all main business activities and should operate as residual category in which all income and expenses are recognized that cannot be allocated to other categories. The investing category embraces income and expenses from investments in associates and joint ventures to which the equity method is applicable, as well as those in non-consolidated subsidiaries, from cash- and cash equivalents and from other financial and non-financial assets if these generate a return individually and largely independently of the company´s other resources (e.g. investments in financial assets other than cash and cash equivalents). In order to allocate income and expenses to the financing category, a distinction between liabilities that result exclusively from finance transactions in which we receive funds in the form of cash, equity or through the expiry of a liability and which we will repay in cash or equity at a later point in time, and other financial and non financial liabilities i.e. pensions, provisions and lease liabilities is

necessary. The expected material effect on BioNTech arises from the split of the finance result in the new "Investing" and "Financing" categories. The operating category will remain essentially unchanged and corresponds to the "operating profit / (loss)".

- Aggregation and disaggregation of information in notes disclosures: IFRS 18 requires information to be broken down in such a way that the consolidated financial statements and accompanying notes fulfil their respective roles as defined in IFRS 18.

- Definition of management-defined performance measures: IFRS 18 introduces the concept of management-defined key performance measures, or MPMs and will require detailed disclosures in the notes. MPMs are specific subtotals of income and expenses derived from items in the income statement that are considered as relevant to understand BioNTech's performance presented in our external communication. The analysis regarding the adjustment of earnings-based key figures for corporate management corresponding to the new defined subtotals in the consolidated statement of profit or loss is still ongoing. For further information with regard of our current Non-IFRS measures please see Item 5 "Non-IFRS Measures as Defined by BioNTech". Whether the defined non-IFRS measures are in line with the concept of MPMs is still ongoing.

With regard to the first-time application of the other standards and interpretations listed in the table and other standards amended in the annual improvements, it is currently estimated that there will be no material impact on our consolidated financial statements.

3 Significant Accounting Judgments, Estimates and Assumptions

The preparation of the consolidated financial statements requires management to make judgments, estimates and assumptions that affect the reported amounts of revenues, expenses, assets and liabilities, the accompanying disclosures and the disclosure of contingent liabilities. Uncertainty about these assumptions and estimates could result in outcomes that require a material adjustment to the carrying amount of assets or liabilities affected in future periods.

Significant accounting judgments, as well as key assumptions concerning the future and other key sources of estimation uncertainty at the reporting date that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year, are described below. We based our assumptions and estimates on parameters available when the consolidated financial statements were prepared. Existing circumstances and assumptions about future developments, however, may change due to market changes or circumstances arising that are beyond the control of the Group. Such changes are reflected in the assumptions when they occur.

Revenues from Contracts with Customers

We applied the following judgments, estimates and assumptions that significantly affect the determination of the amount and timing of revenues from contracts with customers:

Identification and Determination of Performance Obligations

We generate revenues from collaboration and license agreements, which contain multiple elements, including licenses to use, research, develop, manufacture and commercialize candidates and products, research and development services as well as obligations to develop and manufacture preclinical and clinical material and products. We determined that those collaboration and license agreements qualify as contracts with customers. A contract is an agreement between two or more parties that establishes enforceable rights and obligations. If a unit of account, identified as a promised good or service (or bundle of goods or services) that is distinct within a collaboration and license agreement, is with a customer, such agreement is partially within the scope of IFRS 15. At inception of each agreement, we apply judgment when determining which promises represent distinct performance obligations. If promises are not distinct, they are combined until the bundle of promised goods and

services is distinct. For some agreements, this results in accounting for goods and services promised in a collaboration and license agreement as a single performance obligation with a single measure of progress. For these combined performance obligations, we assess which of these promises is the predominant promise to determine the nature of the performance obligation. When licenses are granted, we determined that the grant of the license is the predominant promise within the combined performance obligations. In our view, we grant our customers a right to access or a right to use our intellectual property due to the collaboration and license agreements.

Measurement of the Transaction Price

Our collaboration and license agreements often include variable consideration, which is contingent on the occurrence or non-occurrence of a future event (i.e., reaching a certain milestone). When determining deferred revenues from a collaboration and license agreement, we need to estimate the amount of consideration to which we will be entitled in exchange for transferring the promised goods or services to our customers.

As there are usually only two possible outcomes (i.e., milestone is reached or not), we have assessed that the method of the most likely amount is the best method to predict the amount of consideration to which we will be entitled. At contract inception, the most likely amount for milestone payments is estimated to be zero. We have assessed that the likelihood of achieving the respective milestone decreases depending on how far the expected date of achieving the milestone lies in the future. At each reporting date, we use judgment to determine when to include variable consideration in the transaction price in such a way that it is highly probable that a significant revenue reversal in the amount of cumulative revenue recognized will not occur when the associated uncertainty with respect to the variable consideration is subsequently resolved. We have concluded that future milestone payments are fully constrained at the end of the current financial year.

Future milestone payments would become unconstrained upon the satisfaction of the milestone event, specifically a development event, regulatory approval or achievement of a sales milestone.

Allocation of the Transaction Price to Performance Obligations and Revenue Recognition as Performance Obligations are Satisfied

We allocate the transaction price to performance obligations based on their relative standalone selling prices, which are generally based on our best estimates and interpretations of facts and circumstances of each contractual agreement and may require significant judgment to determine appropriate allocation.

Upfront payments and reimbursement for expenses are initially deferred on our consolidated statements of financial position. We assessed that no significant financing component exists within our collaboration agreements since the overall business purpose of advanced payments is to support the payment structure rather than to provide a significant benefit of financing. For performance obligations in which the costs vary based on progress, an input-based measure that takes into account cost incurred is the most reliable indicator of the progress of the related research activities. In other cases, revenue recognition on a straight-line basis may be the most reliable indicator of our performance toward complete satisfaction. If the contractual activities progress, the achievement of development milestones will be used to measure the progress toward complete satisfaction. We evaluate the measure of progress in each reporting period and, if necessary, adjust the measure of performance and related revenue recognition. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and net profit or loss in the period of adjustment.

Upon successfully commercializing a pharmaceutical product, the collaboration and license agreements also provide for additional profit-sharing or tiered royalties earned when customers recognize net sales of licensed products as well as sales milestone payments. Revenue is recognized based on the sales-based or usage-based royalty exemption; i.e., when, or as, the underlying sales occur, which is when the performance obligation has been satisfied.

Principal-Agent Considerations

Collaboration agreements that involve two or more partners who contribute to the provision of a specific good or service to a customer are assessed in terms of principal-agent considerations. Under our current collaboration agreements, the allocation of marketing and distribution rights defines territories in which the collaboration partner acts as a principal in each case. We recognize revenue net based on the collaboration partners' gross profit in territories where the partner is responsible for supply, and on a gross basis when directly supplying our customers in our territories when control has been transferred. Amounts paid to collaboration partners for their share of our profits earned where we are the principal in the transaction are recorded as cost of sales.

Pfizer Agreement Characteristics

With respect to our collaboration with Pfizer, revenues from contracts with customers are recognized based on our collaboration partner's gross profit from COVID-19 vaccine sales, which is shared under the respective collaboration agreement. In determining revenues from contracts with customers pursuant to this collaboration agreement, we are reliant on our collaboration partner for details regarding its gross profit for the period at hand. Some of the information which our collaboration partner provides us with to identify the gross profit is, by necessity, preliminary and subject to change.

Pfizer's gross profit share is calculated based on sales and takes into account transfer prices. The latter include manufacturing and shipping costs, which represent standard prices and include mark-ups on manufacturing costs as specified by the terms of the agreement. Manufacturing and shipping cost variances were considered as far as those have been identified. Nevertheless, those input parameters may be adjusted once actual costs are determined. The sales as reported by Pfizer have been used to estimate license obligations in terms of royalties and sales milestones. Sales milestones and royalties are recognized as they are earned by the partners. Sales milestones are shared equally, while royalty payments are borne by the partners on the basis of revenues in the territories for which the partners are responsible and subsequently deducted as cost under the gross profit shared. The estimated royalty fees applied to net sales reflect the license obligations to the extent currently identified from third-party contractual arrangements. Changes in estimates are accounted for prospectively, when determined.

Manufacturing cost variances include among others expenses from unused contract manufacturing capacities and overstock inventories finally scrapped. As only materialized costs – which for example means manufacturing capacities finally lapsed or inventories finally scrapped – are shared with the partner in a cash-effective manner, the gross profit share impact is anticipated once assessed as being highly probable to occur. Any changes to this assessment will be recognized prospectively.

Pfizer's determination of manufacturing and shipping costs also affects the transfer prices that have been charged to COVID-19 vaccine supplies that it manufactures and supplies to us and may be subject to adjustment whenever manufacturing and shipping cost variances are identified. Likewise, our own cost of sales and the respective gross profit share owed to our partner may be adjusted prospectively, when changes are determined.

For contract balances related to the Pfizer agreement, see Note 6. Judgment is required in determining whether a right to consideration is unconditional and thus qualifies as a receivable.

BMS Agreement Characteristics

Under the terms of the collaboration agreement between Bristol Myers Squibb Company, or BMS, and us, we have identified two units of account in the contract. One is the grant of the license, identified as a separate unit of account that is distinct within the collaboration agreement and the second unit of account is the development activity. In this context, the contract is in the scope of IFRS 15 and we have applied IFRS 15 to the upfront, anniversary and milestone payments in respect of the license component. In assessing our exercise of joint control with BMS in relation to the development activities, we classified those activities as a joint operation as the

arrangement is not structured through a separate vehicle. These activities fall within the scope of IFRS 11. Therefore we account for our share of the development activities in compliance with this standard. Under the terms of the collaboration agreement, we agreed with BMS to jointly share development and manufacturing costs on a 50:50 basis. In determining the amount payable to or receivable from BMS, we rely on BMS for its costs incurred in the respective reporting period. Reimbursements for research and development by the collaboration partner are offset against research and development expenses in our consolidated statements of profit or loss.

Determining whether the performance obligation in relation to the license granted to BMS is satisfied over time or at a point in time was based on the nature of our promise to grant the license. This assessment involved significant judgment and was essentially based on evaluating whether the intellectual property to which BMS receives rights has significant stand-alone functionality or not. Since the underlying product candidate already reached phase 3 in clinical development and therefore no significant modifications to the form or functionality of the intellectual property are expected, we have classified the license granted to BMS as right-to-use our intellectual property.

We have determined that the contract does not contain a substantive termination penalty and therefore contains a material right at contract inception. The material right comprises three options to cancel the contract which are related to the due dates of the respective maintenance fees payable in the upcoming three years containing an implicit option to extend the contract period by 1 year at each anniversary date of the collaboration agreement. By paying the annual maintenance fees, the right-to-use license will be transferred annually. After the expiry of any option BMS is able to further use the license granted by us (see Note 6).

Intangible Assets

Significant judgments, assumptions and estimates are required for the identification of a potential need to recognize an impairment loss on goodwill and other intangible assets. These estimates include management's assumptions regarding future cash flow projections and economic risks that require significant judgment and assumptions about future developments. They can be affected by a variety of factors, including, but not limited to changes in business strategy, assumptions regarding funding ability of expected R&D expenses, assumptions regarding the size of addressable markets, number of addressable indications, the time and probability to reach market, peak sales assumptions, clinical trial success rates as well as estimation of weighted average cost of capital.

Changes to the assumptions underlying our goodwill and intangible assets impairment assessments could require material adjustments to the carrying amount of our recognized goodwill and intangible assets and may lead to impairment charges recognized in our Consolidated Statements of Profit or Loss.

Significant assumptions and estimates are also required to determine the appropriate amount of amortization of intangible assets. They relate in particular to the determination of the underlying useful life. The useful life of an intangible asset is based on our estimates regarding the period over which the intangible asset is expected to generate economic benefits for us.

Contingencies

Disclosures in respect of third-party claims and litigation for which no provisions have been recognized disclosures are made in the form of contingent liabilities, unless a potential outflow of resources is considered remote. It is not practicable to estimate the financial impact of our contingent liabilities due to the uncertainties around lawsuits and claims.

For further disclosures relating to contingencies see Note 18.

Research and Development Expenses

The nature of our business and primary focus of our activities, including development of our platforms and manufacturing technologies, generate a significant amount of research and development expenses. Research costs are expensed as incurred. Development expenditures on an individual project are recognized as an intangible asset if, and only if, the capitalization criteria are met. Based on our assessment, we have concluded that, due to the inherent risk of failure in pharmaceutical development and the uncertainty of approval, these criteria are usually not met before regulatory approval is achieved. The related expenditure is reflected in the consolidated statements of profit or loss in the period in which the expenditure is incurred. We have entered into agreements under which third parties grant licenses to us, which are known as in-license agreements. If in-licensing results in consideration for the acquisition of intellectual property that meets the definition of an identifiable asset, this is capitalized as an intangible asset. If the transaction also includes research and development services to be provided by the licensor, the share of consideration attributable to these services is recognized in research and development expenses in line with the performance of the services. The allocation of consideration attributable to the acquisition of intellectual property and consideration attributable to the research and development services provided by the licensor requires management to make judgments and assumptions. These judgments and assumptions need to be applied on a case-by-case basis and can materially affect our research and development expenses.

Business Combinations

Judgment is required when accounting for business combinations. This includes determining whether an intangible asset is identifiable and whether it should be recorded separately from goodwill. Additionally, estimating the acquisition date fair values in conjunction with the purchase price allocation and with the settlement of pre-existing relationships involves estimation uncertainty and discretionary decisions. The necessary measurements are based on information available on the acquisition date and on expectations and assumptions that have been deemed reasonable by management. These judgments, estimates and assumptions can materially affect our Consolidated Statements of Financial Position and our Consolidated Statements of Profit or Loss.

Share-Based Payments

Determining the fair value of share-based payment transactions requires the most appropriate valuation for the specific program, which depends on the underlying terms and conditions. We used valuation models such as a binomial or Monte Carlo simulation model for the measurement of the cash- and equity-settled transactions' fair value, taking into account certain assumptions relating to a number of factors, including the volatility of the stock price, the determination of an appropriate risk-free interest rate, expected dividends and the probability of reaching a minimum hurdle to exercise the relevant options. For awards which were granted prior to the initial public offering, at a time where no quoted market prices existed, the valuation model assumptions included the option's underlying share price. For awards which were granted after the initial public offering, the grant date's share prices on the Nasdaq Global Select Market were included in the valuation.

A fluctuation assumption is applied when estimating the number of equity instruments for which service conditions are expected to be satisfied and will be revised if material differences arise. Ultimately, a true-up to the number satisfied by the settlement date will be recorded.

For further disclosures relating to share-based payments, see Note 16.

Income Taxes

We are subject to income taxes in more than one tax jurisdiction. Due to the increasing complexity of tax laws and the corresponding uncertainty regarding the legal interpretation by the fiscal authorities, tax calculations are

generally subject to an elevated amount of uncertainty. To the extent necessary, possible tax risks are taken into account in the form of provisions.

We do not recognize or we would impair deferred tax assets if it is unlikely that a corresponding amount of future taxable profit will be available against which the deductible temporary differences, tax loss carry forwards and tax credits can be utilized. The assessment whether a deferred tax asset can be recognized or is impaired requires significant judgment, as we need to estimate future taxable profits to determine whether the utilization of the deferred tax asset is probable. In evaluating our ability to utilize our deferred tax assets, we consider all available positive and negative evidence, including the level of historical taxable income and projections for future taxable income over the periods in which the deferred tax assets are recoverable. Based on the requirements in IAS 12, to not place reliance on future events that are uncertain as they for example cannot be controlled, managements assessment takes particular into account the fact that there is an inherent risk of failure in pharmaceutical development and an uncertainty of approval which is dependent on external regulatory agencies' opinions. This also includes management's assessment on the character and amounts of taxable future profits, the periods in which those profits are expected to occur, and the availability of tax planning opportunities.

Our management continued to take the view that deferred tax assets on tax losses carried forward that relate to subsidiaries which have a loss-making history cannot be recognized. This includes the assessment that those subsidiaries have neither any taxable temporary differences nor any tax planning opportunities available that could support the recognition of deferred tax assets.

For further disclosures relating to deferred taxes, see Note 8.

4 Group Information

Information about Subsidiaries

The consolidated financial statements include the following subsidiaries:

			% equity interest	
Name	Country of incorporation	Registered office	December 31, 2025	December 31, 2024
BioNTech BioNTainer Holding GmbH	Germany	Mainz	100%	100%
BioNTech Cell & Gene Therapies GmbH	Germany	Mainz	100%	100%
BioNTech Collaborations GmbH	Germany	Mainz	100%	100%
BioNTech Delivery Technologies GmbH	Germany	Halle	100%	100%
BioNTech Diagnostics GmbH	Germany	Mainz	100%	100%
BioNTech Discovery GmbH	Germany	Mainz	100%	n / a[1]
BioNTech Europe GmbH	Germany	Mainz	100%	100%
BioNTech Idar-Oberstein Services GmbH	Germany	Idar-Oberstein	100%	100%
BioNTech Innovation and Services Marburg GmbH	Germany	Marburg	100%	100%
BioNTech Innovation GmbH	Germany	Mainz	100%	100%
BioNTech Innovative Manufacturing Services GmbH	Germany	Idar-Oberstein	100%	100%
BioNTech Manufacturing GmbH	Germany	Mainz	100%	100%
BioNTech Manufacturing Marburg GmbH	Germany	Marburg	100%	100%
BioNTech Real Estate Holding GmbH	Germany	Holzkirchen	100%	100%
CureVac Corporate Services GmbH	Germany	Tübingen	86.75%[2]	n / a[1]
CureVac Manufacturing GmbH	Germany	Tübingen	86.75%[2]	n / a[1]
CureVac SE	Germany	Tübingen	86.75%[2]	n / a[1]
InstaDeep DE GmbH	Germany	Berlin	100%	100%

Continued on next page

Name	Country of incorporation	Registered office	% equity interest December 31, 2025	% equity interest December 31, 2024
JPT Peptide Technologies GmbH	Germany	Berlin	100%	100%
NT Security and Services GmbH	Germany	Mainz	100%	100%
reSano GmbH	Germany	Mainz	100%	100%
BioNTech Australia Pty Ltd.	Australia	Melbourne	100%	100%
BioNTech R&D (Austria) GmbH	Austria	Vienna	100%	100%
CureVac Belgium SA	Belgium	Ottignies-Louvain-la-Neuve	86.75%[2]	n / a[1]
Biotheus (previously Simba Merger Sub)	Cayman Islands	George Town	100%	100%
BioNTech (Shanghai) Pharmaceuticals Co. Ltd.	China	Shanghai	100%	100%
Biotheus (Hengqin) Co. Ltd.	China	Zhuhai	100%	n / a[1]
Biotheus (Nantong) Co. Ltd.	China	Nantong	100%	n / a[1]
Biotheus (Suzhou) Co. Ltd.	China	Suzhou	100%	n / a[1]
Biotheus Inc.	China	Zhuhai	100%	n / a[1]
InstaDeep France SAS	France	Paris	100%	100%
Biotheus (Hong Kong) Ltd.	Hong Kong	Hong Kong	100%	n / a[1]
Cabt-Bio (Hong Kong) Ltd.	Hong Kong	Hong Kong	100%	n / a[1]
Biopharma BioNTech Israel Ltd.	Israel	Tel Aviv	100%	100%
New Technologies Re	Luxembourg	Luxembourg	100%	100%
CureVac Merger B.V.	Netherlands	Amsterdam	86.75%[2]	n / a[1]
CureVac N.V.	Netherlands	Amsterdam	86.75%[2]	n / a[1]
CureVac Netherlands B.V.	Netherlands	Amsterdam	86.75%[2]	n / a[1]
BioNTech Rwanda Ltd.	Rwanda	Kigali	100%	100%
BioNTech Pharmaceuticals Asia Pacific Pte. Ltd.	Singapore	Singapore	100%	100%
BioNTech Pharmaceuticals Spain S.L	Spain	Barcelona	100%	100%
BioNTech Switzerland GmbH	Switzerland	Basel	100%	100%
CureVac Swiss AG	Switzerland	Basel	86.75%[2]	n / a[1]
InstaDeep Tunisia SARL	Tunisia	Tunis	100%	100%
BioNTech Turkey Tıbbi Ürünler Ve Klinik Araştirma Ticaret Anonim Şirketi	Turkey	Istanbul	100%	100%
BioNTech UK Ltd.	United Kingdom	London	100%	100%
InstaDeep Ltd.	United Kingdom	London	100%	100%
BioNTech Delivery Technologies (US), LLC	United States	Cambridge	100%	100%
BioNTech Research and Development, Inc.	United States	Cambridge	100%	100%
BioNTech US Inc.	United States	Cambridge	100%	100%
BioNTech USA Holding, LLC	United States	Cambridge	100%	100%
CureVac Inc.	United States	Boston	86.75%[2]	n / a[1]
InstaDeep LLC	United States	Dover	100%	100%
JPT Peptide Technologies Inc.	United States	Cambridge	100%	100%

(1) Included during the year ended December 31, 2025.

(2) As of December 31, 2025, the subsidiary is fully consolidated in the consolidated financial statements as control was reached in December 2025, and no non-controlling interests existed as of December 31, 2025. As of the acquisition date all closing conditions related to the completion of the post-offer reorganization have been satisfied, even though the tendered shares amount to 86.75% as of December 31, 2025, and reached 100% with the back-end measures as of January 6, 2026 (for details see Note 5).

All entities listed above are included in our consolidated financial statements.

Parent Company

ATHOS KG, Holzkirchen, Germany, is the sole shareholder of AT Impf GmbH, Munich, Germany, and beneficial owner of the following percentage of ordinary shares in BioNTech at the dates as indicated. ATHOS KG via AT

Impf GmbH has de facto control over BioNTech based on its substantial shareholding, which practically enables it to exercise the majority of voting rights to pass resolutions at our Annual General Meeting, or AGM.

			Ownership of ordinary shares in BioNTech (in %)	
Name	Country of incorporation	Registered office	December 31, 2025	December 31, 2024
AT Impf GmbH	Germany	Munich	40.30%	42.44%

Entity with Significant Influence over the Group

Medine GmbH, Mainz, Germany, owned the following percentage of ordinary shares in BioNTech at the following dates as indicated:

			Ownership of ordinary shares in BioNTech (in %)	
Name	Country of incorporation	Registered office	December 31, 2025	December 31, 2024
Medine GmbH	Germany	Mainz	15.97%	16.85%

5 Business Combinations

Acquisition of Biotheus

On November 13, 2024, our subsidiary, BioNTech Collaborations GmbH, entered into an agreement and plan of merger, or the Merger Agreement, with Biotheus, a clinical-stage biotechnology company dedicated to the discovery and development of novel antibodies to address unmet medical needs of patients with oncological or inflammatory diseases, to acquire 100% of the issued share capital of Biotheus. The acquisition supports the global execution of our oncology strategy and provides full global rights to pumitamig (BNT327/BMS986545), an investigational PD-L1 x VEGF-A bispecific antibody, with potential to replace current checkpoint inhibitor standard of care treatments for solid tumors.

On January 31, 2025 we closed the acquisition, gaining full rights to Biotheus' other pipeline candidates and its in-house bispecific antibody-drug conjugate capability. The acquisition has expanded our footprint in China, adding a local research and development hub to conduct clinical trials. In addition, we have gained a biologics manufacturing facility to contribute to our future global manufacturing and supply, and more than 300 Biotheus employees in R&D, manufacturing and enabling functions have joined the BioNTech workforce.

Since the completion of the acquisition took place in January 2025, we performed an allocation of the total consideration and the underlying assets acquired and liabilities assumed based on their fair values using the information available as of the acquisition date. The total consideration and the fair values determined in accordance with IFRS 3 of the identified net assets acquired of Biotheus as of January 31, 2025, are as follows:

(in millions €)	Fair value recognized on acquisition Biotheus
Assets	
Intangible assets	172.8
Property, plant and equipment	70.7
Cash and cash equivalents	122.4
Other assets non-current and current	20.6
Total assets	**386.5**
Liabilities	
Non-current liabilities	36.3
Current liabilities	55.1
Total liabilities	**91.4**
Total identifiable net assets at fair value	**295.1**
Bargain from the acquisition	(15.0)
Total consideration	**280.1**
Consideration	
Total purchase price	847.4
Upfront payment	767.8
Contingent consideration (milestones)	79.6
Payments in connection with pre-existing relationships	(567.3)
Total consideration	**280.1**

Upon closing and under the terms of the agreement, we paid Biotheus shareholders an upfront payment of €767.8 million in cash. Furthermore, we agreed to pay additional performance-based contingent payments, if certain milestones are met. At the acquisition date, the contingent consideration was recognized at its fair value of €79.6 million based on discounted cash flow projections in connection with performance-based contingent payments. The lower end of the bandwidth of possible outcomes of the contingent consideration is zero, and the upper limit is €144.3 million. The performance-based payments will be paid if certain milestones are met.

Under the terms of the agreement, we also transferred ADSs to eligible shareholders who will provide services to the Group. Under IFRS 3, this is considered remuneration and will be recognized as equity-settled share-based payment, based on the grant date fair value (€49.2 million) as personnel expense over a four-year service period.

The purchase price is mainly allocated to the settlement of our pre-existing relationship in connection with the License and Collaboration Agreement with Biotheus entered into in November 2023, which comprised exclusive rights to the development, manufacturing and commercialization of BNT327/PM8002 ex-Greater China. The amount is separated from the remaining purchase price to be transferred for the acquired business of Biotheus and amounts to €565.1 million. This amount for the settlement of the pre-existing relationship is identified based on the fair value of the settled rights of Biotheus in connection with contingent payments in relation to the License and Collaboration Agreement, including development, regulatory and sales milestones and royalties. This fair value was determined using a Discounted Cash flow model based on a business plan for the compound, using an appropriate WACC. The fair value of these rights is recorded as subsequent acquisition cost to our BNT327/PM8002 ex-Greater China rights. As the requirements under IAS 12 for the initial recognition

exemption are fulfilled, we did not record a correspondent deferred tax liability. We did not identify a gain or a loss in connection with the settlement of the pre-existing relationship.

The consideration for the acquired business of Biotheus is allocated to net assets acquired, which mainly include identified intangible assets in connection with Biotheus' BNT327/PM8002 Greater China rights and other clinical pipeline candidates, property, plant and equipment, cash and liabilities assumed. The fair values of the BNT327/PM8002 Greater China rights and other clinical pipeline candidates were determined based on the direct cash flow approach and amount to €167.7 million.

A bargain purchase of €15.0 million was recognized in other operating income, which results from the separation of the identified amount in connection with the settlement of the pre-existing relationships and the application of the initial recognition exemption under IAS 12.

Transaction costs of €6.9 million were expensed and are included in general and administrative expenses.

Since the acquisition, Biotheus' impact on our revenue has been €8.4 million and the net loss for the period was €61.8 million. If the combination had taken place at the beginning of the year, there would have been no significant change for revenues and net loss for the combined group. See our Consolidated Statements of Profit or Loss for the respective figures for the year ended December 31, 2025.

Acquisition of CureVac

On June 12, 2025, we and CureVac N.V. entered into a definitive Purchase Agreement pursuant to which we acquired CureVac, a clinical-stage biotech company developing a novel class of transformative medicines in oncology and infectious diseases based on messenger ribonucleic acid (mRNA). With the successful acquisition, we intend to further complement the capabilities and proprietary technologies in mRNA design, delivery formulations, and mRNA manufacturing. The acquisition builds on our proven track record and established position in the global mRNA industry and supports the execution of the our oncology strategy.

On December 3, 2025 we announced that 184,071,410 shares of CureVac N.V., representing approximately 81.74% of CureVac's issued and outstanding shares, were validly tendered and not properly withdrawn prior to the expiration of the initial offering period. As a result, the minimum condition for the exchange offer was satisfied, and all validly tendered shares were accepted. All closing conditions including customary closing conditions, regulatory approvals and conditions related to the completion of the post-offer reorganization had been satisfied. On December 15, 2025 the acquisition of CureVac N.V. closed and on December 18, 2025 a subsequent offering period of the exchange offer for all outstanding shares of CureVac expired. In total, 86.75% of CureVac shares were tendered. We completed the compulsory acquisition of the remaining CureVac shares at the beginning of January 2026 as part of the previously announced post-offer reorganization (back-end measures). For Accounting purposes, all steps of the tender process are treated as a single linked transaction in which control was obtained in December 2025. Accordingly, CureVac N.V. is accounted for as acquired in December 2025. Based on this approach, we present 100% ownership of CureVac N.V. as of the acquisition date and as of December 31, 2025 accordingly.

Since the completion of the closing took place in December 2025, we performed a preliminary allocation of the total consideration and the underlying assets acquired and liabilities assumed based on their fair values using the information available as of the acquisition date. Due to the complexity of the transaction, this allocation is still

preliminary and is subject to change. The total consideration and the fair values determined in accordance with IFRS 3 of the identified net assets acquired of CureVac as of the acquisition date are as follows:

(in millions €)	Fair value recognized on acquisition CureVac
Assets	
Intangible assets	240.3
Property, plant and equipment and right-of-use assets	116.3
Cash and cash equivalents	264.5
Other assets non-current and current	26.3
Total assets	**647.4**
Liabilities	
Non-current liabilities	43.5
Current liabilities	213.6
Total liabilities	**257.1**
Total identifiable net assets at fair value	**390.3**
Goodwill from the acquisition	10.6
Total consideration	**400.9**
Consideration	
Fair value of shares transferred	1,001.1
thereof fair value of shares from first and second offer period transferred	868.4
thereof fair value of shares for the back-end measures	132.7
Cash paid (fractional shares)	0.1
Effects in connection with pre-existing relationships	(600.3)
Total consideration	**400.9**

The total consideration comprises 12,075,629 ADSs measured at fair value as of the acquisition date, which amounts to €1,001.1 million (including back-end measures). The final exchange ratio (which was fixed on November 25, 2025) was 0.05363 of a BioNTech ADS for each CureVac share. The share price used for measuring the fair value amounts to $96.73 (€82.90; calculated using the exchange rate of 0.86). As of December 31, 2025, 10,475,287 shares (see Note 15) amounting to €868.4 million have been transferred while €132.7 million have been disclosed as an obligation to issue share capital, representing the amount of the back-end measures.

Due to the existence of pre-existing relationships, the consideration was adjusted to reflect the settlement of the transactions separate from the business combination. These relationships resulted from contractual and non-contractual relationships (see Note 18 for non-contractual relationships). In total, €600.3 million was excluded from the business combination, of which €488.9 million effectively settled outstanding balances recognized in current liabilities from contractual relationships with CureVac and €111.4 million reflects the settlement of the non-contractual relationship recognized in other operating expenses in our consolidated statements of profit or loss.

Deferred tax liabilities relating to temporary differences of the assets acquired in the business combination were recognized in an amount of €13.8 million. In line with the deferred tax liabilities assumed, deferred tax assets

relating to temporary differences and tax loss carry forwards which existed as of the acquisition date were recognized. The deferred tax assets and liabilities were offset to the extent that the conditions for offsetting were fulfilled.

The goodwill mainly represents the at-market component of the existing license agreements, which is represented as the intragroup transaction after closing, as well as know-how and skills of the acquired businesses' workforce.

The goodwill is allocated in full to the CGU immunotherapies and is not tax deductible.

The total amount of acquisition-related transaction costs were €9.6 million. Transaction costs of €7.6 million were expensed and are included in general and administrative expenses. Expenses of €2.0 million have been deducted from equity in connection with the capital increase.

Since the acquisition, CureVac's impact on our revenue and profit for the period has been immaterial. If the combination had taken place at the beginning of the year, revenue for the combined group would have been €2,915.6 million and net loss for the Group would have been €1,329.1 million.

6 Revenues from Contracts with Customers

6.1 Disaggregated Revenue Information

Set out below is the disaggregation of the Group's revenues from contracts with customers:

	Years ended December 31,					
(in millions €)	**2025**		**2024**		**2023**	
COVID-19 vaccine revenues	1,995.3	70%	2,432.1	88%	3,776.2	99%
Revenues from out-licensing	613.0	21%	—	—%	—	—%
Other revenues	261.6	9%	319.0	12%	42.8	1%
Total	**2,869.9**	**100%**	**2,751.1**	**100%**	**3,819.0**	**100%**

(in millions €)	Years ended December 31,					
Revenues by customers	**2025**		**2024**		**2023**	
Pfizer	1,602.0	56%	2,011.7	73%	3,293.0	86%
German Federal Ministry of Health	627.5	22%	701.0	25%	473.6	12%
Bristol Myers Squibb	613.0	21%	—	—%	—	—%
Other customers	27.4	1%	38.4	2%	52.4	2%
Total	**2,869.9**	**100%**	**2,751.1**	**100%**	**3,819.0**	**100%**

(in millions €)	Years ended December 31,					
Revenues by countries	**2025**		**2024**		**2023**	
United States	1,794.9	63%	1,847.8	67%	3,010.9	79%
Germany	759.1	26%	706.9	26%	482.7	13%
Ireland	304.8	11%	177.8	6%	203.8	5%
Rest of the World	11.1	—%	18.6	1%	121.6	3%
Total	**2,869.9**	**100%**	**2,751.1**	**100%**	**3,819.0**	**100%**

COVID-19 Vaccine Revenues

Our COVID-19 vaccine revenues were recognized from the supply and sales of our COVID-19 vaccine worldwide during the years ended December 31, 2025 and 2024, mainly comprising our share of the collaboration partner's gross profit derived from sales in the collaboration partner's territory. Overall, our COVID-19 vaccine revenues amounted to €1,995.3 million and €2,432.1 million during the years ended December 31, 2025 and 2024, respectively and decreased as compared to the year ended December 31, 2024, in line with a lower COVID-19 vaccine market demand. Our COVID-19 vaccine revenues are subject to seasonal effects in the fall and winter of the northern hemisphere.

Revenues from Out-Licensing

On June 2, 2025, we and BMS announced a global strategic partnership to co-develop and co-commercialize our next-generation bispecific antibody candidate, pumitamig (BNT327 / BMS986545), broadly for multiple solid tumor types. Under the terms of the agreement, we granted BMS a worldwide, co-exclusive license to use the licensed intellectual property, or IP, for the development, manufacturing and commercialization of our investigational bispecific antibody pumitamig as monotherapy or in combination with other products. We and BMS will jointly share development and manufacturing costs on a 50:50 basis, subject to certain exceptions. Global profits and losses will be equally shared as well. We received an upfront payment amounting to $1.5 billion during the year ended December 31, 2025, and are eligible to receive $2.0 billion total in non-contingent anniversary payments through 2028 as well as up to $7.6 billion in additional development, regulatory and commercial milestone payments contingent on achievement of certain development, regulatory and commercial milestones.

On August 15, 2025, we and BMS entered into an amended and restated agreement that replaced the original agreement. The new agreement governs the collaboration, including in particular the performance-related rights and obligations, without affecting the financial terms agreed in the original agreement. The license granted in respect of our IP was determined to be a separate unit of account from the other promises, which we refer to as development activities, and accounted for under IFRS 15 as the granting of a license to our IP is an output of our ordinary activities. Based on the terms of the contract, we have identified material rights relating to options to cancel the contract. In allocating revenues to the material rights throughout the development period, management determined an expected consideration of $3.5 billion, consisting of the upfront payment and the anniversary payments. The expected consideration is attributed to each option to cancel the contract using the practical alternative under IFRS 15.B43. Each material right is recognized as revenues at the point in time BMS makes use of its option or when such right expires. The upfront payment was recorded as contract liability (€1,313.6 million, converted as of the contract date of the initial agreement, June 2, 2025). We determined that the criteria in IFRS 15.9 were subsequently met with the conclusion of the amended and restated agreement as of August 15, 2025. During the year ended December 31, 2025, revenues in the amount of €613.0 million were recognized on a cumulative catch-up basis as of June 2, 2025, the date the initial agreement was effective, and €700.6 million have been deferred and will be recognized upon BMS makes use of its option or when such right expires. All milestone payments are considered to be constrained, as the achievement of the milestone events

depends on the success of the underlying research and development activities, which is outside our control. Sales-based milestone payments will be recognized when the underlying sale transactions have occurred.

Other revenues

Our remaining other revenues were mainly derived from a pandemic preparedness contract with the German government, during the years ended December 31, 2025 and 2024. The change was mainly due to the catch-up of revenues associated with the pandemic preparedness contract in the amount of €103.1 million in previous year, partly compensated by a one-time effect associated with Pfizer´s opt-out from the further development of our shingles program, BNT167, in the amount of €60.0 million in the year ended December 31, 2025.

Revenues from contracts with customers were recognized as follows:

	Years ended December 31,		
(in millions €)	**2025**	**2024**	**2023**
Timing of revenue recognition			
Goods and services transferred at a point in time	1,391.4	611.4	776.3
Goods and services transferred over time	241.9	298.5	15.4
Revenue recognition applying the sales-based or usage-based royalty recognition constraint model[(1)]	1,236.6	1,841.2	3,027.3
Total	**2,869.9**	**2,751.1**	**3,819.0**

(1) Represents sales based on the share of the collaboration partners' gross profit.

6.2 Contract Assets

The contract assets developed as follows:

	2025			2024		
(in millions €)	**Current**	**Non-current**	**Total**	**Current**	**Non-current**	**Total**
As of January 1	**10.0**	**9.8**	**19.8**	**4.9**	**—**	**4.9**
Additions	—	—	—	—	28.4	28.4
thereof: attributable to performance obligations satisfied in prior periods	—	—	—	—	*23.6*	*23.6*
Reclassification to trade accounts receivables	(9.7)	—	(9.7)	(13.5)	—	(13.5)
Reclassification from non-current to current	7.8	(7.8)	—	18.6	(18.6)	—
As of December 31	**8.1**	**2.0**	**10.1**	**10.0**	**9.8**	**19.8**

Our contract assets were significantly influenced by the rendering of services under the pandemic preparedness contract with the German government during the years ended December 31, 2025 and 2024.

6.3 Contract Liabilities

The development of the contract liabilities is as follows:

	2025			2024		
(in millions €)	Current	Non-current	Total	Current	Non-current	Total
As of January 1	**294.9**	**183.0**	**477.9**	**353.3**	**398.5**	**751.8**
Additions from business combinations	—	0.4	0.4	—	—	—
Other additions	652.4	661.2	1,313.6	—	—	—
Reclassification from non-current to current	756.6	(756.6)	—	215.5	(215.5)	—
Recognition as revenues	(948.7)	—	(948.7)	(272.7)	—	(272.7)
Currency effects functional currency	(0.3)	—	(0.3)	(1.2)	—	(1.2)
As of December 31	**754.9**	**88.0**	**842.9**	**294.9**	**183.0**	**477.9**

Contract liabilities increased compared to the previous year in connection with the upfront payment under the global strategic partnership with Bristol Myers Squibb Company in the amount of €1,313.6 million. As of December 31, 2025, the contract liabilities included €700.6 million (as of December 31, 2024: nil) of such payments, €140.5 million in connection with the amendment of the COVID-19 vaccine purchase agreement with the European Commission, or EC, and €1.1 million of remaining upfront fees from our collaboration agreement with Pfizer (Zoster) (as of December 31, 2024: €416.2 million payments under our COVID-19 vaccine purchase agreement with the European Commission and €61.1 million of remaining upfront fees from our collaboration agreement with Pfizer (Zoster)).

Set out below is the amount of revenue recognized for the periods indicated:

	Years ended December 31,		
(in millions €)	2025	2024	2023
Amounts included in contract liabilities at the beginning of the year	335.7	272.7	3.5

7 Income and Expenses

7.1 General Expenses

Cost of Sales

Our cost of sales increased by €100.5 million, or 19%, from €541.3 million during the year ended December 31, 2024 to €641.8 million during the year ended December 31, 2025. This increase was mainly driven by higher COVID-19 vaccine sales in our commercialization territory, which included the share of gross profit we owe our collaboration partner Pfizer, higher expenses from inventory scrapping and write-downs to net realizable value and impairments on property, plant and equipment from the analysis on CGU External Product Sales JPT of €30.5 million. Expenses arising from inventory write-downs to net realizable value amounted to €162.8 million during the year ended December 31, 2025 compared to €125.8 million for year ended December 31, 2024 (€94.5 million for year ended December 31, 2023). In addition, our cost of sales during the fiscal year 2024 have been impacted by multiple positive extraordinary effects, including from inventory valuation effects.

Comparing the years ended December 31, 2024 and 2023, our cost of sales decreased by €58.5 million, or 10%, from €599.8 million to €541.3 million. This change is mainly due to recognizing lower cost of sales from our

decreased COVID-19 vaccine sales, which included the share of gross profit we owe our collaboration partner Pfizer based on our sales.

Research and Development Expenses

Our research and development expenses decreased by €149.3 million, or 7%, from €2,254.2 million during the year ended December 31, 2024 to €2,104.9 million during the year ended December 31, 2025. This development was mainly driven by cost savings resulting from active portfolio management and positive effects resulting from our cost share with our collaboration partner BMS, partly offset by the acceleration of late-stage trials for our immuno-oncology, or IO, and antibody-drug conjugate, or ADC, programs and by an impairment of Trastuzumab Pamirtecan (BNT323/DB-1303) of €85.4 million (see Note 10).

Comparing the years ended December 31, 2024 and 2023, our research and development expenses increased by €471.1 million, or 26%, from €1,783.1 million to €2,254.2 million, mainly driven by advancing key pipeline candidates, such as our ADC and IO programs and from higher personnel expenses resulting from an increase in headcount.

Sales and Marketing Expenses

Our sales and marketing expenses increased by €42.1 million, or 62%, from €67.9 million during the year ended December 31, 2024 to €110.0 million during the year ended December 31, 2025, mainly due to our ongoing commercial build-up.

Comparing the years ended December 31, 2024 and 2023, our sales and marketing expenses increased by €5.2 million, or 8%, from €62.7 million to €67.9 million, mainly due to increased expenses for setup and enhancement of commercial IT platforms and an increase in personnel expenses resulting from an increase in headcount.

General and Administrative Expenses

Our general and administrative expenses decreased by €16.7 million, or 3%, from €531.1 million during the year ended December 31, 2024 to €514.4 million during the year ended December 31, 2025. The decrease was primarily driven by a reduction in external services and our continued cost discipline.

Comparing the years ended December 31, 2024 and 2023, our general and administrative expenses increased by €36.1 million, or 7%, from €495.0 million to €531.1 million, mainly influenced by increased expenses for IT services as well as by an increase in personnel expenses resulting from an increase in headcount.

7.2 Other Operating Result

	Years ended December 31,		
(in millions €)	**2025**	**2024**	**2023**
Other operating income	**184.6**	**140.6**	**105.0**
Gain on derivative instruments at fair value through profit or loss	65.1	—	67.6
Government and similar grants	63.0	31.5	2.2
Bargain purchase	15.0	—	—
Foreign exchange differences, net	—	84.9	—
Other	41.5	24.2	35.2
Other operating expenses	**(1,088.3)**	**(811.5)**	**(293.0)**
Contractual disputes / settlements	(789.5)	(657.4)	—
Pipeline prioritization costs	(148.3)	—	—
External legal advice services	(73.8)	(113.7)	(29.4)
Loss on derivative instruments at fair value through profit or loss	—	(32.4)	—
Foreign exchange differences, net	(48.9)	—	(252.0)
Impairment losses and reversals of impairment losses on financial assets (operating result), net	(5.9)	—	(0.8)
Other	(21.9)	(8.0)	(10.8)
Total other operating result	**(903.7)**	**(670.9)**	**(188.0)**

Our total other operating result decreased by €232.8 million, or 35%, from a negative operating result of €670.9 million during the year ended December 31, 2024 to a negative operating result of €903.7 million during the year ended December 31, 2025. Our expenses in connection with our pipeline prioritization included impairments of €71.6 million and employee-related costs of €57.0 million. The impairments comprise €57.8 million on property, plant and equipment (see Note 11) and €13.8 million on right-of-use assets (see Note 20), all located outside of Europe. For more information regarding the nature of the government and similar grants, please see Note 19.

As for 2024 and 2023, our total other operating result decreased by €482.9 million, or 257%, from a negative operating result of €188.0 million during the year ended December 31, 2023 to a negative operating result of €670.9 million during the year ended December 31, 2024. The change was mainly due to the settlement of contractual disputes and related expenses to such disputes and other litigations.

7.3 Finance Result

	Years ended December 31,		
(in millions €)	**2025**	**2024**	**2023**
Total finance income	**423.9**	**664.0**	**519.6**
Interest income from effective interest method	262.6	437.6	330.9
Other gains	161.3	210.9	188.7
Gains from financial assets or financial liabilities that are mandatorily measured at fair value through profit or loss	158.2	210.9	162.0
Other gains from financial assets subsequently measured at amortized cost	3.1	—	26.7
Foreign exchange differences, net	—	15.5	—
Total finance expenses	**(69.8)**	**(27.4)**	**(23.9)**
Foreign exchange differences, net	(48.4)	—	(15.9)
Interest expenses from effective interest method and other interest expenses	(14.2)	(16.9)	(7.5)
Other losses	(7.2)	(10.5)	(0.5)
Impairment losses on financial assets	(0.5)	(4.2)	—
Losses from financial assets or financial liabilities that are mandatorily measured at fair value through profit or loss	(5.2)	(6.0)	(0.5)
Fee expense from financial assets and financial liabilities that are not subsequently measured at fair value through profit or loss	(1.5)	(0.3)	—
Total finance result	**354.1**	**636.6**	**495.7**

Our finance result during the years ended December 31, 2025, 2024 and 2023 was mainly derived from returns, such as interest, resulting from our financial investments as well as fair value adjustments of our money market funds. Our total finance result decreased by €282.5 million, or 44%, from a positive finance result of €636.6 million during the year ended December 31, 2024 to a positive finance result of €354.1 million during the year ended December 31, 2025. This change was mainly due to lower interest income and negative impacts from foreign exchange differences, primarily derived from our security investments disclosed as cash equivalents and bank accounts held in foreign currency.

Our total finance result increased by €140.9 million, or 28%, from a positive finance result of €495.7 million during the December 31, 2023 to a positive finance result of €636.6 million during the year ended December 31, 2024. This change was mainly due to higher interest income and positive foreign exchange differences, primarily derived from our security investments disclosed as cash equivalents and bank cash accounts held in foreign currency.

7.4 Employee Benefits Expense

	Years ended December 31,		
(in millions €)	**2025**	**2024**	**2023**
Wages and salaries	915.0	814.0	617.8
Social security costs	110.0	113.7	76.7
Pension costs	4.7	3.5	4.1
Total	**1,029.7**	**931.2**	**698.6**

Wages and salaries include, among other things, expenses for share-based and severance payments. The increase between the year ended December 31, 2024 and 2025 primarily reflects the inclusion of the workforce from the acquisition of Biotheus in 2025 (see Note 5), increased base salaries and severance payments related to our ongoing transformation.

Comparing the years ended December 31, 2024 and 2023, the development is mainly due to changes in headcount between the respective years.

8 Income Tax

Income tax for the years ended December 31, 2025, 2024, and 2023, comprised current income taxes, other taxes and deferred taxes. We are subject to corporate taxes, the solidarity surcharge and trade taxes. Our corporate tax rate in the reporting year remained unchanged (15.0%) as did the solidarity surcharge (5.5%) whereas the average trade tax rate changed resulting in a combined income tax rate of 31.41% in the year ended December 31, 2025 (during the years ended December 31, 2024 and 2023: 27.6% and 27.1%, respectively). Deferred taxes are calculated with an average tax rate considered the enacted corporate in come tax rate deduction in Germany. BioNTech USA Holding, LLC is subject to Federal Corporate Income Tax (21.0%) as well as State Income Tax in various state jurisdictions (effective rate of 3.31%). The deferred tax rates calculations basis remained unchanged compared to the previous period.

The following table illustrates the current and deferred taxes for the periods indicated:

	Years ended December 31,		
(in millions €)	**2025**	**2024**	**2023**
Current income taxes	11.4	(2.3)	243.1
Deferred taxes	73.9	(10.1)	12.7
Income taxes expenses / (income)	**85.3**	**(12.4)**	**255.8**

The following table reconciles the expected income taxes to the income tax expenses. The expected income taxes were calculated using the combined income tax rate of BioNTech SE applicable to the Group and mentioned above which was applied to profit before taxes to calculate the expected income taxes.

	Years ended December 31,		
(in millions €)	**2025**	**2024**	**2023**
Profit / (Loss) before tax	**(1,050.8)**	**(677.7)**	**1,186.1**
Expected tax credit	(330.0)	(186.8)	321.8
Effects			
Deviation due to local tax basis	11.9	12.6	6.6
Deviation due to deviating income tax rate (Germany and foreign countries)	(17.1)	6.6	(0.1)
Change in valuation allowance	68.3	(16.4)	(14.3)
Effects from tax losses and tax credits	321.1	241.1	(66.5)
Change in deferred taxes due to tax rate change	2.7	9.1	(2.4)
Non-deductible expenses and other permanent differences	41.0	(49.1)	3.1
Non tax-effective income	(5.0)	(2.1)	(0.6)
Non tax-effective share-based payment expenses	(0.6)	(37.2)	7.7
Tax-effective equity transaction costs	(0.6)	—	—
Adjustment prior year taxes	(9.8)	—	5.5
Non-tax effective bargain purchase	—	—	—
Other effects	3.4	9.8	(5.0)
Income taxes	85.3	**(12.4)**	**255.8**
Effective tax rate	**(8.1%)**	**1.8%**	**21.6%**

Deferred Taxes

Deferred taxes for the periods indicated relate to the following:

Year ended December 31, 2025

(in millions €)	January 1, 2025	Recognized in P&L	Recognized in OCI	Recognized through business combinations	Recognized directly in equity	December 31, 2025
Fixed assets	3.1	57.5	—	(54.4)	—	6.2
Right-of-use assets	(64.9)	4.8	—	—	—	(60.1)
Inventories	81.9	(27.0)	—	—	—	54.9
Trade and other receivables	(502.1)	489.2	—	—	—	(12.9)
Lease liabilities	70.5	(8.7)	—	—	—	61.8
Contract liabilities	(90.3)	(110.6)	—	—	—	(200.9)
Interest-bearing loans and borrowings	25.2	(6.2)	—	—	—	19.0
Net employee defined benefit liabilities	0.7	0.1	(0.2)	—	—	0.6
Share-based payments	77.4	(16.0)	—	—	(33.3)	28.1
Other provisions	14.2	10.7	—	—	—	24.9
Other (incl. deferred expenses)	368.2	(415.2)	—	(2.1)	—	(49.1)
Tax losses / tax credits	387.8	234.3	—	50.1	(6.5)	665.7
Deferred tax assets net (before valuation adjustment)	**371.7**	**212.9**	**(0.2)**	**(6.4)**	**(39.8)**	**538.2**
Valuation adjustment	(332.4)	(286.8)	—	(11.5)	21.7	(609.0)
Deferred tax assets / (liabilities), net (after valuation adjustment)	**39.3**	**(73.9)**	**(0.2)**	**(17.9)**	**(18.1)**	**(70.8)**
Thereof deferred tax assets	**81.7**	**(124.3)**	**—**	**74.2**	**(18.1)**	**13.5**
Thereof deferred tax liability	**(42.4)**	**50.4**	**(0.2)**	**(92.1)**	**—**	**(84.3)**

Year ended December 31, 2024

(in millions €)	January 1, 2024	Recognized in P&L	Recognized in OCI	Recognized through business combinations	Recognized directly in equity	December 31, 2024
Fixed assets	(8.4)	11.5	—	—	—	3.1
Right-of-use assets	(56.6)	(8.3)	—	—	—	(64.9)
Inventories	113.6	(31.7)	—	—	—	81.9
Trade and other receivables	(90.0)	(412.1)	—	—	—	(502.1)
Lease liabilities	57.2	13.3	—	—	—	70.5
Loans and borrowings	4.8	20.4	—	—	—	25.2
Contract liabilities	(43.0)	(47.3)	—	—	—	(90.3)
Net employee defined benefit liabilities	0.6	0.1	—	—	—	0.7
Other provisions	9.8	4.4	—	—	(85.0)	14.2
Share-based payments	142.1	20.3	—	—	—	77.4
Other (incl. deferred expenses)	(44.9)	413.1	—	—	—	368.2
Tax losses / tax credits	94.4	230.2	63.2	—	—	387.8
Deferred tax assets net (before valuation adjustment)	**179.6**	**213.9**	**63.2**	**—**	**(85.0)**	**371.7**
Valuation adjustment	(138.0)	(133.9)	(60.5)	—	—	(332.4)
Deferred tax assets / (liabilities), net (after valuation adjustment)	**41.6**	**80.0**	**2.7**	**—**	**(85.0)**	**39.3**
Thereof deferred tax assets	**81.3**	**82.7**	**2.7**	**—**	**(85.0)**	**81.7**
Thereof deferred tax liability	**(39.7)**	**(2.7)**	**—**	**—**	**—**	**(42.4)**

As of December 31, 2025, our accumulated tax losses comprised tax losses of German entities that were incurred within and prior to the establishment of a tax group with BioNTech SE or by entities that are not within the tax group or U.S. tax group. Our accumulated tax losses for the periods indicated amounted to the following:

	Years ended December 31,		
(in millions €)	**2025**	**2024**	**2023**
Corporate tax	2,604.0	1,236.7	260.7
Trade tax	2,077.1	989.6	140.1

	Years ended December 31,		
(in millions €)	**2025**	**2024**	**2023**
Federal tax credits	27.3	25.4	21.3
State tax credits	8.9	7.1	8.7

Up until the year ended December 31, 2025, deferred tax assets on tax losses were only partially recognized, as there was not sufficient probability in terms of IAS 12 that future taxable profits will be available against which all the unused tax losses could be utilized.

The amount of deductible temporary differences, unused tax losses, and unused tax credits for which no deferred tax asset is recognized in the statement of financial position as of December 31, 2025, is €4,220.6 million (December 31, 2024: €2,028.8 million). Therefore, as of December 31, 2025, we have not recognized deferred tax assets for unused tax losses and temporary differences in an amount of €609.0 million (December 31, 2024: €332.4 million, December 31, 2023: €138.0 million).

As of December 31, 2025, all previously recognized deferred tax assets for unused U.S. federal and state tax losses, tax credits, and deductible temporary differences were derecognized, resulting in deferred tax expense of €68.4 million, as there is not sufficient probability in terms of IAS 12 that future taxable income will be available against which these unused deferred tax assets can be utilized. The material unrecognized U.S. federal and state tax losses and tax credits will begin to expire in 2036.

We do not recognize deferred tax liabilities for taxable temporary differences associated with investments in subsidiaries, in cases where we are able to control the timing of the reversal of the temporary difference and it is probable that the temporary differences will not reverse in the foreseeable future. The aggregate amount of temporary differences associated with investments in subsidiaries, for which deferred tax liabilities have not been recognized, is €34.3 million (December 31, 2024: €14.5 million).

The global minimum taxation for large multinational groups (known as The Pillar Two regulations) based on Base Erosion and Profit Shifting (BEPS) project by the Organization for Economic Co-operation and Development (OECD) were transposed into German law at the end of 2023 (MinStG) and came into force on January 1, 2024. We do fall within the scope of these regulations. As of December 31, 2024 we carried out an analysis to determine the impact and jurisdictions from which we are exposed to potential effects in connection with a Pillar Two top-up tax. It was checked whether the CbCR Safe Harbor Regulations were fulfilled. In Jurisdictions where the CbCR Regulations do not apply, the effective tax rate was calculated on a simplified basis. Since our relevant effective tax rate calculated for Pillar Two purposes is mainly above 15% in all jurisdictions in which it operates, it has been determined that we are not materially subject to Pillar Two top-up taxes. We apply the exception in IAS 12, according to which no deferred tax assets and liabilities are recognized in connection with the second pillar

(Pillar Two) income taxes of the OECD and no disclosures are made in this regard. We closely monitor the progress of the legislative process in each country in which we operate.

9 Earnings per Share

Basic earnings per share (EPS) is calculated by dividing the profit for the year attributable to ordinary equity holders of the parent by the weighted average number of ordinary shares outstanding during the year.

Diluted EPS is calculated by dividing the profit attributable to ordinary equity holders of the parent by the weighted average number of ordinary shares outstanding during the year, plus the weighted average number of ordinary shares that would be issued on conversion of all the dilutive potential ordinary shares into ordinary shares.

The following table reflects the income and share data used in the basic and diluted EPS calculations:

	Years ended December 31,		
(in millions €, except per share data)	**2025**	**2024**	**2023**
Profit attributable to ordinary equity holders of the parent for basic earnings	**(1,136.1)**	**(665.3)**	**930.3**
Weighted average number of ordinary shares outstanding for basic EPS	**241.7**	**240.4**	**240.6**
Effects of dilution from share options	—	—	2.1
Weighted average number of ordinary shares outstanding adjusted for the effect of dilution	**241.7**	**240.4**	**242.7**
Earnings / (Loss) per share			
Basic earnings / (loss) per share	(4.70)	(2.77)	3.87
Diluted earnings / (loss) per share	(4.70)	(2.77)	3.83

10 Other Intangible Assets and Goodwill

Goodwill

(in millions €)	**Goodwill**
Acquisition costs	
As of January 1, 2024	362.5
Currency differences	18.1
As of December 31, 2024	**380.6**
Additions from business combinations	10.6
Currency differences	(22.8)
As of December 31, 2025	**368.4**

(in millions €)	Goodwill
Cumulative impairment charges	
As of January 1, 2024	—
Impairment	—
As of December 31, 2024	**—**
Impairment	0.5
As of December 31, 2025	**0.5**

(in millions €)	Goodwill
Carrying amount	
As of December 31, 2024	**380.6**
As of December 31, 2025	**367.9**

Intangible Assets with Indefinite Useful Life

	CGU Immunotherapies		CGU External Product Sales of JPT		CGU External Business of InstaDeep		Total	
(in millions €)	As of December 31, 2025	As of December 31, 2024	As of December 31, 2025	As of December 31, 2024	As of December 31, 2025	As of December 31, 2024	As of December 31, 2025	As of December 31, 2024
Goodwill	358.3	369.8	—	0.5	9.6	10.3	367.9	380.6
Intangible assets with indefinite useful life	474.3	486.5	—	—	—	—	474.3	486.5
Total	**832.6**	**856.3**	**—**	**0.5**	**9.6**	**10.3**	**842.2**	**867.1**

For the year ended December 31, 2025, our goodwill relates almost entirely to CGU Immunotherapies. CGU Immunotherapies focuses on the development of therapies in the field of oncology and infectious diseases and comprises our broad pipeline that includes mRNA-based immune activators, antigen-targeting T cells and antibodies and defined immunomodulators of various immune cell mechanisms.

We performed our annual goodwill impairment test in October 2025.

The recoverable amount of CGU Immunotherapies has been determined based on a fair value less cost of disposal, or FVLCD, which we derived based on our market capitalization as an observable input parameter.

The recoverable amounts of the CGU External Business of InstaDeep has been determined based on FVLCD using a multiple valuation.

The recoverable amount of the CGU External Product Sales of JPT has been determined based on its value in use. In assessing value in use, the estimated future cash flows, which are derived based on a bottom-up business plan provided by the management of the entity, are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the assets. A long-term growth rate of 1.5% is applied to project future cash flows after the last year of the detailed planning period.

As a result of the analysis in October 2025, we identified an impairment of the goodwill and property, plant and equipment (see Note 11) related to the CGU External Product Sales of JPT.

Even if our market capitalization had been approximately 10% lower, FVLCD would have still been above the respective carrying amount of the CGU Immunotherapies.

Intangible assets with indefinite useful life decreased from €486.5 million as of December 31, 2024 to €474.3 million as of December 31, 2025 and mainly comprised acquired intangible assets not yet available for use, or in-process R&D, of €473.3 million (as of December 31, 2024: €485.5 million). The additions from the business acquisition of Biotheus (see Note 5) in the amount of €167.7 million and the acquisition of exclusive rights to the development, manufacturing and commercialization of BNT327/PM8002 in the amount to €565.1 million were exceeded by a reclass of BNT327/PM8002 from indefinite to finite useful life in the total amount including cumulated additions and China rights of €644.8 million (during the year ended December 31, 2024: nil) and impairment losses recognized in the amount of €85.4 million (see below, during the year ended December 31, 2024: €55.1 million). This impairment was identified based on a triggering event in connection with the asset related to the product candidate BNT323/DB-1303 during the three months ended September 30, 2025, due to revision of our commercial forecast assumptions. The impairment test performed revealed an impairment loss based on the value in use. The impairment equals the carrying amount of €85.4 million and is recorded under research and development expenses in the consolidated statements of profit or loss. Since such assets are not amortized, they are reviewed for impairments at least annually. The annual impairment test was performed on an individual basis of the assets during the three months ended December 31, 2025. The recoverable amounts were determined based on the value in use. The results did not give rise to any further impairment loss.

We examine the existence of indications of impairment using various factors, particularly deviations from sales forecasts and the analysis of changes in medium-term planning. The identification of indications of impairment takes place with the involvement of the responsible departments, taking external and internal information sources into consideration.

A sensitivity analysis of the key assumptions, future cash flows and weighted average cost of capital, was performed as part of the scheduled impairment testing of the intangible assets not yet available for use. For those assets that have not been impaired, the sensitivity analysis did not give rise to any impairment loss, either for a reduction of 10% in future cash flows or for a 10% increase in the weighted average cost of capital.

Other Intangible Assets

(in millions €)	In-process R&D	Intellectual property rights, licenses, software and similar rights	Work in progress and advance payments	Total
Acquisition costs				
As of January 1, 2024	443.5	455.1	22.4	921.0
Additions	97.1	6.2	11.9	115.2
Disposals	—	(2.9)	—	(2.9)
Reclassifications	—	11.6	(11.6)	—
Currency differences	—	11.1	—	11.1
As of December 31, 2024	**540.6**	**481.1**	**22.7**	**1,044.4**
Additions	565.1	6.6	2.1	573.8
Disposals	—	(0.1)	—	(0.1)
Reclassifications	(644.8)	648.8	(4.0)	—
Currency differences	(14.8)	(6.8)	(0.2)	(21.8)
Additions from business combinations	167.7	245.4	—	413.1
As of December 31, 2025	**613.8**	**1,375.0**	**20.6**	**2,009.4**

(in millions €)	In-process R&D	Intellectual property rights, licenses, software and similar rights	Work in progress and advance payments	Total
Cumulative amortization and impairment charges				
As of January 1, 2024	—	116.9	—	116.9
Amortization	—	54.8	—	54.8
Impairment	55.1	28.2	—	83.3
Disposals	—	(2.8)	—	(2.8)
Currency differences	—	1.8	—	1.8
As of December 31, 2024	**55.1**	**198.9**	**—**	**254.0**
Amortization	—	67.1	—	67.1
Impairment	85.4	3.1	—	88.5
Disposals	—	—	—	—
Currency differences	—	(6.2)	—	(6.2)
As of December 31, 2025	**140.5**	**262.9**	**—**	**403.4**

(in millions €)	In-process R&D	Intellectual property rights, licenses, software and similar rights	Work in progress and advance payments	Total
Carrying amount				
As of December 31, 2024	**485.5**	**282.2**	**22.7**	**790.4**
As of December 31, 2025	**473.3**	**1,112.1**	**20.6**	**1,606.0**

The intangible assets resulting from licensing and collaboration agreements are combined into one class of assets, in-process R&D, due to their similar nature and use in our operations are attributed to the CGU Immunotherapies.

The amortization of the concessions, licenses and similar rights during the year ended December 31, 2025, has been mainly recorded under cost of sales and R&D expenses in the consolidated statements of profit or loss.

The intangible asset in relation to the product candidate pumitamig (BNT327/ BMS986545) was classified as an individual intangible asset that is material to our financial statements. It has been transferred from intangible assets with indefinite useful life to the intangible assets with finite useful life in connection with the execution of the Global Co-Development and Co-Commercialization Agreement with BMS. The carrying amount was €628.3 million and the remaining useful life was 15 years as of December 31, 2025.

During the year ended December 31, 2025, impairment losses in the amount of €3.1 million under research and development expenses were recognized with respect to the intangible assets with definite useful life due to a reassessment of the current use (during the year ended December 31, 2024: €28.2 million).

The increase in other intangible assets by €815.6 million from December 31, 2024, to December 31, 2025, was mainly related to intangible assets acquired in connection with the settlement of our pre-existing relationship for the product candidate pumitamig (BNT327/ BMS986545) of €565.1 million and the business combinations totaling €413.1 million (see Note 5). This was partially offset by impairment losses of €88.5 million in total (during the year ended December 31, 2024: €83.3 million).

11 Property, Plant and Equipment

(in millions €)	Land and buildings	Equipment, tools and installations	Construction in progress and advance payments	Total
Acquisition and production costs				
As of January 1, 2024	235.4	344.1	389.5	969.0
Additions	46.2	49.3	192.4	287.9
Disposals	(0.3)	(4.7)	—	(5.0)
Reclassifications	86.6	36.3	(122.9)	—
Currency differences	1.5	2.7	1.6	5.8
As of December 31, 2024	**369.4**	**427.7**	**460.6**	**1,257.7**
Additions	32.4	25.5	131.3	189.2
Disposals	(0.1)	(9.5)	(0.6)	(10.2)
Reclassifications	143.4	38.5	(181.9)	—
Currency differences	(8.7)	(8.3)	(15.9)	(32.9)
Additions from business combinations	50.0	17.6	85.0	152.6
As of December 31, 2025	**586.4**	**491.5**	**478.5**	**1,556.4**

(in millions €)	Land and buildings	Equipment, tools and installations	Construction in progress and advance payments	Total
Cumulative depreciation and impairment charges				
As of January 1, 2024	36.2	175.6	—	211.8
Depreciation	12.3	38.3	4.3	54.9
Impairment	26.0	32.1	—	58.1
Disposals	(0.1)	(4.0)	—	(4.1)
Currency differences	0.4	1.0	0.3	1.7
As of December 31, 2024	**74.8**	**243.0**	**4.6**	**322.4**
Depreciation	23.8	50.3	—	74.1
Impairment	79.2	12.2	3.1	94.5
Disposals	—	(8.3)	—	(8.3)
Reversal of Impairment	—	(0.5)	—	(0.5)
Currency differences	(2.4)	(3.7)	(0.6)	(6.7)
As of December 31, 2025	**175.4**	**293.0**	**7.1**	**475.5**

(in millions €)	Land and buildings	Equipment, tools and installations	Construction in progress and advance payments	Total
Carrying amount				
As of December 31, 2024	**294.6**	**184.7**	**456.0**	**935.3**
As of December 31, 2025	**411.0**	**198.5**	**471.4**	**1,080.9**

The additions from business combinations related to the acquisition of CureVac and Biotheus (see Note 5).

During the year ended December 31, 2025, impairment losses amounting €94.5 million were recognized (as of December 31, 2024: €58.1 million) based on the value in use. These were mainly related to impairment effects on property, plant and equipment from pipeline prioritization outside of Europe equaling the carrying amount (€57.8 million, recognized as other operating expenses) and to effects on property, plant and equipment from the analysis on CGU External Product Sales JPT (€30.5 million, recognized in cost of sales). The respective recoverable amount of this CGU of €28.3 million as of the year ended December 31, 2025 was based on value in use and was determined at the level of the CGU.

Non-Current Assets by Region

As of December 31, 2025, non-current assets comprised €129.8 million in other intangible assets, goodwill, property, plant and equipment, right-of-use assets and other assets of our subsidiaries incorporated in the United States (as of December 31, 2024: €177.6 million), €464.2 million in the United Kingdom (as of December 31, 2024: €529.6 million) as well as €168.8 million in China (as of December 31, 2024: €0.6 million), respectively. The remaining non-current assets of €2,511.5 million (as of December 31, 2024: €1,682.7 million) mainly relate to entities incorporated in Germany.

12 Financial Assets and Financial Liabilities

12.1 Capital Risk Management

Our capital management objectives are designed primarily to finance our growth strategy.

Our treasury committee reviews the total amount of cash and cash equivalents on a regular basis. As part of this review, the committee considers total cash and cash equivalents, cash outflow, currency translation differences and refinancing activities. We monitor cash using a burn rate. The cash burn rate is defined as the average monthly net cash flow from operating and investing activities during a financial year.

In general, the aim is to protect and maximize the financial resources available for further research and development projects.

Since December 2021, we have had an investment and asset management policy in place that contains policies and processes for managing cash and cash equivalents and security investments. Under this policy, our investment portfolio is to be maintained in a manner that minimizes risks to the invested capital. These risks include mainly credit risk and concentration risk. The portfolio must provide liquidity in a timely manner to accommodate operational and capital needs. The portfolio is managed by the Treasury department.

We are not subject to externally imposed capital requirements. Our capital management objectives were achieved in the years ended December 31, 2025 and 2024.

12.2 Categories of Financial Instruments

Financial Assets and Liabilities at Amortized Cost and at Fair Value through OCI and Profit or Loss

Set out below is an overview of financial assets, liabilities at amortized cost and at fair value through OCI and profit or loss, as of the dates indicated. The table indicates whether financial assets and liabilities fulfill the definition of security investments. Security Investments are debt instruments under our asset management policy that generate a return individually and independently of our core operating activities.

December 31, 2025

(in millions €)	Security Investment	IFRS 9 Category[1]	Carrying amount			Fair value			
			Current	Non-current	Total	Level 1	Level 2	Level 3	Total
Financial assets									
Foreign exchange forward contracts	No	FVTPL	6.3	—	**6.3**	—	6.3	—	**6.3**
Other funds	Yes	FVTPL	199.9	—	**199.9**	—	199.9	—	**199.9**
Deposits	Yes	AC	3,358.5	100.0	**3,458.5**	—	—	—	**3,458.5**
Commercial Paper	Yes	AC	570.2	—	**570.2**	—	—	—	**570.2**
Bonds	Yes	AC	2,135.7	2,301.7	**4,437.4**	—	—	—	**4,437.4**
Repos	Yes	AC	894.2	—	**894.2**	—	—	—	**894.2**
Non-listed equity investments	No	FVTOCI	—	0.6	**0.6**	—	—	0.6	**0.6**
Listed equity investments	No	FVTOCI	—	82.2	**82.2**	82.2	—	—	**82.2**
Trade and other receivables	No	AC	924.2	—	**924.2**	—	—	—	**924.2**
Reimbursement asset	No	AC	36.2	—	**36.2**	—	—	—	**36.2**
Other financial assets	No	AC	0.8	23.1	**23.9**	—	—	—	**23.9**
Other financial assets	No	FVTPL	—	46.6	**46.6**	—	—	46.6	**46.6**
Subtotal			**8,126.0**	**2,554.2**	**10,680.2**	**82.2**	**206.2**	**47.2**	**10,680.2**
Cash and cash equivalents									
Cash at banks and on hand	Yes	AC	827.2	—	**827.2**	—	—	—	**827.2**
Money market funds	Yes	FVTPL	5,063.3	—	**5,063.3**	5,063.3	—	—	**5,063.3**
Deposits, Commercial Paper, Repos (< 90 days)	Yes	AC	1,784.9	—	**1,784.9**	—	—	—	**1,784.9**
Subtotal			**7,675.4**	**—**	**7,675.4**	**5,063.3**	**—**	**—**	**7,675.4**
Financial liabilities									
Foreign exchange forward contracts	No	FVTPL	0.4	—	**0.4**	—	0.4	—	**0.4**
Contingent consideration	No	FVTPL	43.4	77.2	**120.6**	—	—	120.6	**120.6**
Loans and borrowings	No	AC	7.2	29.9	**37.1**	—	—	—	**37.1**
Trade payables and other payables	No	AC	534.9	—	**534.9**	—	—	—	**534.9**
Other financial liabilities	No	AC	307.9	17.7	**325.6**	—	—	—	**325.6**
Lease liabilities	No	n/a	45.0	185.3	**230.3**	—	—	—	**230.3**
Subtotal			**938.8**	**310.1**	**1,248.9**	**—**	**0.4**	**120.6**	**1,248.9**

(1) Fair values for financial assets and liabilities at amortized costs are not disclosed as the book values represent a reasonable approximation.

December 31, 2024

(in millions €)	Security Investment	IFRS 9 Category[1]	Carrying amount			Fair value			
			Current	Non-current	Total	Level 1	Level 2	Level 3	Total
Financial assets									
Foreign exchange forward contracts	No	FVTPL	11.9	—	**11.9**	—	11.9	—	**11.9**
Deposits	Yes	AC	1,643.0	—	**1,643.0**	—	—	—	**1,643.0**
Commercial Paper	Yes	AC	918.3	—	**918.3**	—	—	—	**918.3**
Bonds	Yes	AC	3,521.1	1,061.1	**4,582.2**	—	—	—	**4,582.2**
Repos	Yes	AC	453.8	—	**453.8**	—	—	—	**453.8**
Non-listed equity investments	No	FVTOCI	—	1.5	**1.5**	—	—	1.5	**1.5**
Listed equity investments	No	FVTOCI	—	92.7	**92.7**	92.7	—	—	**92.7**
Trade and other receivables	No	AC	1,463.9	—	**1,463.9**	—	—	—	**1,463.9**
Reimbursement asset	No	AC	473.6	40.9	**514.5**	—	—	—	**514.5**
Other financial assets	No	AC	—	18.2	**18.2**	—	—	—	**18.2**
Other financial assets	No	FVTPL	—	39.6	**39.6**	—	—	39.6	**39.6**
Subtotal			**8,485.6**	**1,254.0**	**9,739.6**	**92.7**	**11.9**	**41.1**	**9,739.6**
Cash and cash equivalents									
Cash at banks and on hand	Yes	AC	450.0	—	**450.0**	—	—	—	**450.0**
Money market funds	Yes	FVTPL	6,947.5	—	**6,947.5**	6,947.5	—	—	**6,947.5**
Deposits, Commercial Paper, Repos (< 90 days)	Yes	AC	2,364.4	—	**2,364.4**	—	—	—	**2,364.4**
Subtotal			**9,761.9**	**—**	**9,761.9**	**6,947.5**	**—**	**—**	**9,761.9**
Financial liabilities									
Foreign exchange forward contracts	No	FVTPL	16.3	—	**16.3**	—	16.3	—	**16.3**
Contingent consideration	No	FVTPL	0.9	46.9	**47.8**	—	—	47.8	**47.8**
Trade payables and other payables	No	AC	426.7	—	**426.7**	—	—	—	**426.7**
Other financial liabilities	No	AC	1,426.2	—	**1,426.2**	—	—	—	**1,426.2**
Lease liabilities	No	n/a	39.5	214.7	**254.2**	—	—	—	**254.2**
Subtotal			**1,909.6**	**261.6**	**2,171.2**	**—**	**16.3**	**47.8**	**2,171.2**

[1] Fair values for financial assets and liabilities at amortized costs are not disclosed as the book values represent a reasonable approximation.

Trade and other receivables

Trade and other receivables significantly decreased compared to the previous year and predominantly comprise trade receivables from our COVID-19 collaboration with Pfizer as well as our direct product sales to customers in our territory. The contractual settlement of the gross profit share has a temporal offset of more than one calendar quarter. As Pfizer's financial quarter for subsidiaries outside the United States differs from ours, it creates an additional time lag between the recognition of revenues and the payment receipt. Consequently, as of December 31, 2025, our trade receivables included, in addition to the profit share for the fourth quarter of 2025, trade receivables which related to the gross profit share for the third quarter of 2025.

Reimbursement asset

During the year ended December 31, 2025, the reimbursement asset decreased compared to the year ended December 31, 2024, which is essentially related to payments.

Other financial assets

During the year ended December 31, 2025, mainly non-current deposits in the amount of €113.9 million have been pledged. The Group has an obligation to transfer the deposit to the counterparties if loans and borrowings are not repaid. There are no other significant terms and conditions associated with the use of collateral.

Other financial liabilities

During the year ended December 31, 2025, the other financial liabilities decreased compared to the year ended December 31, 2024 which is essentially related to payments for settlements of contractual disputes.

Equity investments designated at Fair Value through OCI

(in millions €)	Fair value as of December 31, 2025	Fair value as of December 31, 2024
Investment in Autolus Therapeutics plc	56.5	75.4
Investment in Ryvu Therapeutics S.A.	12.3	17.3
Investment in Dualtiy Biologics Co. Ltd.	13.4	—
Other investments	0.6	1.5
Total	**82.8**	**94.2**

In April 2025, we invested €4.5 million in DualityBio.

Financial investments in equity investments measured at fair value through other comprehensive income comprise the following effects:

	Years ended December 31,		
(in millions €)	**2025**	**2024**	**2023**
Net gain / (loss) on equity instruments designated at fair value through other comprehensive income	(15.9)	(146.6)	3.7
Total	**(15.9)**	**(146.6)**	**3.7**

During the year ended December 31, 2025, the non-listed and listed equity investments decreased by €11.4 million compared to year-end 2024 mainly due to subsequent fair value changes amounting to €15.9 million during the year ended December 31, 2025 which were partly offset by the investment in DualityBio.

Measurement of fair values

The following table shows the valuation techniques used in measuring fair values for financial instruments in our consolidated statements of financial position, as well as the significant unobservable inputs used.

Type	Valuation technique	Significant unobservable inputs
Forward exchange contracts	Discounted cash flow using par method. Expected future cash flows based on foreign exchange forwards discounted over the respective remaining term of the contracts using the respective deposit interest rates and spot rates.	n/a
Non-listed equity investments	Quantitative and qualitative factors such as actual and forecasted results, cash position and financing round valuations.	– Actual and forecasted results – Net Asset Value – Cash position – Nature and pricing indication of latest financing round
Listed equity investments	Stock prices of the listed companies and applicable exchange rates, if the listing is in a foreign currency.	n/a
Money market funds	Quoted prices on an active market.	n/a
Other funds	Quoted prices for OTC transactions	n/a
Contingent consideration	Present value of expected future payments and reflecting changes in expected achievement of underlying performance parameters and compounding effects.	– Expected future payments – Applied cost of capital
Royalty assets	Present value of expected future cash flows.	– Expected future cash flows – Applied cost of capital

12.3 Recurring Fair Values (Level 3)

The following table shows the recurring fair value measurement of the royalty assets included in other financial assets as well as contingent considerations and the effect of the measurements on our consolidated statements of profit or loss for the current period.

	Financial assets	Financial liabilities
(in millions €)	Other financial assets	Contingent consideration
As of January 1, 2024	**—**	**(38.8)**
Additions	43.4	—
Net effect on profit or loss – Finance income / (expense)		
Net change in fair value	(3.8)	(9.0)
As of December 31, 2024	**39.6**	**(47.8)**
As of January 1, 2025	**39.6**	**(47.8)**
Additions	—	(79.6)
Net effect on profit or loss - Other operating income / (expense)		
Net change in fair value	—	11.7
Net effect on profit or loss – Finance income / (expense)		
Net change in fair value	7.0	(4.9)
As of December 31, 2025	**46.6**	**(120.6)**

The sensitivity of the fair values of royalty assets included in other financial assets to the significant, unobservable, variable input factors, with all other factors remaining constant, is shown in the following table:

Royalty assets

Input factor	Change in assumptions	Change in fair value with increasing input factor (in millions €)	Change in fair value with decreasing input factor (in millions €)
Cash flow projections	10%	5.5	(5.5)
Discount rate	1%	(4.2)	4.7

The sensitivity of the fair values of contingent considerations in fair value level 3 to the significant, unobservable, variable input factors, with all other factors remaining constant, is shown in the following table:

Contingent consideration

Input factor	Change in assumptions	Change in fair value with increasing input factor (in millions €)	Change in fair value with decreasing input factor (in millions €)
Cash flow projections	10%	8.2	(8.2)
Discount rate	1%	(3.5)	3.9

The estimated fair value of non-listed equity investments would, for example, increase (decrease) if the price of the latest financing round of the respective investment were to increase (decrease) and the overall company value were higher (lower).

12.4 Financial Instruments Risk Management Objectives and Policies

Our financial liabilities mainly comprise obligations derived from other financial liabilities such as obligation from transactions with licensors, trade and other payables, lease liabilities, contingent consideration, liabilities from exchanges forward contracts. The main purpose of these financial liabilities is to enable our operations. Our principal financial assets include mainly cash, security investments, trade receivables and reimbursement assets that derive directly from our operations.

We are exposed to market risk, credit risk and liquidity risk. Our Management Board oversees the management of these risks.

The treasury committee provides assurance to our Management Board that our financial risk activities are governed by appropriate policies and procedures and that financial risks are identified, measured and managed in accordance with our policies and risk objectives. The Management Board reviews and agrees policies for managing each of these risks, which are summarized below.

12.5 Market Risks

Market risks address the risks that the fair value or future cash flows of a financial instrument will fluctuate due to changes in market prices. Market risks comprise three types of risk: interest risks, foreign currency risks and other price risks. Financial instruments affected by market risks include financial assets such as security investments, trade and other receivables, cash and cash equivalents as well as financial liabilities such as trade payables and other financial liabilities. The interest rate environment has changed. We still do not consider interest risks as well as other price risks as material risks to us.

There were no material changes in the way the risks were managed and valued during the years ended December 31, 2025 and 2024.

Foreign Currency Risks

Foreign currency risks address the risks that the fair value or future cash flows of an exposure will fluctuate because of changes in foreign exchange rates. We are subject to currency risks as the majority of our income and expenditures are denominated in Euro and the U.S. dollar. As such, we are mainly exposed to exchange rate fluctuations between these currencies. Cash inflows denominated in U.S. dollar mainly result from generating proceeds under our collaboration agreements. Our revenues from contracts with customers are primarily from the sale of COVID-19 vaccines as well as from out-licensing of pumitamig (BNT327 / BMS986545) to BMS and represents payments we receive mainly in U.S. dollar.. Cash outflows dominated in U.S. dollar mainly result from amounts spent on research and development activities, license obligations and settlement payments as well as expanding our global footprint further. With the aim of preserving capital, surplus liquidity is mainly invested in domestic currency investments as exchange rate fluctuations can reduce the value of our financial positions. We limit the effects of the identified risks by means of a coordinated and consistently implemented risk strategy. Besides applying natural hedging relationships where possible, foreign exchange forward contracts are concluded, as a matter of principle, as instruments to mitigate foreign currency exchange risk associated with foreign currency-denominated payments. However, the foreign exchange forward contracts which we entered into were not designated as hedging instruments under IFRS.

The carrying amount of the monetary assets and liabilities denominated in U.S. dollar at the dates indicated are as follows:

(in millions €)	December 31, 2025	December 31, 2024
Cash and cash equivalents in U.S. dollar	541.2	617.6
Monetary assets in U.S. dollar	904.3	1,484.7
Monetary liabilities and provisions in U.S. dollar	719.5	1,858.1
Total	**726.0**	**244.2**

The following tables demonstrate the sensitivity to a reasonable, possible change in U.S. dollar exchange rates or U.S. dollar forward rates, with all other variables held constant. The impact on our profit before tax is due to changes in the fair value of monetary assets and liabilities. The exposure to foreign currency changes for all other currencies is not material.

		1 € =	Closing rate		Average rate	
Currency		**Country**	**2025**	**2024**	**2025**	**2024**
U.S. dollar		United States	1.1750	1.0389	1.1300	1.0824

(in millions €)	Change in U.S. dollar rate	Effect on profit / (loss) before tax	Effect on pre-tax equity
2025	+5%	(34.6)	(34.6)
	-5 %	38.2	38.2
2024	+5%	(11.6)	(11.6)
	-5 %	12.9	12.9

12.6 Credit Risk Management

Credit risks address the risks that a counterparty will not meet its obligations under a financial instrument or customer contract, leading to a financial loss. We are exposed to credit risks from our operating activities, including security investments, bank deposits, reverse repos, foreign exchange transactions, trade and other receivables and cash at banks. The maximum exposure to credit risk for the components of the consolidated statements of financial position as of December 31, 2025, and December 31, 2024, are the carrying amounts as illustrated in Note 12.1 and Note 12.2.

Security Investments, Bank Deposits, Reverse Repos and Cash at Banks

Our financial management is dedicated predominantly to the goal of capital preservation. Thus, all our financial activities are focused towards avoiding risks and, where they cannot be avoided, actively managing and minimizing them. Credit risks from balances with security investments, bank deposits, reverse repos and cash at banks are managed by our Treasury department in accordance with our investment and asset management policy.

Our security investments are solely invested in the highest-quality liquid assets (e.g. core European sovereign, supranational and agency bonds) and bank deposits with a maturity of more than 3 months (held at selected banks, exclusively rated as investment grade). They do not bear any currency risks or material credit risks. The bank deposits are held at selected banks, exclusively rated as investment grade. We limit our investment engagements individually and track each credit risk continuously. For reverse repos, only investment-grade counterparties qualify as our business partners and secured investments are solely collateralized by high-quality liquid assets.

Accordingly, credit risks from these financial assets are limited. Before entering into new business relationships and during ongoing business relationships, we evaluate our business partners with regard to their individual default risk. Therefore, we do not presume an increased credit risk as of the balance sheet date and determine the impairment loss based on the upcoming twelve months.

Trade and Other Receivables

Our exposure to credit risks of trade and other receivables is primarily related to transactions with corporate customers in the biopharma / biotech industry that operate in the United States or Germany, as well as governments which are customers, in connection with fulfilling our commercial obligations in our territories as defined in our contracts with customers. An analysis of the aging of receivables and the creditworthiness of customers is used to evaluate this risk at each reporting date. We follow risk control procedures to assess the credit quality of our customers taking into account their financial position, past experience and other factors.

As of December 31, 2025, outstanding trade and other receivables were mainly due from our collaboration partner Pfizer. Besides well-established pharmaceutical companies and governmental institutions, our other customers – to a smaller extent – are medical universities, other public institutions and peers in the biopharma industry. The balances with those customers are not material. Due to this customer portfolio, the credit risk on trade and other receivables is generally very low. We have not incurred material bad debt expense and do not expect that this will change with respect to the trade and other receivables outstanding as of December 31, 2025.

12.7 Liquidity Risk

We plan to invest heavily in R&D as we make a strong drive to build out our global development organization and diversify our therapeutic area footprint. Additionally, we plan to enhance capabilities through complementary acquisitions, technologies, infrastructure and manufacturing. Our liquidity management ensures the availability of cash and cash equivalents, short term financial instruments for operational activities and further investments

through appropriate budget planning. In addition, a sufficient level of cash and cash equivalents, which are managed centrally, is always maintained to finance the operational activities.

We monitor liquidity risks using a liquidity planning tool.

Ultimately, the responsibility for liquidity risk management lies with our Management Board, which has established an appropriate approach to managing short-, medium- and long-term financing and liquidity requirements. We manage liquidity risks by holding appropriate reserves based on our COVID-19 sales, as well as by monitoring forecasted and actual cash flows and reconciling the maturity profiles of financial assets and liabilities. Significant reserves currently exist and were generated during the COVID-19 pandemic.

Risk Concentration

Concentrations arise when the number of counterparties is small or when a larger number of counterparties is engaged in similar business activities, or activities in the same geographical region, or has economic features that would cause their ability to meet contractual obligations to be affected similarly by changes in economic, political or other conditions. Concentrations indicate the relative sensitivity of our performance to developments affecting a particular industry. We only have a limited number of customers mainly comprising pharmaceutical companies and governmental institutions.

The maturity profile of our financial liabilities based on contractual undiscounted payments is summarized as follows:

Year ended December 31, 2025

(in millions €)	Less than 1 year	1 to 5 years	More than 5 years	Total
Loans and borrowings	7.2	24.5	5.4	**37.1**
Trade and other payables	534.9	—	—	**534.9**
Lease liabilities	53.1	144.0	64.0	**261.1**
Contingent consideration	51.3	47.0	50.0	**148.3**
Foreign exchange forward contracts	0.4	—	—	**0.4**
Other financial liabilities	307.9	19.6	—	**327.5**
Total	**954.8**	**235.1**	**119.4**	**1,309.3**

Year ended December 31, 2024

(in millions €)	Less than 1 year	1 to 5 years	More than 5 years	Total
Trade and other payables	426.7	—	—	426.7
Lease liabilities	48.1	152.7	90.3	291.1
Contingent consideration	—	62.5	0.1	62.6
Foreign exchange forward contracts	16.3	—	—	16.3
Other financial liabilities	1,426.2	—	—	1,426.2
Total	**1,917.3**	**215.2**	**90.4**	**2,222.9**

12.8 Changes in Liabilities Arising from Financing Activities

Year ended December 31, 2025

(in millions €)	January 1, 2025	Cash flows	New leases and disposals	Reclassifi-cation	Additions from business combinations	Currency effects	Other	December 31, 2025
Current obligations under lease contracts	39.5	(38.9)	2.5	39.2	5.3	(1.7)	(0.9)	45.0
Non-current obligations under lease contracts	214.7	(0.7)	6.2	(39.2)	30.3	(10.2)	(15.8)	185.3
Current loans and borrowings	—	(12.2)	—	1.3	19.5	(1.4)	—	7.2
Non-current loans and borrowings	—	0.9	—	(1.3)	33.1	(2.7)	(0.1)	29.9
Total	**254.2**	**(50.9)**	**8.7**	**—**	**88.2**	**(16.0)**	**(16.8)**	**267.4**

Year ended December 31, 2024

(in millions €)	January 1, 2024	Cash flows	New leases and disposals	Reclassifi-cation	Other	December 31, 2024
Current obligations under lease contracts	28.1	(43.6)	19.4	35.6	—	39.5
Non-current obligations under lease contracts	188.6	—	56.0	(35.6)	5.7	214.7
Loans and borrowings	2.3	(2.3)	—	—	—	—
Total	**219.0**	**(45.9)**	**75.4**	**—**	**5.7**	**254.2**

13 Inventories

(in millions €)	December 31, 2025	December 31, 2024
Raw materials and supplies	98.1	268.1
Unfinished goods	6.7	7.3
Finished goods	5.9	7.9
Total	**110.7**	**283.3**

Our expenses from inventory write-downs to net realizable value and scrapings due to inventories expected to be unsellable, not fulfilling the specification defined by our quality standards and shelf-life expiry resulted in €162.8 million during the year ended December 31, 2025, compared to €125.8 million in the previous period. The inventories valued at net realizable value in our consolidated statements of financial position as of December 31, 2025, take contractual compensation payments into consideration. We have not pledged any inventories as securities for liabilities. During the years ended December 31, 2025 and 2024, inventories in the amount of €189.3 million and €129.5 million, respectively, were recognized as cost of sales.

14 Other Non-Financial Assets

(in millions €)	December 31, 2025	December 31, 2024
Deferred expenses	117.8	194.5
Other	63.3	44.5
Total	**181.1**	**239.0**
Total current	173.8	212.7
Total non-current	7.3	26.3

Deferred expenses mainly comprise prepayments for future expenses of €8.2 million (€83.1 million as of December 31, 2024) for the settlement fee of the European Commission to our collaboration partner and prepayments for our collaborations with Ryvu Therapeutics S.A., Krakow, Poland, €5.5 million (€8.5 million as of December 31, 2024) and MediLink Therapeutics Co., Ltd, Suzhou, China, €8.4 million (€17.7 million as of December 31, 2024). The remaining deferred expenses mainly comprise insurance obligations, licenses and service contracts. The remaining other non-financial assets mainly comprise receivables from grants of €25.9 million and VAT receivables of €20.1 million.

15 Issued Capital and Reserves

As of December 31, 2025, the number of shares outstanding with a notional amount attributable to each share of €1 was 251,325,340. During the year ended December 31, 2025 we issued 10,475,287 shares for the acquisition of CureVac (see Note 5). The amount of shares outstanding as of December 31, 2025 excludes 7,702,147 shares held in treasury. As of December 31, 2024, the number of shares outstanding was 239,970,804, excluding 8,581,396 shares held in treasury.

16 Share-Based Payments

During the years ended December 31, 2025, 2024, and 2023, our share-based payment arrangements led to the following expenses:

		Years ended December 31,		
(in millions €)	**Note**	**2025**	**2024**	**2023**
Expense arising from equity-settled share-based payment arrangements		**89.0**	**74.9**	**44.1**
BioNTech 2020 and 2024 Restricted Stock Unit Plans for Non-North American Employees	16.1.1	72.3	58.3	36.3
InstaDeep Employee Incentive Plan[1]	16.1.1	4.9	11.4	3.4
Employee Stock Ownership Plan	16.1.1	—	—	—
Management Board Grant	16.1.2	0.9	5.2	3.2
Chief Executive Officer Grant		—	—	1.2
Biotheus Founder SBP Program	16.1.3	10.9	—	—
Expense / (Income) arising from cash-settled share-based payment arrangements		**17.3**	**26.0**	**7.3**
BioNTech 2020 and 2024 Restricted Stock Unit Plans for North American Employees[2]	16.2.1	22.7	23.3	10.6
Employee Stock Ownership Plan	16.2.1	(1.2)	0.1	(0.9)
Management Board Grant	16.2.2	(4.2)	2.6	(2.4)
Total		**106.3**	**100.9**	**51.4**
Cost of sales		7.3	9.0	6.5
Research and development expenses		75.1	63.5	33.4
Sales and marketing expenses		3.6	2.5	1.0
General and administrative expenses		20.3	25.9	10.5
Total		**106.3**	**100.9**	**51.4**

(1) The first tranche of 40,249 RSUs vested in July 2024 and was settled in the three months ended September 30, 2024, in cash.

(2) In the fiscal year 2025 the BioNTech 2024 Restricted Stock Unit Plan for North America Employees was modified and is now settled only in cash. For more details regarding the modification please see note 16.2.1. The expenses relating to the fiscal years 2025 and 2024 also contain the expenses from the former as equity settled classified 2024 Restricted Stock Unit Plan for North American Employees.

During the years ended December 31, 2025, 2024 and 2023, our share-based payment arrangements led to a cash outflow of €25.3 million, €154.5 million and €766.2 million, respectively. We expect to settle the equity-settled share-based payment arrangements remaining from all of our Management Board Grants (see Note 16.1.2) and the Employee Stock Ownership Plan (see Note 16.1.1) on a net basis by delivering to the participant a number of ADSs equal to the net value of the exercised option rights after deduction of (i) the exercise price and (ii) the applicable wage taxes (including solidarity surcharge thereon and church tax, if applicable) and social security contributions resulting from such exercise. This reduces the dilutive impact of the respective rights compared to an all-equity settlement. If all of the equity-settled rights outstanding from these programs as of December 31, 2025, were to be exercised accordingly, the cash outflow to the tax authority in 2026 would amount to approximately €7.6 million (based on the ADS price as of December 31, 2025).

16.1 Equity-settled Share-Based Payment Arrangements

16.1.1 Employee Plans

BioNTech 2020 and 2024 Restricted Stock Unit Plans for Non-North American Employees

In December 2020, we approved the BioNTech 2020 Employee Equity Plan for employees based outside North America, or the European Plan. Under the European Plan, Restricted Stock Units, or RSUs, are offered to our employees.

In December 2024 we approved the 2024 Non-North America Employee Participation Plan for employees based outside North-America. Under this Plan, Restricted Stock Units and Performance Restricted Stock Units, or PRSUs, are offered to our employees. The number of RSUs granted to each participant is determined by multiplying the eligible earnings by a percentage within the applicable range for such individual's BioNTech Job Level and dividing such amount by the ADS price at grant, rounding the result down to the nearest whole number. The number of PRSUs is subject to upward or downward adjustments at each vesting date, such that the actual number of PRSUs that shall vest may be higher or lower than the number of PRSUs initially scheduled to vest at such date, based on the relative performance of BioNTech ADSs against the Nasdaq Biotechnology Index (Index) for the applicable period. The weighted average grant date fair value for the PRSUs has been measured using a Monte-Carlo simulation model. This model incorporates the impact of the performance criteria regarding share price and described index development.

All programs were classified as equity-settled as we have the ability to determine the method of settlement.

RSUs and PRSUs issued under these programs vest annually in equal installments over the respective waiting period, commencing with grant date in December of every year. The fair values of the awards issued under the European Plan were based upon the price of our ADSs representing ordinary shares at the grant date.

	LTI 2020 program	LTI 2021 program	LTI 2022 program	LTI 2023 program	LTI 2024 program - RSUs	LTI 2024 program - PRSUs
Grant dates of the awards	December 2020	January 2022	December 2022	January 2024	January 2025	January 2025
Vesting	25% p.a.	25% p.a.	25% p.a.	25% p.a.	25% p.a.	25% p.a.
Weighted average fair value	€92.21	€203.22	€165.03	€97.99	€116.54	€101.84
Waiting period (in years)	4.0	4.0	4.0	4.0	—	—

The RSUs and PRSUs outstanding as of the respective dates are presented in the table below.

	LTI 2020 program	LTI 2021 program	LTI 2022 program	LTI 2023 program	LTI 2024 program - RSUs	LTI 2024 program - PRSUs
As of January 1, 2024	230,905	101,111	379,969	—	—	—
Granted	—	—	—	834,211	—	—
Forfeited / Modified	(4,541)	(2,332)	(12,507)	(62,902)	—	—
Settled	(225,201)	—	—	—	—	—
As of December 31, 2024	**1,163**	**98,779**	**367,462**	**771,309**	**—**	**—**
As of January 1, 2025	1,163	98,779	367,462	771,309	—	—
Granted / Allocated	—	—	—	—	977,498	21,878
Settled	(1,163)[3]	(96,068)[1]	—	—	(219,984)[2]	(2,521)[2]
Forfeited / Modified	—	(2,711)	(14,292)	(49,235)	(79,740)	(3,611)
As of December 31, 2025	**—**	**—**	**353,170**	**722,074**	**677,774**	**15,746**
thereof vested	—	—	*270,428*	*371,401*	—	—
thereof unvested	—	—	*82,742*	*350,673*	*677,774*	*15,746*

(1) The closing price of an American Depositary Share of BioNTech on Nasdaq on December 10, 2025, the last trading day before the settlement date, converted from USD to Euro using the exchange rate published by the German Central Bank (Deutsche Bundesbank) on the same day was €82.29.

(2) The closing price of an American Depositary Share of BioNTech on Nasdaq on December 5, 2025, the last trading day before the settlement date, converted from USD to Euro using the exchange rate published by the German Central Bank (*Deutsche Bundesbank*) on the same day was €82.65.

(3) The closing prices of an American Depositary Share of BioNTech on Nasdaq on April 3 and June 3, 2025, the last trading days before the settlement dates, converted from USD to Euro using the exchange rates published by the German Central Bank (Deutsche Bundesbank) on the same days were €82.91 and €101.56.

InstaDeep Employee Incentive Plan (RSU and ESOP)

As part of the acquisition of InstaDeep in 2023, we agreed to issue a long-term RSU award with a total target incentive value of £15.0 million. The start of the vesting period was July 2023. The RSUs granted under this award vest annually in equal tranches of 25% over a period of 4 years. There is no waiting period and each tranche is settled with vesting. The weighted average fair value at grant date was €92.08. The program is accounted for as equity-settled and it is at the discretion of the company whether the following three tranches will be settled in equity or in cash in the years 2025-2027.

Furthermore, as part of the acquisition of InstaDeep in 2023, we agreed to issue long-term ESOP awards with a total target incentive value of £15.0 million. The awards are subject to a four-year cliff vesting and will vest and become exercisable in July 2027. The exercise price is $100.34 for 17,561 options granted to two employees located in the US, $111.31 for 8,430 options granted to employees in South Africa and $94.47 for 380,452 options granted to all InstaDeep employees located in Rest of World. The fair value of the ESOP awards has been measured using a Monte Carlo simulation. For the ESOPs granted under the InstaDeep Employee Stock Ownership awards, the same performance requirements that allow the ESOPs to be exercised apply as for the BioNTech Employee Stock Ownership Plan.

	ESOP Award	RSU Award
As of January 1, 2024	406,353	160,997
Granted / Allocated	—	—
Settled	—	(40,249)[1]
As of December 31, 2024	**406,353**	**120,748**
As of January 1, 2025	406,353	120,748
Forfeited	—	(5,182)
Settled	—	(36,874)
As of December 31, 2025	**406,353**	**78,692**

[1] The first tranche of 40,249 RSUs vested in July 2024 and was settled in the three months ended September 30, 2024, in cash.

Employee Stock Ownership Plan (Equity-Settled)

Based on an authorization of the general meeting on August 18, 2017, we established a share option program under which we granted selected employees options to receive our shares. We offered participants a certain number of option rights upon their explicit acceptance of an option rights agreement. The exercise of option rights in accordance with the agreement gives the participants the right to obtain shares against payment of the exercise price. Following the expiry of the waiting period, option rights may be exercised within a period of four weeks from the date of the Annual General Meeting or the publication of the annual financial statements, the semi-annual report or our most recent quarterly report or interim report (exercise windows). The option rights can be exercised up to eight years after the allocation date. If they have not been exercised by that date, they will be forfeited without compensation.

The fair value of the ESOP has been measured using a binomial model. Service conditions attached to the arrangement were not taken into account in measuring the fair value.

The share options can only be exercised by the grantee if the price of the share is equal or exceeds the threshold amount as defined in the ESOP agreement. Moreover, the option rights can only be exercised if the IPO has occurred. Both conditions have been incorporated into the fair value at the grant date.

The inputs used in the measurement of the fair values at the grant date of the ESOP were as follows:

	Grant date November 15, 2018	Grant date February 20, 2019
Weighted average fair value	€7.41	€6.93
Weighted average share price	€14.40	€15.72
Exercise price	€10.14	€15.03
Expected volatility	46.0%	46.0%
Expected life (years)	5.8	6.0
Risk-free interest rate	0.1%	0.1%

Expected volatility has been based on an evaluation of the historical and the implied volatilities of comparable companies over the historical period commensurate with the expected term. The expected term has been based on general option holder behavior for employee options.

Below is an overview of changes to share options outstanding that occurred during the periods indicated:

	Share options outstanding	Weighted average exercise price (€)
As of January 1, 2024	320,393	11.24
Exercised[1]	(139,053)	10.14
As of December 31, 2024	**181,340**	**12.08**
As of January 1, 2025	181,340	12.08
Exercised[1]	(50,936)	10.14
As of December 31, 2025	**130,404**	**12.84**
thereof vested	130,404	12.84

[1] The average closing price of an American Depositary Share of BioNTech on Nasdaq weighted over the various dates immediately preceding the settlement dates, converted from USD to Euro using the exchange rate published by the German Central Bank (Deutsche Bundesbank) on the same days was €91.64 and €83.45 for all settlements during the years ended December 31, 2025 and 2024, respectively.

In September 2022, the Supervisory Board determined the ESOP settlement by the delivery of treasury shares (in the form of ADSs) equal to the net value of the exercised option rights after deduction of (i) the exercise price and (ii) the applicable wage taxes (including solidarity surcharge thereon and church tax, if applicable) and social security contributions resulting from such exercise. The settlement was applied during the exercise windows in 2025 and 2024.

58,404 ESOP options cannot be exercised after September 16, 2026. The remaining ESOP options cannot be exercised after February 21, 2027. Options which have not been exercised by these dates will lapse without compensation.

16.1.2 Management Board Grant

Our Management Board's service agreements provide for long-term, four-year incentive compensation (Management Board Grant - LTI) through an annual grant of a combination of PSUs and options to acquire BioNTech shares, all of which are subject to a four-year waiting period from grant. The options are subject to the terms and conditions of the respective authorizations of the AGM creating our Employee Stock Ownership Plan, or ESOP, and the applicable option- and PSU agreements.

Awards granted under the Compensation systems of the Management Board and the Supervisory Board approved by the AGM on June 22, 2021, and June 1, 2022 (the "Compensation System 2021/2022")

Options

The options vest annually in equal installments over four years commencing on the first anniversary of the allocation date and are exercisable four years after the allocation date. In the case of options granted under the Compensation System 2021/2022, vested options can only be exercised if all of the following performance criteria are met:

- Threshold Amount: At the time of exercise, the current ADS price must be equal to or greater than the threshold amount. The threshold amount is the exercise price, which increases by seven percentage points on each anniversary of the grant date.

- Target Price: At the time of exercise, the current ADS price must be at least equal to the target price, defined as:

- for the twelve-month period starting on the fourth anniversary of the grant date, $8.5 billion divided by the total number of ordinary shares outstanding immediately following the initial public offering (excluding shares owned by BioNTech); and

- for each twelve-month period starting on the fifth or subsequent anniversary, 107% of the target ADS price applicable for the prior twelve-month period.

– Index Performance: The closing price for the fifth trading day prior to the start of the relevant exercise window must be higher than the exercise price by at least the same percentage by which the Nasdaq Biotechnology Index (or a comparable successor index) has increased since the last trading day before the allocation date.

– Additional Terms:

- After the waiting period expires, option rights may be exercised only during the exercise windows specified in the ESOP agreement.

- Option rights can be exercised up to ten years after the grant date; after this period, any unexercised options will be forfeited without compensation.

Awards granted under the Compensation system of the Management Board and the Supervisory Board approved by the AGM on May 17, 2024, (the “Compensation System 2024”)

Performance Share Units, or PSUs

PSUs vest annually in equal installments over four years commencing on the first anniversary of the allocation date. Vested PSUs are only settled when the following performance criteria are met.

PSUs can only be settled if the ADS price has performed as well or better in percentage terms than the Nasdaq Biotechnology Index (or a comparable successor index) in the period from the last trading day before the PSU Issue Date to the fifth trading day before the start of the relevant exercise period. If the ADS price performs as well or better than the index, the target is achieved and the PSUs can be settled. If the ADS price underperforms the index as of the fifth trading day prior to the end of the waiting period, the PSUs cannot be settled and expire immediately without compensation. If the performance criteria are met, we are obliged to settle the PSUs for our Management Board members within a 30 day period following the end of the waiting period.

Options

Vested options granted under the Compensation System 2024 and from the 2025 financial year onwards can only be exercised if the following performance criteria are met.

- Threshold Amount: At the time of exercise, the current ADS price must be at least 180% of the exercise price, which increases by an additional twenty percentage points from the fifth and each subsequent anniversary of the approval date.

- Index Performance: The closing price for the fifth trading day prior to the start of the relevant exercise date must be higher than the exercise price by at least the same percentage by which the Nasdaq Biotechnology Index (or a comparable successor index) has increased since the last trading day before the grant date.

– Additional Terms:

- After the waiting period expires, option rights may be exercised only during the exercise windows specified in the ESOP agreement.

- Option rights can be exercised up to ten years after the grant date; after this period, any unexercised options will be forfeited without compensation.

The right to receive options or PSUs generally represents an equity-settled share-based payment arrangement. Management Board members were awarded phantom options in May 2021 and 2022, options in May 2023 and August 2024, and a combination of options and PSUs in May 2025.

A Monte-Carlo simulation model has been used to measure the fair values at the allocation dates of the Management Board Grant. This model incorporates the impact of the market based performance criteria regarding share price and described index development. The parameters used for measuring the fair values as of the respective allocation dates were as follows:

	Allocation date February 2020	Allocation date May 12, 2021[1]	Allocation date May 17, 2021[1]	Allocation date May 2022[1]	Allocation date May 2023	Allocation date August 2024	Allocation date May 2025 ESOP	Allocation date May 2025 PSU
Weighted average fair value	€10.83	€25.65	€21.60	€29.27	€45.73	€33.49	€46.15	€46.01
Weighted average share price	€28.20	€158.41	€168.77	€139.03	€98.93	€74.48	€83.00	€83.87
Exercise price[2]	€28.32	€157.64	€159.00	€129.45	€96.97	€75.91	€93.35	n/a
Expected volatility	36.6%	58.7%	58.7%	64.5%	47.2%	48.9%	66.4%	57.7%
Expected life (years)	4.7	4.6	4.6	5.8	5.8	5.8	5.8	5.8
Risk-free interest rate	1.6%	3.8%	3.8%	3.9%	3.7%	3.8%	4.5%	4.5%

(1) Classified as cash-settled share-based payment arrangement; all other share-based payment arrangements are classified as equity-settled.

(2) All share options are subject to an effective exercise price cap.

All options are subject to an effective exercise price cap, which means that the exercise price shall be adjusted to ensure that the current price of an ADS as of the exercise date does not exceed 800% of the exercise price. For the LTI 2020, the maximum economic benefit receivable is capped at $246.24, and the effective exercise price is capped at a Euro amount equivalent to $30.78. For the phantom share options issued under the LTI 2021 and 2022 programs, the options issued under the LTI 2023 and 2024 programs and the PSUs and options issued under the LTI 2025 program, the maximum compensation that each member is entitled to receive, together with other compensation components received in the respective grant year, shall not exceed €20.0 million for Ugur Sahin and €10.0 million for all others.

Expected volatility was based on an evaluation of the historical volatilities of comparable companies over the historical period commensurate with the expected option term. The expected term was based on general option holder behavior for employee options.

The share options (including phantom share options) allocated to our Management Board as of the dates indicated are presented in the table below.

	Allocation date February 2020	Allocation date May 12, 2021[1]	Allocation date May 17, 2021[1]	Allocation date May 2022[1]	Allocation date May 2023	Allocation date August 2024	Allocation date May 2025 ESOP	Allocation date May 2025 PSU
(Phantom) share options outstanding as of January 1, 2024	**248,096**	**43,501**	**6,463**	**86,118**	**130,586**	**—**	**—**	**—**
Forfeited	—	—	—	(7,332)	(13,812)	(12,729)	—	—
Granted / Allocated	—	—	—	—	—	193,257	—	—
Exercised[2]	(209,128)	—	—	—	—	—	—	—
(Phantom) share options outstanding as of December 31, 2024	**38,968**	**43,501**	**6,463**	**78,786**	**116,774**	**180,528**	**—**	**—**
(Phantom) share options outstanding as of January 1, 2025	**38,968**	**43,501**	**6,463**	**78,786**	**116,774**	**180,528**	**—**	**—**
Granted / Allocated	—	—	—	—	—		79,255	63,405
Exercised		—	—	—	—	—	—	—
Forfeited	—	—	—	(5,533)	(18,416)	(38,188)	(11,047)	(8,838)
(Phantom) share options outstanding as of December 31, 2025	**38,968**	**43,501**	**6,463**	**73,253**	**98,358**	**142,340**	**68,208**	**54,567**
thereof allocated and vested but subject to performance and / or waiting requirements	38,968	43,501	6,463	60,922	60,689	45,133	—	—
thereof allocated and unvested	—	—	—	12,331	37,669	97,207	68,208	54,567

(1) Classified as cash-settled share-based payment arrangement; all other share-based payment arrangements are classified as equity-settled.

(2) The average closing price of an American Depositary Share of BioNTech on Nasdaq weighted over the various dates immediately preceding the settlement dates, converted from USD to Euro using the exchange rate published by the German Central Bank (Deutsche Bundesbank) on the same days was €75.00 for all options exercised in 2024.

As of December 31, 2025, the share options allocated under our equity-settled share-based payment arrangements had a remaining weighted average expected life of 3.9 years (as of December 31, 2024: 5.0 years).

As of December 31, 2025, the liability related to the phantom option awards of the years 2021 and 2022 amounted to €3.8 million (€5.1 million as of December 31, 2024).

16.1.3 Biotheus Founder SBP Program

As part of the acquisition of Biotheus in January 2025, a portion of the upfront payment to the Biotheus founders, equivalent to €49.2 million, was allocated in ADSs. The payout is connected to the retention of the founders with the company and considered a share-based payment program according to IFRS 2. Under this program, a total of 421,818 RSUs was granted to the Biotheus founders. The grant is subject to a four-year cliff vesting. The ADSs have been transferred to an escrow account and will be allocated to the founders after four years. The grant date fair value was €116.58, and was determined using the closing price of our ADSs on January 29, 2025, the day the ADSs were transferred to the escrow account, converted into Euros using the exchange rate published by the German Central Bank (Deutsche Bundesbank) from the same date.

16.2 Cash-settled Share-Based Payment Arrangements

16.2.1 Employee Plans

BioNTech 2024 North America Employee Participation Plan

During the year ended December 31, 2024, a new long-term incentive plan for employees resident in North America was established. Within this plan, we granted RSUs (and PRSUs for individuals at the job level Vice President or above) with an equity-based LTI program to all of their employees. The number of RSUs granted to each participant is determined by multiplying the eligible earnings by a percentage within the applicable range for such individual's BioNTech Job Level and dividing such amount by the ADS price at grant, rounding the result down to the nearest whole number. The number of PRSUs is subject to upward or downward adjustments at each vesting date, such that the actual number of PRSUs that shall vest may be higher or lower than the number of PRSUs initially scheduled to vest at such date, based on the relative performance of BioNTech ADSs against the Nasdaq Biotechnology Index (Index) for the applicable period.

All RSUs, except the PRSUs, shall vest annually in equal tranches of 25% over a period of four years, starting from the date of the grant and without a four-year waiting period. In the second quarter of 2025, we modified the US LTI 2024 and US LTI 2025 from equity-settled to cash-settled programs. Due to our status as a Passive Foreign Investment Company (PFIC), issuing ADSs to the participants would result in significant personal tax impacts. The settlement of the LTI 2024 Tranche 1 was made in cash in May 2025, and for the foreseeable future, all upcoming settlements are expected to be carried out in cash. The modification led to a reclassification of €14.6 million from an equity settlement to a cash settlement and an expense effect from the revaluation of €0.2 million in 2025. The modification led to a change in the weighted average fair value for the RSUs converted into EUR from €82.43 at grant date to €82.94 at modification date. The modification led to a change in the weighted average fair value for the PRSUs converted into EUR from €58.20 at grant date to €55.98 at modification date. The fair value for the PRSUs is remeasured at each period end and considers the respective criteria by using a Monte-Carlo simulation model. This model incorporates the impact of the performance criteria regarding share price and index development described above. During the year ended December 31, 2025 the settlement of RSUs resulted in a cash outflow, converted into Euros with the exchange rate published by the German Central Bank (Deutsche Bundesbank) on December 31, 2025, of €7.9 million. The non-current outstanding liability from the programs under this plan on December 31, 2025 was €11.3 million and the current outstanding liability €9.3 million. Both numbers were converted into EUR with the exchange rate published by the German Central Bank (Deutsche Bundesbank) on December 31, 2025.

	RSU	PRSU
As of January 1, 2024	—	—
Granted May 15, 2024	356,757	34,481
Granted December 12, 2024	47,115	
Forfeited	(24,284)	(2,915)
As of December 31, 2024	**379,588**	**31,566**
As of January 1, 2025	379,588	31,566
Granted May 14, 2025	330,774	32,160
Granted November 13, 2025	27,743	
Forfeited	(67,430)	(5,465)
Settled	(91,828)	(7,644)
As of December 31, 2025	**578,847**	**50,617**
thereof vested	—	—
thereof unvested	578,847	50,617

BioNTech 2020 Restricted Stock Unit Plan for North America Employees

In December 2020, we approved the BioNTech 2020 Restricted Stock Unit Plan for North America Employees, or the North American Plan. Under the North American Plan, we offer RSUs to our employees. These RSUs vest over four years, with 25% vesting one year after the service commencement date and the remainder vesting in equal quarterly installments thereafter. The first awards under the North American Plan were granted in February 2021. The service date for these awards is the date as of which the employee became employed by BioNTech US. As these RSUs are intended to be settled in cash upon vesting, the awards were classified as a cash-settled share-based payment arrangement. During the years ended December 31, 2025, 2024 and 2023, the settlement of RSUs resulted in a cash outflow of €9.0 million, €13.9 million and €10.0 million, respectively.

As of December 31, 2025, the carrying amount and intrinsic value of the liability related to these awards amounted to €6.1 million (€11.2 million as of December 31, 2024).

Employee Stock Ownership Plan (Cash-Settled)

Phantom options which were granted under the ESOP mainly during the year ended December 31, 2022, each give the participants the right to receive a cash payment equal to the difference between an exercise closing price (average closing price of an American Depositary Share of BioNTech on Nasdaq over the last ten trading days preceding the exercise date) and the exercise price. The phantom options can only be exercised by the grantee if the price of the share is equal or greater to the threshold amount as defined in the ESOP agreement. The majority of options have an exercise price of €10.14. During the years ended December 31, 2025 and 2024, 39,508 and 50,748 cash-settled phantom option rights were exercised and resulted in a cash outflow of €3.2 million and €3.8 million, respectively. The average 10-day closing prices of an American Depositary Share of BioNTech on Nasdaq weighted over the various settlement dates converted from USD to Euro using the exchange rate published by the German Central Bank (Deutsche Bundesbank) on the same days was €90.58 and €92.70. As of December 31, 2025, 19,395 cash-settled option rights remained outstanding. As of December 31, 2025, the carrying amount and intrinsic value of the liability related to cash-settled share-based payment option rights amounted to €1.7 million (€5.0 million as of December 31, 2024). The liability is based on the fair value of the respective rights. The fair value is measured using a binomial model consistent with the grant date fair value measurement of the equity-based option rights described above, which is updated on every reporting date.

	Number of options	Weighted average exercise price (€)
As of January 1, 2024	109,651	10.14
Settled	(50,748)	10.14
As of December 31, 2024	**58,903**	**10.14**
As of January 1, 2025	58,903	10.14
Settled	(39,508)	10.14
As of December 31, 2025	**19,395**	**10.14**
Thereof vested	*19,395*	*10.14*

16.2.2 Management Board Grant – Short-Term Incentive

For STI compensation components granted to the Board Members until and including fiscal year 2024, 50% of each annual award is paid out at the end of the calendar month following the date on which the Supervisory Board approved the consolidated financial statements of the Company for the financial / bonus year that is relevant for the determination of the STI (first installment). The remaining 50% of each annual award is paid out one year after the achievement of the performance targets for the respective bonus year has been determined, subject to an adjustment relative to the performance of the price of the ADSs representing our ordinary shares

during that year (second installment). The second installments represent cash-settled share-based payment arrangements. The fair values of the liabilities are recognized over the awards' vesting periods beginning when entering or renewing service agreements, i.e., the service commencement date, until each separate determination date and are remeasured until the settlement date. As of December 31, 2025, the carrying amount and intrinsic value of the liability related to the second installment of STI 2024 amounted to €1.0 million (€2.8 million as of December 31, 2024).

17 Provisions

(in millions €)	December 31, 2025	December 31, 2024
Contractual disputes / settlements	58.6	85.7
Obligations from onerous contracts	51.8	56.6
Restructuring	39.1	—
Other	31.3	23.4
Total	**180.8**	**165.7**
Total current	145.3	144.8
Total non-current	35.5	20.9

Certain prior period amounts have been reclassified to conform to current period presentation.

As of December 31, 2025, our current provisions included €58.6 million in contractual disputes mainly related to collaborators regarding, among other things, the interpretation of each party's obligations or the amounts payable under the respective agreements. The decrease compared to December 31, 2024 results mainly from consumption which exceeds additions from further progress of the collaboration efforts.

As of December 31, 2025, our current provisions included €51.8 million (€56.6 million as of December 31, 2024) of obligations from onerous contracts, primarily relating to production capacities derived from contracts with contract manufacturing organizations, or CMOs, that became redundant. The change of €4.8 million compared to December 31, 2024 related entirely to consumption.

As of December 31, 2025, our current and non-current provisions included €39.1 million (nil as of December 31, 2024) of obligations from restructuring due to pipeline prioritization. The change is mainly related to additions. The group expects to settle the majority of the provision within the next two years.

As of December 31, 2025, our current and non-current provisions included €31.3 million in other obligations mainly comprising employee related obligations such as social security costs related to share based payment programs as well as inventor remunerations and obligations for dismantling/removing. The change of €7.9 million compared to December 31, 2024, related mainly to additions which exceeded the consumption of the provision.

18 Contingent Liabilities and Other Financial Commitments

Contingent Liabilities

Our contingent liabilities include, but are not limited to, intellectual property disputes and contractual disputes regarding, among other things, the interpretation of each party's obligations or the amounts payable under the respective agreements, product-related disputes and actions by or on behalf of our shareholders.

From time to time, in the normal course and conduct of our business, we may be involved in proceedings with third parties about considering, for example, the use and/or remuneration for use of such third party's intellectual property. As of December 31, 2025, none of the intellectual property-related considerations outlined below, of

which we have either been notified, or for which potential claims could be brought against us or our subsidiaries in the future, fulfill the criteria for recording a provision.

We are subject to an increasing number of product-related disputes. Our product liability claims often involve highly complex issues related to medical causation, correctness and completeness of product information (Summary of Product Characteristics/package leaflet) as well as label warnings and reliance thereon, scientific evidence and findings, actual and provable defectiveness and injury, and other matters. These complexities vary from matter to matter. As of December 31, 2025, none of these claims fulfill the criteria for recording a provision.

We are currently subject to certain claims by or on behalf of our shareholders. As of December 31, 2025, these claims do not fulfill the criteria for recording a provision.

Substantially all of our contingent liabilities are subject to significant uncertainties and, therefore, determining the likelihood of a loss and/or the measurement of any loss can be complex. Consequently, we are unable to estimate the range of reasonably possible loss. Our assessments, which result from a complex series of judgments about future events and uncertainties, are based on estimates and assumptions that have been deemed reasonable by management, but that may prove to be incomplete or inaccurate, and unanticipated events and circumstances may occur that might cause us to change those estimates and assumptions. We currently do not believe that any of these matters will have a material adverse effect on our financial position, and will continue to monitor the status of these and other claims that may arise. However, we could incur judgments, enter into settlements or revise our expectations regarding the outcome of matters, which could have a material adverse effect on our results of operations and/or our cash flows in the period in which the amounts are accrued or paid. We will continue to evaluate whether, if circumstances were to change in the future, the recording of a provision may be needed and whether potential indemnification entitlements exist against any such claim.

Certain pending matters to which we are a party are discussed below.

Moderna Proceedings

Germany

Infringement Proceedings – EP’949 and EP’565

In August 2022, Moderna filed a lawsuit against us and Pfizer and our wholly owned subsidiaries, BioNTech Manufacturing GmbH, BioNTech Europe GmbH and BioNTech Manufacturing Marburg GmbH, Pfizer Manufacturing Belgium NV, Pfizer Ireland Pharmaceuticals and Pfizer Inc. in the Düsseldorf Regional Court alleging Comirnaty’s infringement of two European patents, 3590949B1, or EP’949, and 3718565B1, or EP’565. With respect to EP’565, on November 7, 2023, the Opposition Division of the EPO revoked EP’565 after a one-day oral hearing held in the co-pending opposition proceeding, and on December 7, 2023, it issued the written decision revoking EP’565. On February 7, 2024, Moderna appealed the Opposition Division’s revocation decision on EP’565. An oral hearing on Moderna’s appeal was held on January 27, 2026, and at the conclusion of this hearing, the Technical Boards of Appeal affirmed the revocation of EP’565. With respect to EP’949, on December 8, 2023, the Opposition Division issued a preliminary opinion noting that it believes EP’949 is likely invalid. As a result of those developments in the EPO proceedings, the Düsseldorf Regional Court postponed its hearing on infringement with respect to EP’949, originally scheduled for December 12, 2023, to January 21, 2025. On May 16, 2024, the EPO Opposition Division decided that EP’949 is valid, in amended form, and issued its written decision regarding the same on July 8, 2024. We appealed this decision, and the appeal is currently pending, with an oral hearing scheduled for September 2026. The Düsseldorf Regional Court held an infringement hearing on January 21, 2025, and on March 5, 2025, the Düsseldorf Regional Court issued a first-instance decision declining to stay the infringement proceedings and finding infringement of EP’949 by us and Pfizer. We and Pfizer have appealed the Düsseldorf Regional Court’s infringement decision, and the appeal is currently pending. The court has not ruled on the invalidity of EP’949, which will be decided in a next step by the

EPO in the opposition appeal proceedings. Moderna has not yet taken steps to enforce the Düsseldorf Regional Court's first-instance decision on infringement.

United Kingdom

In August 2022, Moderna filed a lawsuit asserting Comirnaty's infringement of EP'949 and EP'565 against us and our wholly owned subsidiaries, BioNTech Manufacturing GmbH, BioNTech Europe GmbH and BioNTech Manufacturing Marburg GmbH, and Pfizer Limited, Pfizer Manufacturing Belgium NV and Pfizer Inc. in the Business and Property Courts of England and Wales, in the UK High Court. In September 2022, we and Pfizer filed a revocation action in the Business and Property Courts of England and Wales requesting revocation of EP'949 and EP'565.

The UK High Court held a trial between April 22, 2024, and May 21, 2024. On July 2, 2024, the UK High Court released two judgments. The first judgment concerns the validity of EP'949 and EP'565. In this first judgment, the UK High Court found that EP'565 is invalid and therefore not infringed, while EP'949 is valid and infringed. The second judgment concerns whether Moderna's October 2020 commitment not to "enforce [its] COVID-19 related patents against those making vaccines intended to combat the pandemic," or the Patent Pledge, amounted to a consent under UK law to carry out any acts that would otherwise amount to patent infringement. With respect to this judgment, the UK High Court found that Moderna's Patent Pledge amounted to consent to carry out activities that might otherwise infringe its patents prior to March 2022, but not after March 2022.

The UK High Court held a hearing on September 25, 2024, during which the Court granted Pfizer and BioNTech permission to appeal its judgment regarding the validity of EP'949, and declined Moderna's permission to appeal its judgment regarding validity of EP'565. On October 16, 2024, Moderna sought permission from the UK Appeals Court to appeal the EP'565 judgment. On November 11, 2024, the UK Appeals Court denied Moderna's application to appeal; accordingly, the UK designation of EP'565 is finally revoked with no further opportunity to appeal in UK. No party sought permission to appeal the UK High Court's judgment on the patent pledge.

The UK Court of Appeal held an oral hearing on the appeal of EP'949 on July 10-11, 2025. On August 1, 2025, the UK Court of Appeal issued a judgment agreeing with the UK High Court that EP '949 is valid, and dismissed our appeal. We applied for permission to appeal this decision to the UK Supreme Court, and on December 8, 2025, the UK Supreme Court denied permission to appeal. Accordingly, the UK designation of EP '949 is valid and infringed. However, Moderna has not yet taken steps to enforce this final judgment on infringement. Additionally, EP '949 is currently subject to opposition proceedings at the EPO. The Opposition Division initially issued a preliminary opinion noting that EP '949 is invalid, but in May 2024, issued a first-instance decision finding EP '949 valid. BioNTech and Pfizer appealed this first-instance decision, which is currently pending. The oral hearing in this appeal is scheduled for September 2026.

United States

U.S. District Court Litigation

In August 2022, Moderna filed a lawsuit in the U.S. District Court for the District of Massachusetts against us and our wholly owned subsidiaries BioNTech Manufacturing GmbH and BioNTech US Inc. and Pfizer Inc. alleging Comirnaty's infringement of U.S. Patent Nos. 10,898,574; 10,702,600 and 10,933,127 and seeking monetary relief. On April 12, 2024, the U.S. District Court for the District of Massachusetts stayed the litigation pending resolution of the inter partes review of U.S. Patent Nos. 10,702,600 and 10,933,127.

Inter Partes Review

In August 2023, Pfizer and we filed petitions seeking inter partes review of U.S. Patent Nos. 10,702,600 and 10,933,127 before the United States Patent Trial and Appeal Board, or the PTAB. On March 6, 2024, the PTAB issued decisions instituting *inter partes* review proceedings on all challenged claims of U.S. Patent Nos. 10,702,600 and 10,933,127. An oral hearing on the merits occurred on December 10, 2024. On March 5, 2025,

the PTAB found all challenged claims of Moderna's U.S. Patent Nos. 10,933,127 and 10,702,600 to be unpatentable and thus invalid. Moderna appealed this decision on May 6, 2025.

Netherlands

In September 2022, Moderna filed a lawsuit against us and our wholly owned subsidiary BioNTech Manufacturing GmbH and Pfizer B.V., Pfizer Export B.V., C.P. Pharmaceuticals International C.V. and Pfizer Inc. in the District Court of The Hague alleging Comirnaty's infringement of EP'949 and EP'565. The District Court of the Hague held a hearing on October 6, 2023, on infringement and validity with respect to EP'949. On December 6, 2023, the Court found EP'949 to be invalid. On March 5, 2024, Moderna appealed this decision, and the appeal is pending. A hearing on the EP'949 appeal has been set for September 22, 2025, with a decision expected on or around March 31, 2026. The EP'565 case has been stayed pending the outcome of Moderna's appeal of the Opposition Division's revocation of EP'565.

Ireland

In May 2023, Moderna filed a lawsuit against us and our wholly owned subsidiary BioNTech Manufacturing GmbH, Pfizer Inc., Pfizer Healthcare Ireland, Pfizer Ireland Pharmaceuticals, and C.P. Pharmaceuticals International C.V. alleging Comirnaty's infringement of EP'949 and EP'565 in the High Court of Ireland. On February 26, 2024, the High Court of Ireland stayed the lawsuit pending the final determination of the EPO opposition proceedings for EP'949 and EP'565 (in each case including any appeals).

Belgium

In May 2023, Moderna filed a lawsuit against us, our wholly owned subsidiary BioNTech Manufacturing GmbH, Pfizer Inc. and Pfizer Manufacturing Belgium alleging Comirnaty's infringement of EP'949 and EP'565 in the Brussels Dutch-speaking Enterprise Court. On May 29, 2024, the parties filed a joint request to stay the proceedings, which was entered by the Enterprise Court.

All of the above proceedings are currently pending.

We believe we have strong defenses against the allegations claimed relative to each of the patents and intend to vigorously defend ourselves in the proceedings mentioned above. However, our analysis of Moderna's claims is ongoing and complex, and we believe the outcome of the suit remains substantially uncertain. Taking into account discussions with our external lawyers, we do not consider the probability of an outflow of resources to be sufficient to recognize a provision at the balance sheet date. In our opinion, these matters constitute contingent liabilities as of the balance sheet date. However, it is currently impractical for us to estimate with sufficient reliability the respective contingent liabilities.

Arbutus and Genevant Proceedings

In April 2023, Arbutus Biopharma Corp., or Arbutus, and Genevant Sciences GmbH, or Genevant, filed a lawsuit against Pfizer and us in the U.S. District Court for the District of New Jersey alleging that Pfizer and we have infringed the following patents owned by Arbutus: U.S. Patent Nos. 9,504,651; 8,492,359; 11,141,378; 11,298,320; and 11,318,098, through the use of Genevant's lipid nanoparticle technology and methods for producing such lipids in Comirnaty, and seeking monetary relief. This proceeding is currently pending.

We believe we have strong defenses against the allegations claimed relative to each of the patents and intend to vigorously defend ourselves in the lawsuit mentioned above. However, our analysis of Arbutus and Genevant's claims is ongoing and complex, and we believe the outcome of the suit remains substantially uncertain. Taking into account discussions with our external lawyers, we do not consider the probability of an outflow of resources to be sufficient to recognize a provision at the balance sheet date. In our opinion, these matters constitute contingent liabilities as of the balance sheet date. However, it is currently impractical for us to estimate with sufficient reliability the respective contingent liabilities.

GlaxoSmithKline Proceedings

In April 2024, GlaxoSmithKline Biologicals SA and GlaxoSmithKline LLC, or GSK, filed a lawsuit against Pfizer and us and our wholly owned subsidiaries BioNTech Manufacturing GmbH and BioNTech US Inc. in the U.S. District Court for the District of Delaware alleging that the cationic lipid used in Comirnaty infringes U.S. Patent Nos. 11,638,693; 11,638,694; 11,666,534; 11,766,401; and 11,786,467; and seeking monetary relief. On August 14, 2024, GSK filed an amended complaint to assert infringement of three additional patents, U.S. Patent Nos. 11,759,422; 11,655,475; and 11,851,660. A trial is scheduled to occur in June 2027. This proceeding is currently pending.

Ireland

In July 2025, GlaxoSmithKline Biologicals SA filed a lawsuit against our wholly owned subsidiary BioNTech Manufacturing GmbH, Pfizer Ireland Pharmaceuticals Unlimited Company, and Pfizer Healthcare Ireland Unlimited Company, alleging Comirnaty's infringement of European Patent Nos. 2,590,626, 4,066,856, and 4,226,941 in the High Court of Ireland. This proceeding is currently pending.

Unified Patent Court

In July 2025, GlaxoSmithKline Biologicals SA filed two lawsuits against BioNTech SE, BioNTech Europe GmbH, BioNTech Manufacturing GmbH, and BioNTech Manufacturing Marburg GmbH, as well as 26 Pfizer entities, in the Unified Patent Court (Hague Division). In the first lawsuit, GSK alleges Comirnaty's infringement of European Patent No. 2,590,626 ("EP 626"), and in the second lawsuit, GSK alleges Comirnaty's infringement of European Patent Nos. 4,066,856 ("EP 856") and 4,226,941 ("EP 941"). Oral hearings wherein the UPC will hear the parties' arguments regarding infringement and invalidity of EP 626, EP 856, and EP 941 have been scheduled for September/October 2026. This proceeding is currently pending.

United Kingdom

In September 2025, we and Pfizer filed a revocation action against GlaxoSmithKline Biologics S.A. in the Business and Property Courts of England and Wales, in the U.K. High Court, requesting revocation of European Patent Nos. 2,590,626, 4,066,856, and 4,226,941. On October 7, 2025, GSK filed a defense and counterclaim for infringement against BioNTech SE and BioNTech Manufacturing GmbH, alleging Comirnaty's infringement of European Patent Nos. 2,590,626, 4,066,856, and 4,226,941. A trial has been scheduled for February 2027. This proceeding is currently pending.

We believe we have strong defenses against the allegations claimed relative to each of the patents and intend to vigorously defend ourselves in the lawsuit mentioned above. However, our analysis of GlaxoSmithKline's claims is ongoing and complex, and we believe the outcome of the suit remains substantially uncertain. Taking into account discussions with our external lawyers, we do not consider the probability of an outflow of resources to be sufficient to recognize a provision at the balance sheet date. In our opinion, these matters constitute contingent liabilities as of the balance sheet date. However, it is currently impractical for us to estimate with sufficient reliability the respective contingent liabilities.

Promosome Proceedings

In January 2025, Promosome LLC, or Promosome, filed a lawsuit against us and Pfizer in the Unified Patent Court, or UPC, Munich Division, alleging that Comirnaty infringes EP 2 401 365 and seeking monetary relief. An oral hearing wherein the UPC will hear the parties' arguments regarding infringement and invalidity has been scheduled for May 12-13, 2026. This proceeding is currently pending.

We believe we have strong defenses against the allegations claimed relative to the patent and intend to vigorously defend ourselves in the lawsuit mentioned above. However, our analysis of Promosome's claim is ongoing and complex, and we believe the outcome of the suit remains substantially uncertain. Taking into account discussions with our external lawyers, we do not consider the probability of an outflow of resources to

be sufficient to recognize a provision at the balance sheet date. In our opinion, this matter constitute a contingent liabilities as of the balance sheet date. However, it is currently impractical for us to estimate with sufficient reliability the respective contingent liability.

CureVac Proceedings

Although the CureVac proceedings no longer qualify as contingent liabilities in accordance with IAS 37 as of December 31, 2025, we summarize below the current status of the CureVac proceedings to enhance comparability with our prior-year disclosure.

Infringement Proceedings – EP'122, DE'961, DE'974, DE'575, and EP'668

In July 2022, CureVac AG, or CureVac, filed a lawsuit against us and our wholly owned subsidiaries, BioNTech Manufacturing GmbH and BioNTech Manufacturing Marburg GmbH, in the Düsseldorf Regional Court, alleging Comirnaty's infringement of one European patent, EP1857122B1, or EP'122, and three Utility Models DE202015009961U1, DE202015009974U1, and DE202021003575U1. In August 2022, CureVac added European Patent EP3708668B1, or EP'668, to its German lawsuit.

On August 15, 2023, the Düsseldorf Regional Court held a hearing on infringement with respect to all five IP rights. At the hearing, the Court stated it would render its infringement ruling with respect to EP'122 on December 28, 2023. On September 28, 2023, the Court issued orders suspending its infringement rulings with respect to the remaining four IP rights (DE'961, DE'974, DE'575, and EP'668) pending validity decisions in the DE'961, DE'974, and DE'575 cancellation proceedings before the German Patent and Trademark Office and in the EP'668 opposition proceedings before the Opposition Division of the European Patent Office, or the EPO. In the September 28th orders, the Court explained that it was suspending its infringement rulings until validity decisions are reached, while contemporaneously noting concerns regarding the validity of DE'961, DE'974, DE'575, and EP'668. After EP'122 was declared invalid in the first-instance nullity proceedings by the Federal Patent Court on December 19, 2023 (see below), on December 27, 2023, the Düsseldorf Regional Court canceled the December 28, 2023 decision date and stayed the infringement proceedings as to EP'122 until a final appellate decision is rendered as to the validity of EP'122 by the Federal Court of Justice. On June 7, 2024, CureVac waived DE'575 and withdrew this utility model from the infringement proceedings.

On July 1, 2024, the EPO Opposition Division issued a preliminary opinion noting that it believes EP'668 is likely invalid. The EPO Opposition Division held an oral hearing regarding the validity of EP'668 between March 25-27, 2025. At the conclusion of this hearing, the Opposition Division upheld EP'668 in amended form, but only after finding that the alleged technical effect – increased protein expression – was not achieved across the broad scope of the amended claim. The written decision by the Opposition Division to uphold EP'668 in amended form was issued on July 11, 2025, and we and Pfizer appealed this written decision. An oral hearing with respect to infringement of EP'668 was scheduled by the Düsseldorf Regional Court for July 1, 2025, but it was rescheduled for January 27, 2026. On July 3, 2025, GlaxoSmithKline Biologicals SA filed a request seeking to intervene in the EP'668 infringement proceedings. This request to intervene was to be heard at the January 27, 2026 hearing. On December 15, 2025, we completed our acquisition of CureVac. On December 19, 2025, CureVac withdrew its claims of infringement with respect to EP '122, DE '961, DE '974, and EP '668. As a result of CureVac's withdrawal of its claims of infringement, the January 27, 2026 hearing is cancelled and these infringement cases have been dismissed.

Infringement Proceedings – EP'755, DE'123, and DE'130

In July 2023, CureVac SE filed a second lawsuit against us and our wholly owned subsidiaries, BioNTech Manufacturing GmbH and BioNTech Manufacturing Marburg GmbH, in the Düsseldorf Regional Court, alleging Comirnaty's infringement of one European patent, EP4023755B1, or EP'755, and two Utility Models DE202021004123U1, and DE202021004130U1. On June 7, 2024, CureVac waived DE'123 and withdrew this utility model from the infringement proceedings. The Court has stayed the infringement proceedings with respect to DE'130 pending a validity decision in the co-pending cancellation proceeding before the German Patent and

Trademark Office. On July 24, 2024, the EPO Opposition Division issued a preliminary opinion noting that it believes EP'755 is likely invalid, and held a three-day oral hearing beginning on May 13, 2025. At the conclusion of the hearing, the EPO Opposition Division upheld EP'755 in amended form. We appealed the Opposition Division's written decision upon its issuance. A hearing on infringement with respect to EP'755 was to occur in the Düsseldorf Regional Court on July 1, 2025, but this was rescheduled to January 27, 2026. On July 3, 2025, GlaxoSmithKline Biologicals SA filed a request to intervene in the EP'755 infringement proceedings. This request to intervene was to be heard at the January 27, 2026 hearing. On December 15, 2025, we completed our acquisition of CureVac. On December 19, 2025, CureVac withdrew its claims of infringement with respect to EP '755 and DE '130. As a result of CureVac's withdrawal of its claims of infringement, the January 27, 2026 hearing has been cancelled and these infringement cases have been dismissed.

Nullity Proceedings – EP'122

In September 2022, we filed a nullity action in the Federal Patent Court of Germany seeking a declaration that EP'122 is invalid. In April 2023, the Federal Patent Court of Germany issued a preliminary opinion in the EP'122 nullity action in support of the validity of EP'122. The preliminary opinion does not address any infringement of EP'122. The preliminary opinion is a preliminary assessment by the court of the merits of a claim, and is non-binding. On December 19, 2023, the Federal Patent Court held an oral hearing, after which it nullified EP'122. On April 25, 2024, the Federal Patent Court issued a judgment containing its written reasons for nullifying EP'122. On May 6, 2024, CureVac appealed the judgment, which is currently pending. On December 15, 2025, we completed our acquisition of CureVac. As of this date, CureVac became a wholly-owned subsidiary of BioNTech. As a result, the parties to these proceedings are no longer adverse. An oral hearing on this appeal is scheduled for July 2026.

Cancellation Proceedings – DE'961, DE'974, and DE'575

In November 2022, we filed cancellation actions seeking the cancellation of the three German Utility Models in the German Patent and Trademark Office. On December 20, 2023, the German Patent and Trademark Office issued a preliminary opinion that DE'974 is likely to be cancelled. On January 23, 2024, the German Patent and Trademark Office issued a preliminary opinion that DE'961 is likely to be cancelled. Both preliminary opinions are based on invalidity pursuant to para. 1 (2) no. 5 Utility Model Act. On March 7, 2024, the German Patent and Trademark Office issued a preliminary opinion that DE'575 is likely to be cancelled. On June 6, 2024, CureVac submitted a written statement to the German Patent and Trademark Office waiving DE'575. On June 12, 2024, we withdrew our request for cancellation of DE'575. On June 25 and 26, 2024, the German Patent and Trademark Office heard oral arguments regarding DE'961 and DE'974, and at the conclusion of the hearing on June 26, 2024, confirmed that both DE'961 and DE'974 were cancelled. In November 2024, the German Patent and Trademark Office issued its written decisions cancelling DE'961 and DE'974. CureVac has filed an appeal in both cancellation proceedings, which are currently pending.

Cancellation Proceedings– DE'123 and DE'130

In November 2023, we filed cancellation actions seeking the cancellation of German Utility Models DE'123 and DE'130 in the German Patent and Trademark Office. On June 6, 2024, CureVac submitted a written statement to the German Patent and Trademark Office waiving DE'123. On June 12, 2024, we withdrew our request for cancellation of DE'123. On December 5, 2024, the German Patent and Trademark Office issued a preliminary opinion that DE'130 is likely to be cancelled. An oral hearing regarding the validity of DE'130 before the German Patent and Trademark Office was scheduled for March 10, 2026, but a postponement has been requested. As a result, the March 10, 2026 hearing will not go forward.

Other Financial Commitments

The other financial commitments were as follows:

(in millions €)	December 31, 2025	December 31, 2024
Commitments under purchase agreements for property, plant and equipment	165.6	186.7
Contractual obligation to acquire intangible assets	851.2	1,193.1
Total	**1,016.8**	**1,379.8**

Contractual obligations to acquire intangible assets exist in connection with in-licensing and research and development collaborations. We have entered into obligations to make milestone payments once specific targets have been reached. Provided that all of the milestone events are achieved, we would be obligated to pay up to €851.2 million as of December 31, 2025, (€1,193.1 million as of December 31, 2024) in connection with the acquisition of intangible assets. The amounts shown represent the maximum payments to be made, and it is unlikely that they will all fall due. We have excluded any milestone payments subject to in-licensing agreements with Biotheus as such payments are treated as intra-group transactions following the acquisition of Biotheus, which closed in January 2025. Commitments from the acquisition of Biotheus are disclosed under Note 5.

The amounts and the dates of the actual payments may both vary considerably from those stated in the table, since the achievement of the conditions for payment is possible but uncertain. Other financial obligations from possible future sales-based milestone and license payments were not included in the table above.

The expected maturities of payment obligations under purchase agreements for property, plant and equipment and contractual obligations to acquire intangible assets are as follows:

Year ended December 31, 2025

(in millions €)	Less than 1 year	1 to 5 years	More than 5 years	Total
Commitments under purchase agreements for property, plant and equipment	101.6	64.0	—	165.6
Contractual obligation to acquire intangible assets	114.5	396.3	340.4	851.2
Total	**216.1**	**460.3**	**340.4**	**1,016.8**

Other financial obligations were disclosed at nominal value.

The Group has lease contracts that have not yet commenced as at December 31, 2025. There are no lease payments for these non-cancellable lease contracts within one year. The future undiscounted lease payments for these non-cancellable lease contracts are €7.5 million within five years and €11.1 million thereafter.

19 Other Non-Financial Liabilities

(in millions €)	December 31, 2025	December 31, 2024
Liabilities to employees	128.9	99.8
Government and similar grants	108.8	85.2
Liabilities from share-based payment arrangements	47.3	26.6
Liabilities from wage taxes and social securities expenses	39.6	22.7
Other	17.3	22.6
Total	**341.9**	**256.9**
Total current	237.7	169.4
Total non-current	104.2	87.5

Other non-financial liabilities of €108.8 million as of December 31, 2025 are related to funds received. The received funds for which no related expense has been recognized during the year ended December 31, 2025, were deferred and recognized in the other non-financial liabilities. The government grants and similar grants are mainly related to assets such as buildings and equipment. The funding will be recognized in profit or loss within other operating income over the respective useful life of the underlying assets, see Note 2.3.10. The grants are subject to conditions such as incurring eligible expenses.

Other non-financial Liabilities from share-based payment arrangements include a liability amounting to €15.0 million relating to share-based payment programs that were issued by CureVac to its employees prior to the acquisition date. The cash settlement took place in January 2026.

20 Leases

20.1 Amounts Recognized in the Consolidated Statements of Financial Position

Right-of-Use Assets

The following table presents the movements in right-of-use assets during the years ended December 31, 2025 and 2024 and their amounts within the consolidated statements of financial position as of the dates indicated:

(in millions €)	Land and buildings	Other operating equipment	Total
As of January 1, 2024	**209.8**	**4.6**	**214.4**
Additions	67.2	7.2	**74.4**
Depreciation	(42.2)	(3.4)	**(45.6)**
Currency effects	3.3	1.7	**5.0**
Other	0.1	(0.2)	**(0.1)**
As of December 31, 2024	**238.2**	**9.9**	**248.1**
Acquisition of subsidiaries and businesses	37.1	1.7	**38.8**
Additions	8.8	0.2	**9.0**
Depreciation	(40.8)	(1.9)	**(42.7)**
Impairment	(14.5)	—	**(14.5)**
Currency effects	(10.0)	(1.6)	**(11.6)**
Other	(16.6)	(0.3)	**(16.9)**
As of December 31, 2025	**202.2**	**8.0**	**210.2**

Lease Liability

The following amounts are included in lease liabilities, loans and borrowings as of the dates indicated:

(in millions €)	December 31, 2025	December 31, 2024
Current	45.0	39.5
Non-current	185.3	214.7
Total	**230.3**	**254.2**

20.2 Amounts Recognized in the Consolidated Statements of Profit or Loss

Total Depreciation and Impairment Charge of Right-of-Use Assets

	Years ended December 31,		
(in millions €)	2025	2024	2023
Land and buildings	55.3	42.2	40.7
Production facilities	—	—	3.0
Other operating equipment	1.9	3.4	1.5
Total depreciation and impairment charge	**57.2**	**45.6**	**45.2**
Interest on lease liabilities	8.2	8.6	5.7
Expense related to short-term leases and leases of low-value assets	43.3	43.3	58.9
Total amounts recognized in profit or loss	**108.7**	**97.5**	**109.8**

20.3 Amounts Recognized in the Consolidated Statements of Cash Flows

During the year ended December 31, 2025, the total cash outflow for leases amounted to €39.6 million (during the year ended December 31, 2024: €43.6 million; during the year ended December 31, 2023: €46.0 million).

20.4 Extension Options

We have several lease contracts that include extension options. These options are negotiated by management to provide flexibility in managing the leased asset portfolio and align with the need of the business. Management exercises judgment in determining whether these extension options are reasonably certain to be exercised. The undiscounted potential future lease payments, which relate to periods after the exercise date of renewal options and are not included in lease liabilities, amount to up to €253.6 million as of December 31, 2025, considering terms up until 2049 (as of December 31, 2024: €152.1 million considering terms up until 2049).

21 Related Party Disclosures

21.1 Parent and Ultimate Controlling Party

ATHOS KG, Holzkirchen, Germany is the sole shareholder of AT Impf GmbH, Munich, Germany and beneficial owner of our ordinary shares. ATHOS KG via AT Impf GmbH has de facto control over BioNTech based on its substantial shareholding, which practically enables it to exercise the majority of voting rights to pass resolutions at our Annual General Meeting, or AGM.

21.2 Transactions with Key Management Personnel

Our key management personnel have been defined as the members of the Management Board and the Supervisory Board. Key management personnel compensation is comprised of the following:

	Years ended December 31,		
(in millions €)	**2025**	**2024**	**2023**
Management Board[1]	**6.9**	**13.0**	**8.3**
Fixed compensation	3.8	4.0	3.9
Fringe benefits	0.3	0.2	—
Short-term incentive – first installment[2]	2.1	0.8	0.7
Short-term incentive – second installment[2],[3]	—	0.6	1.0
Other variable compensation[4]	0.9	1.3	0.8
Share-based payments (incl. long-term incentive)[5]	(0.2)	6.1	1.9
Supervisory Board	**1.2**	**0.9**	**0.6**
Total compensation of key management personnel	**8.1**	**13.9**	**8.9**

(1) During 2025, Jens Holstein and Ryan Richardson stepped down from the Management Board effective July 1, 2025, and October 1, 2025, respectively. Therefore, their compensation up to the date of their departure dates is presented on a pro-rata basis in this table. Following his departure, and thus as a former Management Board member, Ryan Richardson received a severance payment of €687,500 in accordance with his separation agreement, which is not included in this table. During 2024, Sean Marett retired from the Management Board with effect as of July 1, 2024. His compensation until his departure date is also presented a pro-rata basis in this table. The following compensation pursuant to his separation agreement subsequent to his departure date and thus as former Management Board member in 2024 are not included in this table: a severance payment of €275,000, an additional payment of €39,000 in respect of the 2024 STI, a grant of 5,760 phantom options in respect of the 2024 LTI and a payment of €477,030 in relation to his initial 12-months consultancy agreement.

(2) The structure of the STI payout was changed with the adoption of the Compensation System 2024. Under the Compensation System 2024, 100% of the STI relating to the year ended December 31, 2025 will be paid out in the month after the approval of the 2025 consolidated financial statements. In contrast, under the Compensation System 2021 / 2022, 50% of the STI relating to the year ended December 31, 2024 was paid out in the month after the approval of the 2024 consolidated financial statements and the remaining 50% will be paid out (and adjusted) in March 2026.

(3) The fair value of the second installment of the short-term incentive compensation which has been classified as a cash-settled share-based payment arrangement was determined pursuant to the regulations of IFRS 2 “Share-based Payments”. This table shows the pro-rata share of personnel expenses for the respective financial year, which are recognized over the award’s vesting period beginning as of the service commencement date (date when entering or renewing service agreements) until each separate determination date and are remeasured until settlement date.

(4) Represents for the financial year 2025 the cash payment related to the one-time signing bonus granted to Ramón Zapata as part of his appointment to the Management Board. For 2024, the amount represents the cash payment related to the one-time signing bonus granted to Annemarie Hanekamp as part of her appointment to the Management Board, designed to compensate her for lower bonus payments that she would receive as part of her compensation package with BioNTech and to recognize and appreciate her move to BioNTech. For 2023, the amount represents the one-time signing cash payment related to James Ryan’s appointment to the Management Board to provided compensation in lieu of participation in the LTI 2023 program and the one-time special cash payment related to Jens Holstein to honor his contribution to BioNTech’s extraordinary financial performance.

(5) The fair value of the share-based payments was determined pursuant to the regulations of IFRS 2 “Stock-based Payments”. This table shows the pro-rata share of personnel expenses resulting from stock-based compensation for the respective financial year. During the years ended December 31, 2024 and 2023 the amounts included expenses derived from a one-time signing bonus granted to Jens Holstein as of his appointment to the Management Board in the form of 4,246 phantom shares as well as expenses derived from the one-time signing bonus granted to Annemarie Hanekamp as of her appointment to the Management Board in the form of shares in the amount of €500,000.

The amounts disclosed in the table are the amounts recognized as an expense during the period.

Management Board members participated in our ESOP program (see Note 16). Out of the 5,152,410 option rights granted to our Management Board under the ESOP 2018 program, 4,921,630 options were exercised during the year ended December 31, 2022. The remaining 230,780 option rights were exercised by Sean Marett in May 2023. During the year ended December 31, 2024, our CEO Prof. Ugur Sahin, M.D., exercised all 4,374,963 options granted under the CEO Grant 2019 and Members of the Management Board, who participated in the LTI 2020 Board Program, exercised 209,128 options in August 2024 while 38,968 vested options are still outstanding as of December 31, 2025 (see Note 16). Options granted under the LTI 2021 Board

Program fully vested in May 2025 but are currently not exercisable due to an exercise price of €157.64 ($185.23 converted into Euros using the exchange rate published by the German Central Bank from December 31, 2025) for the May 12, 2021 Grant for all Board Members except Jens Holstein and €159.00 ($186.83 converted into Euros using the exchange rate published by the German Central Bank from December 31, 2025) for Jens Holstein's May 17, 2021 Grant. Options granted under the LTI 2021 Board Program will be settled in cash if they become exercisable in the future. For further information regarding outstanding options for each Management Board member from LTI 2021-2025 Board Programs, see Note 16.

21.3 Related Party Transactions

The total amount of transactions with ATHOS KG or entities controlled by it was as follows for the periods indicated:

	Years ended December 31,		
(in millions €)	**2025**	**2024**	**2023**
Purchases of various goods and services from entities controlled by ATHOS KG	1.4	0.2	0.3
Total	**1.4**	**0.2**	**0.3**

The amounts disclosed in the table are the amounts recognized as an expense during the period.

As of December 31, 2025 and 2024, there were no outstanding balances of transactions with ATHOS KG or entities controlled by them.

A number of individuals in key positions can control or exercise significant influence over BioNTech SE. There were no business relationships with individuals in key positions during the year ended December 31, 2025.

22 Events After the Reporting Period

Bayer/Monsanto

In January 2026, Bayer CropScience LLC, Monsanto Company, and Monsanto Technology, LLC, or collectively, Bayer, filed a lawsuit against us and Pfizer in the United States District Court for the District of Delaware, alleging that COMIRNATY® infringes U.S. Patent No. 7,741,118 and seeking monetary relief. This proceeding is currently pending.

We believe we have strong defenses against the allegations claimed relative to the patent and intend to vigorously defend ourselves in the lawsuit mentioned above. However, our analysis of Bayer and Monsanto's claims is ongoing and complex, and we believe the outcome of the suit remains substantially uncertain. Taking into account discussions with our external lawyers, we do not consider the probability of an outflow of resources to be sufficient to recognize a provision at the balance sheet date. In our opinion, the matter constitutes a contingent liability as of the balance sheet date. However, it is currently impractical for us to estimate with sufficient reliability the respective contingent liability.

Kylie Jimenez – Appointment to Management Board as Chief People Officer

With effect as of March 1, 2026 the Supervisory Board appointed Kylie Jimenez to the Management Board as Chief People Officer (CPO). The appointment is in line with BioNTech's strategy to become a multi-product oncology company by 2030 and underscores the importance of its global, highly skilled workforce in achieving this objective. In the newly created Management Board role, Kylie Jimenez will be responsible for shaping and

leading BioNTech's people strategy and its execution in alignment with our priorities and business goals. She will focus on attracting, developing and retaining talents and strengthening an inclusive culture. She will be based in our headquarters in Mainz, Germany.

BioNTech's Lawsuit Against Moderna

In February 2026, we filed a lawsuit against ModernaTX, Inc., Moderna, Inc., and Moderna US, Inc. ("Moderna") in the United States District Court for the District of Delaware, alleging that Moderna's mNEXSPIKE COVID-19 vaccine infringes our U.S. Patent No. 12,133,899 and seeking monetary relief. This proceeding is currently pending.

Corporate Update

Our co-founders Prof. Ugur Sahin, M.D., (CEO) and Prof. Özlem Türeci, M.D (CMO) plan for an independent company to be established and led by them. The new company with distinct resources, operations and funding options will advance next-generation mRNA innovations. We plan to contribute related rights and mRNA technologies to the new company to enable and support the prioritized development of next-generation mRNA innovations with disruptive potential. With both companies focusing on their respective strategic priorities, we expect to maximize value for patients and shareholders alike. Our CEO and CMO will transition into the management of their new company by the end of 2026 after their current service agreements end. Our Supervisory Board has initiated an executive search to identify successors for the positions to ensure a smooth transition and the seamless execution of our strategy.