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

FORM 20-F

(Mark One)

☐ **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, 2019

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)

An der Goldgrube 12

D-55131 Mainz

Germany

(Address of principal executive offices)

Prof. Ugur Sahin, M.D.,

c/o BioNTech SE

An der Goldgrube 12

D-55131 Mainz

Germany

+49 6131-9084-0 (Tel), +49 6131 9084-390 (Fax), info@biontech.de (E-mail)
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

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 as of March 31, 2020, no par value: 226,779,744

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 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 ("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 "$" mean U.S. dollars and all references to "€" mean Euros and all references in this Annual Report to "k$" and "k€" refer to thousands of U.S. dollars and thousands of Euros, respectively.

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 initiation, timing, progress, results, and cost of our research and development programs and our current and future preclinical studies and clinical trials, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available and our research and development programs;
- the timing of and our ability to obtain and maintain regulatory approval for our product candidates;
- our ability to identify research opportunities and discover and develop investigational medicines;
- the ability and willingness of our third-party collaborators to continue research and development activities relating to our development candidates and investigational medicines;
- our expectations regarding the size of the patient populations for our product candidates, if approved for commercial use;
- the impact of the COVID-19 pandemic on our development programs, supply chain, collaborators and financial performance;
- claims for personal injury or death arising from the use of products and product candidates produced by us;
- our estimates of our expenses, ongoing losses, future revenue and capital requirements and our needs for or ability to obtain additional financing;
- our ability to identify, recruit and retain key personnel;
- our and our collaborators' ability to protect and enforce our intellectual property protection for our proprietary and collaborative product candidates, and the scope of such protection;
- the development of and projections relating to our competitors or our industry;
- our ability to commercialize our product candidates, if approved;
- the pricing and reimbursement of our investigational medicines, if approved;
- the rate and degree of market acceptance of our investigational medicines;
- the amount of and our ability to use net operating losses and research and development credits to offset future taxable income;
- our ability to manage our development and expansion;
- regulatory developments in the United States and foreign countries;
- our ability to manufacture our product candidates with advantages in turnaround times or manufacturing cost;
- our ability to implement, maintain and improve effective internal controls;
- the ability to satisfy the conditions to the merger of Endor Lights, Inc., our wholly owned subsidiary, with Neon Therapeutics, Inc., in an all-stock transaction, or the Merger, including the ability to obtain the shareholder approval, on the proposed terms and timeframe;

- the ability to realize the anticipated benefits of transactions related to the Merger and other acquisitions, restructuring activities, including in connection with the Merger, or other initiatives in a timely manner or at all;
- the risk of unanticipated costs, liabilities or delays relating to the Merger, including the outcome of any legal proceedings relating to the Merger;
- risks relating to expectations regarding the capitalization, resources and ownership of the consolidated company;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act and a foreign private issuer; 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. Selected Consolidated Financial Data

The tables below present the selected consolidated financial data as of the dates and for the periods indicated. The selected consolidated financial data as of December 31, 2019 and December 31, 2018 as well as for the years ended December 31, 2019, December 31, 2018 and December 31, 2017 have been derived from our audited consolidated financial statements presented elsewhere in this Annual Report. Our audited consolidated financial statements have been prepared in accordance with the International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB, and have been audited by our independent registered public accounting firm. The selected consolidated financial data as of December 31, 2017 is derived from audited consolidated financial statements not included in this Annual Report. As an emerging growth company, the presentation of selected historic financial data is limited to periods for which audited financial statements have been presented in connection with our first registration statement that became effective under the Securities Act of 1933, or the Securities Act.

Our historical results are not necessarily indicative of results that may be expected in the future. The information should be read in conjunction with the information provided in the consolidated financial statements and the related notes to these statements as well as the information described within the section “Operating and Financial Review and Prospects”.

Consolidated Statements of Operations Data	**Years ended December 31,**		
	2019	**2018**	**2017**
(in thousands)			
Revenues from contracts with customers	€108,589	€127,575	€61,598
Cost of sales	(17,361)	(13,690)	(9,318)
Gross profit	**€91,228**	**€113,885**	**€52,280**
Research and development expenses	(226,466)	(143,040)	(85,496)
Operating loss	**€(181,518)**	**€(53,854)**	**€(61,277)**
Loss before tax	**€(179,440)**	**€(47,662)**	**€(85,905)**
Income taxes	268	(600)	(45)
Loss for the period	**€(179,172)**	**€(48,262)**	**€(85,950)**
Attributable to:			
Equity holders of the parent	(179,056)	(48,019)	(85,653)
Non-controlling interests	(116)	(243)	(297)
	€(179,172)	**€(48,262)**	**€(85,950)**
Earnings per share			
in EUR			
Basic & diluted, loss per share for the year attributable to ordinary equity holders of the parent	€(0.85)	€(0.25)	€(0.51)
Weighted average number of ordinary shares			
Basic	211,499	190,710	166,764
Diluted	211,499	190,710	166,764

Consolidated Statements of Financial Position Data	As of December 31,		
(in thousands, except number of shares)	**2019**	**2018**	**2017**
Cash and cash equivalents	€519,149	€411,495	€172,106
Total assets	797,647	652,986	374,713
Total current liabilities	138,142	126,121	158,544
Total non-current liabilities	166,013	259,865	264,375
Total equity	493,492	267,000	(48,206)
Ordinary shares, par value	232,304	193,296	166,764
Ordinary shares issued	232,304	193,296	166,764
Ordinary shares outstanding	226,779	193,296	166,764

Consolidated Statements of Cash Flows Data	Years ended December 31,		
(in thousands)	**2019**	**2018**	**2017**
Net cash flows used in operating activities	€(198,537)	€(58,877)	€(52,562)
Net cash flows used in investing activities	(77,115)	(66,452)	(52,549)
Net cash flows from/(used in) financing activities	383,290	365,177	(1,643)

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

Risks Related to our Financial Condition and Capital Requirements

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

We have incurred net losses in each year since our inception in 2008, including net losses of €179.2 million and €48.3 million for the years ended December 31, 2019 and December 31, 2018, respectively. As of December 31, 2019, we had accumulated losses of €424.8 million (€245.8 million as of December 31, 2018).

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

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

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

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

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

- delays or failures in advancement of existing or future product candidates into the clinic or in clinical trials;
- our ability to develop, manufacture and commercialize our programs;
- our ability to manage our growth;
- the outcomes of research programs, clinical trials, or other product development or approval processes conducted by us and our collaborators;
- the ability of our collaborators to develop and successfully commercialize products developed from our suite of therapeutic classes;
- our relationships, and any associated exclusivity terms, with collaborators;
- our contractual or other obligations to provide resources to fund our product candidates, and to provide resources to our collaborators or to the collaborations themselves;
- our operation in a net loss position for the foreseeable future;
- risks associated with the international aspects of our business outside Germany, including the conduct of clinical trials in multiple locations and potential commercialization in such locations;

- our ability to consistently manufacture our product candidates;
- our ability to accurately report our financial results in a timely manner;
- our dependence on, and the need to attract and retain, key management and other personnel;
- our ability to obtain, protect, maintain, defend and enforce our intellectual property rights;
- our ability to prevent the theft or infringement, misappropriation or other violation of our intellectual property, trade secrets, know-how or technologies;
- potential advantages that our competitors and potential competitors may have in securing funding, obtaining the rights to critical intellectual property or developing competing technologies or products;
- our ability to obtain additional capital that may be necessary to expand our business;
- our collaborators' ability to obtain additional capital that may be necessary to develop and commercialize products under our collaboration agreements;
- business interruptions such as power outages, strikes, acts of terrorism or natural disasters; and
- our ability to use our net operating loss carryforwards to offset future taxable income.

Each of the factors listed above may be affected by the COVID-19 pandemic currently affecting 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.

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

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

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

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

- completing research and preclinical and clinical development of our product candidates;
- seeking and obtaining U.S. and non-U.S. marketing approvals for product candidates for which we complete clinical trials;
- furthering the development of our own manufacturing capabilities and manufacturing relationships with third parties in order to provide adequate (in amount and quality) products and services to support clinical development and the market demand for our product candidates, if approved;
- obtaining market acceptance of our product candidates as a treatment option;
- launching and commercializing product candidates for which we obtain marketing approval and reimbursement, either through collaborations or, if launched independently, by establishing a sales force, marketing and distribution infrastructure;

- addressing any competing technological and market developments;
- implementing additional internal systems and infrastructure;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- maintaining, defending, protecting, enforcing and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

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

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

In Germany, we have unused tax loss carryforwards for corporate taxes, though we have not recognized deferred tax assets related to such loss carryforwards for International Financial Reporting Standards, or IFRS, reporting purposes. In general, net operating loss, or NOL, carryforwards in Germany do not expire. They are, however, subject to review and possible adjustment by the German tax authorities. Furthermore, under current German tax laws, certain substantial changes in the Company's ownership and business may further limit the amount of NOL carryforwards that can be used annually to offset future taxable income. In addition, we may in the future have U.S. federal and state NOL carryforwards due to our subsidiary in the United States.

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

Under German tax laws, we are obligated to withhold a percentage of royalty payments we make to third party licensors of intellectual property rights and remit those withholdings to German tax authorities, and late withholding tax payments may subject us to penalties and fees.

Under German tax laws, we are obligated to withhold a percentage of royalty payments we make to third parties in consideration of the grant of rights under their intellectual property, and remit those withholdings to German tax authorities. As a result of an internal review, we have discovered that in the 11-year period before April 2019 we and certain of our subsidiaries did not withhold, report and remit certain withholding taxes in connection with the in-licensing of intellectual property as required to be withheld under German tax laws, and have not made the requisite recordings in our and their financial books and records in relation thereto. We have notified the tax authorities of the late payments and made the respective payments still in 2019. No administrative offence or criminal proceeding were opened or are expected in the future.

It is possible to seek the refund of these withholding taxes from the German Federal Central Tax office after filing exemption and refund applications. We started to process of filing such refund and exemption applications and part of the taxes paid have already been refunded and we expect further refunds to be paid out in the future. However, there is a possibility that the relevant claims against the licensors and/or the authority, may in some instances, not be enforceable as a result of a licensor no longer existing, the lapse of time or any other facts preventing the enforcement of such claims.

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

As of December 31, 2019, we had €519.1 million in cash and cash equivalents. We expect that our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements into the third quarter of 2021. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, government or other third-party funding, sales of assets, marketing and distribution arrangements, other collaborations and licensing arrangements, or a combination of these approaches. In any event, we will require additional capital to obtain regulatory approval for, and to commercialize, our product candidates. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations. Our spending will vary based on new and ongoing development and corporate activities. Due to high uncertainty of the length of time and activities associated with discovery and development of our product candidates, we are unable to estimate the actual funds we will require for development, marketing and commercialization activities.

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

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

To date, we have financed our operations primarily through the sale of equity securities and revenue from collaborations and we cannot be certain that additional funding will be available on favorable terms, or at all. Until we can generate sufficient product sales or royalty revenue to finance our operations, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, sales of assets, licensing arrangements, and other marketing or distribution arrangements. Any fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts, at the right time, on favorable terms, or at all, including as a result of the impact that the COVID-19 pandemic 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 our shares to decline. If we raise additional

funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that may adversely affect our shareholders' rights.

Further, to the extent that we raise additional capital through the sale of ADSs, ordinary shares or securities convertible or exchangeable into ordinary shares, share ownership interest will be diluted. We have entered into three secured credit facilities with an aggregate drawing capacity of €70 million. In addition, we may enter into additional credit facilities from time to time, which may be secured, to fund certain of our operations. If we raise additional capital through debt financing, we would be subject to fixed payment obligations and may be subject to security interests in our assets and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital through marketing and distribution arrangements, sales of assets or other collaborations, or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs. We also could be required to seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or intellectual property that we otherwise would seek to develop or commercialize ourselves. If we are unable to raise additional capital in sufficient amounts, at the right time, on favorable terms, or at all, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our products or product candidates, or one or more of our other research and development initiatives. Any of the above events could significantly harm our business, prospects, financial condition and results of operations, cause the price of the ADSs to decline, and negatively impact our ability to fund operations.

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

As of December 31, 2019, we had more than 1,300 full-time employees and, in connection with the growth and advancement of our pipeline and becoming a public company, we expect to increase the number of employees and the scope of our operations. To manage our anticipated development and expansion, we must continue to implement and improve our managerial, operational, legal, compliance and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Also, our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these development activities.

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

We face risks related to health epidemics, such as the current coronavirus outbreak, that could adversely affectour operations.

Our business could be adversely impacted by the effects of COVID-19 (more commonly referred to as coronavirus) or other epidemics. The recent COVID-19 outbreak may negatively impact our revenue or operations in the future. The COVID-19 pandemic could also affect our ability to enroll patients in clinical studies and complete clinical trials on the timelines we currently anticipate.

Our suppliers, licensors or collaborators could also be disrupted by conditions related to COVID-19, or other epidemics, possibly resulting in disruption to our supply chain, clinical trials, partnerships or operations. If our suppliers, licensors, CROs or collaborators are unable or fail to fulfill their obligations to us for any reason, our business could be adversely affected. Our customers could also be disrupted by conditions related to COVID-19 or other epidemics, possibly through deferring purchasing decisions or delaying research programs. Our operations, including research and

manufacturing, could also be disrupted due to the potential of the impact of staff absences as a result of self-isolation procedures or extended illness.

At this point in time, there is uncertainty relating to the potential effect of COVID-19 on our business. Infections may become more widespread and a significant health epidemic could adversely affect the economies and financial markets of many countries, resulting 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 insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter and insurance coverage is becoming increasingly expensive. We do not know if we will be able to maintain existing insurance with adequate levels of coverage, and any liability insurance coverage we acquire in the future may not be sufficient to reimburse us for any expenses or losses we may suffer. If we obtain marketing approval for any product candidates that we or our collaborators may develop, we intend to acquire insurance coverage to include the sale of commercial products, but we may be unable to obtain such insurance on commercially reasonable terms or in adequate amounts. We currently maintain insurance coverage for losses relating to an interruption of our development, manufacturing or commercialization efforts caused by contamination in an amount of €50,000,000 per claim up to an aggregate cap of €160,000,000 in any two-year period, and the coverage or coverage limits of our insurance policies may not be adequate. If our losses exceed our insurance coverage, our financial condition would be adversely affected. In the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources. Clinical trials or regulatory approvals for any of our product candidates could be suspended, which could adversely affect our results of operations and business, including by preventing or limiting the development and commercialization of any product candidates that we or our collaborators may develop. Additionally, operating as a public company has made it more expensive for us to obtain director and officer liability insurance. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our Supervisory Board, our board committees or our Management Board.

Risks Related to our Business

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

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

Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any biopharmaceutical product candidates from regulatory authorities in any jurisdiction, and it is possible that none of our product candidates, or any product candidates we may seek to develop in the future, will ever obtain regulatory approval. We have limited experience in filing and supporting the applications necessary to gain marketing approvals and may need to rely on third-party contract research organizations, or CROs, regulatory consultants or collaborators to assist us in this process. To our knowledge, there is no current precedent for an mRNA-based immunotherapy such as the type we are developing being approved for sale by the FDA, European Commission or any other regulatory agency elsewhere in the world. Although we expect to submit BLAs for our mRNA-based product candidates in the United States, and in the European Union, mRNA therapies have been classified as gene therapy medicinal products, other jurisdictions may consider our mRNA-based product candidates to be new drugs, not biologics or gene therapy medicinal products, and require different marketing applications. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the

various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Any product candidates we develop may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

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

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

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

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

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

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

- discovery efforts aimed at identifying potential immunotherapies may not be successful;
- nonclinical or preclinical study results may show product candidates to be less effective than desired or have harmful or problematic side effects;
- clinical trial results may show the product candidates to be less effective than expected, including a failure to meet one or more endpoints or have unacceptable side effects or toxicities;
- manufacturing failures or insufficient supply of GMP materials for clinical trials, or higher than expected cost could delay or set back clinical trials, or make our product candidates commercially unattractive;

- our improvements in the manufacturing processes may not be sufficient to satisfy the clinical or commercial demand of our product candidates or regulatory requirements for clinical trials;
- changes that we make to optimize our manufacturing, testing or formulating of GMP materials could impact the safety, tolerability and efficacy of our product candidates;
- pricing or reimbursement issues or other factors could delay clinical trials or make any immunotherapy uneconomical or noncompetitive with other therapies;
- the failure to timely advance our programs or receive the necessary regulatory approvals, or a delay in receiving such approvals, due to, among other reasons, slow or failure to complete enrollment in clinical trials, withdrawal by trial participants from trials, failure to achieve trial endpoints, additional time requirements for data analysis, data integrity issues, BLA, MAA or the equivalent application, discussions with the FDA or the EMA, a regulatory request for additional nonclinical or clinical data,
or safety formulation or manufacturing issues may lead to our inability to obtain sufficient funding; and
- the proprietary rights, products and technologies of our competitors may prevent our immunotherapies from being commercialized.

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

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

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

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

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

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

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

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

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

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

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

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

product candidates. If we are required to produce new batches of our product candidates due to insufficient shelf life, it may delay the commencement or completion of preclinical or clinical trials of such product candidates. For example, we cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA or other regulatory authorities will accept the results of our preclinical testing or our proposed clinical programs or if the outcome of our preclinical testing, studies and CMC activities will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin.

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

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

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

trials or other reasons, or participants may withdraw from clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;

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

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

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

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

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

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

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

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

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

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

In particular, certain conditions for which we plan to evaluate our current product candidates are rare diseases with limited patient pools from which to draw for clinical trials. The eligibility criteria of our clinical trials will further limit the pool of available trial participants. Additionally, the process of finding and diagnosing patients may prove costly. Each of the risks set forth above may be exacerbated by the COVID-19 pandemic currently affecting the global community and the global economy.

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

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

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

The extent to which the COVID-19 pandemic impacts our operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak, new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others. In particular, the spread of the coronavirus globally could adversely impact our clinical trial operations, including the availability of specialist raw materials required to manufacture our clinical candidates and our ability to deliver clinical candidates to clinical trial sites, In the future, similar events could affect our ability to manufacture and commercialize our product candidates.

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

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

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

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and 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 reveal significant adverse events not seen in our preclinical or nonclinical studies and may result in a safety profile that could delay or terminate clinical trials, or delay or prevent regulatory approval or market acceptance of any of our product candidates.

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

Some of our product candidates are being developed or are intended to be co-administered with other developmental therapies or approved medicines. For example, RO198457 (BNT122) is being developed to be co-administered with

checkpoint inhibitors. Such combinations may have additional side effects which may be difficult to predict in future clinical trials.

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

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

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

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

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

being supportive of licensure. Other regulatory authorities in Europe and other countries may make similar findings with respect to these endpoints.

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

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

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

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

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

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

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

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

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

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

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

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

We may also seek Fast Track Designation in the United States for some of our product candidates. If a therapy is intended for the treatment of a serious or life-threatening condition and the therapy demonstrates the potential to address significant unmet medical needs for this condition, the drug sponsor may apply for Fast Track Designation. The FDA has broad discretion whether or not to grant this designation, and even if we believe a particular product candidate is eligible for this designation, we cannot 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or the ACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or the BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first approved.

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

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

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

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

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

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

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

The regulatory requirements 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, or IBC, a local institutional committee that reviews and oversees basic and clinical research conducted at the institution participating in the clinical trial. In addition, adverse developments in clinical trials of gene therapy products conducted by others may cause the FDA or other regulatory bodies to change the requirements for approval of any of our product candidates.

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

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

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

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

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

other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods.

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

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

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

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

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

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

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

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval or revoke a license;
- suspend any ongoing clinical studies;

- refuse to approve a pending BLA or supplements to a BLA submitted by us;
- seize product; or
- refuse to allow us to enter into supply contracts, including government contracts.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- logistics associated with the collection of a patient's tumor, blood or other tissue sample;
- shipping such samples to a facility for genetic sequencing;
- next-generation sequencing of the tumor mRNA;
- 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, due to the custom nature of the equipment and single-use assemblies, we may not be able to supply this expanded need reliably without significant investments. In addition, there will be considerable time to scale up our facilities or build new facilities before we can begin to meet any commercial demand if one or more of our product candidates are approved. This expansion or addition of new facilities could also lead to product comparability issues, which can further delay introduction of new capacity.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The manufacturing process for any products that we may develop is subject to the FDA's, the EMA's and other regulatory authorities' approval processes, and we may need to contract with manufacturers who we believe can meet applicable regulatory authority requirements on an ongoing basis. If we or our third-party manufacturers are unable to reliably produce product candidates to specifications acceptable to the FDA, the EMA or other regulatory authorities, we or our collaborators may not obtain or maintain the approvals we or they need to commercialize such products. Even if we or our collaborators obtain regulatory approval for any of our immunotherapies, there is no assurance that either we or our CMOs will be able to manufacture our product candidates to specifications acceptable to the FDA, EMA or other

regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates, impair commercialization efforts or increase our cost of goods. The occurrence of any of the foregoing could have an adverse effect on our business, financial condition, results of operations and growth prospects.

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

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

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

Risks Related to the Commercialization of our Pipeline

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

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

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products, including genetic medicines. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health

and Human Services, or HHS, as CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payors tend to follow CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for novel products such as ours. Reimbursement agencies in Europe may be more conservative than CMS. For example, a number of cancer drugs have been approved for reimbursement in the United States but have not been approved for reimbursement in certain European countries.

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

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

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

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

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

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

We will face intense competition from drugs that have already been approved and accepted by the medical community for the treatment of the conditions for which we may develop drugs. We also expect to face competition from new drugs that enter the market. There are a number of drugs currently under development, which may become commercially available in the future, for the treatment of conditions for which we are trying, or may in the future try, to

develop drugs. These drugs may be more effective, safer, less expensive, or marketed and sold more effectively, than any products we develop.

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

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

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

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

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

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

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

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

Given our stage of development, we have no sales, distribution or marketing capabilities, and we have not designed our preclinical studies and clinical trials with specific commercialization or marketing considerations in mind. To

successfully commercialize any products that may result from our development programs, we will need to develop sales and marketing capabilities in the United States, Europe and other regions, either on our own or with others. We may enter into collaborations with other entities to utilize their mature marketing and distribution capabilities, but we may be unable to enter into marketing agreements on favorable terms, if at all. If our future collaborators do not commit sufficient resources to commercialize our future products, if any, and we are unable to develop the necessary marketing capabilities on our own, we may be unable to generate sufficient product sales revenue to sustain our business. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without a significant internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year. These reductions will remain in effect through 2025 unless additional congressional action is taken.

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

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

collaborations may no longer be deemed commercially viable to pursue based on our collaborators' assessments of the impact of any proposed, announced, or legislated pricing reforms.

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

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

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

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

Risks Related to our Reliance on Third Parties

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

We have had a longstanding relationship with Translational Oncology at the University Medical Center of the Johannes Gutenberg University Mainz (Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH), or TRON, a non-profit limited liability company engaged in biopharmaceutical research. During the year ended December 31, 2019 until the resignation of Prof. Ugur Sahin, M.D., as Managing Director for Science and Research at TRON on September 10, 2019, and during the year ended December 31, 2018, the aggregate value of the transactions related to these arrangements with TRON amounted to €6.6 million and €6.6 million, respectively, and TRON's research has historically constituted a significant portion of our discovery pipeline and target discovery engine. Prof. Ugur Sahin, M.D., our co-founder and Chief Executive Officer, co-founded TRON and served as Managing Director at TRON until 2019 and currently serves as a Professor of Medicine at the University of Mainz. Prof. Sahin resigned from this position with TRON, effective September 10, 2019. Additionally, Prof. Christoph Huber, M.D., a member of our Supervisory Board, served on TRON's supervisory board until his resignation in April 2019. We and TRON also share certain intellectual property. Prof. Ugur Sahin, M.D., our co-founder and Chief Executive Officer, owns a significant amount of shares in TRON. During the year ended December 31, 2019, the aggregate value of transactions related to these agreements with TRON amounted to €10.0 million pursuant to these agreements (€6.6 million during the year ended December 31, 2018).

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

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

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

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our regulatory or contractual responsibilities. We 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 also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity, and civil and criminal sanctions. For any violations of laws and regulations during the conduct of our preclinical studies and clinical trials, we could be subject to warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

We and our CROs 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 also are responsible for ensuring that the rights of our clinical trial participants are protected. These regulations are enforced by the FDA, the competent authorities of the member states, and comparable regulatory authorities of other jurisdictions for any product candidates in clinical development. The FDA enforces GCP regulations through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable regulatory authorities of other jurisdictions may require us to perform additional clinical trials before approving our marketing applications. We cannot 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;
- have human errors; or
- be subject to cyberattacks.

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

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. Each of the risks set forth above may be exacerbated by the COVID-19 pandemic currently affecting the global community and the global economy.

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

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

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

with respect to such product candidates, or may result in litigation or arbitration, any of which would be time-consuming and expensive;

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

If our collaborations do not result in the successful development and commercialization of programs, or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone, earn-out, royalty, or other contingent payments under the collaborations. If we do not receive the funding we expect under these agreements, our development of product candidates could be delayed and we may need additional resources to develop our product candidates. In addition, in general our collaborators have the right to terminate their agreements with us for convenience. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and the perception of us in the business and financial communities could be adversely affected. All of the risks relating to product development, regulatory approval and commercialization described in this 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 we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include, among other things and as applicable for the type of potential product or technology, an assessment of the opportunities and risks of our technology, the design or results of studies or trials, the likelihood of approval, if necessary, of the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products and technologies and industry and market conditions generally.

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

address those targets. Similarly, our collaboration agreements have in the past and may in the future contain non-competition provisions that could limit our ability to enter into collaborations with future collaborators.

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

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

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

The success of products developed based on in-licensed technology will depend in part on the ability of our current and future licensors to prosecute, obtain, maintain, protect, enforce and defend patent protection for our in-licensed intellectual property. Our current and future licensors may not successfully prosecute the patent applications we license. Even if patents 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; and
- the priority of invention of patented technology.

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

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

If we commit certain material breaches and fail to cure them (if such breach is curable), we are required to repurchase shares held by the Bill & Melinda Gates Foundation.

If we commit a specified material breach under the letter agreement with the Bill & Melinda Gates Foundation, or BMGF, and such breach remains uncured after a specified period of time (if curable), we are required to either (i) repurchase the shares held by BMGF or locate a third party to purchase the shares from BMGF, in either case at a price that is the greater of the original purchase price or the fair market value of the shares at the time of repurchase, or (ii) if we cannot meet the requirements under (i) (e.g., because we do not have sufficient cash reserves), then we must use our best efforts to effect BMGF's withdrawal right as soon as practicable, which may mean acquiring the shares in tranches over time. If we are required to repurchase BMGF's shares, our financial position could be materially and adversely affected.

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Intellectual Property

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

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

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

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

- the USPTO and various other governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application or a finding that a patent is unenforceable, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- issued patents that we own (solely or jointly) or have in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use, sell, import or otherwise exploit our product candidates or other technologies;
- other parties may have designed around our patent claims or developed technologies that may be related or competitive to our product candidates or other technologies, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent filings, either by claiming the same or overlapping methods, products, reagents or devices or by claiming subject matter that could dominate one or more of our patent claims;

- any successful opposition to any patents owned by or in-licensed to us could deprive us of rights necessary for the development and exploitation of our product candidates and other technologies or the successful commercialization of any product candidates and other technologies that we may develop;
- because patent applications in the United States and most other jurisdictions are confidential for a period of time after filing, we cannot be certain that we, our co-owners or our licensors were the first to file any patent application related to our product candidates, proprietary technologies and their uses;
- a court or patent office proceeding, such as a derivative action or interference, can be provoked or instituted by a third party or a patent office, and might determine that one or more of the inventions described in our patent filings, or in those we licensed, was first invented by someone else, so that we may lose rights to such invention(s);
- a court or other patent proceeding, such as an *inter partes* review, post grant review or opposition, can be instituted by a third party to challenge the inventorship, scope, validity and/or enforceability of our patent claims and might result in invalidation or revision of one or more of our patent claims, or in a determination that such claims are unenforceable;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing competitors a better opportunity to create, develop and market competing product candidates.

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

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

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

royalty payments to us from our licensees. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Furthermore, our pending and future patent applications may not result in patents being issued which protect our technology or product candidates or which effectively prevent others from commercializing competitive technologies and product candidates. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

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

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

- any of our patents, or any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect our product candidates and other technologies;
- any of our pending patent applications or those of our licensors may issue as patents;
- others will not or may not be able to make, use, offer to sell or sell products that are the same as or similar to our own but that are not covered by the claims of the patents that we own or license;
- we will be able to successfully commercialize our products on a substantial scale, if approved, before the relevant patents that we own or license expire;
- we were the first to make the inventions covered by each of the patents and pending patent applications that we own or license;
- we, our co-owners or our licensors were the first to file patent applications for these inventions;
- others will not develop similar or alternative products or technologies that do not infringe the patents we own or license;
- any of the patents we own or license will be found to ultimately be valid and enforceable;
- any patents issued to us or our licensors will provide a basis for an exclusive market for our commercially viable product candidates and other technologies or will provide us with any competitive advantages;
- a third party may not challenge the patents we own or license and, if challenged, a court would hold that such patents are valid, enforceable and infringed;
- we may develop or in-license additional proprietary technologies that are patentable;
- the patents of others will not have an adverse effect on our business;

- our competitors do not conduct research and development activities in countries where we do not have enforceable patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we will develop additional proprietary technologies or product candidates that are separately patentable; or
- our development and commercialization activities, including our manufacturing processes, or products will not infringe upon the patents of our competitors or any other third parties, including any non-practicing entities or patent assertion entities.

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

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

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

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

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

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

There are many issued and pending patent filings that claim aspects of technologies that we may need for our mRNA product candidates or other product candidates, including patent filings that relate to relevant delivery technologies. There

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

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

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

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

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

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

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

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first effective non-provisional filing date, assuming maintenance fees are timely paid after the patent has issued. Most

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

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

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

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

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

Where we obtain licenses from, or collaborate with, third parties, in some circumstances we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications covering the technology that we license from third parties, or such activities, if controlled by us, may require the input of such third parties. In some cases, patent prosecution of our in-licensed intellectual property is controlled solely by the licensor. We may also require the cooperation of our licensors and collaborators to enforce or defend any in-licensed patent rights, and such cooperation may not be provided. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, protected, enforced or defended in a manner consistent with the best interests of our business. Any patents or patent applications that we in-license may be challenged, narrowed, circumvented, invalidated or held unenforceable, or our licensors may not properly maintain such patents or patent applications and they may expire. If our licensors fail to obtain, maintain, defend, protect or enforce the intellectual property we license from them, we could lose our rights to the intellectual property and our competitors could market competing products using the inventions in such intellectual property. In certain cases, we control the prosecution of patents included from in-licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our collaborators. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

As is the case with other biotechnology companies, our success is heavily dependent on our intellectual property rights, particularly patents that we own and in-license. Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity, and therefore obtaining and enforcing biotechnology patents is costly,

time-consuming and inherently uncertain. Moreover, there are periodic changes in patent law. For example, after March 2013, under the America Invents Act, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. The America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

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

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

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

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

We have received confidential and proprietary information from third parties in the course of our research and other collaborations with others in the industry, academic institutions and other third parties. In addition, many of our employees, consultants and advisors are currently or were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants, independent contractors and advisors do not use the confidential or proprietary information, trade secrets or know-how of others in their work for us, we may be subject to claims that we have inadvertently or otherwise used or disclosed confidential or proprietary information, trade secrets or know-how of these third parties, or that our employees, consultants, independent contractors or advisors have inadvertently or otherwise used or disclosed confidential information, trade secrets or know-how of such individual's current or former employer. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Litigation

may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees. Claims that we, our employees, consultants or advisors have misappropriated the confidential or proprietary information, trade secrets or know-how of third parties could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

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

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

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

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

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement, misappropriation or other violation of our patents and other intellectual property or development, marketing and commercialization of competing products in violation of our intellectual property and other proprietary rights generally. Proceedings to enforce our intellectual property rights in such jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and

could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or in-license.

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

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

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

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

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

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

- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

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

Risks Related to Government Regulation

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

We may be subject to additional healthcare regulation and enforcement by the U.S. federal government and by authorities in the United States, the European Union and other jurisdictions in which we conduct our business.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations will be directly, or indirectly through our prescribers, customers and purchasers, subject to various federal and state fraud and abuse laws and regulations, including, without limitation, the federal Health Care Program Anti-Kickback Statute, the federal civil and criminal False Claims Act, and the Physician Payments Sunshine Act and regulations. Many states and other jurisdictions have similar laws and regulations, some of which may be broader in scope. These laws will impact, among other things, our proposed sales, marketing and educational programs. In addition, we may be subject to patient privacy laws enacted by both the federal government and the states in which we conduct our business. The laws that will affect our operations include, but are not limited to the following:

- The federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in return for the purchase, recommendation, leasing or furnishing of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers, and formulary managers on the other. The ACA amends the intent requirement of the federal Anti-Kickback Statute to provide that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it.
- The federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment or approval from Medicare, Medicaid or other government payors. The ACA provides, and recent government cases against pharmaceutical and medical device manufacturers support, the view that federal Anti-Kickback Statute violations and certain marketing practices, including off-label promotion, may implicate the False Claims Act.
- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit a person from knowingly and willfully executing a scheme or making false or fraudulent statements to defraud any healthcare benefit program, regardless of the payor (*e.g.*, public or private).
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and their implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization by entities subject to the rule, such as health plans, health care clearinghouses and health care providers.
- The U.S. Federal Food, Drug, and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices.
- the U.S. Public Health Service Act, which prohibits, among other things, the introduction into interstate commerce of a biological product unless a biologics license is in effect for that product.
- Federal transparency laws, including the federal Physician Payment Sunshine Act, which require disclosure of payments and other transfers of value provided to physicians and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations.

- State law equivalents of each of the above federal laws, state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, and state laws governing the privacy and security of health information in certain circumstances which are also applicable to us, and many of them differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts in certain circumstances.
- the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, U.S. companies and their employees and agents, as well as non-U.S. companies that are registered with the Securities and Exchange Commission, or the SEC, from authorizing, promising, offering or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof; and
- similar healthcare laws and regulations in the European Union and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

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

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

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

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

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

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

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

to evolve and may result in ever-increasing public scrutiny and escalating levels of enforcement, sanctions and increased costs of compliance.

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

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

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

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

Although we take measures to protect sensitive data from unauthorized access, use or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other malicious or inadvertent disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, manipulated, publicly disclosed, lost or stolen. Any such access, breach or other loss of information could result in legal claims or proceedings, and liability under federal or state laws that protect the privacy of personal information, as well as regulatory penalties. In the United States, notice of breaches must be made to affected individuals and the U.S. Secretary of HHS, and for extensive breaches, notice may need to be made to the media or U.S. state Attorneys General. Such a notice could harm our reputation and our ability to compete. HHS has the discretion to impose penalties without attempting to resolve violations through informal means. In

addition, U.S. state Attorneys General are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. Although we have implemented security measures to prevent unauthorized access to patient data, such data is currently accessible through multiple channels, and there is no guarantee we can protect our data from breach. Unauthorized access, loss or dissemination could also damage our reputation or disrupt our operations, including our ability to conduct our analyses, deliver test results, process claims and appeals, provide customer assistance, conduct research and development activities, collect, process and prepare company financial information, provide information about our tests and other patient and physician education and outreach efforts through our website, and manage the administrative aspects of our business.

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

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

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

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

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

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

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

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

General Risks Related to our Business

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

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent upon

members of our management and scientific teams. We may not be able to retain these persons due to the competitive environment in the biotechnology industry. The loss of any of these persons' services may adversely impact the achievement of our research, development, financing and commercialization objectives. We currently do not have "key person" insurance on any of our employees.

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

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

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

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators and consultants. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in the European Union and other jurisdictions, provide accurate information to the FDA, the EMA and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions.

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

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

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

Our internal computer systems and those of our current and any future collaborators, vendors, and other contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism,

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

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

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

We recognize the need for, and are in the early stages of, developing disaster recovery, business continuity and document retention plans that would allow us to be operational despite casualties or unforeseen events impacting our corporate headquarters or distribution center. Without disaster recovery, business continuity and document retention plans, if we encounter difficulties or disasters with our manufacturing facilities or at our corporate headquarters, our critical systems, operations and information may not be restored in a timely manner, or at all, and this could have an adverse effect on our business.

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

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

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

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

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

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

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

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

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

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

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

Risks Related to the Merger

Our agreement with Neon Therapeutics, Inc., or Neon, under which we will acquire Neon in an all-stock transaction, which we refer to as the Merger, is subject to a number of conditions, some of which are outside of the parties' control, and, if these conditions are not satisfied, the Merger Agreement may be terminated and the Merger may not be completed.

The Agreement and Plan of Merger, by and among us, Neon and our wholly owned subsidiary, Endor Lights, dated as of January 15, 2020, or the Merger Agreement, contains a number of conditions that must be fulfilled to complete the Merger. These conditions include, among other customary conditions, (i) the approval and adoption of the Merger Agreement by the shareholders of Neon, (ii) the absence of an enacted or promulgated law by any federal or state governmental entity of competent jurisdiction that precludes, restrains, enjoins or prohibits the consummation of the Merger, (iii) the absence of any temporary restraining order, preliminary or permanent injunction or any other order in effect precluding, restraining, enjoining, prohibiting, suspending or making illegal the consummation of the Merger, (iv) the SEC having declared effective a registration statement on Form F-4 to be filed with the SEC and the absence of a stop order suspending such effectiveness and the absence of any proceeding initiated for that purpose by the SEC, and not

subsequently withdrawn, (v) the approval for listing on Nasdaq, subject to official notice of issuance, of our ADSs to be issued in the Merger, (vi) subject to certain materiality exceptions, the accuracy of certain representations and warranties of each of the parties contained in the Merger Agreement and the compliance by each party with the covenants contained in the Merger Agreement, and (vii) the absence of a material adverse effect with respect to each of the parties thereto.

The required satisfaction (or waiver) of the foregoing conditions could delay the completion of the Merger for a significant period of time or prevent it from occurring. Any delay in completing the Merger could cause the combined company not to realize some or all of the benefits that the parties expect the combined company to achieve. Further, there can be no assurance that the conditions to the closing of the Merger will be satisfied or waived or that the Merger will be completed.

In addition, if the Merger is not completed by October 15, 2020 (subject to potential extensions), either we or Neon may choose to terminate the Merger Agreement. Either party may also elect to terminate the Merger Agreement in certain other circumstances, and the parties can mutually decide to terminate the Merger Agreement at any time prior to the closing of the Merger, before or after shareholder approval, as applicable.

Failure to complete the Merger could negatively affect our share price.

We have incurred and will continue to incur significant transaction expenses in connection with the Merger regardless of whether the Merger is completed. Furthermore, we may experience negative reactions from the financial markets, including negative impacts on our stock price, or negative reactions from suppliers or other business partners, should the Merger not be completed.

The foregoing risks, or other risks arising in connection with the failure to consummate the Merger, including the diversion of management attention from conducting our business and pursuing other opportunities during the pendency of the Merger, may have a material adverse effect on our business, operations, financial results and share price. We could also be subject to litigation related to any failure to consummate the Merger or any related action that could be brought to enforce a party's obligations under the Merger Agreement.

The exchange ratio is fixed and will not be adjusted in the event of any changes in either party's stock price.

Upon completion of the Merger, each share of Neon common stock outstanding immediately prior to the completion of the Merger will be converted into the right to receive 0.063 of an ADS of BioNTech without interest. This exchange ratio will not be adjusted for changes in the market price of either our ADSs or Neon common stock between the date the Merger Agreement was signed and completion of the Merger. As a result, changes in the price of our ADSs prior to the completion of the Merger will affect the value of our ADSs delivered upon completion of the Merger. An increase in the price of our ADSs will increase the value of the consideration we deliver. Similarly, a decrease in the price of Neon's shares will increase the premium that we pay per Neon share.

Stock price changes may result from a variety of factors, including, among others, general market and economic conditions, changes in our and Neon's respective businesses, operations and prospects, risks inherent in their respective businesses, changes in market assessments of the likelihood that the Merger will be completed and/or the value that may be generated by the Merger, and changes with respect to expectations regarding the timing of the Merger and regulatory considerations.

Litigation against us and/or Neon, or the members of the Neon Board of Directors, could prevent or delay the completion of the Merger or result in the payment of damages following completion of the Merger.

It is a condition to the Merger that no temporary restraining order, preliminary or permanent injunction or other order preventing the consummation of the Merger Agreement or the transactions contemplated thereby shall have been issued by any court of competent jurisdiction or other governmental authority of competent jurisdiction and remain in effect. No party to the Merger Agreement is aware of any lawsuit or proceeding specific to the Merger having been filed to date. If such a lawsuit or other proceeding is commenced and if in any such litigation or proceeding a plaintiff is successful in obtaining a restraining order or injunction prohibiting the consummation of the Merger Agreement or the transactions contemplated thereby, then the closing of the Merger may be delayed or may never occur. Even if the Merger is permitted to occur, the parties may be required to pay damages, fees or expenses in respect of claims related to the Merger or the transactions contemplated thereby.

Uncertainty about the Merger may adversely affect the relationships of the parties with their respective suppliers and employees, whether or not the Merger is completed.

In response to the announcement of the Merger, existing or prospective suppliers of either party may:

- delay, defer or cease providing goods or services to us, Neon or the consolidated company;
- delay or defer other decisions concerning us, Neon or the consolidated company, or refuse to extend credit to us, Neon or the consolidated company; or
- otherwise seek to change the terms on which they do business with us, Neon or the consolidated company.

Any such delays or changes to terms could harm the business of each company or, if the Merger is completed, the consolidated company.

In addition, as a result of the Merger, current and prospective employees could experience uncertainty about their future with the consolidated company. These uncertainties may impair the consolidated company's ability to retain, recruit or motivate key management, technical and other personnel.

Until the completion of the Merger or the termination of the Merger Agreement in accordance with its terms, in consideration of the agreements made by the parties in the Merger Agreement, the parties are each prohibited from entering into certain transactions and taking certain actions that might otherwise be beneficial to the parties and their respective shareholders.

Until the Merger is completed, the Merger Agreement restricts us and Neon from taking specified actions without the consent of the other party, and requires Neon to operate in the ordinary course of business consistent with past practices. These restrictions may prevent Neon or us from making appropriate business changes or pursuing attractive business opportunities that may arise prior to the completion of the Merger.

Risks Related to the Consolidated Company

The consolidated company may not fully realize the anticipated benefits of the Merger or realize such benefits within the timing anticipated.

The parties entered into the Merger Agreement because each company believes that the Merger will be beneficial to each company and its respective shareholders. The consolidated company may not be able to achieve the anticipated long-term strategic benefits of the Merger within the timing anticipated or at all. For example, the benefits from the Merger will be partially offset by the costs incurred in completing the transaction. Any delays and challenges that may be encountered in completing the Merger or in the post-Merger process of consolidation could have an adverse effect on the business and results of operations of the consolidated company, and may affect the value of our ordinary shares and the ADSs representing our ordinary shares after the completion of the Merger.

The consolidated company will incur significant transaction-related costs in connection with the Merger.

We and Neon expect to incur significant costs associated with the Merger. The amount of these costs may not be determined as of the Effective Time and may be material to the financial position and results of operations of the consolidated company. We expect that the substantial majority of expenses resulting from the Merger will be comprised of transaction costs related to the Merger and employee-related costs. We and Neon will also incur fees and costs related to integration and systems consolidation. The elimination of duplicative costs may not offset incremental transaction-related and other integration costs in the near term.

The consolidated company's goodwill or other intangible assets may become impaired, which could result in material non-cash charges to its results of operations.

The consolidated company will have a substantial amount of goodwill and other intangible assets resulting from the Merger. At least annually, or whenever events or changes in circumstances indicate a potential impairment in the carrying value as defined by IFRS, the consolidated company will evaluate this goodwill for impairment based on the recoverable value, being the higher of fair value less costs to sell and value in use, of the cash generating units to which goodwill has been allocated. Estimated fair values could change if there are changes in the consolidated company's capital structure, cost of debt, interest rates, capital expenditure levels, operating cash flows or market capitalization. Impairments of goodwill or other intangible assets could require material non-cash charges to the consolidated company's results of operations.

Future results of the consolidated company may differ materially from the unaudited pro forma financial information included in subsequent reports.

The consolidated company's future results may be materially different from those shown in the unaudited pro forma financial information presented in this report that show only a combination of our and Neon's historical results. We expect to incur significant costs associated with completing the Merger and combining the operations of the two companies, and the exact magnitude of these costs is not yet known. Furthermore, these costs may decrease capital that could be used by us for future income-earning investments.

The financial analyses and forecasts considered by us, Neon and our respective financial advisors may not be realized.

While the financial projections utilized by us, Neon and our respective advisors in connection with the Merger were prepared in good faith based on information available at the time of preparation, no assurances can be made regarding future events or that the assumptions made in preparing such projections will accurately reflect future conditions. In preparing such projections, our management and the management of and Neon made assumptions regarding, among other things, future economic, competitive, regulatory and financial market conditions and future business decisions that may not be realized and that are inherently subject to significant uncertainties and contingencies, including, among others, risks and uncertainties described or incorporated by reference in this section and in "Cautionary Statement Regarding Forward-Looking Statements," all of which are difficult to predict and many of which are beyond the control of us and Neon and will be beyond the control of the consolidated company. There can be no assurance that the underlying assumptions or projected results will be realized, and actual results will likely differ, and may differ materially, from such projections, which could result in a material adverse effect on the consolidated company's business, financial condition, results of operations and prospects.

Risks Related to Ownership of our ADSs

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

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

- results of clinical trials of our product candidates or those of our competitors;
- the success of competitive products or technologies;
- commencement or termination of collaborations;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents, or other intellectual property or proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and

- the numerous programs in our pipeline, the development of which could each generate news or significant adverse events that could impact financial results or recommendations by securities analysts.

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

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

We have incurred increased costs as a result of operating as a public company, and our management has been required to devote substantial time to new 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, and particularly after we are no longer an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, we expect to incur significant legal, accounting and other expenses that we did not incur as a private company. We expect that we will cease to be an emerging growth company beginning January 1, 2021, and thus will not be able to rely on emerging growth company rules for our 20-F filed for FY2020. In addition, the federal securities laws, including the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and rules subsequently implemented by the SEC and the Nasdaq Stock Market LLC, or Nasdaq, have imposed various requirements on public companies, including requirements to file annual and event-driven reports with respect to our business and financial condition, and to establish and maintain effective disclosure and financial controls and corporate governance practices. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and have made some activities more 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, concurrent with our second Annual Report on Form 20-F 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. Per the above, we will likely be subject to this requirement in our 20-F to be filed for FY2020; however, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm in our annual filings with the SEC. To achieve compliance with Section 404 within the prescribed period, we have initiated the process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, have engaged outside consultants, and are adopting 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 neither we nor our independent registered public accounting firm (once we are no longer an emerging growth company) will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years from the pricing of our initial public offering. We intend to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Shareholder activism, the current political environment, and the current high level of government

intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives.

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

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

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

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

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

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

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

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

- the last day of the fiscal year following the fifth anniversary of the date of the completion of our initial public offering.

We expect that we will cease to be an emerging growth company beginning January 1, 2021. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to public companies that are not emerging growth companies. These exemptions include:

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

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

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

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

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

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

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

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

As a foreign private issuer, we are permitted to follow home country practice in lieu of the above requirements. We therefore 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 Supervisory Board, 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.

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

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

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

Sales of a substantial number of ordinary shares or the ADSs could occur at any time, subject to certain restrictions described below. These sales, or the perception in the market that holders of a large number of shares intend to sell shares, could reduce the market price of the ADSs. As of December 31, 2019, we have 226,779,744 ordinary shares outstanding.

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

We intend to file one or more registration statements on Form S-8 under the Securities Act of 1933, as amended, or the Securities Act, to register all ordinary shares issued or issuable under our equity plans. Any such Form S-8 registration statements will automatically become effective upon filing. Accordingly, shares registered under such registration statements will be available for sale in the open market following the expiration of the applicable lock-up period.

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

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

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

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

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

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

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

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

Under German law, the existing shareholders of a company 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, 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.

ADS holders will not be entitled to exercise or sell such rights unless we register the rights and the securities to which the rights relate under the Securities Act or an exemption from the registration requirements is available. In addition, the deposit agreement provides that the depositary need not make rights available to ADS holders unless the distribution to ADS holders of both the rights and any related securities are either registered under the Securities Act or exempted from registration under the Securities Act. We are under no obligation to file a registration statement with respect to any such rights or securities or to endeavor to cause such a registration statement to be declared effective. Moreover, we may not be able to establish an exemption from registration under the Securities Act. Accordingly, ADS holders may be unable to participate in our rights offerings and may experience dilution in their holdings. In addition, if the 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 ADS holders will receive no value for these rights.

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

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

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

The specific treatment of ADSs under German tax law is based on administrative provisions by the fiscal authorities, which are not codified law and are subject to change. Tax authorities may modify their interpretation and the current treatment of ADSs may change. According to the circular issued by the German Federal Ministry of Finance (*BMF-Schreiben*), dated May 21, 2019, (reference number IV C 1 – S 1980-1/16/10010 :001, ADSs are not treated as capital participation (*Kapitalbeteiligung*) within the meaning of Section 2 Para. 8 of the Investment Tax Code (*Investmentsteuergesetz*). Such interpretation by the fiscal authorities may have adverse effects on the taxation of investors.

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

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

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

costly process, and certain matters of procedure would still be governed by the law of the jurisdiction in which the foreign court resides.

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

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

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

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

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

If securities analysts publish negative evaluations of us, the price of the ADSs could decline.

The trading market for the ADSs will rely, in part, on the research and reports that industry or financial analysts publish about us or our business. If one or more of the analysts covering our business downgrade their evaluations of us, the price of the ADSs could decline. If one or more of these analysts cease to cover the ADSs, we could lose visibility in the market for the ADSs, which in turn could cause price of the ADSs to decline.

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

Our executive officers, directors, five percent shareholders, and their affiliates beneficially own approximately 83.40% of our ordinary shares as of January 31, 2020. Therefore, these shareholders will have the ability to influence us through their ownership positions. For example, these shareholders, acting together, may be able to exert significant influence over matters such as elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our ordinary shares that holders may believe are in their best interest as one of our shareholders.

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

There is no plan to declare or pay cash dividends on our ordinary shares. The intention is to retain all future earnings, if any, to finance the growth and development of the business. Additionally, the terms of any future debt agreements may preclude dividend payments. Our ability to pay dividends is also limited under the terms of the investment agreement we

have entered into with BMGF. As a result, capital appreciation, if any, on the ADSs will be the sole source of gain for the foreseeable future.

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

As a German tax resident company, if we were to pay dividends, such dividends will be subject to German withholding tax. Currently, the applicable German withholding tax rate is 26.375% of the gross dividend. This German tax can be reduced to the applicable U.S.-Germany income tax treaty, or Treaty, rate, which is generally 15%, if the applicable taxpayer is eligible for such Treaty rate and files an application containing a specific German tax certificate with the German Federal Central Tax Office (*Bundeszentralamt für Steuern*). If such a tax certificate cannot be delivered to the ADS holder due to applicable settlement mechanics or lack of information regarding the ADS holder, holders of the ADSs may be unable to benefit from the double tax treaty relief (including "Eligible U.S. Holders" as defined under the Treaty) and may be unable to file for a credit of such withholding tax in its jurisdiction of residence. Further, the payment made to the ADS holder equal to the net dividend may, under the tax law applicable to the ADS holder, qualify as taxable income that is in turn subject to withholding, which could mean that a dividend is effectively taxed twice. There can be no guarantee that the information delivery requirement can be satisfied in all cases, which could result in adverse tax consequences for affected ADS holders. ADS holders should note that the applicable interpretation circular (*Besteuerung von American Depositary Receipts (ADR) auf inländische Aktien*) issued by the German Federal Ministry of Finance *(Bundesministerium der Finanzen*), dated May 24, 2013 (reference number IV C 1-S2204/12/10003), as amended by the circular dated December 18, 2018 (reference number IV C 1-S2204/12/10003), or the ADR Tax Circular, is not binding on German courts, and there is no certainty as to whether a German tax court will follow the ADR Tax Circular in determining the German tax treatment of the ADSs. In addition, the ADR Tax Circular does not include details on how an ADR program should be designed. If the ADSs were determined not to fall within the scope of application of the ADR Tax Circular, or a German tax court did not follow the ADR Tax Circular, and profit distributions made with respect to the ADSs were not treated as a dividend for German tax purposes, a holder of the ADSs would not be entitled to a refund of any taxes withheld on the dividends under German tax law and profit distributions made with respect to the ADSs may be effectively taxed twice.

We could be subject to securities class action litigation.

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

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

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

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

If ADS holders bring a claim against us or the depositary in connection with matters arising under the deposit agreement or relating to the ADSs, including claims under federal securities laws, they may not be entitled to a jury trial

with respect to such claims, which may have the effect of limiting and discouraging lawsuits against us or the depositary. If a lawsuit is brought against us or the depositary under the deposit agreement, it may be heard only by a judge or justice of the applicable trial court, which would be conducted according to different civil procedures and may result in different outcomes than a trial by jury would have had, including results that could be less favorable to the plaintiffs in that action.

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

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

Item 4. Information on the Company

A. History and Development of the Company

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 http://www.biontech.de. The information contained on, or that can be accessed through, our website is not part of this document. Our agent for service of process in the United States is BioNTech USA Holding, LLC, 228 E 45th Street, Suite 9e, New York, NY 10017, +1 (347) 694-5321.

B. Business Overview

I. Overview

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

We and our collaborators have advanced a development pipeline of over 20 product candidates, of which 10 have entered into 11 ongoing clinical trials. While we believe our approach is broadly applicable across a number of therapeutic areas, our most advanced programs are focused on oncology, where we have treated over 400 patients across 17 tumor types to date. Our immunotherapy drug classes consist of messenger ribonucleic acid, or mRNA, therapeutics, engineered cell therapies, antibodies and small molecule immunomodulators. Our product candidates span oncology, infectious diseases and rare diseases.

We have assembled an exceptional team of over 1,300 employees and have established relationships with eight pharmaceutical collaborators, including Genentech, Inc., or Genentech, Sanofi S.A., or Sanofi, Genmab A/S, or Genmab, Genevant Sciences GmbH, or Genevant, Eli Lilly and Company, or Eli Lilly, Bayer AG, or Bayer, Pfizer Inc., or Pfizer, and Shanghai Fosun Pharmaceutical (Group) Co., Ltd., or Fosun Pharma (the latter was agreed to as of March 16, 2020). We have built out comprehensive, highly automated, on-demand in-house manufacturing capabilities that complement the development of our individualized immunotherapies.

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

- **mRNA Therapeutics.** We are utilizing messenger ribonucleic acid, or mRNA, to deliver genetic information to cells, where it is used to express proteins for therapeutic effect. We are developing a portfolio of immunotherapies that utilize four different mRNA formats and three different formulations to derive five distinct platforms for the treatment of cancer. Three of these platforms are currently in human testing: (i) our off-the-shelf shared antigen immunotherapy, or FixVac; (ii) our individualized neoantigen specific immunotherapy, or iNeST, in collaboration with Genentech; and (iii) our intratumoral immunotherapy, in collaboration with Sanofi. In addition, we are developing two platforms in which we use mRNA to express directly in the patient either (a) particular antibodies, or RiboMabs, or (b) specific cytokines, or RiboCytokines. In collaboration with Pfizer, the University of Pennsylvania, Genevant, and Fosun Pharma we are also leveraging our mRNA technology beyond oncology to treat influenza, other infectious diseases and rare diseases.
- **Engineered Cell Therapies.** We are developing a range of novel cell therapies in which the patient's T cells are modified to target cancer-specific antigens. These include two platforms for the treatment of solid tumors: chimeric antigen receptor, or CAR, T cells and T cell receptor, or TCR, programs. We are also combining our

mRNA FixVac platform with our first CAR-T product candidates, using "CARVac" immune boosters to enhance the persistence of CAR-T cells *in vivo*.

- **Antibodies.** We are developing, in collaboration with Genmab, next-generation bispecific antibodies that are designed to target immune checkpoints that modulate the patient's immune response to cancer. We are also exploring additional targeted cancer antibody approaches utilizing our in-house and recently acquired antibody capabilities.
- **Small Molecule Immunomodulators.** We use small molecules to augment the activity of other drug classes by inducing specific and discrete patterns of immunomodulation. We are developing a small molecule toll-like receptor 7, or TLR7, immunomodulator for the treatment of solid tumors.

We have leveraged these four drug classes to build a robust pipeline of product candidates. Our pipeline includes 10 product candidates in 11 ongoing clinical trials. Our most advanced programs are focused on oncology, where we have to-date treated over 400 patients across 17 solid tumor types. We also are developing more than 10 additional preclinical programs and expect to initiate clinical testing with several of them in the near future. We are targeting the advancement of up to three product candidates into the clinic in 2020, with clinical data updates for up to five programs expected by the end of 2020. In our Phase 1 trials, we have observed antigen-specific immune responses in over 90% of advanced melanoma patients treated with BNT111, our lead FixVac off-the-shelf product candidate, as a single agent. In addition, we have observed single-agent antigen-specific immune responses in patients treated with BNT121, the precursor to RO7198457 (BNT122), our lead iNeST product candidate. In both trials, we have observed durable objective responses (reduction in tumor volume) in both the monotherapy and checkpoint-combination settings.

We have established multiple collaborations to advance our science and development capabilities and provide non-dilutive capital. We have entered into selective collaborations with leading pharmaceutical companies where a collaborator may bring incremental expertise or resources that we currently do not possess in-house. To date, we have formed relationships with eight pharmaceutical companies, which comprise Genentech, Sanofi, Genmab, Genevant, Eli Lilly, Bayer, Pfizer and Fosun Pharma. We have entered into some of these collaborations in order to advance our technologies and business outside of our initial focus on cancer. We are collaborating with Pfizer to develop an influenza vaccine and Pfizer and Fosun Pharma to develop a COVID-19 vaccine, each through our mRNA-based immunotherapy technology. We also have a collaboration with Genevant to develop protein replacement therapies in up to five rare disease indications. We have also collaborated with the University of Pennsylvania, or Penn, to develop mRNA-based vaccines in up to 10 additional infectious disease indications. In addition, we have a relationship with Translational Oncology at the University Medical Center of the Johannes Gutenberg University Mainz (Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH), or TRON, to further our immunotherapy research. We either wholly own or retain significant rights to all of our clinical stage programs, either in the form of a global share of profit and co-commercialization rights with our collaborators in certain markets or significant royalties and milestones.

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

We were founded in 2008, and to date we have raised $1.4 billion of capital in private placements of our shares, our initial public offering and from our collaborators. Our investors include the Strüngmann family office, which is our majority shareholder, MIG Fonds, Fidelity Management & Research Company, Redmile Group, Janus Henderson Investors, the Invus Group, LLC and the Bill & Melinda Gates Foundation.

Our Team

Our team combines proven biotechnology entrepreneurs, world-renowned immunologists and sophisticated biopharma investors. We were founded in 2008 by our scientific founders, Prof. Ugur Sahin, M.D., Prof. Christoph Huber, M.D. and Özlem Türeci, M.D., with a seed investment of €150 million from the Strüngmann family, through its investment vehicle AT Impf, and MIG Fonds, or MIG. Andreas and Thomas Strüngmann are serial entrepreneurs, having co-founded Hexal AG, a German pharmaceutical firm, which they built and sold to Novartis, along with their majority stake in Eon

Labs, Inc., a U.S. public pharmaceutical firm, for a combined €5.6 billion (at the time, $8.3 billion). After selling Hexal, they founded a family office focused on healthcare. The Strüngmann family office and MIG have invested in, helped build and sold, either on their own or together, a number of biotechnology and healthcare companies, such as SuppreMol, Ganymed AG, or Ganymed, CorImmun, Sivantos (former Siemens hearing aid business), Press Ganey (surgery survey company) and Apceth (cell therapy manufacturing company). Helmut Jeggle and Michael Motschmann, on behalf of the Strüngmann family and MIG, respectively, along with Dr. Huber, were founding members of our Supervisory Board.

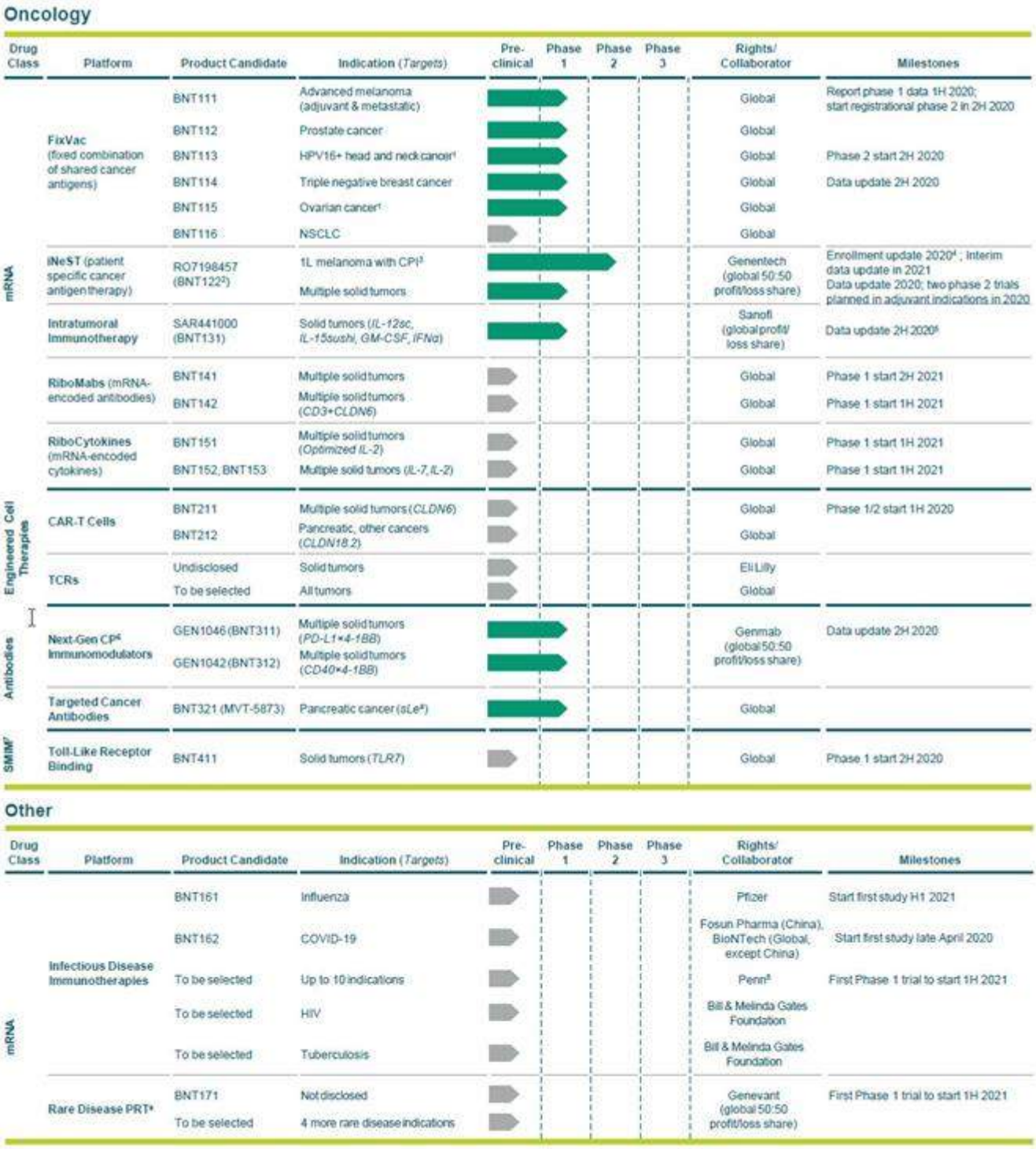
BioNTech has been supported since its inception by Prof. Rolf Zinkernagel, M.D., Ph.D. and Prof. Hans Hengartner, Ph.D., who serve on our Scientific Advisory Board. Dr. Zinkernagel is a Professor Emeritus at the University of Zurich, University Hospital, and former head of the Institute of Experimental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

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

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

A. Our Pipeline of Product Candidates

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



1. Oncology

FixVac. Our FixVac product candidates contain selected combinations of pharmacologically optimized uridine mRNA encoding known cancer-specific shared antigens. They feature our proprietary immunogenic mRNA backbone and proprietary RNA-lipoplex, or RNA-LPX, delivery formulation, designed to enhance stability and translation, target dendritic cells and trigger both innate and adaptive immune responses. We and investigators are currently evaluating five FixVac product candidates in clinical trials, including BNT111 in a Phase 1 trial in advanced melanoma, BNT112 in a Phase 1/2 trial in prostate cancer, BNT113 in a Phase 1 trial in HPV+ head and neck cancers, BNT114 in a Phase 1 trial in triple negative breast cancer and BNT115 in a Phase 1 trial in ovarian cancer.

As of the July 2019 interim cut-off, 95 patients with metastatic melanoma had been dosed at least once in our Phase 1 clinical trial of BNT111. Forty-two of these patients had macroscopic tumor lesions at the time they were enrolled, and these patients were evaluated for preliminary clinical activity, with 25 receiving BNT111 as a monotherapy and 17 receiving BNT in combination with a checkpoint inhibitor. Three of the 25 patients who received BNT111 as a monotherapy demonstrated a partial response, one patient had a metabolic complete response as measured by FGD-PET imaging and seven had stable disease following treatment. Six of the 17 patients who received BNT111 in combination with a checkpoint inhibitor demonstrated a partial response and two had stable disease following treatment.

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

Individualized neoantigen specific immunotherapy (iNeST). Our iNeST immunotherapies contain unmodified, pharmacologically optimized mRNA encoding up to 20 patient-specific neoantigens and also feature our proprietary RNA-LPX formulation. We are conducting, in collaboration with Genentech, clinical trials of our iNeST product candidate, RO7198457 (BNT122). The iNeST Phase 1a (monotherapy)/1b (in combination with atezolizumab) trial is a non-registrational, signal seeking study recruiting mostly patients with late stage advanced cancers, including patients that failed multiple lines of *prior* treatment. We believe that iNeST is particularly well suited for patients with a lower tumor burden. This notion is supported by clinical activity shown in our previously reported Phase 1 trial, in which BNT121 was administered intranodally in 13 patients with metastatic melanoma. In this trial, as of October 2019 we have observed stable, progression-free survival in nine patients for up to 41 months following surgery and treatment with BNT121. In addition, three out of five patients had an objective response, two patients received iNeST alone and the third patient also received checkpoint immunotherapy. We also observed a significant decrease in the cumulative recurrence rate post-treatment as compared to pre-treatment. Based on these findings, we, in collaboration with Genentech, initiated a randomized iNeST Phase 2 trial in first-line metastatic melanoma in combination with pembrolizumab. We and Genentech expect to report a data update from our RO7198457 (BNT122) Phase 1 trial in multiple solid tumors in 2020, and topline data update from our RO7198457 (BNT122) Phase 2 trial in first-line melanoma in the second half of 2020. We expect this topline data update to include an update on the ongoing study, including patient enrollment numbers, with full efficacy and safety data for an interim update expected in the second half of 2021. We and Genentech plan to initiate two additional clinical trials for RO7198457 (BNT122) in 2020 in first-line solid cancers in the adjuvant setting, one in combination with atezolizumab and the other as a monotherapy.

mRNA intratumoral immunotherapy. In collaboration with Sanofi, we are conducting a Phase 1 trial of SAR441000 (BNT131), our first mRNA-based intratumoral immunotherapy, as a monotherapy and in combination with cemiplimab in patients with solid tumors. SAR441000 (BNT131) consists of a modified mRNA that encodes the IL-12sc, IL-15sushi, GM-CSF and IFN-a cytokines. SAR441000 (BNT131) is designed to be administered directly into the tumor in order to alter the tumor *microenvironment* and enhance the immune system's ability to recognize and fight cancer within the tumor (proximal) as well as in other untreated locations (distal).

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

Next-generation checkpoint immunomodulators. We are developing, in collaboration with Genmab, novel next-generation bispecific antibodies that are designed for conditional activation of immunostimulatory checkpoint molecules. Our first bispecific candidates are GEN1046 (BNT311), which targets PD-L1 in conjunction with 4-1BB, and GEN1042 (BNT312), which targets *CD40* in conjunction with 4-1BB. While 4-1BB is a known immune checkpoint target that is expressed on T cells and natural killer, or NK, cells, prior attempts to target 4-1BB with monoclonal antibodies have been severely limited by liver toxicities. Our 4-1BB targeting product candidates are designed to avoid toxicities by conditionally activating a 4-1BB receptor only together with the binding of either PD-L1 or CD40. We have initiated Phase 1/2a trials of GEN1046 (BNT311) and GEN1042 (BNT312) in solid tumors.

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

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

- *RiboMabs:* novel classes of mRNA-based therapeutics that are designed to encode antibodies directly in the patient's body. We expect to initiate Phase 1 clinical trials for our first two RiboMab product candidates, BNT141 and BNT142, in the first half of 2021.
- *RiboCytokines*: novel classes of mRNA-based therapeutics that are designed to encode cytokines directly in the patient's body. We expect to initiate Phase 1 clinical trials for our first RiboCytokine product candidates, BNT151 and BNT152/BNT153 (combination), in the first half of 2021.
- *TCR therapy*: T cells with engineered TCRs that are designed to specifically target cancer cells.
- *Small molecule immunomodulators:* novel intratumoral agents that trigger inflammation and improvement of antigen presentation by antigen-presenting cells. We filed an IND for our first small molecule immunomodulator product candidate, BNT411, in the fourth quarter of 2019 and expect to initiate a Phase 1 clinical trial for BNT411 in solid tumors in the second half of 2020.

2. Infectious Disease Immunotherapies

We have collaborated with third parties to exploit the immunotherapeutic properties of our mRNA drug class for the treatment and prevention of *infectious* diseases. We expect to advance our flu vaccine into the clinic by the first half of 2021, and our first programs under our Penn collaboration into the clinic by the first half of 2021.

- *Flu vaccine:* In August 2018, we entered into a collaboration with Pfizer to the develop mRNA-based immunotherapies for the prevention of influenza, product candidate *BNT161*.
- *Infectious diseases:* In October 2018, we entered into a research collaboration with Penn, under which we have the exclusive option to develop and commercialize mRNA immunotherapies for the treatment of up to 10 infectious disease indications. In August 2019, we entered into a letter agreement and investment agreement with the Bill & Melinda Gates Foundation to advance the development of immunotherapies for the prevention and/or treatment of HIV and tuberculosis and up to three additional infectious diseases.

In response to the Coronavirus global pandemic, we are developing a potential vaccine based on mRNA technology to induce immunity and prevent COVID-19 infection in response to the growing global health threat posed by the disease. We intend to initiate clinical testing for the product candidate, BNT162, in late April 2020, subject to regulatory approval, as part of a global clinical development program in Europe (commencing in Germany), the United States and China.

In March 2020, we entered into a strategic alliance with Fosun Pharma to co-develop a COVID-19 vaccine in China. Upon *regulatory* approval, Fosun Pharma will commercialize the vaccine in China, while we retain the full rights to develop and commercialize the vaccine in the rest of the world.

Building on our existing collaboration with Pfizer, in March 2020, we signed a letter of intent to co-develop and distribute a COVID-*19* vaccine outside of China. We have also executed a Material Transfer and Collaboration Agreement to enable immediate collaboration.

3. Rare Disease Protein Replacement Therapies

We are collaborating with Genevant in order to capitalize on opportunities for our mRNA technology in rare disease indications potentially *featuring* expedited paths to market. We are combining our mRNA technology with Genevant's lipid nanoparticle, or LNP, delivery technology to create up to five mRNA protein replacement therapies for the treatment of rare diseases with high unmet medical needs. We expect our first compound to enter the clinic in the first half of 2021.

II. Our Strengths

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

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

- We have established leadership and expertise in immunology and oncology. Through 11 years of rigorous scientific investigation and clinical translation, we have developed a portfolio of disruptive immunotherapy technologies designed to address the challenges of disease heterogeneity and patient variability.
- Our team has consistently been first-movers and has published over 150 scientific papers in leading peer-reviewed journals. We were the first to develop an intravenously delivered mRNA-based human therapeutic, the first to advance an individualized mRNA-based cancer immunotherapy into clinical trials, and the first to establish scaled in-house manufacturing for such a product candidate.
- Since our founding in 2008, we have advanced four of our therapeutic platforms into human clinical trials, generated promising early evidence of clinical activity in several cancer types, raised $1.4 billion of capital from renowned global biopharmaceutical investors, formed collaborations with eight leading pharmaceutical companies, and acquired complementary assets ranging from research and manufacturing units to clinical programs.
- Our efforts are driven by a group of over 1,300 employees including over 400 in research and development, overseen by our founders who are internationally recognized thought leaders in their disciplines.

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

- Our portfolio includes four drug classes, spanning mRNA therapeutics, engineered cell therapies, antibodies and small molecule immunomodulators, which can be used alone or in combination to enhance therapeutic effect and produce potentially synergistic effects, as demonstrated in our combination of our BNT211 CAR-T product candidate with a CARVac immune primer.
- Our oncology pipeline includes 10 product candidates in 11 ongoing clinical trials, and more than 10 preclinical programs.
- We have developed significant expertise in the selection of optimal combinations of targets for the specific and individualized treatment of particular cancers. We have assembled libraries of more than 200 proprietary or known shared antigens and have developed predictive algorithms capable of efficiently identifying multiple neoantigens on an individualized basis for any patient.
- Our approach enables real-time monitoring of therapeutic effect on the immune system in a feedback loop of biological surveillance that we believe has the potential to further enhance the success of individualized immunotherapy approaches.

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

- Our most advanced programs are focused on oncology where we have to-date dosed over 400 patients across 17 solid tumor types.
- In our Phase 1 trials, we observed single-agent antigen specific immune responses in over 90% of advanced melanoma patients treated with BNT111, our lead off-the-shelf immunotherapy product candidate leveraging

our wholly owned FixVac platform. In addition, we observed single-agent antigen-specific immune responses in patients treated with BNT121, the precursor to our lead individualized neoantigen specific immunotherapy product candidate derived from our iNeST platform. For both candidates, we have observed durable objective responses in both the monotherapy and checkpoint combination settings.

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

- We have over a decade of experience pioneering the use of mRNA as a drug class, yielding five distinct mRNA platforms in oncology, each with the potential to generate multiple first-in-class product candidates.
- We have developed four distinct mRNA formats, each tailored to specific therapeutic applications. We have also developed and optimized multiple delivery formulations for our mRNA product candidates, including our proprietary non-viral RNA-LPX, to deliver our mRNA systemically and target it to relevant organs in the body.
- The combination of these platforms, formats and delivery formulations is designed to address a wide range of disease targets, and tailor drug products for systemic or intratumoral delivery, as well as directly encode mAbs or cytokines in vivo.
- This broad mRNA expertise is a core strategic asset of our company. It is protected by a global patent portfolio and our proprietary technical knowledge and trade secrets.

We have a deep, diversified pipeline and expect data updates for up to five oncology programs by the end of 2020.

- We have already advanced our portfolio to a critical stage of maturity with multiple programs progressing in parallel. We expect numerous near-term product candidate development updates, including:
  - data updates in up to five clinical programs by the end of 2020; and
  - advancement of up to three product candidates into the clinic in 2020.
- Our preclinical oncology pipeline is progressing rapidly. We initiated clinical trials for both of our lead checkpoint immunomodulator antibody product candidates in 2019, enrolled the first patients in clinical trials of BNT112 and BNT321 (MVT-5873). We expect to initiate a clinical trial for our lead CAR-T product candidate, as well as BNT162 for COVID-19, in the first half of 2020, and our and small molecule product candidate in the second half of 2020. We also expect to initiate clinical a clinical trial for our RiboMab and RiboCytokine product candidates in the first half of 2021.
- We expect to report our target indications and first product candidates for our infectious and rare disease platforms in 2020.

We have formed multiple collaborations with leading pharmaceutical companies and have retained significant development, commercial and financial rights across our portfolio.

- We have chosen to form collaborations in oncology to rapidly advance our science and enhance our development capabilities, bring our potentially disruptive therapies to patients more quickly and provide non-dilutive capital.
- We are currently collaborating with four pharmaceutical companies with expertise in oncology, including Genentech, Sanofi, Genmab and Eli Lilly, and have retained significant rights in each of our collaborations.
- In addition, we have formed collaborations with leading pharmaceutical companies to broaden our footprint beyond oncology. We have collaborations with Pfizer focused on influenza influenza and COVID-19, and Fosun Pharma for COVID-19. We are collaborating with Penn to develop mRNA-based immunotherapies for up to 10 additional infectious disease indications. We have also formed a collaboration with Genevant for up to five rare disease indications.
- We have retained worldwide rights to all product candidates under our FixVac, RiboMabs, RiboCytokines and CAR-T platforms.

We have created a vertically integrated business with comprehensive in-house manufacturing capabilities.

- We believe that to successfully bring individualized immunotherapies to patients, it is critical to control the manufacturing and supply processes. We therefore have chosen to invest early in scaling our in-house capabilities.

- We currently operate four manufacturing facilities in Germany spanning mRNA and peptide production, viral vectors and engineered T cells, and we continue to invest significant human and financial capital into these activities.
- In collaboration with Siemens, we are optimizing our iNeST production process, reducing turnaround time from over three months to less than six weeks currently, with the goal of delivering on-demand commercial supply.

Our Company's scientific DNA, which is the foundation of the BioNTech approach, has attracted a talented team from nearly 50 countries around the world.

- Prof. Ugur Sahin, M.D., our co-founder and Chief Executive Officer, and Özlem Türeci, M.D., our Chief Medical Officer, are physicians, scientists and innovators. They have made groundbreaking scientific and technological contributions in the field of personalized cancer immunotherapy and are co-inventors on more than 100 patents. Their daily work is motivated by their experience as researchers and cancer physicians aiming to exploit scientific insights and drive technological progress to develop commercially viable products that could help individual patients, an attitude and culture that has become the DNA of BioNTech.
- Our DNA, with a deep culture of intellectual curiosity and innovation, has made us a destination of choice for scientific pioneers. This culture has attracted an exceptionally talented team from nearly 50 countries around the world.
- We have participated in nearly 300 scientific publications, of which over 100 are in leading peer-reviewed journals.

III. Our Strategy

Our vision is to harness the power of the human immune system to develop truly individualized and patient-centric therapies for cancer and other serious diseases. We aim to rapidly develop, manufacture and, if approved, commercialize a portfolio of novel immunotherapies, including both off-the-shelf drugs and individualized treatments. The key elements of our strategy to achieve this vision are as follows:

Rapidly advance our potential first-in-class product candidates derived from our FixVac and iNeST platforms toward market approvals in oncology, either on our own or with our collaborators.

- We and investigators are conducting five Phase 1 clinical trials with our wholly owned off-the-shelf FixVac mRNA immunotherapy. Our most advanced current FixVac product candidate, BNT111, is currently being evaluated in 115 patients with advanced melanoma, and we expect to initiate a Phase 2 trial with registrational potential in the second half of 2020.
- We are also advancing, in collaboration with Genentech, our iNeST individualized neoantigen specific mRNA immunotherapy in two clinical trials, targeting more than eight tumor types, and have two additional clinical trials planned for 2020. Our most advanced iNeST program is a Phase 2 trial of our product candidate, RO7198457 (BNT122), in 132 patients with metastatic melanoma, evaluating iNeST in combination with pembrolizumab as a first-line therapy.
- We believe both FixVac and iNeST have therapeutic potential in a wide variety of solid tumors. We have identified significant market opportunities in additional indications and plan to pursue potentially expedited routes to market approval.

Progress additional product candidates through clinical development, leveraging our multiple drug classes and the synergies between them in order to expand our oncology pipeline.

- In addition to FixVac and iNeST, we are also conducting a Phase 1 clinical trial of our intratumoral immunotherapy product candidate SAR441000 (BNT131) in collaboration with Sanofi, as a monotherapy in patients with advanced melanoma and as a combination therapy with an anti-PD-1/PD-L1 checkpoint inhibitor in patients with certain solid tumors.
- Beyond mRNA, we plan to rapidly advance other product candidates from our immunotherapy drug classes into clinical proof-of-concept studies in solid tumor indications.

- In collaboration with Genmab, we have initiated Phase 1/2a clinical trials for our product candidates GEN1046 (BNT311) and GEN1042 (BNT312) in solid tumors. These product candidates are based on our novel checkpoint immunomodulator bispecific monoclonal antibodies, which we believe have potential in a broad range of cancers.
- We also plan to initiate a Phase 1/2 clinical trial in the first half of 2020 for our wholly owned CAR-T product candidate, BNT211, in multiple solid tumors, targeting a novel solid-tumor specific antigen, CLDN6.

Maximize the potential and leverage the broad applicability of our mRNA drug class in additional therapeutic areas beyond cancer, including through selective collaborations.

- Beyond oncology, we intend to leverage our mRNA technology to direct the immune system to fight a range of infectious diseases and address missing or defective proteins in certain rare diseases.
- Our collaborations with Pfizer in influenza and with Genevant in rare diseases underscore the potential of our approach. We intend to continue to seek value adding collaborations with leading industry players who contribute their competencies and know-how to complement our powerful suite of technologies to address challenging diseases outside of our core therapeutic focus on oncology.

Strengthen our position as a leader in the highly automated, on-demand manufacturing of individualized therapies with the goal of delivering our therapies globally.

- We will continue to invest to reduce cycle times and increase the automation of our processes, and to expand our manufacturing capacity across all platforms to support the efficient progression of our product candidates into late-stage clinical trials and commercialization.
- We will continue to invest in and scale up our advanced, in-house GMP manufacturing capabilities and capacity across mRNA and cell therapy production.

Establish a commercial organization to bring our portfolio of cancer immunotherapies to patients.

- We believe that developing our own commercial infrastructure will be key to maximizing the value of our programs. We intend to jointly participate in the commercialization of our collaborative programs where we retain significant commercial rights.
- We have expanded our footprint in the United States, and will continue to do so with the acquisition of Neon Therapeutics, if consummated, creating a U.S. research and development hub.

Expand our current technology suite by continuing to develop existing and new drug classes and platforms, and selectively in-licensing technologies that are complementary to our existing pipeline.

- As our understanding of immunology and oncology evolves, we plan to continue developing existing as well as new drug classes and platforms that are consistent with our strategy, with particular focus on those that can benefit from our in-house expertise.
- As evidenced by our recent acquisition of MabVax Therapeutics, we also continuously assess the external environment for novel drug classes, platforms and product candidates that can further expand and improve our pipeline of innovative immunotherapeutics, and help us to execute our strategy.

Maintain our culture of scientific excellence to continue to drive future innovation.

- We are committed to maintaining close ties to the scientific and academic community by fostering our many long-standing university relationships.
- We also intend to continue our leadership in the Association for Cancer Immunotherapy, or CIMT, which provides us potential new sources of innovation and academic collaboration opportunities.

IV. Immunotherapy in Cancer

The immune system has evolved over hundreds of millions of years to identify and eradicate what is foreign to the body with a high level of efficiency. The immune system's efficacy is attributable to approximately one trillion highly diversified immune cells that constantly travel throughout the body and interact in a coordinated manner. They are able to

detect and eliminate diseased cells and pathogens with high precision by relying on a broad range of immune recognition receptors. Their powerful mechanisms both synergize and regulate each other.

The goal of immunotherapy in the field of oncology is to harness the power of the immune system to recognize malignant cells as "foreign," overcome immune evasion mechanisms employed by cancers, eradicate cancer cells and thereby eliminate tumors.

Immunotherapy approaches in cancer have a long history. Recent years have seen an acceleration of scientific advancements and clinical breakthroughs in this field. The introduction over the last decade of checkpoint inhibitors such as Yervoy, Opdivo and Keytruda, and CAR-T therapies such as Yescarta and Kymriah has demonstrated that even leveraging one single mechanism to harness the immune system may result in unprecedented, significantly improved clinical outcomes for a subset of patients.

While these first-generation immunotherapies have ignited the paradigm shift toward immuno-oncology, they also have limitations. For example, less than 40% of patients respond to checkpoint inhibitors, while CAR-T therapies have been primarily limited to blood cancers in subsets of patients, and have been hampered by toxicities.

Realizing the full potential of immunotherapy is the objective of the next generation of immuno-oncology drugs to be developed.

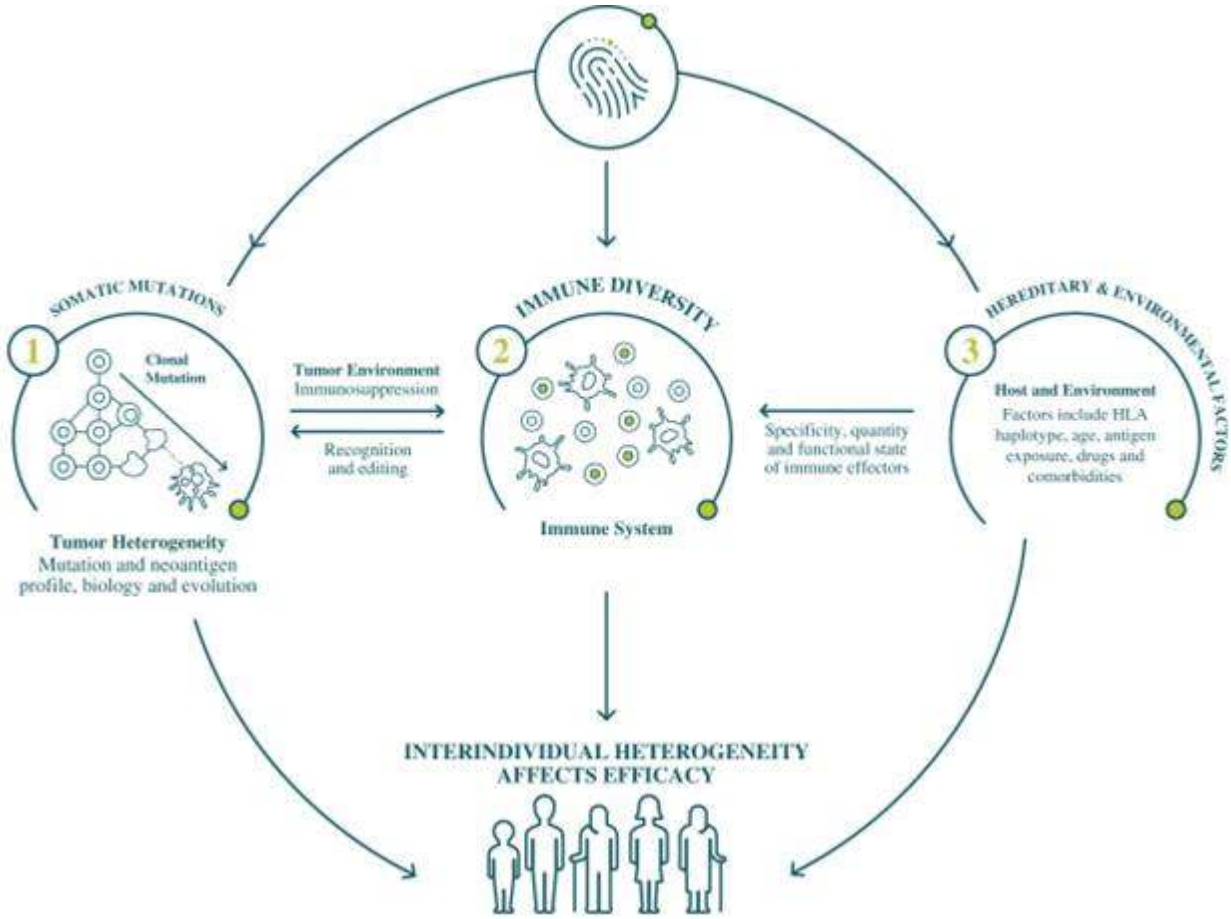
V. Challenges and Opportunities of Cancer Therapies

Cancer results from an accumulation of abnormalities, known as somatic mutations, in the genome of cells over time leading to malignant transformation, combined with a failure by the immune system to detect and eradicate such transformed cells. Due to their random nature, the vast majority of these aberrations are unique to the individual patient.

As a consequence, heterogeneity is an intrinsic hallmark of cancer, posing a key challenge for cancer therapy:

- **Interindividual tumor heterogeneity.** Tumors, even within the same cancer type, differ at the molecular level. For example, two patients with the same type of cancer usually share less than five percent of their mutations. As a result, patients often respond very differently to the same drug.
- **Intratumor heterogeneity.** Within the same patient, cancer also evolves over time so that different tumor cell clones co-exist, in a manner known as clonal evolution. As a result, a patient's cancer may be intra-tumorally as well as inter-tumorally heterogeneous. Therapies might target only a subfraction of tumor cell clones. This can lead to immune escape and therapy failure.
- **Cancer evolution and immune escapes**. Cancer cells can adapt to therapeutic pressure, which results in treatment resistance. During immunotherapy, tumor cell clones may evolve that no longer express T cell recognized antigens or have defects in their antigen presentation machinery.
- **Tumor microenvironment**. Tumors induce various forms of immunosuppressive microenvironments that prevent T cells from proliferating and executing their anti-tumor effector function.
- **Host, environment and immune system**. The functional state of each patient's immune system is dependent on the patient's age, genetic makeup and environmental exposures. For example, the HLA haplotype, or the genetic makeup that encodes the major histocompatibility complex, is highly individual and decisive for which epitopes of an antigen are presented to T cells. Whereas a given tumor antigen might be a good target in one patient, a second patient might not be able to respond to it at all.

The graphic below depicts the interaction between three key factors influencing the patient unique tumor profile:



Interindividual heterogeneity of patients. The interaction between cancer and immune system is shaped by various host, tumor and environmental factors. The complex interplay of these sources of interpatient heterogeneity affects both the course of disease and the efficacy of immunotherapy.

Together, these factors make cancer an extremely complex and heterogeneous disease. As a consequence, in the majority of cancer types, less than 40% of treated individuals benefit from highly potent approved therapies, and responses are often not durable. While these hallmarks of cancer are a challenge for cancer therapy, they also present opportunities for immunotherapy. These interconnected layers of complexity and variability require a deep understanding of an individual cancer and call for a patient-centric approach in order to find an optimal treatment.

Transformation of Cancer Therapies

We believe the recent convergence of breakthrough technologies in life sciences has enabled innovative concepts to address the immunobiology of cancer at its core. One of these breakthroughs has been the establishment of cancer immunotherapy in the armamentarium of cancer treatments. Another has been the emerging progress towards individualized medicine. Technologies such as next-generation sequencing, or NGS, have confirmed beyond doubt the problematic diversity of tumors on the inter-patient level. At the same time, NGS enables fast, cost-efficient and precise high-resolution mapping of each patient's individual disease. We believe the application of these breakthrough technologies has the potential to change drug development and profoundly alter the oncology treatment landscape.

The ability to translate a comprehensive molecular map of an individual tumor into treatment decisions, and make individually tailored therapeutics available, have become the focus of the next generation of cancer therapy. The technology necessary for leapfrog advancements in oncology now exists, but to realize its potential, a radical paradigm shift is required in drug development.

VI. The BioNTech Approach

We are focused on bringing cancer immunotherapy into the next generation. We believe that we can accomplish this by applying the following principles:

- **Exploiting the full potential of the immune system.** Our broad pipeline includes mRNA-based immune activators, antigen-targeting T cells and antibodies, and defined immunomodulators of various immune cell mechanisms. This portfolio is designed to mirror the evolution of the immune system to rely on multiple complementary pathways.
- **Broadening the universe of patients benefiting from cancer immunotherapy.** We discover and exploit novel targets and target combinations. Our aim is to extend the utility of immunotherapy to patient populations that are not currently amenable or do not benefit from the targets of current immunotherapies. One example are patients with low mutational load tumors, such as pancreatic and prostate cancer, which we address with tumor-associated antigens.
- **Improving the success rate.** We engineer and develop highly potent drug candidates designed to achieve precision for the specific target. We further augment activity and counteract resistance mechanisms by combining compounds with non-overlapping, synergistic mechanisms of action, such as combining our FixVac immunotherapy (CARVac) with our novel CAR-T therapies.
- **Focusing on curative approaches.** The root cause of recurrence or for lack of tumor eradication is interindividual variability and cancer heterogeneity. Addressing this biological reality is one of the mandatory design aspects of the product candidates we develop. For example, each of our cancer immunotherapies incorporates multiple targets in order to account for this variability.

We have applied these four guiding principles to a broad suite of therapeutic platforms optimized for a distinct mode of action, high precision targeting, high potency and efficacy. We expect each platform to yield a pipeline of drug candidates for further development.

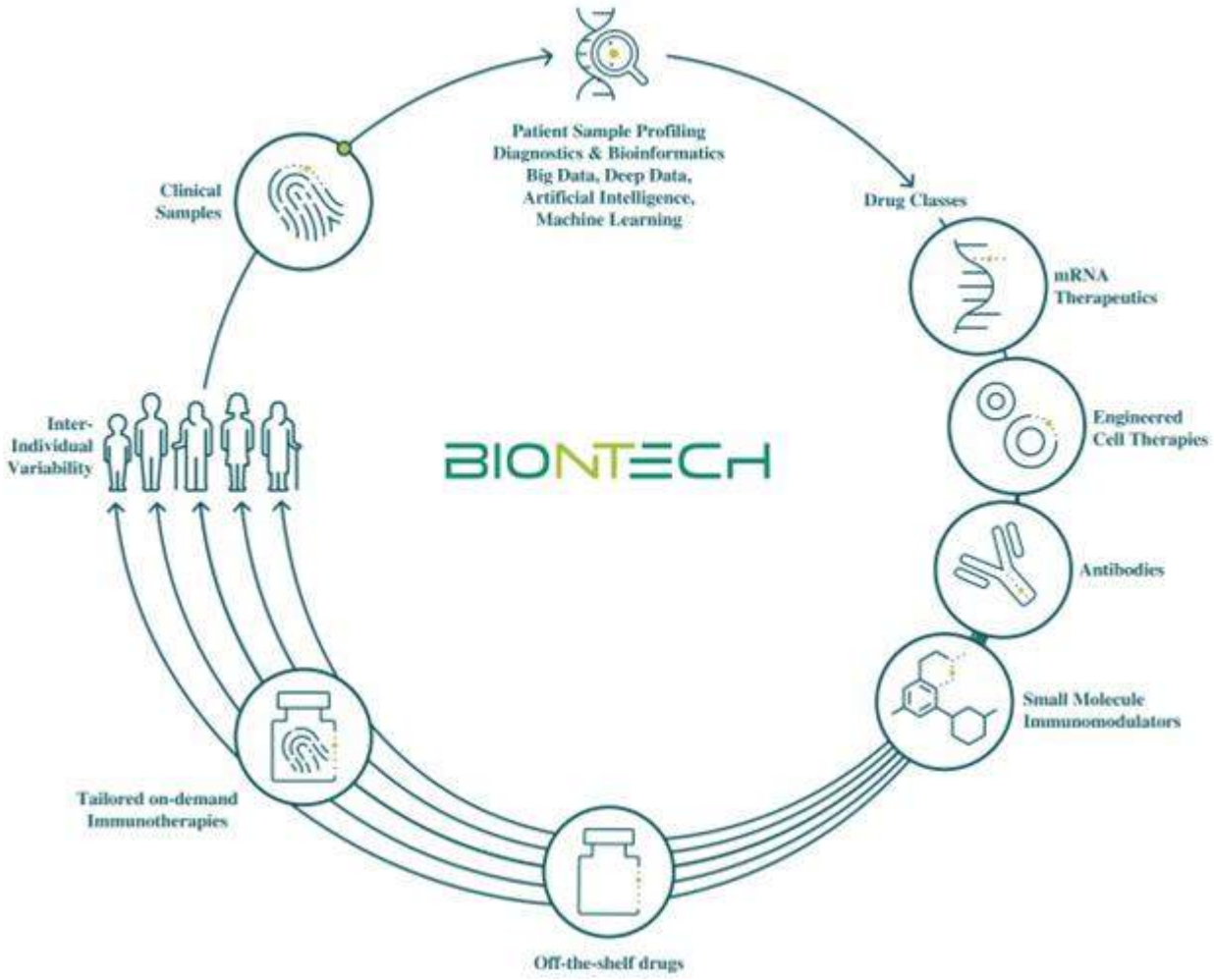
We believe this technology-agnostic range of platforms and product candidates positions us to remain at the forefront of the shift toward an individually tailored, patient-centric therapeutic approach in oncology.

Patient-Centric Model

We believe the next generation of cancer immunotherapy will start from the perspective of the molecular changes that have occurred in an individual patient, and then will provide a specific therapy *for that patient*. We believe that BioNTech is ideally positioned to drive this transformation.

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

Our patient-centric model is illustrated and described below:



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

Utilizing this model:

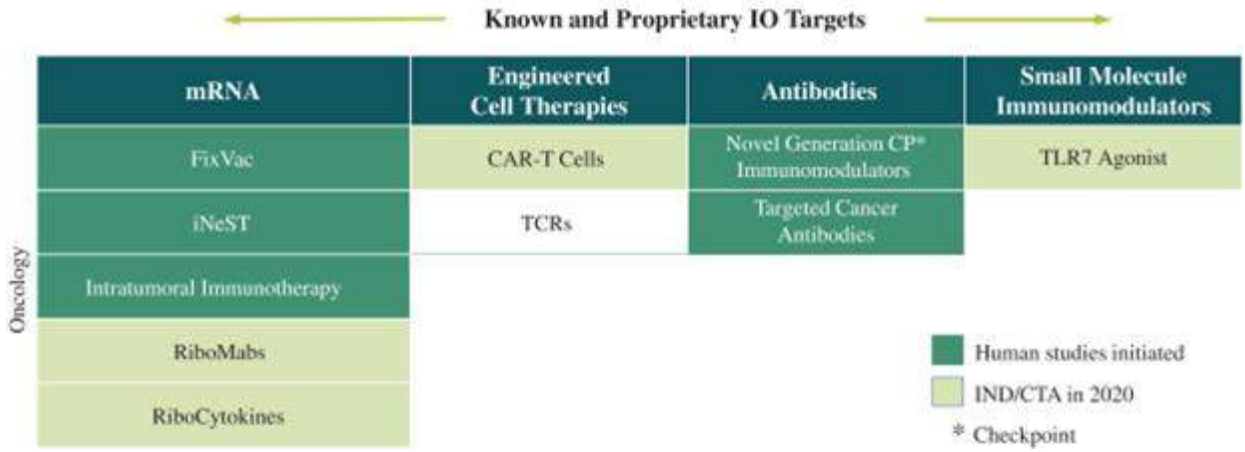
1. We develop and leverage our competencies in target discovery, biomarker science and computational medicine to thoroughly profile a patient's tumor sample and immune cells for the selection of suitable targets and treatments. Combined with our deep domain expertise in immuno-oncology and product vision, we are able to use this data to develop next-generation product candidates.
2. We have developed and are iteratively optimizing next-generation therapeutic platforms leveraging four drug classes. Each therapeutic platform bundles innovations designed to deliver a distinct mode of action with high-precision targeting, high potency and efficacy. Each platform is being developed to provide a pipeline of drug candidates with complementary and potentially synergistic modes of action.
3. Our drug platforms are highly versatile and support the fast development of scalable manufacturing processes. We develop and establish highly digitalized and automated manufacturing technologies and quality controlled processes enabling fast delivery of customized therapies comprising off-the-shelf drugs, on-demand immunotherapies, and combinations thereof.

We invest in innovation whenever we encounter technology barriers which may constrain clinical success. We are technology-agnostic and we seek to utilize the technology that is most suited for the respective purpose. By focusing on the

three pillars discussed above over the last decade, we have integrated all of the building blocks of immunotherapy under one roof, enabling an approach with the potential to optimize patient outcomes.

Broad and Potentially Synergistic Suite of Platforms

We believe the depth and breadth of our understanding of immune system and cancer biology allows us to create an extensive pipeline of specific and potentially efficacious product candidates. We are exploiting a comprehensive repertoire of known and proprietary therapeutically relevant immuno-oncology targets and are developing a diverse spectrum of immunotherapeutic approaches, as shown in the chart below.



We believe that harnessing complementary, potentially synergistic modes of action increases the likelihood of therapeutic success, reduces the risk of emergence of secondary resistance mechanisms, and also unlocks a larger potential market. Critically, this approach allows us to pursue a technology agnostic approach, providing the most appropriate therapeutic platform or a combination thereof for the intended patient and purpose.

For example, we believe our neoantigen immunotherapies are particularly well-suited to treat high mutation load cancers in the adjuvant setting to prevent the tumor from spreading or recurring following initial treatment such as surgery. In this setting, tumor volumes tend to be low and there remains the potential for strong T cell responses since the patient's immune system has not been weakened by prior lines of treatment, and checkpoint inhibition alone often offers a poor risk-benefit profile or low response rate. Similarly, we believe our FixVac, CAR-T and next-generation checkpoint immunomodulator platforms may have especially strong potential in lower mutation burden tumors such as ovarian or prostate cancers, which comprise a significant proportion of tumors and often also have a poor response to checkpoint inhibition. Likewise, we believe that monoclonal targeted cancer antibodies and CAR-T cell therapies are particularly well-suited for tumors that have defects in their antigen-presentation machinery.

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

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

Diversity of cancer patient populations, challenges and our therapeutic strategies. We believe our diversified portfolio allows us to potentially address a large share of cancer patients. Abbreviations: B2M, beta-2 microglobulin, a component of MHC.

VII. Selection of Therapeutic Targets and Therapies

Immunotherapy targets can be categorized as *antigens* for targeted immunotherapy with antibody- or T cell-based effector mechanisms and *immunomodulatory targets* to be exploited to improve the anti-tumoral function of immune cells.

A. Targeting Cancer Antigens

In order to address the broadest possible number of patients, our therapeutically targeted cancer antigen library comprises tumor associated antigens, viral neoantigens and mutant neoantigens:

1. Tumor Associated Antigens

Tumor associated antigens, or TAAs, are cancer selective targets that typically have a highly restricted expression pattern in normal tissues but are frequently expressed in a wide range of human cancers. Over the last 15 years, we have built up a database of approximately 200 cancer-selective antigens, including proprietary disease targets that could be used as targets for immunotherapy-based approaches.

- Cancer-Germline and Cancer-Embryo-Fetal Antigens, which are normally expressed during embryonal development and silenced after birth or restricted to germline cells. These antigens are aberrantly expressed in a variety of human malignancies and are generally not expressed in healthy tissue, making them particularly suitable for our FixVac-, antibody- and CAR-T cell-based therapeutic approaches.
- Differentiation antigens, which are normally expressed in a highly tissue-specific manner in normal tissues (*e.g.*, on melanocytes or on prostate cells) but are also present in a high proportion of tumors derived from these tissues, are well-suited for therapeutic targeting with FixVac and antibody approaches.
- Tumor-associated carbohydrate antigens are carbohydrate-based cell surface tumor antigens generated by cancer cell-specific aberrant glycosylation that enable the development of antibody and CAR-T cell therapies.

2. Viral Neoantigens

Viral oncoproteins, or viral neoantigens, are virus-derived proteins that drive the oncogenic transformation of infected cells by viruses that can cause cancer. Examples are the E6 and E7 oncoproteins from human papilloma virus, or HPV. Viral oncoproteins are commonly acknowledged as safe and promising targets for immunotherapy as

they are (i) absent from any non-infected tissue, (ii) highly immunogenic since they are not prone to central tolerance mechanisms and (iii) not subject to immune escape by gene silencing as they are crucial to maintaining the transformed state of the tumor cells. We leverage viral neoantigens as targets for our BNT113 FixVac program in HPV16+ head and neck cancer.

3. Mutant Neoantigens

Somatic mutations, or mutations of non-germline cells, are a hallmark of cancer. Driver mutations promote the oncogenic process, whereas passenger mutations are considered as functionally irrelevant. Both types of mutations, however, can alter the sequence of proteins and create new epitopes which are processed and presented on specialized major histocompatibility complex, or MHC, molecules. Mutated epitopes that are recognized by T cells are called neoepitopes and the sequence-altered proteins they are derived from are neoantigens. They are promising targets for cancer immunotherapy as (i) activation of the immune system against such antigens is highly specific (they are only expressed on cancer cells) and (ii) mutant neoantigens are exempt from central tolerance and thus T cell affinity for neoantigens may be significantly superior. We utilize individualized mutant neoantigens as targets for our iNeST product candidates.

B. Immunomodulatory Targets

The activity of immune cells can be controlled or manipulated by the targeting of receptors that control key biological processes in these cells, known as immunomodulation. Immunomodulatory targeting strategies include:

1. Checkpoint Inhibition

Checkpoint inhibition is a therapeutic approach by which T cell function is stimulated with mAbs that block their inhibitory receptors, which can be exploited by cancer cells to shut down T cell activity. Examples of checkpoint targets are PD-1, PD-L1, CTLA-4, TIGIT, LAG3 and many others. The concept is known as “releasing the brakes” and has been shown to be therapeutically effective in tumors with strong pre-existing immune cell infiltration. Our GEN1046 (BNT311) product candidate is a next-generation bispecific checkpoint immunomodulator, with one arm targeting PD-L1.

2. Immunostimulation

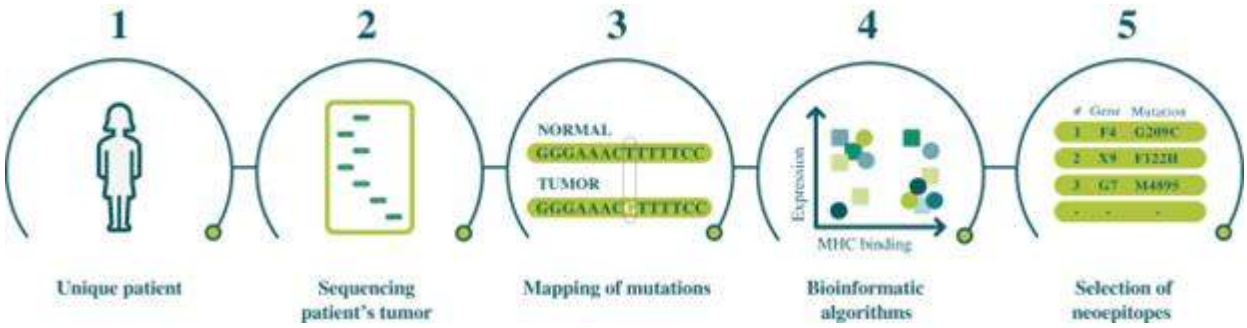
Immunostimulatory approaches are directed against receptors known to directly activate immune cells. Examples of these targets include co-stimulatory molecules such as CD40 and 4-1BB or cytokine receptors such as IL-2R, IL-7R and IL-12R. Immunostimulatory approaches provide a powerful opportunity to enhance immune activation, even in types of cancer that are not responsive to checkpoint inhibition due to lack of immune cell infiltration. However, this approach is often limited by a narrow therapeutic window associated with dose-limiting toxicity.

We believe that both concepts can be combined in a potentially synergistic and safe fashion by developing precisely engineered molecules, such as our BNT151 RiboCytokine program or GEN1042 (BNT312), our next-generation bispecific checkpoint immunomodulator targeting both CD40 and 4-1BB.

C. Our Computational Approach to Individualized Immunotherapy

Bioinformatics are critical in the production of individualized therapies. We have accumulated a high level of experience in bioinformatic approaches to mutation detection, cancer genomics and immunotherapy through our ongoing research and preclinical studies and clinical trials.

Our validated patient-centric bioinformatic process, as illustrated below, allows the application of complex algorithms to the patient's data in the context of drug manufacturing. Our bioinformatics processes are robust and scalable, incorporating our experience handling genomic data in a high-throughput environment, as we target making on-demand production of individualized immunotherapies commercially viable.



From Patient to Analysis. Our bioinformatic process for the selection of neoepitopes.

1. Sequencing

We sequence the patient's tumor and healthy tissue samples using NGS technology. Comparison of the patient's sequenced tumor and healthy samples provides us with the data from which we can identify targets for the design of individualized cancer immunotherapies. This is a multi-step process in which mutation detection and neoantigen prediction are particularly important.

2. Mutation Detection

Mutation detection, which defines which tumor-specific mutations are present in any cancer, is the starting point for defining targets for individualized immunotherapy. Determining mutations from NGS data with high precision and sensitivity is challenging because numerous factors can lead to false positives, which can mask mutations. Despite advances in the field, commonly used mutation detection algorithms still exhibit high false positive mutation detections. In order to address these challenges, we have exclusively licensed a technology from TRON that combines tumor modeling with mutation detection, called MyMUT. MyMUT is a next-generation mutation detection system, which we believe has the following key characteristics:

- **High specificity and robustness.** By combining tumor modeling, sophisticated statistical and genomic filters, and replicate sampling, MyMUT achieves clinical precision in detecting mutations with comparable sensitivity to state-of-the-art mutation detection systems. Higher specificity translates to potentially more effective immunotherapies, with faster and cheaper production. MyMUT is designed to deliver uniform performance for all patients regardless of tumor complexity, mutation burden or sample purity. MyMUT's performance with low mutation tumors also allows us to offer individualized immunotherapies to patients with low tumor mutation burdens.
- **Intratumor heterogeneity.** By performing tumor modeling, MyMUT can also identify clonal and subclonal mutations with high precision, allowing us to prioritize the former in neoantigen-directed immunotherapies and address intratumoral heterogeneity by targeting mutations that are common in a higher proportion of cancer cells within a tumor.
- **Quality control (QC).** By analyzing the genomic properties of sequenced samples, MyMUT can detect errors that pass standard sequencing QC, ensuring the quality and safety of individualized immunotherapies.

3. Neoepitope Selection

Only a portion of mutated peptides (neoepitopes) are suitable for raising an immune response *in vivo*. Our approach focuses on evoking responses involving both $CD8^+$ T cells and $CD4^+$ T cells. We do this by discerning the likelihood of presentation of the neoepitope to the T cell receptor as an MHC peptide complex using data from mRNA expression levels and MHC binding affinity predictions, among other factors. For example, in our first

individualized neoepitope immunotherapy clinical study, all 13 stage III and IV melanoma patients selected for treatment developed a $CD4^+$ and/or $CD8^+$ T cell response, achieving an overall 60% immune response rate to predicted neoepitopes.

Presentation of a neoepitope on an MHC molecule does not, however, guarantee recognition by T cells, and an integrated view combining several properties impacting immunogenicity is necessary. Our algorithms are continuously being improved and extended with data collections from various sources such as our past and current clinical studies as well as HLA data. By using machine learning approaches applied to these large datasets we aim to further improve prediction of overall presentation of neoepitopes tailored to patients' specific HLA types.

VIII. Our mRNA Drug Class

At a glance: mRNA as a Therapeutic Drug Class

- Natural molecule found universally within cells, with well-characterized properties.
- Suitable to encode for antibodies, antigens, cytokines and any other type of protein.
- Transient, with adaptable activity and half-life. Avoids genomic integration problems sometimes seen in gene therapy, potentially resulting in a better safety profile.
- Can be designed and optimized pharmacologically and immunologically, making it suitable for a broad range of applications.
- Fast manufacturability, making it an inexpensive and flexible therapeutic to produce.

In the last decade mRNA has progressed into a promising new class of medicine, with the potential to treat a wide variety of diseases with high unmet medical needs. mRNA is a long, polymeric molecule, composed of four different building blocks called nucleotides. In mRNA, hundreds or thousands of these nucleotides are linked in a unique order to convey genetic information to cells, where it is used to express proteins with biological effects.

Considering that all mRNA is generated with four different building blocks, but with unique sequence order, all therapeutic mRNAs have highly similar compositions, while having the capacity to encode a variety of different proteins. These characteristics allow for rapid development of mRNA therapeutics that are broadly applicable for treatment of many diseases, including cancer, infectious diseases and rare diseases. Our mRNA pipeline addresses all of these therapeutic areas.

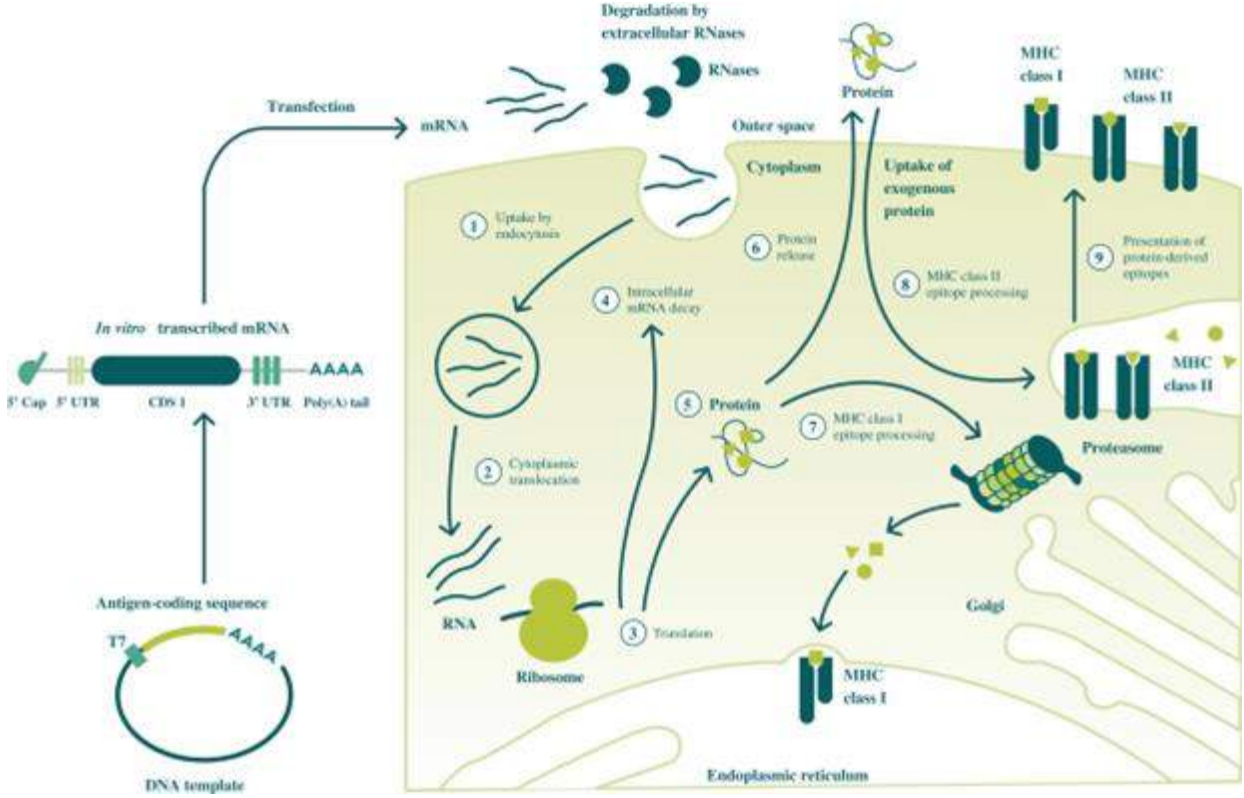
A. General Principles of mRNA Pharmacology

As a drug, manufactured mRNA provides instructions to a target cell to produce a desired therapeutic protein. The mRNA drug will temporarily change the status of the target cell where these instructions are translated into proteins. Based on the information encoded by the mRNA, the proteins will be either secreted or remain intracellular. The mRNA drug will eventually be degraded and eliminated from the body.

Our mRNA drugs are synthesized from a DNA template. With the exception of the 5' cap, the template determines all structural elements of the mRNA. The mRNA molecule comprises:

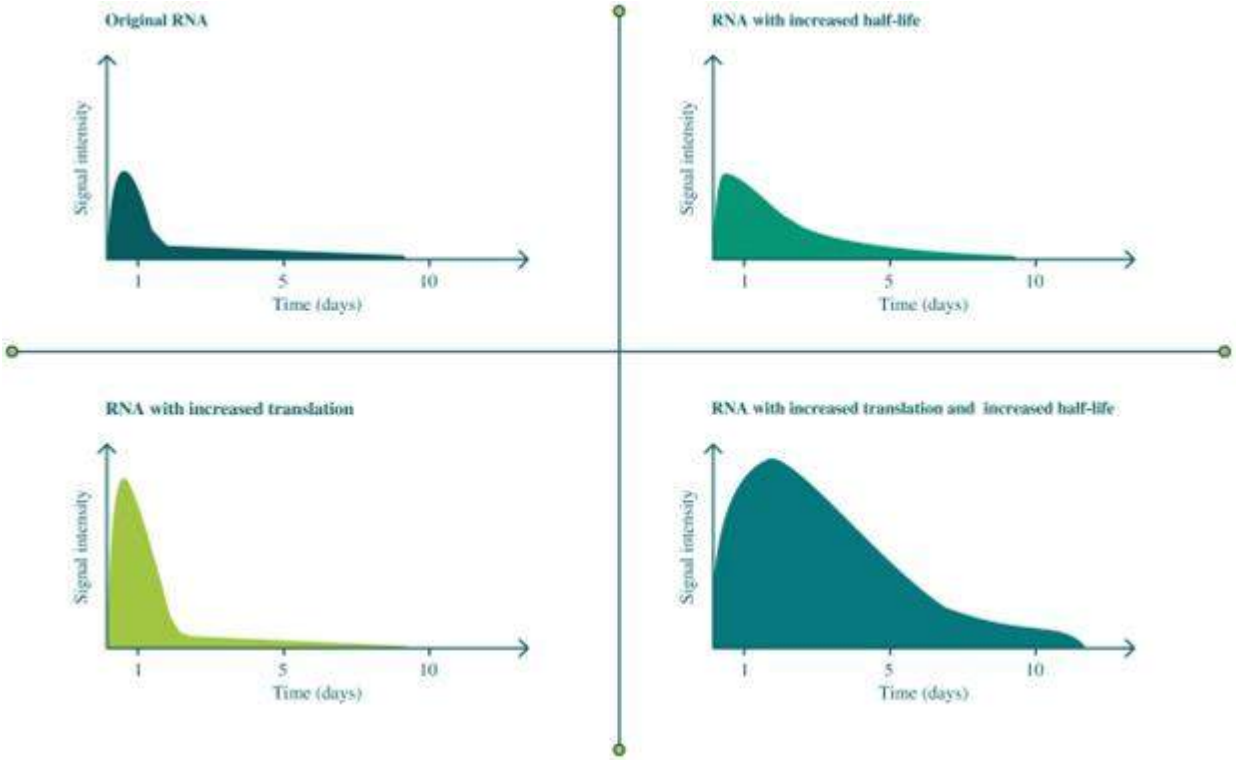
- an open reading frame, or ORF, which encodes for the protein of interest;
- untranslated regions, or UTRs, which flank the ORF; and
- the cap and the poly(A) tail, which are the two terminal structures of the linear mRNA, and are responsible for increased stability and translational efficiency of mRNA.

The mRNA drug needs to be appropriately formulated in order to protect it from breakdown by extracellular RNAses. The formulation is selected based on the intended application and route of delivery. After uptake into the target cell, the mRNA molecules are loaded into ribosomes, where translation into protein takes place. Subsequently, the mRNA is degraded by cellular mechanisms. In case of an immunotherapy application, the protein is degraded into immunogenic epitopes. These are loaded onto specialized molecules, namely MHC I or MHC II. These molecules present the epitopes to immune cells to provoke the desired immune response. In the case of other mRNA applications, the mRNA encodes proteins that are secreted from the cells, such as antibodies, and function extracellularly.



General principles of mRNA pharmacology. Step 1: mRNA is either delivered in a buffered solution as naked molecules or formulated as nano-particles to protect degradation by extracellular enzymes and is taken up by cells. Step 2: Subsequently, mRNA is released from endosomes into the cytoplasm. Step 3: mRNA is translated by the protein synthesis machinery of host cells. Step 4: Termination of translation by degradation of mRNA. Step 5: The translated protein product acts in the cell in which it has been generated. Step 6: Alternatively, the protein product is secreted and may act via autocrine, paracrine or systemic, body-wide mechanisms. Steps 7 and 8: For vaccine activity, mRNA encoded antigens are degraded into shorter fragments and loaded onto MHC class I and class II molecules. Step 9: Protein-derived epitopes can then be presented on the cell surface by both MHC class I and MHC class II molecules, enabling stimulation of $CD8^+$ and $CD4^+$ T cells.

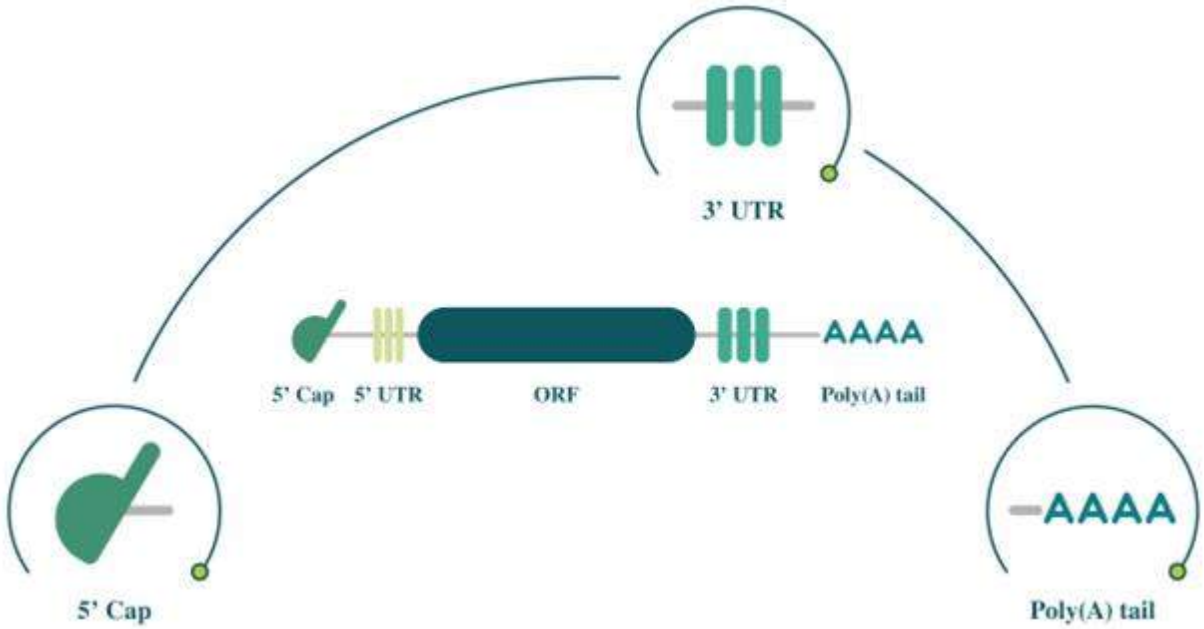
The structural elements of the mRNA have an impact on its performance. This includes potential immunogenicity, efficacy of translation and stability of the molecule. We leverage our extensive experience to design, synthesize, manufacture and formulate our therapeutic mRNA, and adapt its composition to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



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

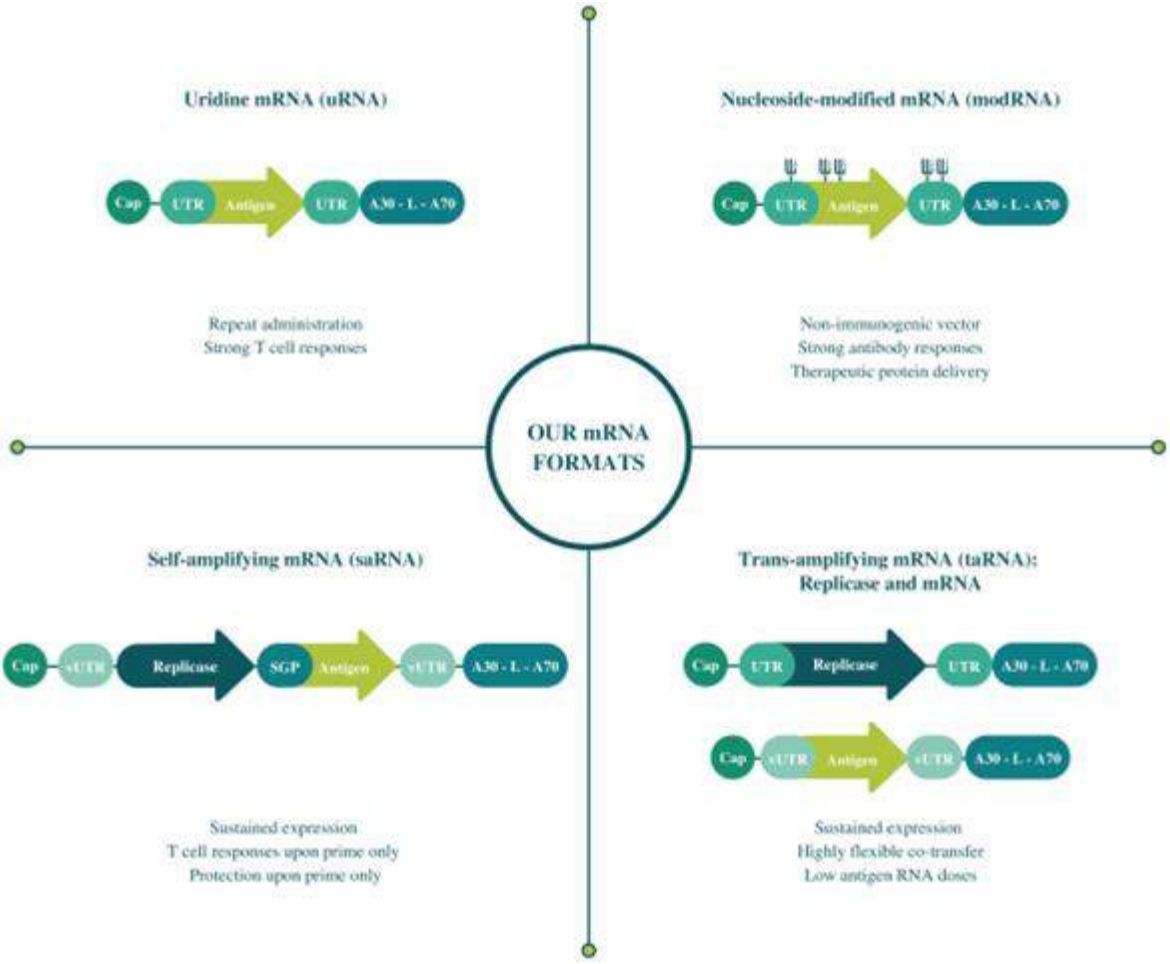
B. Our mRNA Backbone Concepts and Technologies

Our mRNAs all contain basic structural elements, including the 5' cap, the untranslated regions and the poly(A) tail, in addition to a coding sequence, that are all encoded by our DNA template.



- The cap is added to the 5' end of the mRNA during its synthesis. Our studies have demonstrated that incorporation of a unique cap analogue into the mRNA helps to achieve superior translational performance by stabilizing the mRNA molecule and directing the immune response. This unique cap analogue is extremely useful for our immunotherapy approaches.
- The composition and structure of the 5' and 3' untranslated regions of the mRNA molecule are important determinants of the intracellular stability of mRNA. As a result of rigorous screening of different mRNA sequences, we identified specific UTRs that promote increased protein translation for long duration.
- We have performed extensive research on the structure of the poly(A) tail and the translational performance of mRNA and customized our template design accordingly.

The translational performance of mRNA can be increased by removing contaminating double-stranded RNA from the mRNA. We have extensive expertise in different mRNA purification procedures. We have also invented a novel mRNA purification method that greatly impacts translatability of our mRNA. Depending on the protein characteristics needed for treatment of a disease, we optimize the DNA template through a proprietary codon optimization process, changing the nucleotide sequence of the template without altering the amino acid composition of the encoded protein. We make further adjustments during mRNA production. We believe these fine tunings of the respective molecules are essential for the purpose-adapted performance of our mRNA.



Our mRNA formats. As shown above, we have developed four mRNA formats, each optimized for different therapeutic applications. Abbreviations: y, 1-methylpseudouridine; UTR, untranslated region.

Our mRNA formats include:

1. Optimized Uridine mRNA (uRNA)

The nucleotide sequence of mRNA determines the amino acid sequence of the protein. In addition, the nature of nucleosides used for production of mRNA drugs can also influence recognition of the molecule by the immune system. Presence of naturally occurring uridine (U) in our optimized uridine mRNA makes it immunogenic by activating immune sensors. We have further optimized our uridine mRNA for immunogenicity (augmented antigen presentation on MHC I and MHC II) and pharmacological activity (enhanced stability and translational efficiency). Immunogenicity of the mRNA is an added benefit when mRNA is used for immunotherapy applications, by acting as an immunotherapy adjuvant. This makes our therapeutics for iNeST and FixVac even more potent.

2. Nucleoside-modified mRNA (modRNA)

Immunogenic reaction against mRNA drugs needs to be avoided in applications where therapeutic proteins are produced, such as in our RiboMab and RiboCytokine platforms. We have profound expertise in incorporating naturally-occurring modified nucleosides into our therapeutic mRNAs. We have demonstrated that the presence of a variety of modified nucleosides in the manufactured mRNA suppresses its intrinsic immune activation, while leading to superior protein production for long duration. Deimmunizing mRNA by incorporating modified nucleosides helps to avoid production of anti-drug antibodies and broaden the therapeutic application of these types of mRNA drugs. We believe this customization has resulted in therapeutic mRNA that is both potent and well tolerated.

3. Self-amplifying mRNA (saRNA)

Our self-amplifying mRNA, or saRNA, drugs use the concept of viral replication, while not being an infectious, disease-causing agent itself. saRNA resembles conventional mRNA encoding the protein of interest, but also encoding a polymerase, called replicase, that multiplies part of the mRNA within the target cell. During self-amplification inside the cell, a double-stranded RNA intermediate is generated, which is recognized by intracellular immune sensors. This makes saRNA a very potent activator of the immune system and therefore an excellent category of immunotherapy. As we have demonstrated, our saRNA ensures high levels of sustained antigen production with a small amount of initial mRNA input. Our scientific team has designed this mRNA technology to act as a potent tool for prophylactic vaccination, with the potential application in infectious diseases with high medical needs.

4. Trans-amplifying mRNA (taRNA)

We have also expanded on our self-amplifying mRNA capabilities, developing a novel mRNA amplification technology by separating the target mRNA to be amplified and the replicase encoding mRNA. This advancement broadens the spectrum of applications by making the development of therapeutic mRNAs even more flexible, as the replicase can amplify mRNA encoding of not only one protein, but several different ones. In the case of vaccines, this allows us to produce the replicase in advance for use with different vaccines. Our trans-amplifying mRNA is a proprietary mRNA format that is particularly well-suited for prophylactic vaccines to prevent infectious diseases.

C. Our mRNA Delivery Formulation Technologies

We have deep and broad expertise in the targeted delivery of mRNA therapeutics. We are convinced that our development of suitable delivery formulations in conjunction with our own therapeutic mRNAs is a key competitive advantage.

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

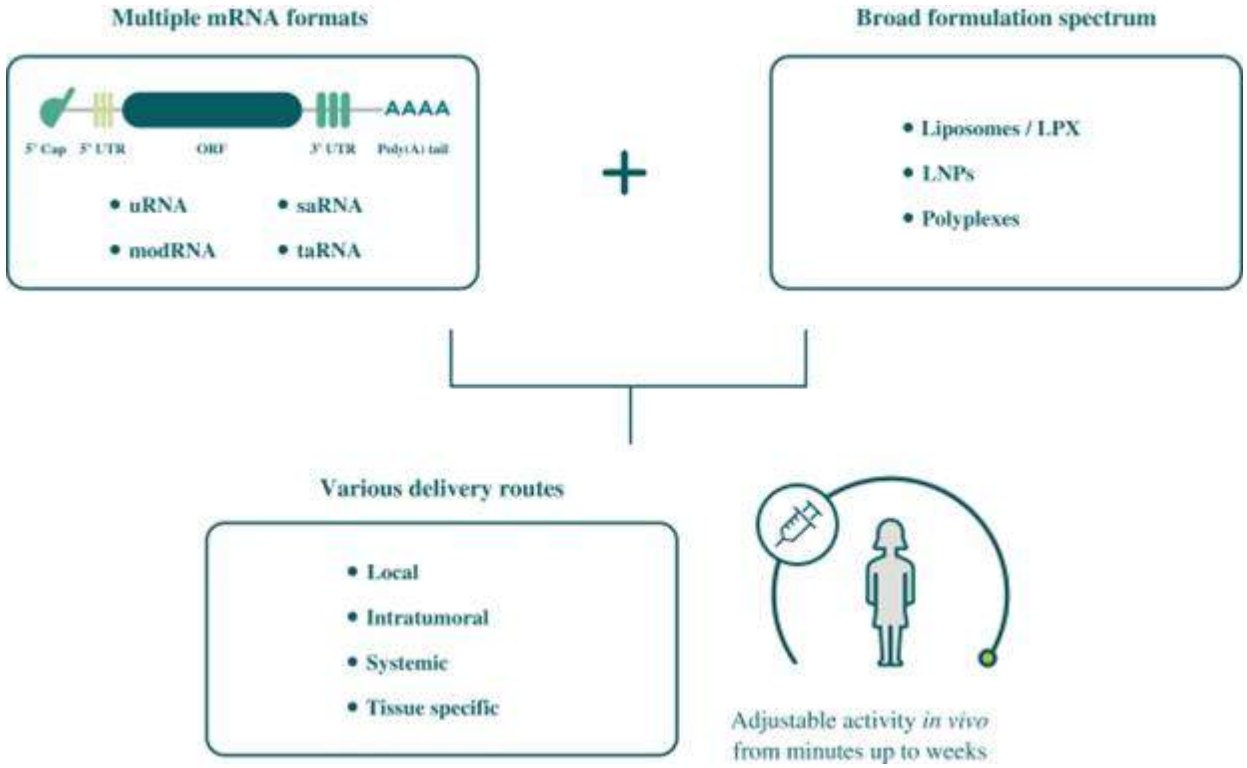
We employ multiple mRNA delivery formulations, each designed for different functions and optimized for therapeutic product needs:

- **Lipoplex:** Our lipoplex formulation, or LPX, embeds the mRNA between a lipid bilayer, which is used for our FixVac and iNeST platforms. We use a proprietary size- and charge-based non-viral mRNA lipoplex that was

developed to deliver mRNA to dendritic cells in lymphoid compartments such as the spleen for optimal antigen presentation and immune response activation.

- **LNPs:** For other applications, we encapsulate our mRNA in lipid nanoparticles, or LNPs. These formulations are suitable for our RiboMab, RiboCytokine and rare disease protein replacement platforms. Our LNP formulations can be adjusted according to our needs for delivery to particular target tissues, such as the liver in the case of our rare disease protein replacement platform.
- **Polyplexes:** Our portfolio also comprises polyplexes, which are being utilized in certain of our discovery programs, in which the mRNA is bound to a polymer and then forms nanoparticles.

As shown in the graphic below, our mRNA platforms utilize our wide range of mRNA formats, mRNA delivery formulations and mRNA delivery routes to optimize and tailor treatments.



Our therapeutic mRNA technology toolbox. Our product candidates utilize multiple mRNA formats, a broad spectrum of delivery formulations and applications using various delivery routes.

D. Our mRNA Platforms

We are developing multiple mRNA-based therapeutic platforms. These include FixVac, iNeST, mRNA-based intratumoral immunotherapy, RiboMabs and RiboCytokines in the oncology space. In addition, we have implemented mRNA platforms for the development of infectious disease vaccines and protein replacement therapies for rare diseases.

Importantly, each of these platforms enables the development of multiple pharmaceutical product candidates or programs.

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

Our mRNA Platforms. We have multiple mRNA-based platforms utilizing different mRNA formats and delivery formulations, directed at a range of biological targets in oncology and infectious and rare diseases.

1. Cancer Immunotherapies

Our goal is to develop safe, potent, efficacious and cost-effective cancer immunotherapies which stimulate and potently expand tumor cell specific $CD4^+$ and $CD8^+$ T cells in cancer patients. Our cancer immunotherapy development integrates our competencies in mRNA backbone optimization, formulation development and immunological research.

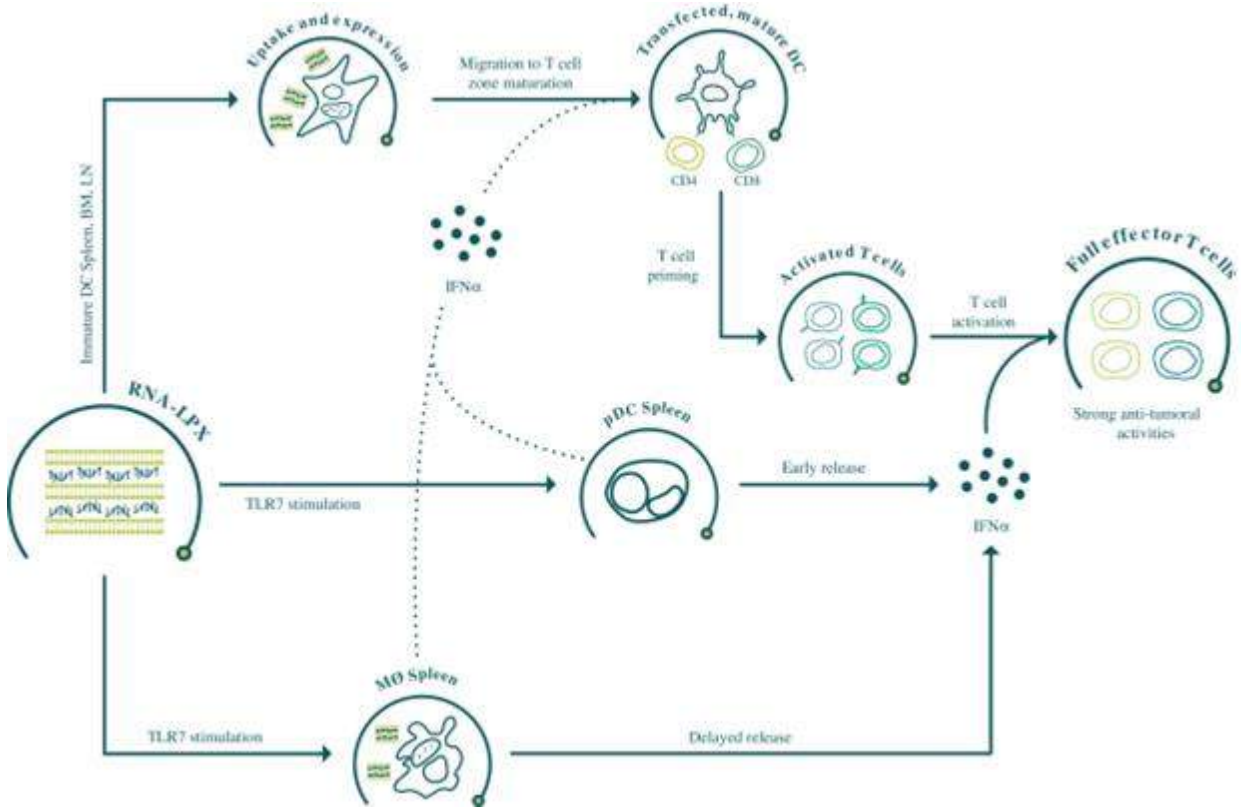
We have developed novel immunotherapy approaches to replicate the highly potent and effective natural activation of the immune system in response to a viral infection. Our first generation mRNA cancer immunotherapies were delivered as naked mRNA by ultrasound guided injection into a patient's lymph node and induced T cell responses and antitumoral activity when targeting mutant neoantigens in advanced melanoma patients. To further improve this potency and antigen specificity we have developed a nano-particulate mRNA lipoplex immunotherapy for intravenous delivery.

RNA-LPX Technology

At a glance: RNA-LPX Cancer Immunotherapy Technology

- Potential first-in-class clinical intravenous nano-particulate mRNA immunotherapy, allowing systemic delivery.
- Strong potency by systemic targeting to dendritic cells in lymphoid tissues.
- Universally applicable for all cancer antigens.
- Opportunity to deliver multiple antigens in parallel, enabling the induction of poly-specific T cell responses.
- Synchronized adjuvant effect mediated by toll-like receptor 7 (TLR7)-triggering and type-I interferon-driven innate and adaptive immune stimulation.
- Preclinical anti-tumoral activity demonstrated against multiple tumors.
- Unprecedented clinical immune responses against shared TAAs.
- Beneficial clinical activity demonstrated in advanced melanoma patients.

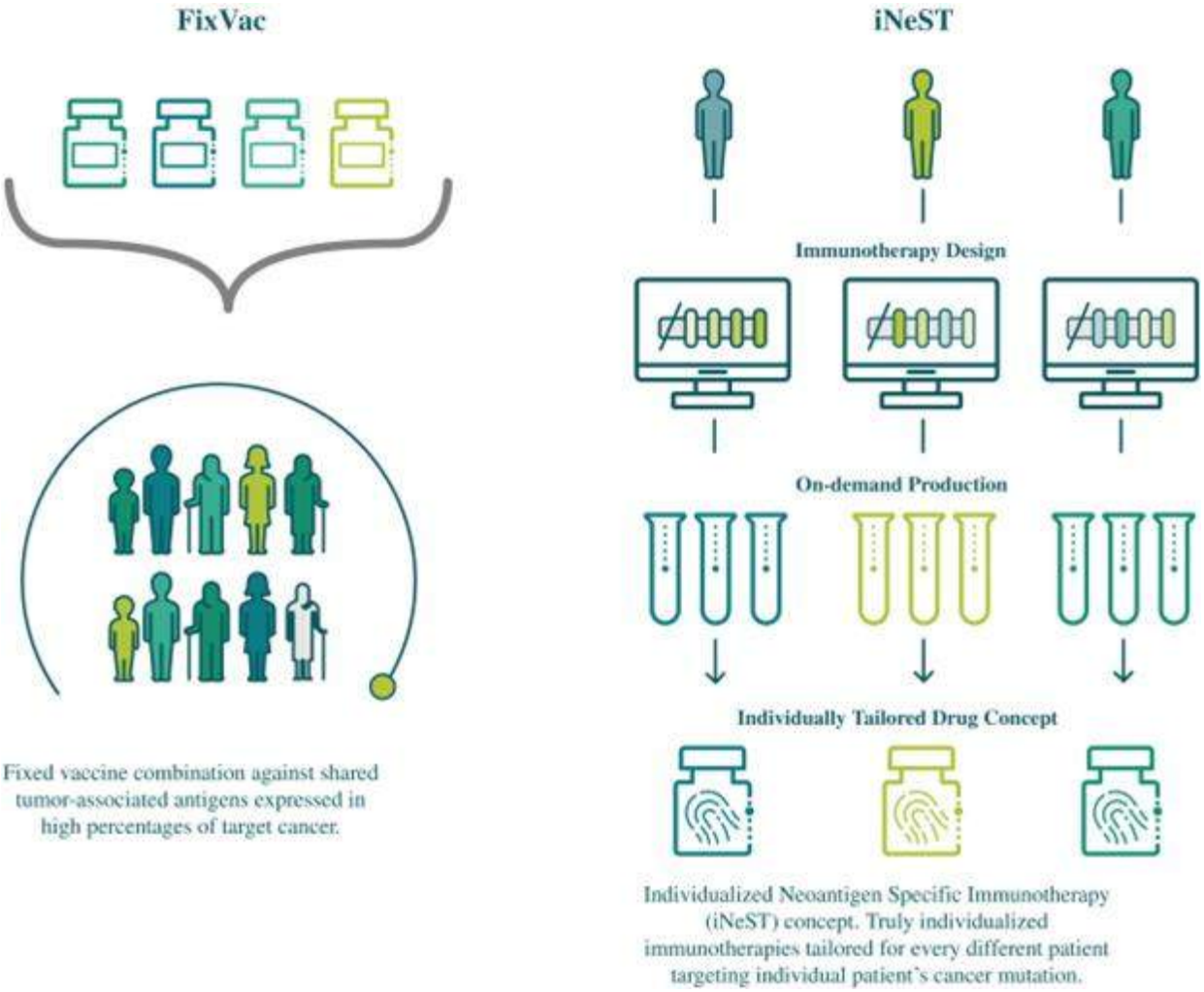
To advance from local to systemic dendritic cell, or DC, targeting, we developed an innovative liposome-based RNA-lipoplex formulation, RNA-LPX, that allows for intravenous administration of our mRNA cancer immunotherapies. We have demonstrated in the clinic that systemic DC targeting by mRNA cancer immunotherapies can result in potent activity at very low doses. Consequently, less material is required for treating high patient numbers, making manufacturing more cost-effective.



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

RNA-LPX protects mRNA from degradation outside of the cell and mediates its efficient uptake and expression of encoded antigens in various dendritic cell populations.

Our RNA-LPX technology is designed to target a wide variety of antigens and address cancer patients with all possible HLA haplotypes. Utilizing RNA-LPX, we can target fixed groups of known shared antigens with our FixVac platform and a whole new class of patient-specific neoantigen targets with our iNeST platform.



a) FixVac

At a glance: Our FixVac Platform

- **Concept:** Cancer immunotherapies targeting shared antigens that we have identified to be frequently expressed across patients with a specific cancer type.
- **mRNA Format:** Optimized uridine mRNA providing superior immunogenicity.
- **mRNA Delivery Formulation:** Proprietary size- and charge-based RNA-LPX targeting DCs.
- **Development Approach:** Worldwide rights; wholly owned.
- **Lead Candidate:** BNT111 for metastatic melanoma.
- **Data Highlights:** Three partial responses, one complete response and seven stable diseases in 25 patients with metastatic lesions at enrollment, following BNT111 monotherapy.

Our FixVac approach involves off-the-shelf mRNA immunotherapies targeting cancer cell-specific shared tumor associated antigens for selected patient populations. Our FixVac product candidates target TAAs which are commonly expressed by a significant portion of patients in a given cancer type. We have developed a sophisticated target selection process which enables us to produce poly-specific FixVac immunotherapies that

cover up to 95% of patients with a given cancer type. The use of off-the-shelf FixVac immunotherapies allows for large-batch manufacturing and prompt supply to patients with ready-to-use medication, ensuring a straight-forward cost- and time-efficient manufacturing process with favorable logistics.

Besides targeting commonly expressed TAAs, our target selection strategy facilitates the identification of suitable viral oncoproteins for the treatment of virus-induced cancers like HPV+ head and neck cancer. Patient stratification, if needed, can easily be performed at the clinical site or a central lab using standard biotechnological methods, thereby reducing treatment costs. As the viral genome is comparatively small, encoding only for a few proteins, we believe our FixVac approach is ideally suited for the treatment of virus-induced cancers.

Our FixVac Development Plan

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

Candidate	Antigens	Development Phase	Next Potential Milestone
BNT111	Melanoma-specific antigens: NY-ESO-1, tyrosinase, MAGE-A3 and TPTE	Phase 1: Advanced melanoma	Report Phase 1 data in 1H 2020; initiate Phase 2 trial with registrational potential in 2H 2020
BNT112	Five prostate cancer-specific antigens, including PAP and three internally identified antigens	Phase 1/2: Prostate cancer	—
BNT113	HPV E6 and E7 oncoproteins	Phase 1: HPV+ head and neck cancer (IST)	Initiate Phase 2 trial with registrational potential in 2H 2020
BNT114	Selected breast cancer-specific antigens	Phase 1: TNBC	Report data update in 2H 2020 and assess antigen immunogenicity
BNT115	Selected ovarian cancer-specific antigens	Phase 1	—
BNT116	Non-small cell lung cancer	Preclinical	—

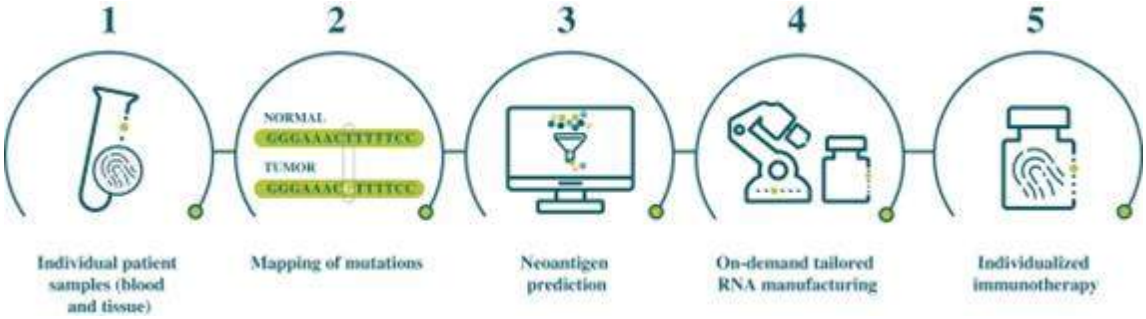
b) Individualized Neoantigen Specific Immunotherapy (iNeST)

At a glance: Our iNeST Platform

- **Concept:** Individualized cancer immunotherapy targeting neoantigens identified on a patient by patient basis and selected for immunogenicity.
- **mRNA Format:** Optimized uridine mRNA providing superior immunogenicity.
- **mRNA Delivery Formulation:** Proprietary size- and charge-based RNA-LPX targeting DCs.
- **Development Approach:** 50:50 cost share with Genentech.

- **Lead Indication:** RO7198457 (BNT122) as a first-line melanoma therapy in combination with pembrolizumab.
- **Data Highlights:** In a previous Phase 1 trial of BNT121, we observed first-in-human data in 13 patients with metastatic melanoma demonstrating stable progression-free survival in nine patients for up to 41 months, and additional objective responses in three of five patients with metastatic disease at time of treatment with iNeST, including one patient receiving combination therapy. We also observed a significant decrease in the cumulative recurrence rate post-treatment as compared to pre-treatment.

We are a pioneer and global leader in developing fully individualized cancer immunotherapies. We have developed a first of its kind, on-demand manufacturing process to treat each individual patient based on the mutation profile of the patient's tumor. We are investigating this treatment approach in the clinic in collaboration with Genentech.



Our iNeST process. The figure above depicts our iNeST process for the on-demand production of individualized mRNA cancer immunotherapies.

Our iNeST process is summarized below:

- A blood sample and tumor biopsy is taken from the patient to obtain healthy cells and tumor tissue. We extract healthy cells from the patient's blood sample and tumor cells from the tumor sample. We use NGS to analyze genetic material (DNA and RNA) of these cells to identify which mutations are present in the cancer cells compared to healthy cells.
- We apply proprietary bioinformatic algorithms to identify tumor-specific mutations. The mutations within a cancer cell differ widely from patient to patient and form a unique signature for each tumor. This genomic information can be further utilized to analyze tumor heterogeneity and microenvironment as well as individual aspects of the immune system like the HLA type.
- Based on these bioinformatic algorithms, we then select mutations that are the most promising therapeutic targets. The specific traits of the patient's immune system, including HLA type, are key to the selection of the most appropriate targets. Picking multiple mutations increases the chance to induce potent T cell responses and reduces the risk that the tumor evades T cell attack over time. We account for heterogeneity of each tumor by preferentially selecting mutations that are expressed on all tumor cells. Importantly, the selected mutations are intended to ensure both $CD4^+$ and $CD8^+$ T cell induction.
- Following mutation selection, we design the structure for the iNeST product. The chosen mutations have to be arranged in a certain order and the DNA sequence of the mutations has to be optimized. This is important to ensure a robust production of the starting material, or DNA matrix, for the GMP manufacturing of the iNeST product.
- Next we produce the patient-specific iNeST product under GMP conditions and the iNeST product undergoes numerous different quality control tests.
- The iNeST product is transferred to the hospital and injected into the same patient by the physician.
- This process has been designed for the on-demand delivery of our iNeST products, and currently takes approximately six weeks.

Our iNeST Development Plan

We are currently developing iNeST therapeutics for the treatment of metastatic melanoma and multiple solid tumors. We are conducting two clinical trials of iNeST in collaboration with Genentech, including one randomized Phase 2 trial in first-line melanoma in combination with pembrolizumab and a Phase 1a/1b trial in patients with locally advanced or metastatic tumors (including in melanoma, non-small cell lung cancer, bladder cancer and other solid tumors) as a monotherapy and in combination with atezolizumab. We expect to announce a topline data update from the first-line melanoma trial in the second half of 2020 and a data update from the Phase 1a/1b trial in solid tumors in 2020. We and Genentech plan to initiate two additional clinical trials for RO7198457 (BNT122) in 2020 in first-line solid cancers in the adjuvant setting, one in combination with atezolizumab and the other as a monotherapy.

Candidate	Antigens	Development Phase	Next Potential Milestone
RO7198457 (BNT122)	Up to 20 neoantigens selected on a patient by patient basis	Phase 2: first-line melanoma in combination with pembrolizumab	Report topline data update in 2H 2020[1]
		Phase 1a/1b: multiple solid tumors	Report data update in 2020

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

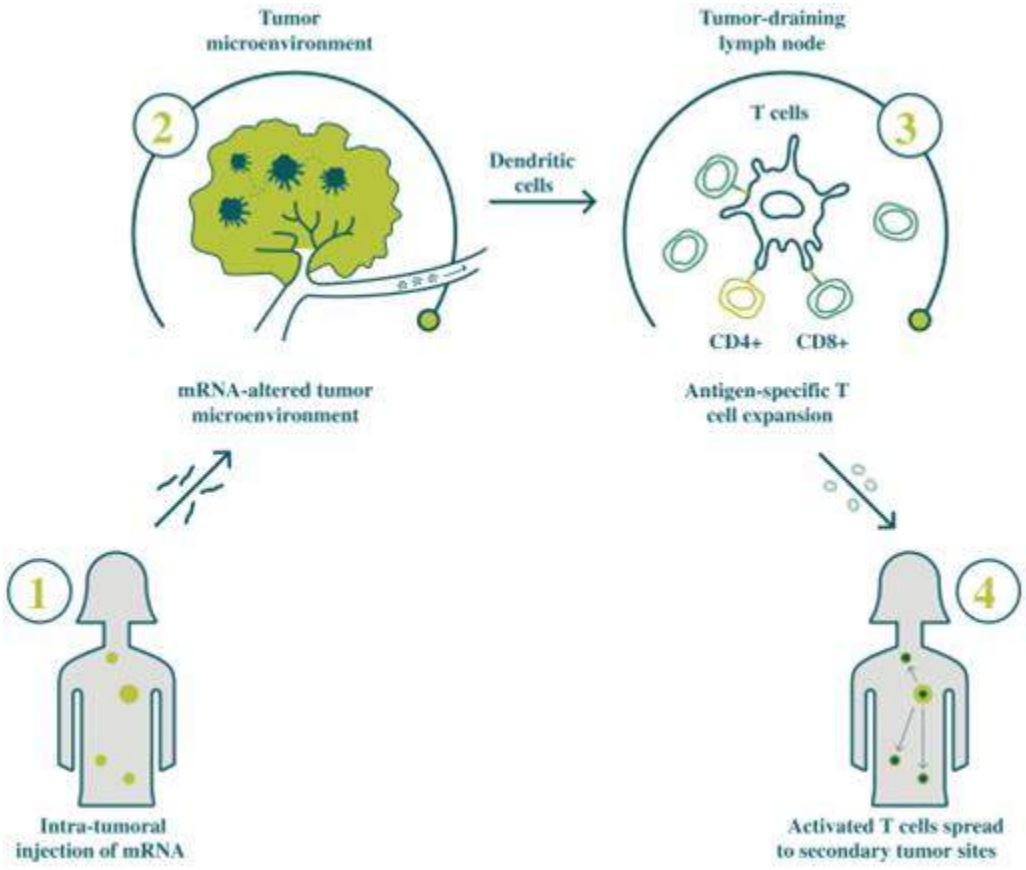
c) ***Intratumoral mRNA Immunotherapy***

At a glance: Our Intratumoral mRNA Platform

- **Concept:** Immunomodulator-encoding mRNA injected directly into the tumor in order to avoid off-target toxicities.
- **mRNA Format:** Nucleoside-modified mRNA engineered for minimal immunogenicity in order to avoid immune detection and allow translation of the encoded cytokines to occur within the cells.
- **mRNA Delivery Formulation:** Various formulations, delivered by intratumoral injection.
- **Development Approach:** Co-development and co-commercialization, at our option, in collaboration with Sanofi.
- **Lead Candidate:** SAR441000 (BNT131) for advanced solid tumors as a monotherapy and in combination with cemiplimab.

In collaboration with Sanofi, we are leveraging our mRNA technology to develop intratumoral immunotherapies for the treatment of solid tumors. Intratumoral immunotherapy is designed to promote innate and adaptive immune responses against tumors, without toxicities related to systemic administration. Our intratumoral immunotherapy involves injection of cytokine-encoding mRNA directly into a tumor in order to alter the tumor microenvironment and promote greater T cell activity. This approach has been found in preclinical studies to boost cancer-specific immune responses locally, while also producing tumor responses in remote parts of the body due to the circulation of properly activated anti-tumor immune cells, known as an abscopal effect.

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



Therapeutic mode of action of intratumoral mRNA immunotherapy. The figure above demonstrates how SAR441000 (BNT131) promotes cytokine expression within the tumor itself.

Our Intratumoral Development Plan

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

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

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

2. Infectious Disease Vaccines

At a glance: Our Infectious Disease Vaccine Platform

- **Concept:** mRNA-based vaccines targeting infectious disease pathogens.
- **mRNA Format:** Modified mRNA.

- **mRNA Delivery Formulation:** LNPs.
- **Development Approach:** Collaboration with Pfizer and exclusive option arrangement with Penn.
- **Lead Candidate:** Influenza vaccine, product candidate BNT161.

Expanding beyond our research in oncology, we are leveraging our mRNA technologies to direct the immune system more effectively against infectious diseases. Our infectious disease vaccine candidates contain self-replicating or trans-replicating, modified mRNA-encoding antigens specific to a target pathogen, delivered in various LNP formulations in order to activate and direct T cells and B cells to fight the pathogen.

Influenza Vaccine

We are collaborating with Pfizer to develop an influenza vaccine using our mRNA-based immunotherapy technology. Current influenza vaccines consist of antigens from inactivated influenza viruses, recombinant influenza haemagglutinin, or HA, proteins or live attenuated influenza viruses and are available as trivalent (containing two influenza A strains and one influenza B strain) or quadrivalent (containing two influenza A strains and two influenza B strains) vaccines. Currently available influenza vaccines are produced in chicken eggs or cell culture and take about five to six months to produce. This requires the composition of the coming season's vaccine to be selected by the World Health Organization, or WHO, far in advance for the vaccine to be available on time, which reduces the reliability of that prediction.

We anticipate that our mRNA-based vaccine can be manufactured within three months from the time the recommendation is published, including cloning and production and therefore the WHO's review of the vaccine components can occur closer to the influenza season to obtain a more reliable prediction. In addition, the mRNA manufacturing process is designed to produce an HA vaccine antigen that matches the HA of circulating influenza strains, in contrast to egg- or cell-based processes which can introduce mutations in the HA amino acid sequence. The flexibility of the mRNA vaccine platform could allow for generation of vaccines against genetically drifted seasonal viruses or pandemic strains. We currently expect to initiate a first clinical trial for one of our influenza vaccine mRNA formulations in the first half of 2021.

Other Infectious Diseases

In October 2018, we entered into a research collaboration with Penn, under which we have the exclusive option to develop and commercialize prophylactic mRNA immunotherapies for the treatment of up to 10 infectious disease indications. We expect to report our first product candidates under this collaboration, and advance our first product candidate into the clinic, in the first half of 2021.

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

We are also developing a potential vaccine based on our mRNA technology to induce immunity and prevent COVID-19 infection. We intend to initiate clinical testing for the product candidate, BNT162, in late April 2020, subject to regulatory approval, as part of a global clinical development program in Europe (commencing in Germany), the United States and China.

In March 2020, we entered a strategic alliance with Fosun Pharma to advance BNT162 and jointly develop the COVID-19 vaccine in China. Upon regulatory approval, Fosun Pharma will commercialize the vaccine in China, while we retain the full rights to develop and commercialize the vaccine in the rest of the world.

Additionally, in March 2020, we signed a letter of intent with Pfizer to co-develop and distribute a COVID-19 vaccine outside of China. We have also executed a Material Transfer and Collaboration Agreement to enable immediate collaboration.

3. mRNA-based Protein Replacement Platform for Rare Diseases

At a glance: Our Protein Replacement Platform for Rare Diseases

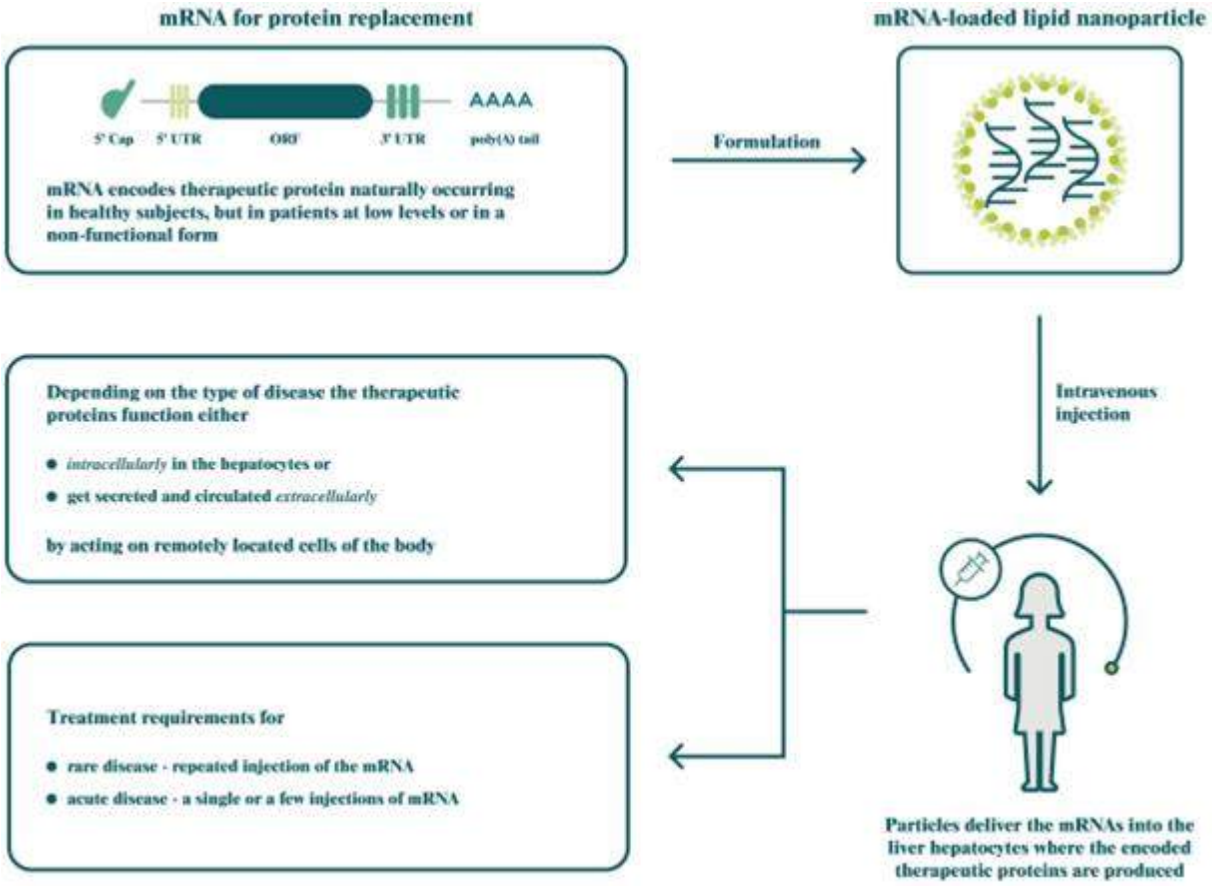
- **Concept:** Therapeutic proteins encoded by mRNA and produced in the patient as an alternative to recombinant protein replacement.
- **mRNA Format:** Nucleoside-modified mRNA, deimmunized to avoid immune activation in order to allow for translation of the therapeutic protein in the cells.
- **mRNA Delivery Formulation:** Liver-targeting LNPs.
- **Development Approach:** 50:50 cost and profit share with Genevant.

By incorporating modified nucleosides into our mRNA, we are able to reduce the immunogenicity of our product candidates, thereby allowing their use for therapeutic protein production. In addition, we utilize advanced mRNA delivery methods to protect the mRNA cargo *en route* to its target and promote its uptake into liver cells. Current protein-based replacement therapies were developed to treat rare diseases by administering recombinant proteins. Such therapies are limited to diseases where the missing protein function is extracellular. However, mRNA-based protein replacement therapy also has the potential to treat illnesses with intracellular protein defects, as long as the mRNA can be delivered into the affected cells.

Our mRNA-based protein replacement therapy features:

- **Nucleoside-modified mRNA.** Replacing uridines in mRNA with modified analogues is important to avoid immune activation that can provoke anti-drug antibody production and would limit efficacy of the treatment.

- **Liver targeted expression.** mRNA encoding therapeutic proteins are formulated into LNPs using in-licensed clinically-validated LNP delivery technology owned by Genevant. The mRNA-loaded LNPs are less than 100nm in size. When injected intravenously, these particles are selectively taken up by hepatocytes, the major cell component of the liver.



Our mRNA-based protein replacement technology. The illustration above depicts our mRNA-based protein replacement process for the treatment of rare diseases.

Our protein replacement technology is designed for the treatment of:

- Genetic disorders that manifest due to a missing or defective protein, where mRNA would need to be administered regularly for a lifetime.
- Acute diseases caused by transient depletion of a protein, such as a hormone, where treatment of such diseases with a single or a few doses of the encoding mRNA could be curative.

Therapeutic proteins encoded by the mRNA can either act intracellularly or be secreted and act extracellularly, in order to produce the desired therapeutic effect.

mRNA-based protein replacement technology has several advantages over recombinant proteins:

- **No need to develop a procedure for protein purification.** The development of recombinant proteins is a laborious and expensive procedure due to the requirement for a unique purification protocol for each protein. During mRNA-based protein replacement the protein is produced by the patient, which we believe avoids the need for purification and also accelerates drug development.
- **The protein has proper post-translational modification.** To function properly, most recombinant proteins need to be modified after synthesis. Proteins produced in patients from mRNA are more likely to obtain the correct modifications than recombinant proteins produced in cultured bacterial or mammalian cells.

- **Continuous *in vivo* supply of encoded protein.** Recombinant proteins, especially those with short half-lives, can be cleared from the body very quickly, thereby limiting therapeutic effect. During mRNA-based therapy, the encoded therapeutic protein is produced for a longer duration (*e.g.*, 10-14 days).
- **Production of intracellular proteins.** Recombinant proteins have limited intracellular therapeutic effects. In contrast, proteins encoded by mRNA can reach any cellular compartment and potentially help to cure diseases where the therapeutic protein needs to function in different subcellular locations, including the mitochondria, nucleus or cell membrane.

Our Protein Replacement Development Plan in Rare Diseases

We expect to initiate our first rare disease clinical trial in the first half of 2021.

4. RiboMabs

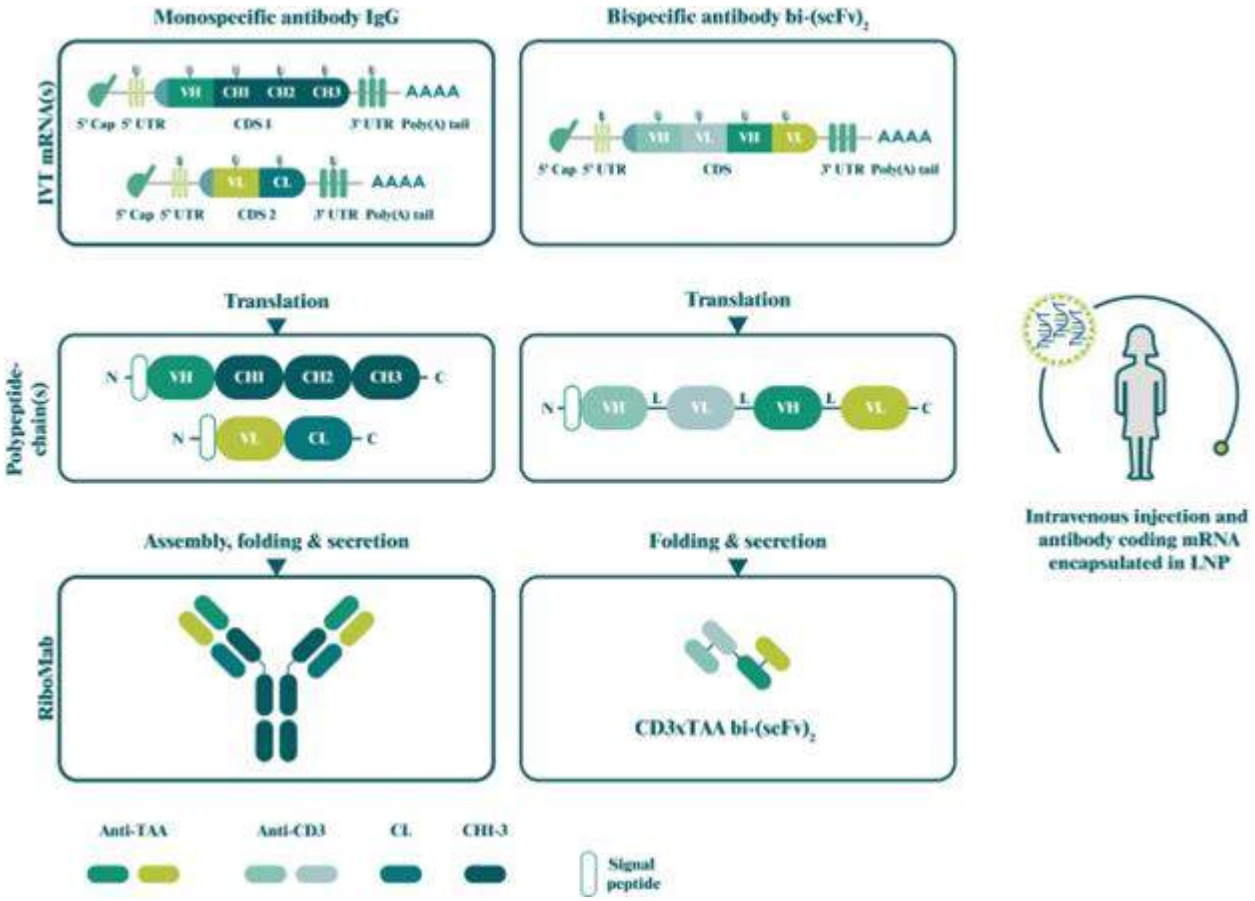
At a glance: Our RiboMab Platform

- **Concept:** Antibodies encoded by mRNA and produced in the patient as an alternative to recombinant antibodies.
- **mRNA Format:** Nucleoside-modified mRNA engineered for minimal immunogenicity in order to avoid immune detection and allow translation of the encoded antibodies to occur within the cells.
- **mRNA Delivery Formulation:** Various liver-targeting LNP formulations, delivered intravenously, to ensure systemic availability and prolonged production of the antibody *in vivo*.
- **Development Approach:** Worldwide rights; wholly owned.
- **Lead Candidate:** BNT141 in multiple solid tumors.

Our RiboMab product candidates are designed to encode secreted antibodies for expression *in vivo* by the patient's cells. We believe our RiboMab technology represents the next generation of antibody-based drugs. Antibody drugs are a leading class of biologics for the treatment of various diseases, but have a number of limitations. The development of antibodies is currently challenged by demanding and costly procedures of production, purification and formulation of a recombinant protein, which we believe hampers the rapid development and clinical testing of new drugs in this class. Recombinant protein antibodies require development of a cell line, establishment and adaptation of processes for production, purification and analytical testing. The whole process typically takes 18 to 30 months to optimize, scale-up and produce first clinical batches. Some of these antibodies are produced in low yields making them unsuitable for therapeutic application.

By contrast, mRNA not only involves a simpler and less expensive manufacturing process, but also is effective in much lower volumes than are required to produce similar effects using recombinant proteins. RiboMabs provide an antibody's mRNA sequence, and the body does the production work itself. This simplicity is designed to allow for both shorter development times and a greater diversity of druggable targets. For efficient RiboMab production, the encoding mRNA is encapsulated in LNPs that deliver the mRNA to the liver cells. For cancer treatment, we focus on tumor-associated antigens to keep adverse effects for the patients as low as possible. We believe we can integrate any antibody sequence in our RiboMab-encoding mRNA.

We have demonstrated the feasibility of our RiboMab technology for a variety of antibody formats, such as full immunoglobulins (Ig), primarily IgG, or different bispecific antibody variants, all of which engage the patient's own immune cells to eradicate antigen-positive tumor cells.



Our RiboMab technology. The figure above depicts the structure of *in vitro* transcribed (IVT) IgG and bi-(scFv)2 RiboMabs. IVT-mRNA encoding the therapeutic antibody is encapsulated in LNPs and injected intravenously into patients. The mRNA is delivered to the liver where it is translated into antibodies and secreted into the blood stream. Abbreviations: A100, poly adenosine tail; bi-(scFv)2, bispecific single chain variable fragment; C, C-terminus; CH, constant heavy domain; CL, constant light domain; IgG, immunoglobulin G; IVT, *in vitro* transcribed; L, linker; LNP, lipid nanoparticles; m1y, 1-methylpseudouridine; N, N-terminus; TAA, tumor-associated antigen; VH, variable heavy domain; VL, variable light domain; UTR, untranslated region.

We believe our broad portfolio of antibody formats will enable us to produce mRNAs encoding the appropriate antibody format for the individual patient's medical need and the desired treatment regimen (*e.g.,* monotherapy or combination therapy).

Our RiboMab Development Plan

Our first development candidate, BNT141, is an IgG antibody, which we expect to enter the clinic in the first half of 2021 in a basket trial targeting multiple solid tumor types. We are also currently evaluating multiple additional RiboMab development candidates in the preclinical setting, including RiboMabs encoding bispecific antibodies, one of which, BNT142, we expect to enter the clinic in the first half of 2021.

Candidate	Target	Development Phase	Next Potential Milestone
BNT141 (monospecific)	Undisclosed	Preclinical	Initiate Phase 1 trial in 1H 2021
BNT142 (bispecific)	CD3xCLDN6	Preclinical	Initiate Phase 1/2 trial in 1H 2021

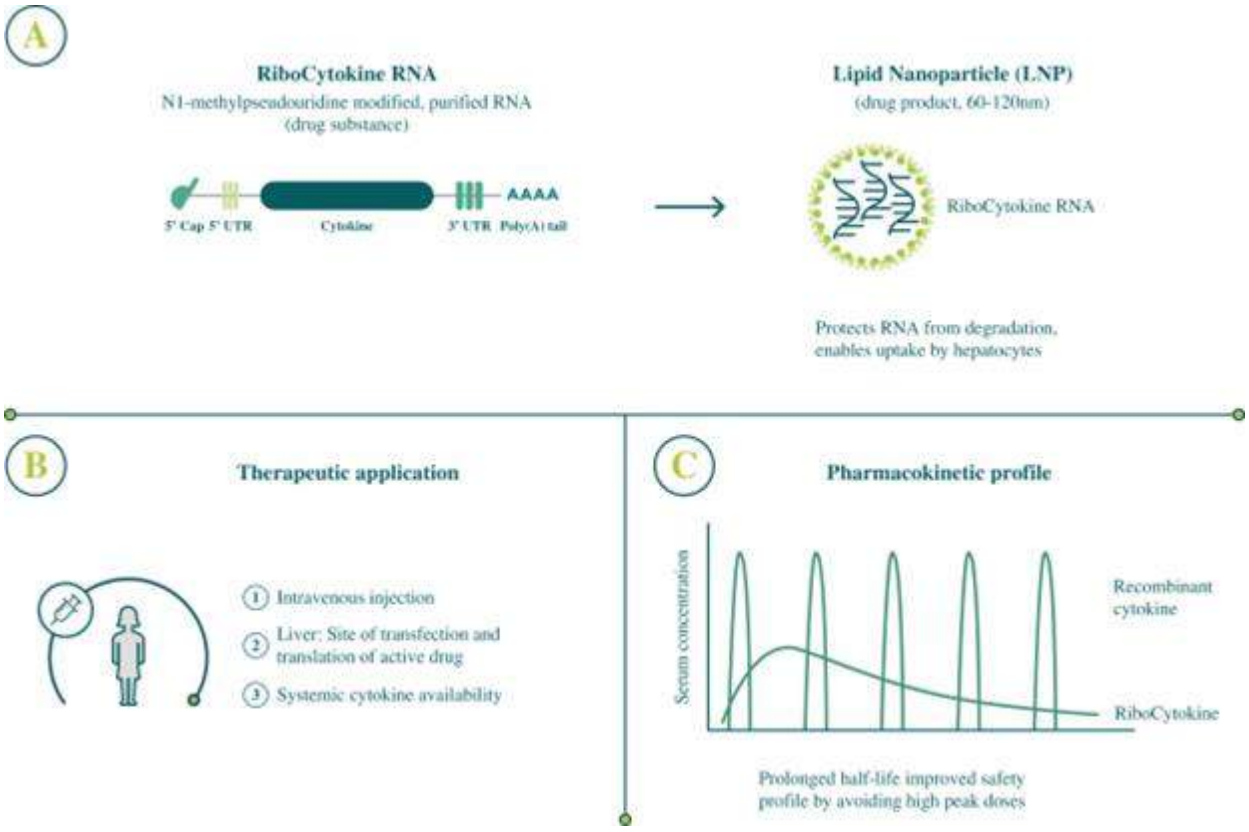
5. RiboCytokines

At a glance: Our RiboCytokine Platform

- **Concept:** Cytokines encoded by mRNA and produced in the patient as an alternative to recombinant cytokines.
- **mRNA Format:** Nucleoside-modified mRNA engineered for minimal immunogenicity in order to avoid immune detection and allow translation of the encoded cytokines to occur within the cells.
- **mRNA Delivery Formulation:** Various liver-targeting LNP formulations, delivered intravenously, to ensure systemic availability and prolonged production of the cytokine *in vivo*.
- **Development Approach:** Worldwide rights; wholly owned.
- **Lead Candidate:** BNT151 in multiple advanced malignancies.

Our RiboCytokine product candidates utilize mRNA that encodes the desired cytokines for expression *in vivo* by the patient's cells. Cytokines represent a large group of relatively small proteins (<30 kDa) that regulate a variety of biological functions as they elicit signaling for immune and non-immune cells. In particular, cytokines play a pivotal role in orchestrating the initiation, execution and extinction of innate and adaptive immunity against pathogens as well as malignant cells. Due to their natural role as immunomodulators, recombinant cytokines are currently used for the treatment of a number of infectious, inflammatory, autoimmune and malignant diseases. One of the major challenges associated with the therapeutic use of cytokines relates to their short serum half-life and low bioavailability. This impedes therapeutic efficacy as it necessitates high and frequent dosing, which often results in dose-limiting toxicities.

We have developed a wholly owned, novel mRNA-based platform technology called RiboCytokines, designed to address the limitations of recombinantly expressed cytokines.



Concept of our RiboCytokine technology. The graphic above depicts our RiboCytokine technology, including mRNA formulated in LNPs and administered by injection, having a beneficial pharmacokinetic profile.

Our RiboCytokine platform allows for sustained delivery of the encoded cytokines with prolonged half-life, including through:

- **Usage of N1-methylpseudouridine modified mRNA.** N1-methylpseudouridine as a nucleoside analogue prevents the recognition of mRNA by TLRs, avoiding immune attack against the RiboCytokines.
- **Liver targeted expression.** RiboCytokines are formulated using clinically validated LNP delivery technology owned by Genevant. LNPs selectively target the liver resulting in high-level expression.

We believe that apart from a beneficial pharmacokinetic profile, our mRNA-based RiboCytokine technology has a number of additional advantages over other types of cytokine therapies:

- **Less immunogenic than recombinant cytokines.** Expression of self and foreign antigens in the liver is associated with immune tolerance due to a unique anti-inflammatory microenvironment. We expect RiboCytokines to be less likely to trigger an immune response when compared to their recombinant counterparts.
- **Shorter development times and greater diversity.** The development of recombinant cytokines is a challenge due to demanding and costly CMC procedures of production, purification and formulation. The simplicity of our mRNA manufacturing allows for both shorter development times and a greater diversity of druggable targets.

We believe that our RiboCytokine technology is particularly well-suited to identify candidates for combination treatment with our proprietary CAR-T cell and cancer immunotherapies platforms.

Our RiboCytokine Development Plan

We expect our first two RiboCytokine product candidates, BNT151 and BNT152/BNT153 (combination), to enter the clinic in the first half of 2021 in basket trials targeting multiple advanced malignancies.

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

IX. Our Engineered Cell Therapies Drug Class

The tailored reprogramming of autologous T cells from cancer patients to recognize and attack their tumors has become a disruptive medical innovation. Retargeting of T cells can be achieved via introduction of tumor-specific receptors into patient-derived T cells. For that purpose, T cells are mostly engineered by retroviral gene transfer to express either T cell receptors, or TCRs, or chimeric antigen receptors, or CARs. Recently, CAR expressing T cells, or CAR-T cells, became the first engineered T cell therapy to obtain FDA approval for some B cell derived hematological malignancies.

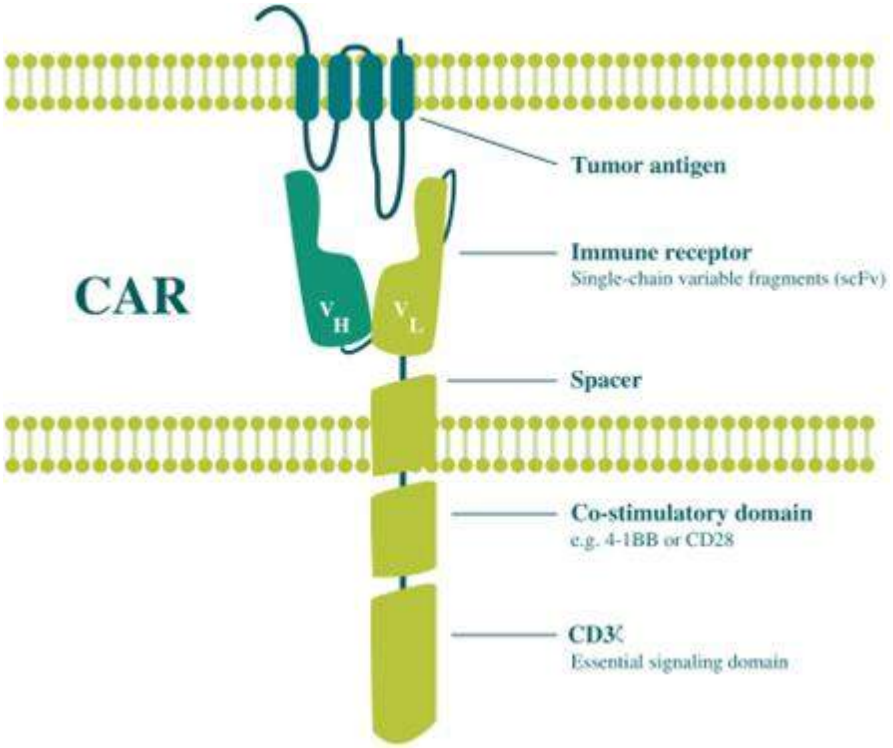
A. CAR-T Cells

At a glance: Our CAR-T Platform

- **Concept:** Second-generation CAR-T therapy designed to overcome the shortcomings of CAR-T therapy in solid tumors.
- **Mechanism:** T cells with CARs engineered to target cancer-specific antigens, including novel antigens selected from our proprietary antigen library and administered with an mRNA-based immune booster, which we refer to as CARVac, to enhance CAR-T cell expansion and persistence.
- **Development Approach:** Worldwide rights; wholly owned.
- **Lead Candidate:** BNT211 for multiple solid tumors.

CARs are artificial receptors that consist of an antigen recognition domain derived from a tumor-specific antibody linked to intracellular T cell signaling domains. CARs redirect T cells to eradicate tumors through specific recognition of

native surface proteins expressed on tumor cells in a non-MHC-restricted manner. Therefore, CAR-T cells can be used for the treatment of all individuals whose tumor expresses the respective target, independent of the individual's HLA genotype. CARs can be used for redirection of both $CD4^+$ and $CD8^+$ T cells.



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

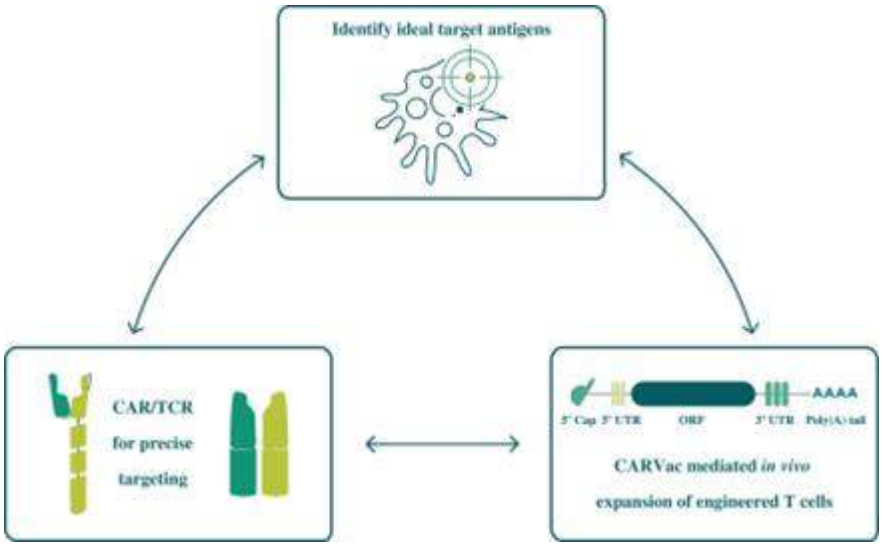
While CAR-T therapy has shown potent anti-tumor responses in patients with B cell malignancies, clinical efficacy in solid tumors so far is limited. The main hurdles for application of CAR-T therapies in solid tumors are:

- Lack of highly tumor-selective targets, which are needed for safe and effective tumor targeting; and
- Low anti-tumoral activity due to insufficient expansion of engineered T cells.

We are developing the next generation of engineered T cell therapies that:

- target novel and known tumor-specific antigens, including mutant neoantigens, and a broad spectrum of tumor-associated antigens expressed in a wide range of cancers; and

- leverage our proprietary CARVac technology for controlled *in vivo* stimulation, activation and expansion of engineered T cells.



Our platforms for development of next-generation engineered T cell therapies. Our engineered cell therapies combine our antigen selection capabilities with our vaccine immunotherapy to enhance T cell activation and expansion.

The powerful characteristics of CAR-T cells, including their potential to eradicate targeted tumor cells in combination with their potentially life-long persistence in the host, require careful target selection. We believe the essential features of an ideal antigen for T cell-based immunotherapy are:

- Absence of expression from any toxicity-relevant non-malignant tissue, to prevent off-tumor/on-target toxicity; and
- Expression on the cell surface of tumor cells at sufficient levels to allow for recognition and lysis by CAR-T cells.

We are developing CAR-T programs targeting two different members of the Claudin family, namely CLDN6 and CLDN18.2. Claudins, or CLDNs, are central components of tight junctions that regulate epithelial-cell barrier function and polarity. Most of the CLDNs are broadly expressed, while CLDN6 and CLDN18.2 are exclusively expressed in different high medical need cancers. Disturbance and dysregulation of tight junction molecules is a frequent hallmark of cancer cells and often associated with malignant transformation and metastasis and, hence, disease progression.

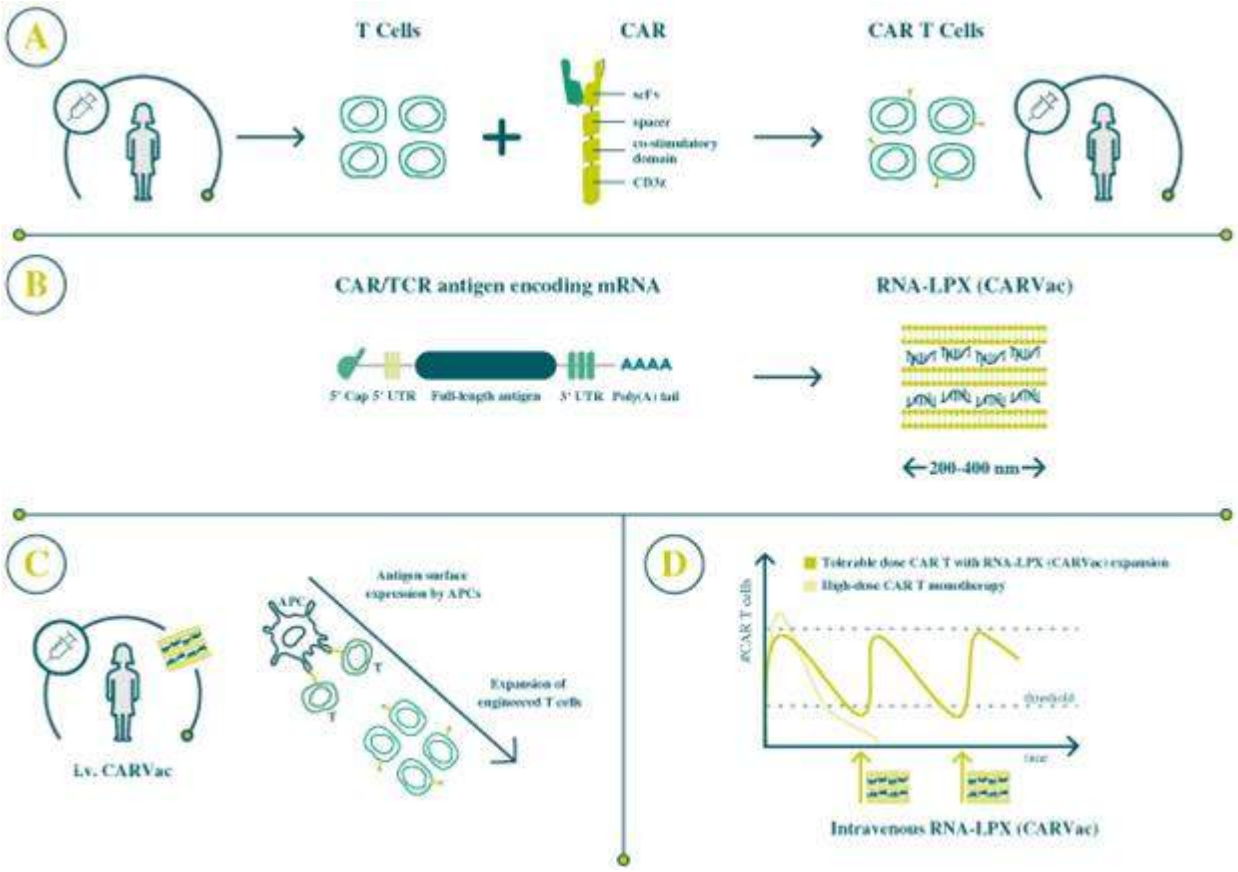
CLDN6 is an oncofetal cell surface antigen expressed in embryonic stem cells during fetal development. The gene encoding CLDN6 is strictly silenced and not expressed in healthy adult tissues but re-activated in different cancers with a high medical need including ovarian, endometrial, testicular and lung cancers.

In contrast to CLDN6, CLDN18.2 is a tissue restricted marker that is exclusively expressed in short-lived differentiated cells of the gastric mucosa. CLDN18.2 is observed in a large fraction of gastric cancers. In addition, CLDN18.2 is aberrantly activated in a variety of tumor entities, including esophageal cancer, pancreatic adenocarcinoma and cholangiocarcinoma.

In-vivo *expansion of engineered T cells using liposomally formulated mRNA*

Besides targeting an ideal tumor-specific antigen, the frequency and the persistence of CAR-T cells in the respective patient is a critical factor determining antitumor efficacy. A positive correlation between clinical outcome and CAR-T cell engraftment and persistence has been shown in several CD19-targeting CAR-T trials. Both tend to be much more limited in the solid tumor setting, likely due to the lack of circulating antigen-presenting cells, or APCs, such as dendritic cells expressing the target CAR antigen.

To address this critical factor, we developed an approach for *in vivo* stimulation of CAR-T cells that relies on our proprietary FixVac technology for systemic mRNA delivery in combination with our CAR-T product candidates. Intravenous administration of a FixVac encoding for the tumor antigen induces expression of the desired target on antigen-presenting cells in secondary lymphoid tissues. FixVac treatment facilitates *in vivo* expansion of CAR-T cells in a dose-dependent manner. Moreover repetitive administration of FixVac results in an improved CAR-T cell persistence as well as increased anti-tumor activity.



Our CAR-T cell immunotherapies combined with CARVac-mediated *in vivo* expansion. (A) Autologous T cells engineered to express a CAR are adoptively transferred into the patient. (B) Full-length CAR target-encoding mRNA is complexed with liposomes to form RNA-LPX lipoplexes (CARVac). (C) Intravenously administered CARVac selectively targets APCs in secondary lymphoid organs facilitating uptake, antigen expression and maturation of APCs. Exposure of CAR-T cells to their target results in CAR-T cell *in vivo* expansion. (D) CARVac can be administered repetitively to achieve controlled expansion and persistence of CAR-T cells within the therapeutic window.

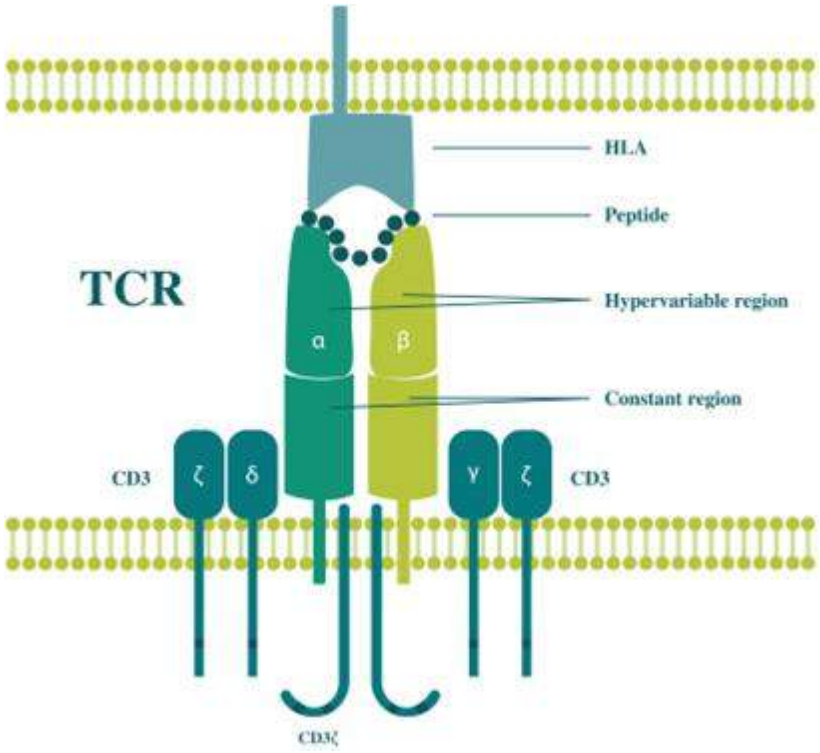
Our CAR-T Development Plan

Our first CAR-T product candidate, BNT211, includes a second-generation CAR directed against CLDN6. Our second product candidate is BNT212, which includes a CLDN18.2-targeting CAR. We expect to initiate a Phase 1/2 basket trial of our novel combination CLDN6 CAR-T cell and CLDN6 CARVac product candidate in multiple solid tumors in the first half of 2020.

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

B. TCRs

The T cell receptor, or TCR, is part of a complex signaling machinery, which includes the TCR a and ß chains that are responsible for antigen recognition, the co-receptor $CD4^+$ or $CD8^+$ and the CD3 signal transduction complex. TCRs recognize antigens presented on the cell surface as small peptides loaded on the patients' HLA molecules. Those peptides are derived from proteins after intracellular degradation. In contrast to CARs that recognize solely native membrane proteins, the repertoire of suitable TCR target antigens include TAAs and mutant neoantigens.



TCR Complex. The illustration above shows the basic structure of a TCR complex.

Our TCR Discovery and Validation Platform

We have developed an integrated technology platform for the systematic identification of functional, fully human TCRs from single antigen-reactive T cells. This technology consists of a proprietary high-throughput approach for the fast retrieval, cloning and rapid validation of novel paired T cell receptor sequences. Our approach facilitates the isolation of tumor cell specific TCRs against multiple antigens and various HLA class I and II alleles.

We believe our TCR discovery technology has the potential to unlock an array of patient- and tumor-specific TCRs suitable for clinical use. We believe this technology has potential utility for:

- therapeutic TCR products encompassing single TCRs to target a specific antigen;
- a therapeutic TCR warehouse encompassing multiple TCRs to target one or more tumor antigens; or
- individualized T cell therapy involving on-demand identification and timely manufacturing of customized, engineered T cells with autologous TCRs against neoepitopes for adoptive transfer.

Our TCR Development Plan

We and our collaborator Eli Lilly are studying potential TCR product candidates in preclinical studies. On September 5, 2019, Eli Lilly notified us that it has selected its first target under the collaboration.

X. Our Antibodies Drug Class

In the past decades, monoclonal antibodies, or mAbs, have transformed from scientific tools to powerful human therapeutics. As one of the fastest growing classes of drugs, to date, more than 40 mAbs have been approved to treat a variety of diseases including cancer, inflammation, autoimmune diseases and others. In addition, identified antigen-binding domains are also fundamental elements for the construction of novel therapeutic formats and formulations, such as CAR-T cells, bispecific therapeutics and targeted nanoparticles.

We have developed and integrated multiple complementary antibody and antibody-mimetic protein technologies into our overall portfolio of treatment approaches.

A. Our Next-generation Checkpoint Immunomodulators

At a glance: Our Next-generation Checkpoint Immunomodulators

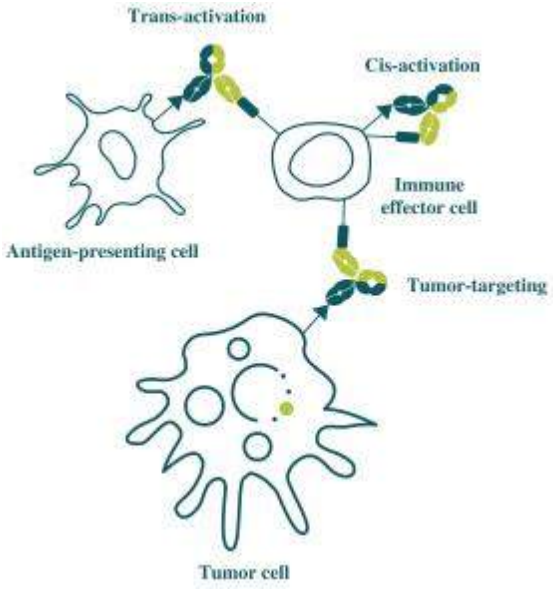
- **Concept:** Bispecific antibodies for dual immunomodulation, initially targeting 4-1BB, an immune checkpoint that is expressed on T cells and NK cells and can enhance immune cell proliferation and activation, in combination with simultaneous checkpoint inhibition.
- **Mechanism:** Conditional activation of 4-1BB checkpoint only upon simultaneous binding of PD-L1 or CD40 (in the case of our initial candidates), potentially avoiding toxicities seen in prior attempts at 4-1BB agonism by localizing 4-1BB activation to the tumor environment.
- **Development Approach:** 50:50 cost and profit share with Genmab, combining our and Genmab's immunostimulatory antibodies and extensive immunology expertise with Genmab's DuoBody® bispecific antibody platform.
- **Lead Candidate:** GEN1046 (BNT311), our PD-L1x4-1BB product candidate for multiple solid tumors.

Following the success of immune checkpoint-blocking antibodies targeting CTLA-4, PD-1 or PD-L1 in cancer treatment, bispecific antibody approaches represent the next generation of emerging immunotherapies with the potential to further improve clinical efficacy. In addition to bispecific T cell engager formats, which redirect T-cell cytotoxicity to malignant cells, bispecific antibodies can be formatted as tumor-targeted immunomodulators and dual immunomodulators. Tumor-targeted immunomodulators direct potent immune costimulation to the tumor-infiltrating immune cells, whereas dual immunomodulators simultaneously address two immunomodulating targets, resulting in blockade of inhibitory targets, depletion of suppressive cells or activation of immune effector cells.

We are developing, in collaboration with Genmab, bispecific antibodies that function as tumor-targeted and dual immunomodulators, applying Genmab's proprietary DuoBody® technology in combination with our joint target identification and product concept expertise. These next-generation checkpoint immunomodulators are thought to induce beneficial co-stimulation, promoting specific T cell activation, survival, proliferation and T cell effector functions. Our collaboration encompasses three potential classes of immunotherapeutic bispecific antibodies:

- Tumor-targeted DuoBody® molecules are bispecific antibodies targeting a tumor-specific antigen expressed by the malignant cell, and an immunomodulatory receptor expressed by tumor-infiltrating immune cells. This is expected to induce powerful activation of tumor-specific effector immune cells with reduced risk of immune-related adverse events.
- Cis-activating DuoBody® molecules are bispecific antibodies that bind two distinct immunomodulating targets presented on the same cell. These targets are specifically expressed on activated immune cells with the rationale to boost existing immune responses by additive or synergistic effects of dual immunomodulation.

- Trans-activating DuoBody® molecules are bispecific antibodies that bind two distinct immunomodulating targets expressed on two separate cell subsets. By simultaneously targeting, for example, effector immune cells and antigen-presenting cells, these compounds are thought to amplify the immune cell priming process and augment subsequent effector responses.



Next-generation checkpoint immunomodulators. Our collaboration with Genmab potentially includes bispecific antibodies from three different classes: trans-activating, cis-activating and tumor-targeting antibodies.

Our Next-generation Checkpoint Immunomodulator Development Plan

We are currently developing two next-generation checkpoint immunomodulator product candidates in collaboration with Genmab: GEN1046 (BNT311), our jointly owned PDL1x4-1BB bispecific antibody, and GEN1042 (BNT312), our jointly owned CD40x4-1BB bispecific antibody.

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

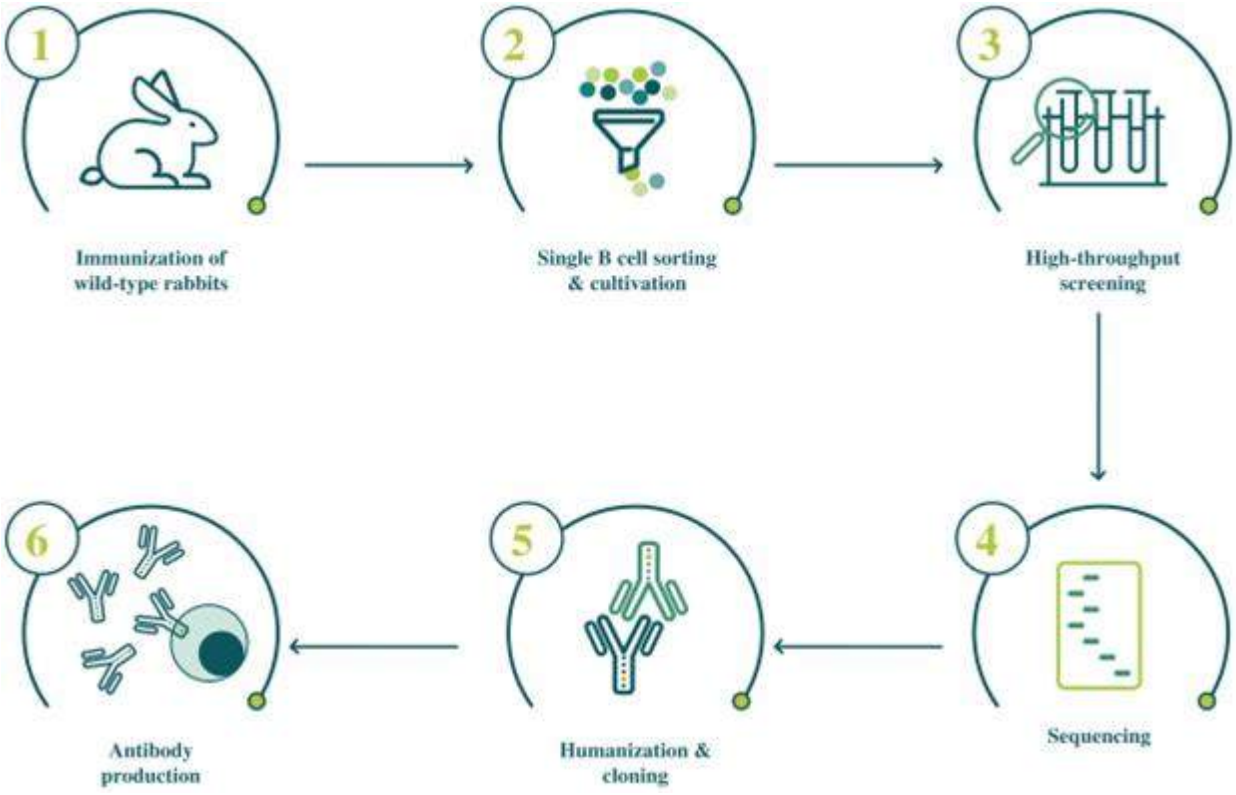
B. Our Antibody Discovery Engines

We believe that our multiple antibody discovery engines significantly expand our targeting repertoire and enable us to directly, rapidly and efficiently produce new mAb candidates. In addition, antigen-binding domain sequences identified through our antibody discovery engines also feed into our proprietary CAR-T cell and mRNA-encoded RiboMab platforms as well as our next-generation checkpoint immunomodulator collaboration. For instance, binders to human 4-1BB were identified from a previous antibody generation campaign and are currently under clinical and preclinical development as part of our next-generation checkpoint immunomodulator collaboration with Genmab. HuMab, our human antibody discovery engine acquired from MabVax Therapeutics in 2019, led to the clinical development of our fully human IgG1 monoclonal antibody product candidate targeting Sialyl Lewis^a (sLe^a), a carbohydrate moiety that is present in over 90% of pancreatic and a large percentage of gastrointestinal cancers.

1. Our Rabbit-based Antibody Discovery Engine

With the acquisition of MAB Discovery GmbH's antibody generation unit in 2019, we integrated a unique and proprietary rabbit-based antibody discovery platform that can generate and develop high quality, functional mAbs targeting traditional proteins and receptors as well as a wide variety of more challenging targets. Rabbit monoclonal

antibodies are highly diverse and do not require affinity maturation, due to consistently high affinities. They often recognize epitopes on human antigens that are not immunogenic in rodents, thus increasing the total number of targetable epitopes. The mechanisms of antibody diversification in rabbits allow an easy and quick translation of preclinical data into the clinic with an improved probability of success. We established a streamlined semi-automated process of rabbit immunization for the efficient production of high-affinity rabbit mAbs.

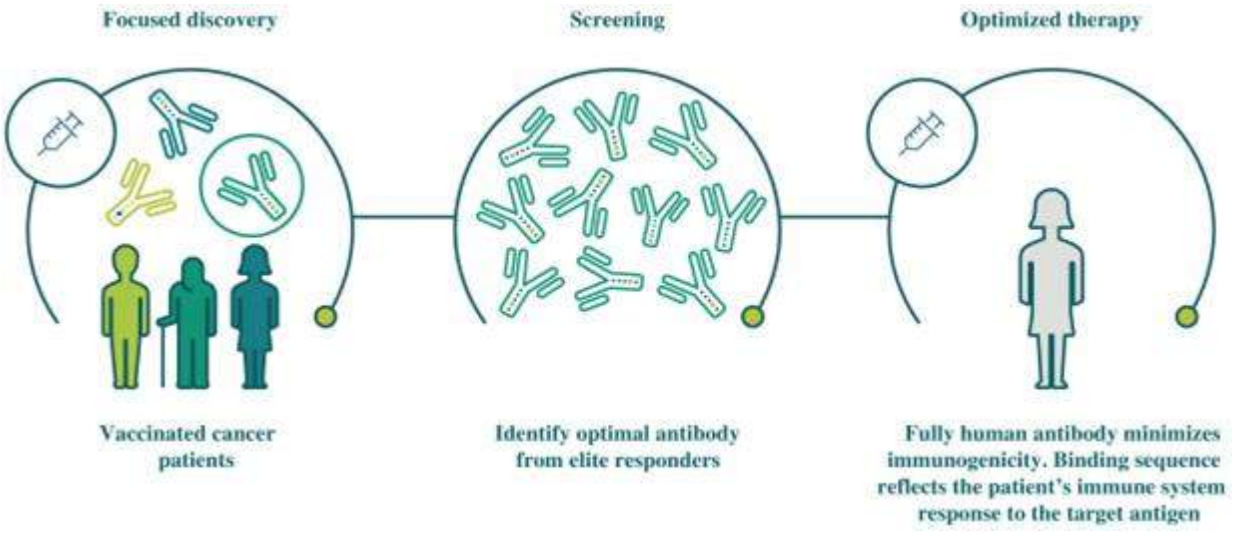


Our rabbit-based antibody discovery engine. The figure above depicts our semi-automated process for the discovery and production of high-affinity rabbit mAbs.

2. Our Fully Human Antibody Discovery Engine

Our HuMab discovery technology focuses on abnormal carbohydrate targets upregulated on solid tumors. Aberrant glycosylation is a common phenotypic change of cancer cells that mainly affects the outer part of glycans. These abnormal carbohydrate structures are known as tumor-associated carbohydrate antigens, or TACAs, and are associated with malignancy grade, invasion, metastasis and poor prognosis. TACAs are considered promising novel targets for therapeutic intervention using, in particular, mAbs or CAR-T cells. However, TACAs usually induce only low-affinity humoral immune responses, since carbohydrate moieties do not trigger the necessary T cell responses.

Using B cell sorting, hit identification, sequencing, antibody production and high-throughput antibody screening, we are able to select optimal TACA-specific antibodies from multiple clinically confirmed immunotherapy responders. All antibodies emanating from this platform are fully human with no need for additional humanization at minimal risk for immunogenicity.



Our fully human antibody discovery engine. The figure above shows our proprietary approach to the discovery and development of novel fully human antibody therapeutic and diagnostic agents.

Our Targeted Cancer Antibody Development Plan

Candidate	Targets	Development Phase	Next Potential Milestone
MVT-5873 (BNT321)	sLe[a]	Phase 1 basket trial in multiple solid tumors; first patient enrolled	—

XI. Our Small Molecule Immunomodulator Drug Class

At a glance: Our Small Molecule Immunomodulators

- **Concept:** Small molecule therapies, with a specific focus on TLRs, that can be used synergistically with other cancer therapeutics, including other product candidates in our portfolio.
- **Development Approach:** Worldwide rights; wholly owned.
- **Lead Candidate:** BNT411, our TLR7 agonist product candidate intended for combination therapies.

Small molecule cancer therapeutics can be used to regulate cancer growth, halt blood vessel formation in tumors, deliver toxins to cancer cells and mark cancer cells for destruction by the immune system. Unlike larger antibody-based cancer therapies, small molecule compounds are often developed for targets located within cells since they can enter the cells more easily as a result of their physical properties and low molecular weight. Small molecules also often have other intrinsic benefits including relative ease and cost of production compared to larger compounds, as well as more frequently having the potential for oral administration to patients. They can also often be used synergistically in combination with other therapeutics such as mRNA, checkpoint inhibitors, radiation therapy and chemotherapy.

We aim to discover and develop the next generation of small molecule immunomodulatory compounds to improve the standard of care. We have a team of approximately 25 scientists and technicians, with extensive small molecule experience, focused on drug discovery.

Our immunomodulatory small molecule product class focuses on a range of endosomal and intracellular targets that are known to stimulate the activity of a wide range of immune cells. We have a particular emphasis on TLRs. TLRs are a family of pattern recognition receptors that function as primary sensors of the innate immune system to recognize

pathogens. We believe TLRs represent a promising target class for cancer immunotherapy, particularly for inflammatory re-programming of the tumor microenvironment. In many cancers, tumors are protected by an anti-inflammatory environment, which reduces the ability of the immune system to attack the cancer cells. TLR7 agonists are able to initiate a direct cellular immune response, for example, by activating immature dendritic cells, cytotoxic T cells and NK cells, as well as stimulating the release of signal molecules such as cytokines and chemokines including IFN-a and IP-10, which can be directed against tumor cells. The activation of the innate and adaptive immune system and the release of cytokines and chemokines, for instance by our small molecule TLR7 agonist, results in the potent stimulation of antigen-specific T cells, B cells and innate immune cells such as NK cells and macrophages.

Our initial focus is on small molecule product candidates that activate the innate and adaptive immune system via TLR7 and are designed to be used in combination with chemotherapeutics as well as checkpoint inhibitors.

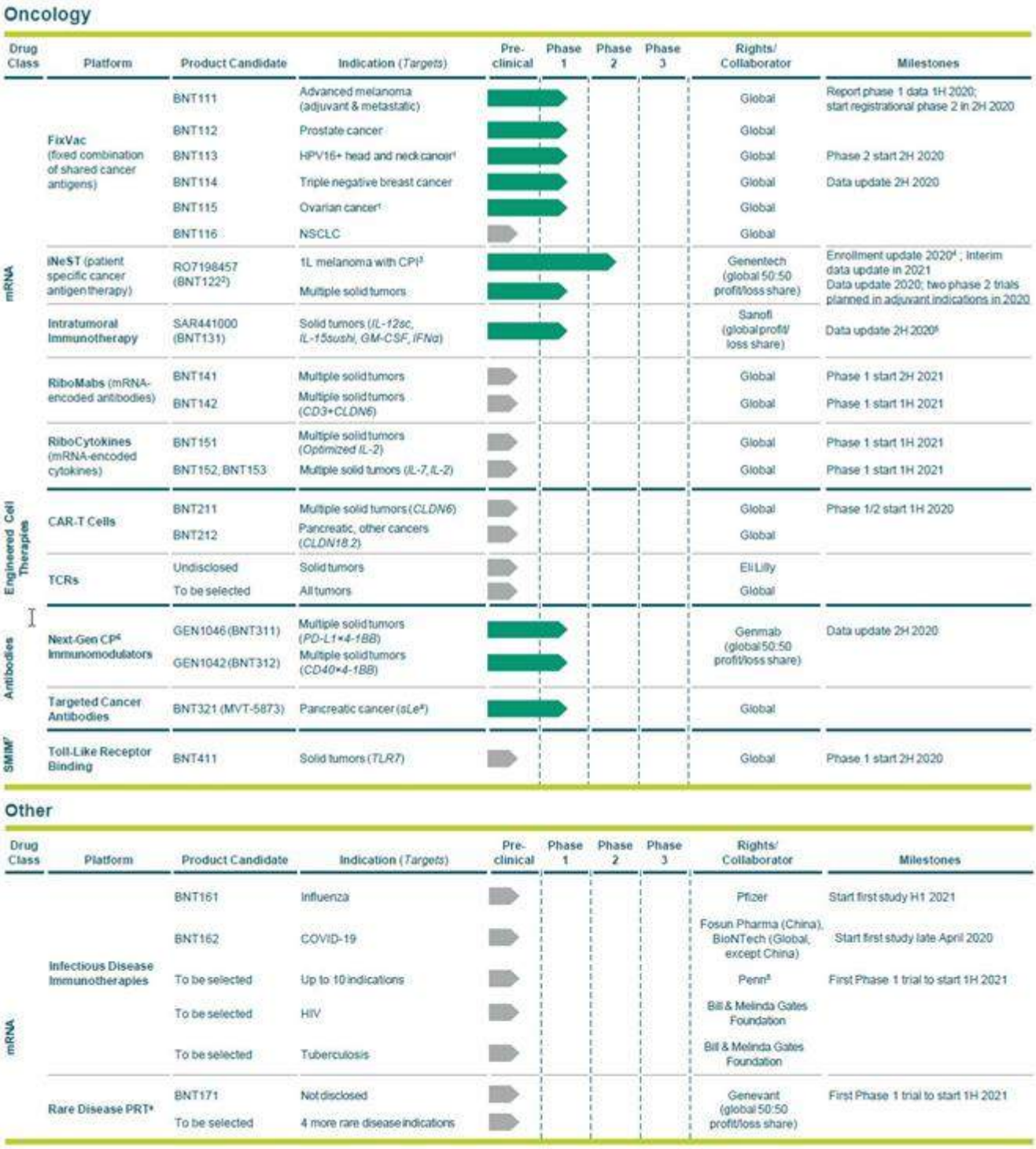
Our Small Molecule Immunomodulator Development Plan

Our initial development candidate is a potent TLR7 agonist, which we plan to develop as a combination therapy for small cell lung cancer and other solid tumors.

Candidate	Target	Development Phase	Next Potential Milestone
BNT411	TLR7	Preclinical	Initiate Phase 1 trial in 2H 2020

XII. OUR PRODUCT CANDIDATES

We are developing a broad and deep pipeline of over 20 product candidates across our four drug classes. Our product candidates are currently being investigated in 11 clinical trials.



A. Our mRNA Product Class in Oncology

1. FixVac

FixVac is our wholly owned, systemic, off-the-shelf mRNA-based cancer immunotherapy platform, from which we are developing several first-in-human and potential first-in-class product candidates. Our FixVac product candidates contain selected combinations of pharmacologically optimized uridine mRNA encoding known cancer-specific shared antigens. FixVac product candidates feature our proprietary immunogenic mRNA backbone and proprietary RNA-LPX delivery formulation, which are designed to enhance stability and translation as well as trigger both innate and adaptive immune responses.

a) BNT111: Our FixVac Cancer Immunotherapy for the Treatment of Advanced Melanoma

We are developing our mRNA-based FixVac product candidate BNT111 for the treatment of advanced melanoma in patients with metastatic tumors and as an adjuvant treatment after tumor resection. We are currently studying BNT111 in an ongoing Phase 1 clinical trial.

Melanoma

Melanoma is an increasingly prevalent, deadly form of skin cancer in which melanocytes, which are the cells that color the skin, form malignant cells. With 132,000 new cases diagnosed globally each year, melanoma constitutes less than five percent of all skin cancers. In recent decades, however, the incidence rate of melanoma has risen faster than almost any other cancer type, on average by 1.5% per year over the last 10 years. In 2018, approximately 91,000 new melanoma cases were diagnosed in the United States, representing 5.3% of all new cancer cases in the United States.

Melanoma is the most lethal form of skin cancer, accounting for the majority of skin cancer deaths. There were an estimated 9,300 deaths from melanoma in the United States in 2018. While the five-year survival rate for melanoma, regardless of disease stage, is approximately 91.8%, patients with stage III melanoma have a five-year survival rate of approximately 63%. The five-year survival rate for metastatic melanoma (stage IV) is approximately 20%.

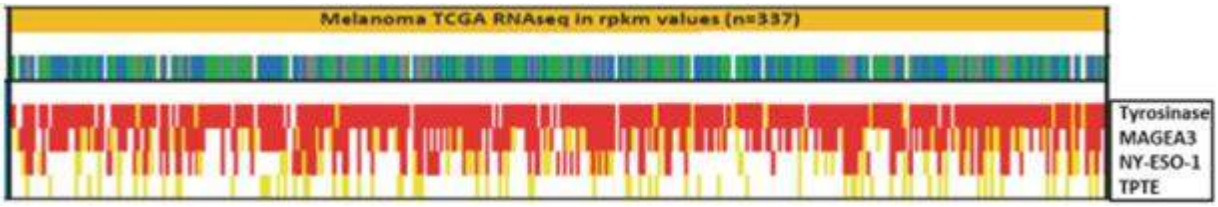
The current treatment regimen involves surgical removal for earlier stages, while a number of targeted therapies, such as BRAF and MEK inhibitors, and checkpoint inhibitors, or CPIs, are approved for advanced disease. CPIs include nivolumab (Opdivo) for advanced or metastatic melanoma after resection, and pembrolizumab (Keytruda) in unresectable or metastatic disease.

Our BNT111 Targets

BNT111 is designed to elicit an immune response to the following four antigens that have each been found to be associated with melanoma:

- New York esophageal squamous cell carcinoma 1, or NY-ESO-1, a well-known cancer-testis antigen that is also expressed in numerous cancers, including melanoma;
- melanoma-associated antigen A3, or MAGE-A3, which is not expressed in normal tissues, except the testis and the placenta;
- tyrosinase, an enzyme that is required for melanin production and that is produced in increased levels in melanoma; and
- trans-membrane phosphatase with tensin homology, or TPTE, a novel cancer/testis antigen that we discovered internally.

We sequenced 337 melanoma tumors and detected at least one of these four antigens in over 90% of such melanoma tumors.



BNT111 antigens detected in over 90% of melanoma tumors. The graphic above shows expression of BNT111 target antigens on a patient by patient basis. Each row at the bottom of the graphic represents an antigen, and each vertical line represents a patient, depicting whether or not that patient expressed each antigen.

Our BNT111 Clinical Trials

Ongoing Phase 1 Trial in Advanced Melanoma Patients (LIPOMERIT study)

We are conducting a multi-center, open-label, first-in-human, Phase 1 dose escalation study evaluating the safety and tolerability of multiple intravenous administrations of BNT111 in patients with advanced melanoma. This is the first clinical trial worldwide in which an mRNA-based cancer immunotherapy is administered intravenously for systemic treatment.

The trial employs a conventional 3+3 design in which patients are dosed in groups of three at incrementally greater dosages until the maximum tolerated dose is identified, during the dose escalation phase, which is then followed by expanded dose cohorts. Patients are treated with doses from 7.2µg up to the highest administered dose of 400µg of total mRNA.

July 2019 Interim Data

As of the July 2019 interim cut-off date, 95 patients with metastatic melanoma had been dosed at least once at one of four centers in Germany. Baseline and demographic characteristics were largely as expected for a trial recruiting advanced stage IIIB-IIIC and stage IV melanoma patients with and without measurable disease. Approximately half of the patients were resected and had radiographically non-evaluable disease at baseline. The other half of the patients had radiographically evaluable disease at baseline and most of these patients were heavily pretreated. Only the subset of patients with evaluable disease at baseline was assessed for preliminary clinical activity.

Immunogenicity. Immune responses induced by BNT111 were assessed using various orthogonal assay systems by analyzing T cells against each vaccine antigen in pre- and post-treatment blood samples of patients. So far, about half of the dosed patients have been analyzed for immune responses in this ongoing study. A first analysis in a subset of 18 patients evaluated vaccine antigen reactivity of $CD4^+$ and $CD8^+$ T cells by IFN-α ELISpot after *in vitro* stimulation. All tested patients showed either a de novo or an augmented (as compared to baseline) immune response against at least one of the BNT111-encoded tumor antigens. Most patients exhibited either $CD4^+$ or concurrently $CD4^+$ and $CD8^+$ T cell responses against the individual vaccine targets. A second analysis looked at the magnitude of immune responses on the individual level by using an *ex vivo* IFN-α ELISpot, which due to its sensitivity level would capture only very strong T cell responses, and showed that more than 75% of patients exhibited vaccine-induced $CD4^+$ or $CD8^+$ T cell responses. The kinetics of *de novo*-induced $CD8^+$ T cells were further characterized in selected patients of interest by a third method using ex *vivo* MHC peptide multimer staining of blood samples collected at baseline and at different time points after start of vaccination. Mostly, antigen-specific T cell counts showed a fast ramp-up from being undetectable at baseline to levels ranging from 1,000 to more than 100,000 per million circulating $CD8^+$ T cells within the first 4-8 weeks. Under monthly maintenance treatment, frequencies of individual antigen-specific T cells continued to slowly increase or remained stable up to over one year.

Clinical activity. As of the July 2019 cut-off date, in our review of interim data, we assessed 42 patients with radiographically evaluable, measurable disease at baseline for preliminary clinical activity according to Response Evaluation Criteria in Solid Tumors, Version 1.1, or RECIST v1.1. Twenty-five of these 42 patients

received BNT111 as a monotherapy, and 17 patients received BNT111 in combination with an anti-PD-1 checkpoint inhibitor, or CPI (either pembrolizumab or nivolumab).

In the BNT111 monotherapy cohort, we observed clinical activity for all 25 patients. All of these patients had received at least one line of prior treatment with a checkpoint inhibitor, and 24 of the 25 patients had failed prior sequential or combination treatment with anti-PD-1 and anti-CTLA4 antibodies. Three of 25 patients (12%) showed a partial response, or PR, one patient had a metabolic complete response as measured by FGD-PET imaging and seven patients (28%) demonstrated stable disease. The clinical benefit rate, or CBR, is 44%. Two of the PRs manifested early on during treatment (at imaging day 90); the two others manifested at imaging days 180 and 360, respectively.

In the BNT111 in combination with anti-PD-1 checkpoint inhibitor cohort, 16 of the 17 patients had prior treatment with CPI. Six patients (35%) showed a partial response, and two patients (12%) demonstrated stable disease. The CBR is 47%. Objective responses were observed across all dose levels explored in expansion cohorts (14µg, 50 µg and 100µg). Five of 10 (50%) patients who received the highest target dose of 100µg demonstrated a PR. By contrast, the expected ORR for anti-PD1 treatment in an anti-PD1 experienced patient population is in the range of 10%.

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

Completed Phase 1 Trial in Patients with Advanced Melanoma (MERIT study)

In 2016, we published results of a first-in-human dose escalation study evaluating the safety and tolerability of intranodal administration of an earlier generation of BNT111 in patients with advanced melanoma. In this study, the earlier formulation of BNT111 targeted only NY-ESO-1 and tyrosinase.

This international, multi-center, open-label interventional study's primary endpoints were the maximum tolerated dose for multiple dosing, safety and adverse reactions and tolerability profile of multiple dosing. The secondary endpoints were (i) to observe immunotherapy-induced immune responses following multiple treatment cycles and (ii) clinical benefit (complete response, partial response and stable disease).

Five dosages were administered to patients sequentially: 50µg, 100µg, 300µg, 600µg, and 1,000µg. The sample size for the first three doses was three each. The 600µg dose cohort was comprised of 13 patients and the 1,000µg dose cohort was comprised of seven patients. In the 100µg, 300µg and 600µg dose cohorts, seven patients in total received continued treatment. The overall individual treatment period was 43 to 51 days and comprised eight treatment cycles of ultrasound-guided intranodal injections on days one, four, eight, 11, 15-17, 22-26, 29-35 and 43-51. In case of an optional continued treatment for patients who neither exhibited unacceptable drug-related toxicity nor disease progression, four additional treatment cycles were administered at the same dosage that the patient had received in his or her cohort. The first cycle of continued treatment was scheduled 14-42 days after the last visit, with the second and third additional treatment cycles following after a one-month interval each. The fourth treatment cycle then followed after an interval of three months.

The occurrence of new measurable lesions was observed in only one patient of the 1,000µg dose cohort, while new non-measurable lesions were identified in seven patients. Twenty-one patients, or 75%, were

classified as having immune-related stable disease and six patients, or 21.4%, had immune-related progressive disease.

The most frequent adverse events included administration-site conditions, infections and infestations, musculoskeletal and connective tissue disorders, nasopharyngitis, fatigue, headache and back pain. No life-threatening adverse events nor deaths occurred in this study. Thirteen severe adverse events were reported, including infections and infestations and vascular disorders. Sixteen patients were affected by adverse events with a suspected relationship to the study drug. These were most frequently fatigue, application site erythema and application site pain. None of the drug-related adverse events was categorized as serious. No dose-limiting toxicities were observed.

Next Steps

We expect to report Phase 1 data from the LIPOMERIT trial and to initiate a Phase 2 clinical trial with registrational potential for BNT111 in the second half of 2020.

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

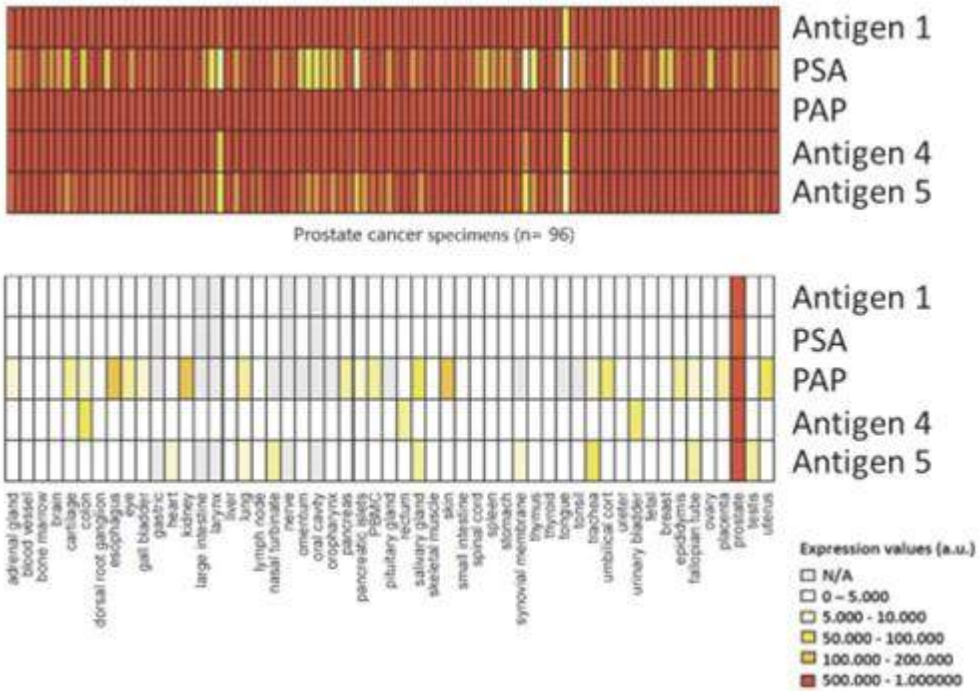
We are developing BNT112 for the treatment of prostate cancer.

Prostate Cancer

Prostate cancer is the second most common cancer amongst men worldwide and the fourth most commonly occurring cancer overall, with around 1.3 million new cases recorded worldwide in 2018 and 174,650 cases expected in 2019 in the United States alone. The stage of the prostate cancer (I-IV), alongside the prostate-specific antigen and Gleason score, are the key factors for defining the treatment options for individual cases. Surgical or radiation based approaches are often used in first-line therapy, however after relapse (up to 30-40% of patients), androgen-deprivation therapies are employed, which in turn also often becomes redundant (metastatic castration-resistant prostate cancer, or mCRPC) at which point patients are treated with either further hormonal agents or chemotherapy.

Our BNT112 Targets

BNT112 is designed to elicit an immune response to five prostate cancer-specific antigens, including prostate-specific antigen, or PSA, a transmembrane protein that is expressed by virtually all prostate cancers, prostatic acid phosphatase, or PAP, and three additional tumor-associated antigens.



Our BNT112 Clinical Trials

Phase 1/2 Clinical Trial

We enrolled the first patient in an open-label, multi-center, first-in-human Phase 1/2 individual dose titration study of BNT112 in patients with mCRPC and high-risk localized prostate cancer, or LPC, in the second half of 2019. Eligible patients have newly-diagnosed, high-risk, localized prostate cancer and will be treated with BNT112 as a single agent, in combination with cemiplimab and goserelin acetate or in combination with goserelin acetate alone. We anticipate a total enrollment of 60 to 80 patients at up to 20 investigational sites.

The study is designed to evaluate the safety, tolerability, immunogenicity and preliminary efficacy of BNT112 in mCRPC and LPC patients. The primary objective of this study will be to establish the safety and tolerability of BNT112 alone, or in combination with goserelin acetate with or without cemiplimab. The secondary objectives of the trial will be to examine the immunogenicity of BNT112 alone or in combination with goserelin acetate with or without cemiplimab, and to evaluate anti-tumor activity based on levels of prostate-specific antigen, or PSA.

The study will consist of three arms. The first arm will start with a dose titration phase for the initial safety assessment and recommended expansion dose range assessment. We anticipate enrollment of approximately 20 patients in arm one who will receive BNT112 alone, with up to nine patients participating in the dose titration part of the arm (with staggered starting groups of three patients one week apart). Titration will continue until unacceptable toxicity or disease progression. Efficacy in the first arm will be assessed by on-treatment imaging and in the second and third arms by tumor volume measurement.

After at least six patients are treated and evaluable for at least one treatment cycle, we plan to commence enrollment of the second and third arms, each enrolling approximately 20 patients with newly diagnosed LPC. Patients in the second arm will receive BNT112 combined with goserelin acetate and cemiplimab, and patients in the third arm will receive BNT112 combined with goserelin acetate alone. Treatment periods in the second

and third arms will last until unacceptable toxicity or until the end of the eighth cycle, which will be followed by planned radical prostatectomy.

c) BNT113: Our FixVac Cancer Immunotherapy for the Treatment of HPV+ Head and Neck Cancer

We are developing BNT113 for the treatment of HPV+ head and neck cancer. BNT113 is currently being studied by the University of Southampton in an ongoing investigator-sponsored Phase 1/2 basket study in HPV+ cancers, including head and neck cancer.

HPV+ Head and Neck Cancer

Head and neck cancer defines a heterogeneous group of tumors originating in the squamous cells that line the moist, mucosal surfaces inside the head and neck. Head and neck cancer is the sixth most common malignancy worldwide, accounting for approximately 6% of all cancer cases, and is responsible for 1-2% of all cancer deaths. An increasing percentage of this cancer is now attributed to HPV infection in the United States and Europe, particularly those arising from the oropharynx. In the U.S., HPV-related oropharynx cancer, or OPC, is one of only five cancers with rising incidence and prevalence. The percentage of OPC related to HPV rose from approximately 16% in 1984 to 1989 to approximately 72% during 2000 to 2004. Early stage head and neck cancer is typically either treated with surgery or radiation alone, however approximately 66% of patients present with advanced disease and fewer than 30% of these are cured. The management of advanced disease consists of multiple-modality therapy with surgery, radiation and chemotherapy. Long-term survival rates in these patients have not increased significantly in the past 30 years: five-year survival rates are 60-80%.

Our BNT113 Targets

BNT113 is designed to elicit an immune response against the well-characterized HPV16-derived oncoproteins E6 and E7, which are strongly immunogenic, viral neoantigens that are found in HPV16+ solid cancers such as head and neck squamous cell carcinoma.

Our BNT113 Clinical Trials

Ongoing Phase 1/2 Basket Study (Investigator-Sponsored)

BNT113 is being studied in an investigator sponsored open-label, Phase 1/2 dose escalation basket study with two different arms in approximately 44 patients with HPV+ head and neck and other cancers. The first arm will perform dose escalation in patients with previously treated HPV+ head and neck cancer using two dose cohorts to establish a safe, tolerable and recommended dose of BNT113. The second arm will perform dose escalation in patients with advanced HPV+ cancers, including head and neck, anogenital, penile and cervical cancers, using a single cohort to establish a safe, tolerable and recommended dose.

Next Steps

We intend to initiate a Phase 2 trial with registrational potential of BNT113 in HPV+ cancers in the second half of 2020.

d) BNT114: Our FixVac Cancer Immunotherapy for the Treatment of Triple Negative Breast Cancer

We are currently studying antigens selected for BNT114 in a three-arm clinical trial as both a monotherapy and in combination with our RO7198457 (BNT122) individualized iNeST immunotherapy in patients with triple negative breast cancers.

Triple Negative Breast Cancer (TNBC)

Breast cancer is the most commonly occurring cancer in women and the second most common cancer overall with over two million new cases globally in 2018 with an expected 268,600 cases in 2019 in the United States alone. There are three broadly defined categories of breast cancer. About 80% of breast cancers are

defined as ER+, meaning that they grow in response to the hormone estrogen, while 65% of these are also defined as PR+, as they also grow in response to another hormone, progesterone. Such cancers can be identified by the presence of estrogen receptors, or ER, and/or progesterone receptors, or PR, on the cancer cell surface and are more likely to be treatable by hormone therapies than cancers that are ER or PR negative. In about 20% of cancers, the tumor can be identified by its production of an excess of the HER2 protein. Such HER2+ cancers tend to be aggressive and fast moving. Breast cancers that neither express ER or PR, nor over-express HER2-, are known as triple negative breast cancers, or TNBCs. TNBC patients represent approximately 12-15% of all breast cancer cases, however it remains an area of high unmet medical need given it is typically the most aggressive form of breast cancer. There are currently no effective treatments for TNBC. While initial treatment options include surgery or chemotherapy, TNBC is characterized by rapid resistance to chemotherapy, and few remaining treatment options remain thereafter.

Our BNT114 Targets

BNT114 is designed to elicit an immune response to selected antigens that are found in breast cancers.

Our BNT114 Clinical Trials

Ongoing Phase 1 Clinical Trial (BNT114 monotherapy and in combination with RO7198457 (BNT122))

We are currently conducting an international, multi-center, open-label, three-arm Phase 1 study of BNT114 as a monotherapy and in combination with our RO7198457 (BNT122) individualized iNeST immunotherapy in 39 TNBC patients who had previously received the standard of care therapy (*i.e.*, surgery, chemotherapy and/or radiotherapy). The primary endpoints of the study are to assess safety and tolerability. Safety will be analyzed by adverse event documentation and clinical observation and tolerability will be analyzed based on patients' vital signs and clinical chemistry. The secondary endpoint of the study is the observation of the treatment-induced immune responses, expressed as treatment-induced T cell responses, resulting from multiple treatment cycles.

Patients in the first arm receive BNT114, patients in the second arm receive BNT114 in combination with RO7198457 (BNT122) and patients in the third arm receive BNT114 in combination with mRNA encoding tetanus-toxin help epitopes.

Next Steps

We expect to report a data update in the second half of 2020 and assess the immunogenicity of the selected antigens.

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

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

Our BNT115 Targets

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

Our BNT115 Clinical Trial

Ongoing Phase 1 Trial (Investigator Sponsored)

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

f) Other FixVac Indications

We are also exploring FixVac development candidates in other cancer indications, including non-small cell lung cancer.

2. Individualized Neoantigen Specific Immunotherapy (iNeST)

Our iNeST product candidate is an individualized cancer immunotherapy that targets specific neoantigens that are present on a patient's tumor. Our iNeST immunotherapies contain pharmacologically optimized uridine mRNA encoding up to 20 patient-specific neoantigens, as well as our proprietary RNA-LPX formulation. We are developing our iNeST cancer immunotherapy in collaboration with Genentech.

a) BNT122: Our iNeST Cancer Immunotherapy for Multiple Potential Indications

We and our collaborator Genentech are developing RO7198457 (BNT122) for the treatment of metastatic melanoma and other solid tumors. We are currently conducting a randomized Phase 2 trial of RO7198457 (BNT122) in collaboration with Genentech in first-line melanoma in combination with pembrolizumab. In collaboration with Genentech, we are also studying RO7198457 (BNT122) as a monotherapy and in combination with atezolizumab in a Phase 1a/1b study of patients with locally advanced or metastatic solid tumors (including in melanoma, non-small cell lung cancer, bladder cancer as well as other solid tumors). The Phase 1a/1b trial is a non-registrational, signal-seeking study recruiting mostly patients with late-stage advanced cancers including patients who failed multiple lines of prior treatment.

Our RO7198457 (BNT122) Targets

RO7198457 (BNT122) is an individualized neoantigen-specific immunotherapy. Each RO7198457 (BNT122) dose includes up to 20 different neoepitopes selected on a patient-by-patient basis. We believe that neoepitope-specific T cells induced by RO7198457 (BNT122) can enhance the therapeutic efficacy of immune checkpoint blockade.

Our RO7198457 (BNT122) Clinical Trials

Ongoing Phase 2 Clinical Trial (First-line with pembrolizumab)

In January 2019, we and Genentech initiated a Phase 2, open-label, multi-center, randomized clinical trial investigating the safety and efficacy of RO7198457 (BNT122) in combination with pembrolizumab in 132 patients with previously untreated metastatic melanoma. Patients in the experimental arm will receive pembrolizumab by intravenous infusion every three weeks, plus a selected dose of RO7198457 (BNT122) at defined intervals. Patients in the active comparator arm will receive 200mg of pembrolizumab by intravenous infusion every three weeks. Following treatment in the comparator arm, patients will be permitted to cross over to combination therapy with RO7198457 (BNT122).

The primary endpoint is:

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

Secondary endpoints include:

- objective response rate, or ORR, in patients treated with RO7198457 (BNT122) compared with patients receiving pembrolizumab alone, defined as the proportion of participants with complete response, or CR, or partial response, or PR.
- overall survival, or OS, of patients treated with RO7198457 (BNT122) compared with patients receiving pembrolizumab only;
- duration of response according to RECIST v1.1 of patients treated with RO7198457 (BNT122) compared with patients receiving pembrolizumab only;
- mean change in health-related quality of life, scores of patients treated with RO7198457 (BNT122) compared with patients receiving pembrolizumab only;

- percentage of patients with CR or PR following cross-over from pembrolizumab monotherapy to combination therapy following cross-over, according to RECIST v1.1; and
- incidence and severity of adverse events.

Ongoing Phase 1 Clinical Trial

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

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

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

We and our collaborator, Genentech, have assessed preliminary clinical results from 29 patients in the Phase 1a trial and 132 patients in the Phase 1b trial. Phase 1a patients had received a median of 5 prior therapies (range 1-17), and Phase 1b patients had received a median of 3 prior therapies (range 1-11). BNT122, both with and without atezolizumab, has a manageable safety profile with predominantly transient and reversible grade 1 and grade 2 adverse events such as infusion related reaction/cytokine release syndrome manifesting as fever and chills. Analyses with complementary quantitative immunoassays showed that BNT122, both with and without atezolizumab, induces strong neoepitope-specific immune responses, including in patients with tumors of low and intermediate mutational burden. Vaccine-induced neo-antigen specific T cells were detected in post-vaccine biopsies. We observed a best response of stable disease in almost half of BNT122 treated patients, including objective responses in a limited number of patients, including both patients with and without prior checkpoint inhibitor regimens. This indicates a level of clinical activity for BNT122 in combination with atezolizumab, however randomized data is needed to assess the individual contribution of BNT 122 on top of a checkpoint inhibitor. A randomized Phase 2 trial testing BNT122 plus pembrolizumab vs pembrolizumab alone is currently ongoing and intended to evaluate clinical efficacy of iNeST in patients with previously untreated advanced melanoma.

Moreover, based on data from our study of BNT121 as an adjunct to surgery in patients with metastatic melanoma, we believe that BNT122 is potentially well suited to control metastatic relapses in patients with a lower tumor burden. Accordingly, we and our collaborator, Genentech, intend to initiate two additional randomized Phase 2 trials in the adjuvant setting in solid cancer indications in the second half of 2020.

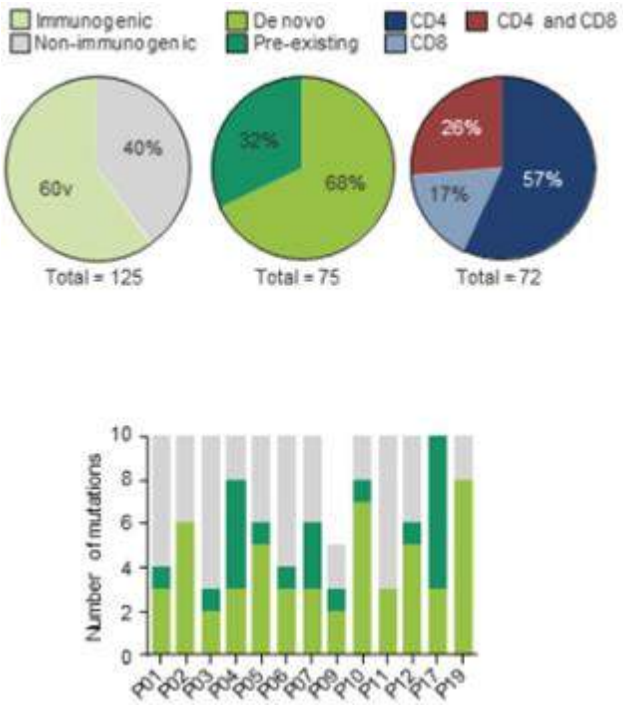
Completed Phase 1 Clinical Trial (BNT121 First Generation iNeST)

In 2017, we published the results of a 13-patient, first-in-human trial of our first-generation intranodal iNeST product candidate, BNT121, in patients with late-stage malignant melanoma. The objective of this clinical trial was to study the feasibility, safety, tolerability, immunogenicity and potential anti-tumoral activity of iNeST. All patients had stable disease at enrollment with a high risk for relapse.

All 13 patients developed T cell immune responses against multiple immunotherapy neoepitopes at up to high single-digit percentages. As shown below, 60% of the selected neoepitopes elicited a T cell response. The detected immune response was elicited by both $CD4^+$ and $CD8^+$ T cells and the majority was induced *de novo*,

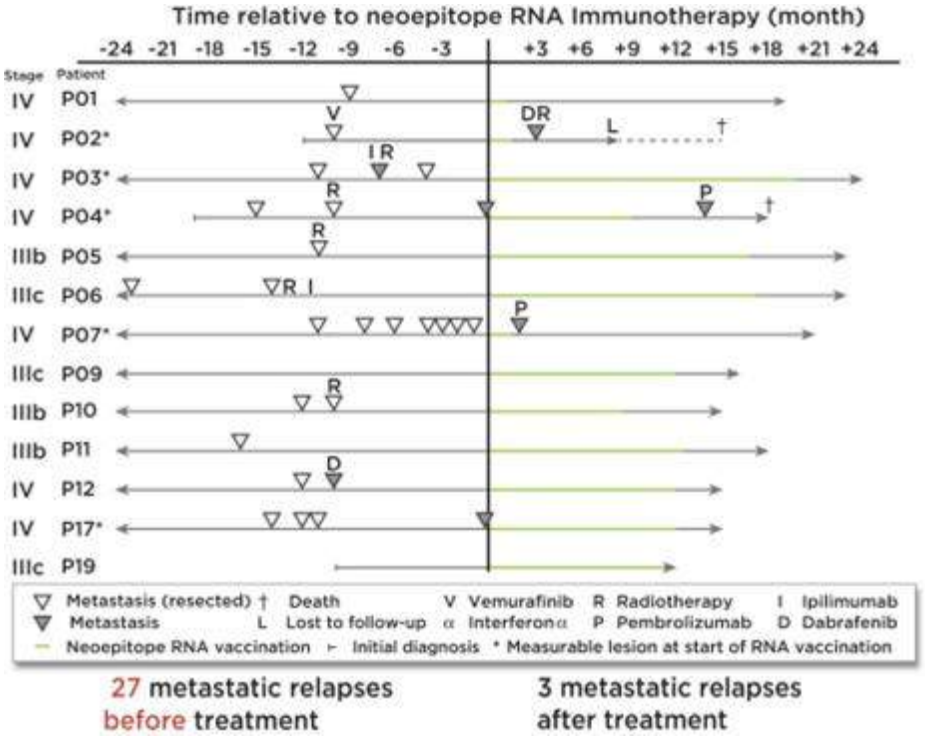
which we believe to be an important requirement for an effective immune response and an added benefit beyond checkpoint inhibition alone.

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



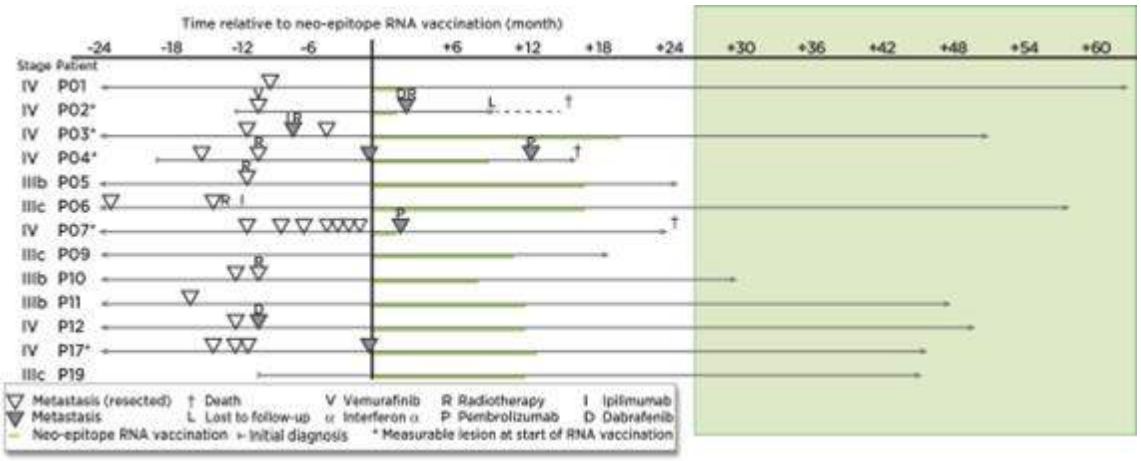
Immune responses documented in our prior BNT121 study. Patients showed immune responses, including both $CD4^+$ and $CD8^+$ responses, against multiple neoantigens. Source: Nature 547, 222-226 (13 July 2017)**.**

In addition, metastases resected from two patients following treatment with BNT121 demonstrated evidence of treatment-induced infiltration with BNT121-induced neoepitope-specific T cells and neoepitope-specific killing of tumor cells. The cumulative rate of metastatic events was significantly reduced after the start of treatment, resulting in a sustained progression-free survival. Of the 13 patients entering the trial, eight patients that had no radiologically detectable lesions at start of neo-epitope vaccination were relapse free and remained recurrence-free for the whole follow-up period (12 to 23 months). Five patients experienced melanoma relapses shortly after inclusion in the trial and despite initiation of standard treatment had progressing metastases at start of their neoepitope treatment. Of these, three patients developed neoepitope treatment-related objective clinical responses. One of these patients exhibited a complete response and remained relapse-free for 26 months. The second patient had an immunotherapy-related partial response. This patient had a late relapse owing to outgrowth of ß2-microglobulin-deficient melanoma cells as an acquired resistance mechanism. A third patient developed a complete response to treatment in combination with PD-1 blockade therapy.



Metastatic relapses before and after treatment with BNT121. The chart above shows the metastatic relapses of patients before and after treatment with BNT121. Each horizontal line represents the time course of a single patient. The vertical line indicates the treatment start of BNT121. Source: Nature 547, 222-226 (13 July 2017).

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



Next Steps

We expect to report a topline data update from our RO7198457 (BNT122) first-line Phase 2 melanoma trial in the second half of 2020 and report a data update from our RO7198457 (BNT122) Phase 1a/1b solid tumor trial in 2020. We and Genentech plan to initiate two additional clinical trials for RO7198457 (BNT122) in 2020 in first-line solid cancers in the adjuvant setting, one in combination with atezolizumab and the other as a monotherapy.

3. Intratumoral Immunotherapy

We, in collaboration with Sanofi, are developing intratumoral immunotherapies utilizing our proprietary mRNA technology. These immunotherapies are designed to be administered directly into the tumor in order to alter the tumor microenvironment and enhance the immune system's ability to recognize and fight cancer within the tumor (proximal) as well as in other untreated locations (distal).

a) SAR441000 (BNT131): Our Initial Intratumoral Immunotherapy for the Treatment of Solid Tumors

We and Sanofi are developing SAR441000 (BNT131) as an intratumoral immunotherapy for the treatment of solid tumors. SAR441000 (BNT131) consists of modified mRNA that is injected directly into the tumor, where it is thought to express cytokines to alter the tumor microenvironment. SAR441000 (BNT131) is being studied in a Sanofi-sponsored Phase 1 clinical trial as a monotherapy in patients with advanced melanoma and in combination with an anti-PD-1/PD-L1 checkpoint inhibitor in patients with advanced melanoma and certain advanced solid tumors.

Our SAR441000 (BNT131) Targets

SAR441000 (BNT131) comprises mRNA that encodes the cytokines IL-12sc, IL-15sushi, IFN-α and GM-CSF. By expressing these cytokines in the tumor microenvironment, the immune system may more easily recognize and fight cancer.

Our SAR441000 (BNT131) Clinical Trials

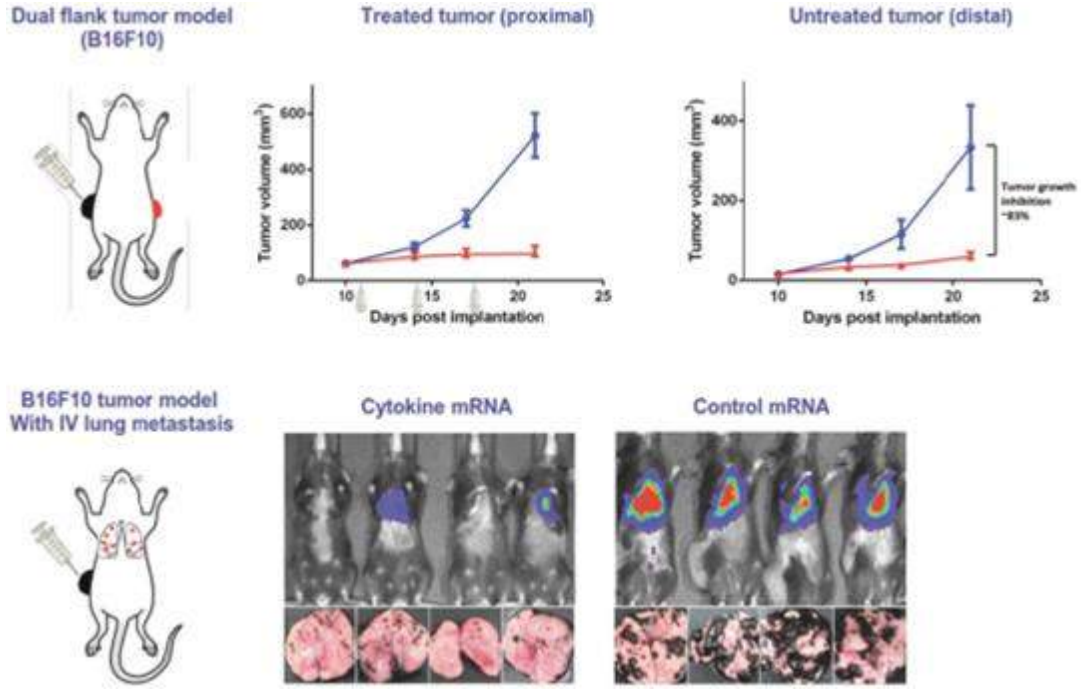
Ongoing Phase 1 Clinical Trial

Sanofi, in collaboration with BioNTech, has commenced a first-in-human, multi-center, open-label, Phase 1, dose escalation and expansion trial to evaluate the safety, pharmacokinetics, pharmacodynamics and anti-tumor activity of SAR441000 (BNT131) administered intratumorally as monotherapy and in combination with cemiplimab, with an estimated enrollment of 264 patients with certain advanced solid tumors.

Our SAR441000 (BNT131) Preclinical Studies

In collaboration with Sanofi, we conducted a preclinical study of SAR441000 (BNT131) in mouse tumor models. In these *in vivo* models, the anti-tumor activity of cytokines encoded by mRNA was driven by the action of T cells as well as NK cells and was accompanied by robust intratumoral induction of interferon gamma, systemic expansion of antigen-specific T cells and increased granzyme B positive $CD8^+$ T cell infiltration.

SAR441000 (BNT131) was shown to form immunological memory toward both dominant and subdominant antigens, which protected long-term survivors from re-challenge with autologous tumors. Importantly, although cytokine mRNAs were administered intratumorally, resulting in local target expression, anti-tumor activity extended beyond the injected tumor to effectively control the growth of distal tumors in both a dual-tumor model and an experimental lung metastasis model. Finally, SAR441000 (BNT131) demonstrated improved overall survival and higher incidence of complete tumor regressions across several preclinical models.



Systemic anti-tumor effects in mouse model. As shown above, BNT131 demonstrated local and systemic anti-tumor effects of intratumoral cytokine mRNA. In this study, mice were implanted with a tumor on each of the right and left flank. One tumor was injected with intratumoral cytokine mRNA (or control mRNA) while the other was not. The top center figure shows the tumor volume of the treated tumor (red line) against the control (blue line). The top right figure shows an anti-tumor effect on the untreated tumor (red line) against the control (blue line). The figures on the bottom show the abscopal effect of an intratumoral cytokine mRNA (center bottom) on distal lung metastases compared to the control mRNA (right bottom). Source: Wagenaar et al., Local immunotherapy with a mixture of mRNAs encoding pro-inflammatory cytokines promotes potent anti-tumor immunity and tumor eradication across multiple preclinical tumor models; poster presented at SITC 2018.

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

Next Steps

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

4. RiboMabs

Our RiboMab product candidates are designed to encode secreted antibodies for expression *in vivo* by the patient's cells. RiboMab product candidates consist of our proprietary nucleoside-modified mRNA that is designed to

minimize the immunomodulatory activity of the mRNA, and these candidates are formulated using liver-targeting LNPs for intravenous delivery. RiboMabs potentially address the limitations of recombinant antibodies, including costly manufacturing processes and unfavorable pharmacokinetics, such as short plasma half-life. We are conducting preclinical studies for two development candidates, and have published compelling preclinical data.

RiboMab Preclinical Studies

We have generated RiboMabs targeting different tumor antigens and tested their therapeutic potency in mice engrafted with human tumors that were repopulated with human immune cells. We demonstrated in preclinical studies that injection with a RiboMab product candidate encoding bispecific RiboMabs directed against CD3 and CLDN6 antigens resulted in elimination of aggressively growing, large tumors. Intravenously administering a microgram dose of mRNA encoding RiboMabs resulted in bispecific RiboMab production in the liver cells and rapid secretion into circulation, reaching peak plasma concentration within hours and remaining at therapeutically effective levels for one week. The dosage and frequency of dosing of recombinant bispecific antibodies required to produce similar effects was substantially greater. This was the first preclinical study to demonstrate *in vivo* application of mRNA-encoded antibodies for the successful treatment of cancer.

a) BNT141: Our Initial RiboMab for the Treatment of Solid Tumors

BNT141 is our RiboMab product candidate for the treatment of solid tumors. BNT141 is designed to encode secreted IgG antibodies.

Our BNT141 Targets

BNT141 is designed to encode secreted antibodies that target multiple epithelial solid tumors, including gastric and pancreatic cancers.

Next Steps

We expect to initiate a Phase 1 basket trial of BNT141 for the treatment of various solid tumors, including gastrointestinal tumors, in the first half of 2021.

b) BNT142: Our Second RiboMab for the Treatment of Solid Tumors

BNT142 is our RiboMab product candidate for the treatment of solid tumors. BNT142 is designed to encode a secreted bispecific antibody that targets CD3 and CLDN6.

Our BNT142 Targets

BNT142 is designed to encode bispecific antibodies that target CD3, a T cell receptor that plays a key role in the activation of $CD8^+$ and $CD4^+$ T cells, and CLDN6, a highly specific oncofetal cell surface antigen that is found in solid tumors, but not in normal cells.

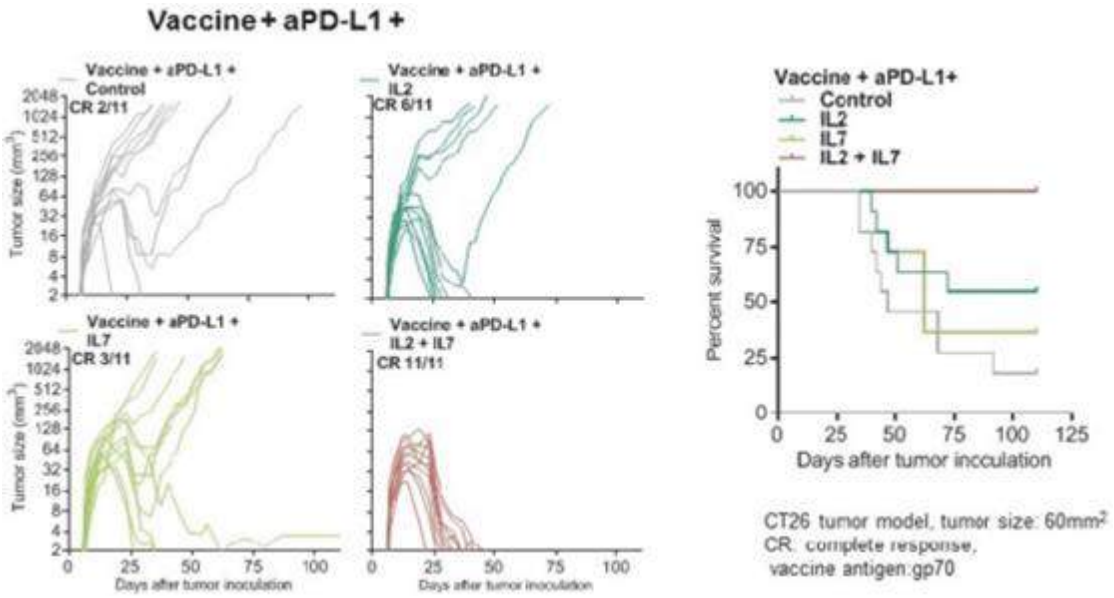
Next Steps

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

5. RiboCytokines

Our RiboCytokine product candidates utilize mRNA that encodes the desired cytokines for expression *in vivo* by the patient's cells. RiboCytokine product candidates consist of modified mRNA designed to encode secreted cytokines that are formulated to use liver-targeting LNP for intravenous delivery.

Our RiboCytokine product candidates are designed to address the limitations of recombinantly expressed cytokines, including limited serum half-life and production costs. We are developing RiboCytokines to be used primarily in combination with other drugs, including our other pipeline candidates.



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

a) BNT151: Our Initial RiboCytokine for the Treatment of Solid Tumors

We are developing BNT151, our RiboCytokine designed to encode a modified version of the human interleukin-2, or optimized IL-2, cytokine for the treatment of solid tumors. BNT151 is designed to stimulate T cells without triggering immunosuppression in the tumor microenvironment.

Our BNT151 Target

BNT151 comprises our nucleoside-modified mRNA that encodes mRNA for a function-modified IL-2. IL-2 is a key cytokine in T cell immunity, supporting the differentiation, proliferation, survival and effector functions of T cells.

Recombinant IL-2, aldesleukin, was the first approved cancer immunotherapy, and has been marketed globally for the treatment of late stage melanoma and renal cell cancer for decades. Most patients with complete responses after IL-2 treatment remain regression free for more than 25 years after initial treatment, but overall response rates are low due in part to the limitations of recombinant cytokines. Recombinant IL-2 has a very short half-life, requiring high and frequent dosing and a partially unfavorable activity profile, which leads to increased side effects, thus limiting its utility as a cancer treatment.

Next Steps

We expect to initiate a Phase 1 clinical basket trial of BNT151 for the treatment of multiple solid tumors in the first half of 2021.

b) BNT152: Our Second RiboCytokine for the Treatment of Solid Tumors

We are developing BNT152, our RiboCytokine designed to encode IL-7 for the treatment of solid tumors.

Next Steps

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

c) BNT153: Our IL-2 variant RiboCytokine for the Treatment of Solid Tumors

We are developing BNT153, our RiboCytokine designed to secrete IL-2 for the treatment of solid tumors.

Next Steps

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

B. Our Oncology Engineered Cell Therapy Product Candidates

1. CAR-T

We are advancing multiple CAR-T product candidates, the most advanced of which, BNT211, is targeting the novel and highly specific target CLDN6^{+} in solid tumors, and which we expect to enter the clinic in the second half of 2019 for the treatment of CLDN6^{+} solid tumors, including ovarian cancer. We plan to use our initial CAR-T cell product candidates in combination with a FixVac immunotherapy that encodes the same target as the CAR-T. The FixVac selectively targets dendritic cells, which leads to uptake, antigen expression and maturation of the dendritic cells. The co-stimulation provided by dendritic cell maturation has been shown in preclinical studies to amplify and expand CAR-T cells *in vivo*, leading to increased persistence of the CAR-T.

a) BNT211: Our CAR-T Cell Therapy for the Treatment of CLDN6^{+} Solid Tumors

BNT211 is our CAR-T cell therapy for the treatment of CLDN6^{+} solid tumors. BNT211 targets CLDN6 and will initially be evaluated in combination with a CARVac that encodes CLDN6.

Our BNT211 Target

BNT211 targets Claudin 6, or CLDN6, a highly specific oncofetal cell surface antigen that is found in multiple cancers, including ovarian, testicular and lung cancers, but not in normal cells.

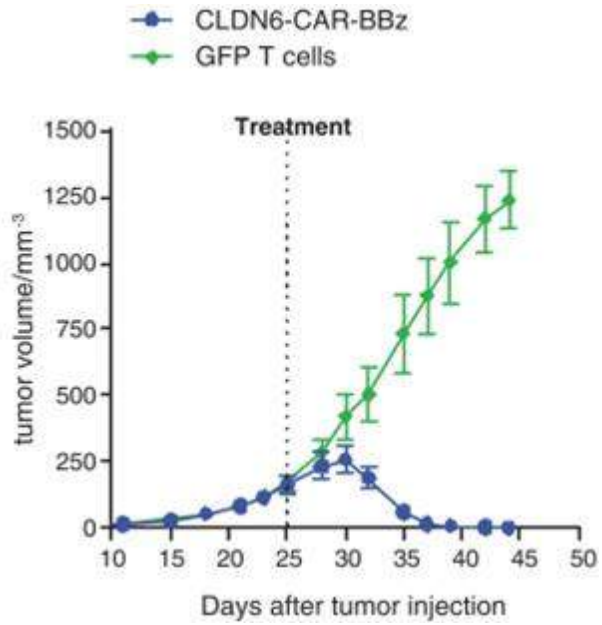
Our BNT211 Trials

Planned Phase 1/2 Clinical Trial

We anticipate initiating a Phase 1/2 open-label, multi-center dose escalation and dose expansion basket study of BNT211 with or without a CLDN6 CARVac immunotherapy in the first half of 2020. We anticipate enrolling patients with advanced solid tumor malignancies who express CLDN6. While our preclinical focus has been on ovarian cancer, we expect patients with uterine, testicular, lung and gastric cancers may also be enrolled in our upcoming CAR-T trials.

Preclinical Studies

We have observed compelling preclinical data of BNT211 demonstrating potent anti-tumoral activity, including eradication of advanced tumors in an ovarian carcinoma xenograft model.



Potent anti-tumoral activity. As shown above, BNT211 demonstrated eradication of advanced tumors in a mouse model.

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

Next Steps

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

b) BNT212: Our CAR-T Cell Therapy for the Treatment of CLDN18.2^{+} Solid Tumors

BNT212 is our CAR-T cell therapy for the treatment of CLDN18.2-positive solid tumors. BNT212 will initially be evaluated in combination with a CARVac that encodes CLDN18.2.

Our BNT212 Target

BNT212 targets Claudin 18.2, or CLDN18.2, a highly specific target that is only expressed in cancer and in differentiated epithelial cells of the gastric mucosa, but it is absent from the gastric stem cell zone. CLDN18.2 is expressed in numerous epithelial solid tumors, including gastric, pancreatic, esophageal, ovarian and lung tumors.

C. Our TCR Product Candidates in Oncology

We are developing T cell receptor therapies for the treatment of cancer, including in collaboration with Eli Lilly. Under our collaboration, Eli Lilly has an exclusive option to pursue clinical development of certain potential TCR product candidates. We and Eli Lilly have concluded the research phase of the collaboration and Eli Lilly has exercised its option and selected a target to develop and commercialize.

D. Our Antibody Product Candidates in Oncology

1. Next-Generation Checkpoint Immunomodulators

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

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

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

Our GEN1046 (BNT311) Targets

GEN1046 (BNT311) is a PD-L1x4-1BB bispecific antibody that induces conditional activation of T cells through 4-1BB stimulation which is dependent on simultaneous binding to PD-L1. In addition, the PD-L1-specific arm of DuoBody-PD-L1x4-1BB functions as a classical immune checkpoint inhibitor by blocking the PD-1/PD-L1 axis, also in the absence of 4-1BB binding. PD-L1 is a validated target that is expressed on tumor cells. 4-1BB is a trans-membrane receptor belonging to the TNF super-family and is expressed predominantly on activated T cells. DuoBody® is a registered trademark of Genmab.

GEN1046 (BNT311) Trials

Ongoing Phase 1/2a Clinical Trial

The ongoing Phase 1/2a, open-label, single-arm GEN1046 (BNT311) trial with multiple expansion cohorts, conducted in collaboration with Genmab, is expected to enroll approximately 192 patients with malignant solid tumors. The trial consists of a dose escalation part and an expansion part. The dose escalation part will determine the safety profile of GEN1046 (BNT311) in subjects with certain relapsed or refractory, advanced and/or metastatic malignant solid tumors who are no longer candidates for standard therapy. The expansion part will be initiated once the recommended Phase 2 dose has been established in Phase 1. In the expansion part, GEN1046 (BNT311) will be administered intravenously once every 21 days. The primary endpoints of the trial are dose-limiting toxicities, adverse events and safety laboratory parameters, including hematology, biochemistry, coagulation and endocrinology.

Preclinical Studies

In preclinical settings, GEN1046 (BNT311) induces conditional activation of T cells through 4-1BB stimulation which is dependent on simultaneous binding to PD-L1. In addition, the PD-L1-specific arm of DuoBody-PD-L1x4-1BB functions as a classical immune checkpoint inhibitor by blocking the PD-1/PD-L1 axis.

Next Steps

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

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

GEN1042 (BNT312), our jointly owned CD40x4-1BB antibody product candidate, is a potential first-in-class bispecific antibody designed to induce conditional immune activation by crosslinking CD40 and 4-1BB positive cells. We and Genmab began recruitment and screening for a Phase 1/2a trial of GEN1042 (BNT312) for the treatment of malignant solid tumors in August 2019.

GEN1042 (BNT312) Targets

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

GEN1042 (BNT312) Preclinical Studies

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

2. Targeted Cancer Antibodies

a) MVT-5873 (BNT321): Our Targeted Cancer Antibody for the Treatment of Pancreatic Cancer

In May 2019, we acquired certain antibody assets from MabVax Therapeutics Holding, Inc., including MVT-5873 (BNT321), a clinical-stage targeted cancer antibody.

Pancreatic Cancer

In 2019, the American Cancer Society estimated that approximately 56,770 people will be diagnosed with pancreatic cancer in the United States annually. Pancreatic cancer is an aggressive cancer, with a five-year survival rate from diagnosis, across all stages combined, of 9%.

Our MVT-5873 (BNT321) Target

MVT-5873 (BNT321) is a fully human IgG1 monoclonal antibody targeting sialyl Lewis A (sLe^a), an epitope on CA19-9 that is expressed in pancreatic and other gastrointestinal cancers that plays a role in tumor adhesion and metastasis formation, and is a marker of an aggressive cancer phenotype.

Our MVT-5873 (BNT321) Trials

MVT-5873 (BNT321) is being investigated in an open-label, multi-center, non-randomized dose escalation Phase 1/2 study evaluating the safety and recommended Phase 2 dose of MVT-5873 (BNT321) both as a monotherapy and in combination with a standard of care chemotherapy in approximately 68 subjects with pancreatic and other CA19-9+ malignancies. Secondary objectives include evaluating tumor response rate by RECIST 1.1, duration of response, and determining pharmacokinetics. This study utilizes a conventional 3+3 design to identify the recommended Phase 2 dose.

Interim data for the combination cohort was reported in February 2018. In this cohort, MVT-5873 (BNT321) was given in combination with nab-paclitaxel and gemcitabine to patients newly diagnosed with CA19-9+ pancreatic cancer. MVT-5873 (BNT321) at a dose of 0.125mg/kg when added to first-line chemotherapy was generally well tolerated by all subjects. All six patients evaluated had measurable tumor reductions by RECIST, with four patients meeting the criteria for partial response and two patients meeting the criteria for stable disease.

We have resumed this trial and dosing has begun.

E. Our Oncology Small Molecule Immunomodulator Product Candidates

1. BNT411: Our Small Molecule TLR7 Agonist for the Treatment of Colorectal and Bladder Cancer

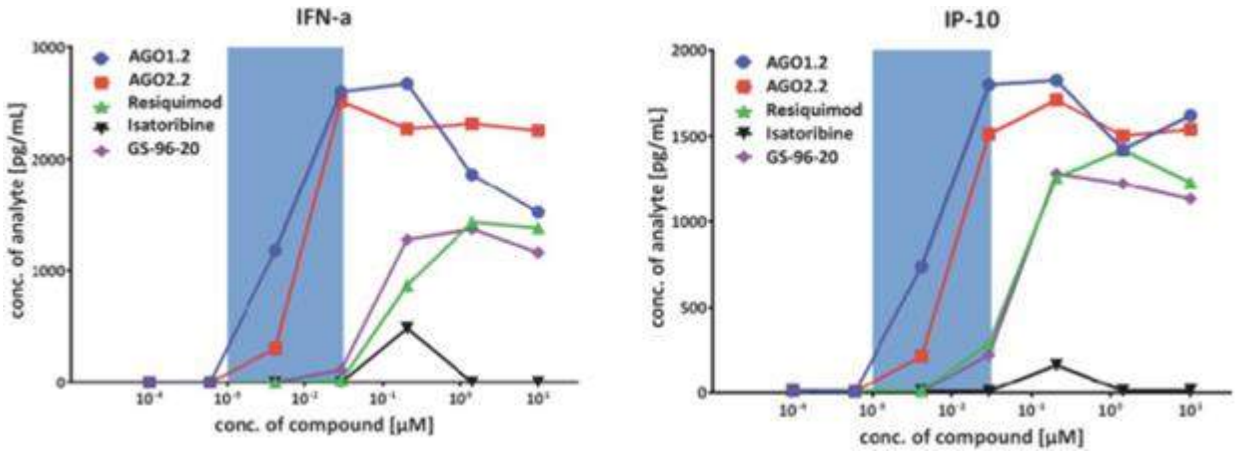
BNT411 is our novel small molecule TLR7 agonist product candidate. BNT411 is designed to activate both the adaptive and innate immune system through the TLR7 pathway. We are designing BNT411 to be used in combination with chemotherapy and checkpoint inhibitors. We filed an IND for BNT411 in November 2019.

Our BNT411 Target

BNT411 is a TLR7 agonist that is designed to activate both the adaptive and innate immune system through the TLR7 pathway. This activity and the release of cytokines and chemokines are designed to result in the potent stimulation of antigen-specific $CD8^+$ T cells, B cells and innate immune cells such as NK cells and macrophages.

Our BNT411 Preclinical Studies

In preclinical studies, BNT411 (SC1.2/Ago1.2) was shown to be more potent in the induction of IFN-α compared to the clinical competitor compound resiquimod (R848), even at lower concentrations (minimal effective concentration of BNT411 *in vitro* is 4nM). In contrast to the tested competitor compound, BNT411 was shown to induce at low concentrations especially IFN-α whereas other (pro-)inflammatory and CRS-related cytokines (IL-6, IL-10, TNF-a, IL-8) are only observed at higher concentrations.



Next Steps

We expect to initiate a Phase 1 clinical trial of BNT411 as a combination therapy in solid tumors in the second half of 2020.

F. Our Infectious Disease mRNA Product Candidates

1. Prophylactic Vaccine for the Prevention of Influenza

We are collaborating with Pfizer to develop an influenza vaccine based on our mRNA drug classes. The product candidate, BNT161, will encode influenza virus antigens selected by the WHO in advance of the flu season.

Next Steps

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

2. Other Infectious Diseases

We have a research collaboration with Penn, under which we have the exclusive option to develop and commercialize prophylactic mRNA immunotherapies for the treatment of up to 10 infectious disease indications. On September 20, 2019, Penn announced positive preclinical results of a vaccine product candidate using its mRNA technology. The preclinical study vaccinated mice and guinea pigs against Herpes simplex virus type 2. Penn reported that the immunization led to "mostly sterilizing immunity" from the virus.

We also have two collaborations to develop a potential vaccine based on our mRNA technology to induce immunity and prevent COVID-19 infection. We intend to initiate clinical testing for the product candidate, BNT162, in late April 2020, subject to regulatory approval, as part of a global clinical development program in Europe (commencing in Germany), the United States and China.

In March 2020, we entered a strategic alliance with Fosun Pharma to advance BNT162 and jointly develop the COVID-19 vaccine in China. Upon regulatory approval, Fosun Pharma will commercialize the vaccine in China, while we retain the full rights to develop and commercialize the vaccine in the rest of the world.

Additionally, in March 2020 BioNTech signed a letter of intent with Pfizer to co-develop and distribute a COVID-19 vaccine outside of China. We have also executed a Material Transfer and Collaboration Agreement to enable immediate collaboration.

Next Steps

We expect to initiate our first Phase 1 clinical trial under Penn collaboration in the first half of 2021, and clinical trials for BNT162 in late April 2020.

G. Our Rare Disease Protein Replacement mRNA Product Candidates

We are collaborating with Genevant, in order to combine our mRNA technology with Genevant's LNP delivery technology, to create up to five mRNA protein replacement therapies for the treatment of rare diseases with high unmet medical needs. We expect our first compound from this collaboration to enter the clinic by the first half of 2021. The first product candidate under the Genevant collaboration, BNT171, is currently being developed for an undisclosed indication. Our mRNA replacement product candidate is associated with a favorable tolerability profile and good protein expression (in mice) and demonstrated phenotype rescue in a mouse disease model.

H. Other

Our legacy commercial stage product, MammaTyper, is a molecular *in vitro* diagnostic test for the quantitative detection of the mRNA expression of ERBB2, ESR1, PGR and MKI67 in breast cancer tissue. MammaTyper has been shown in a variety of scientific publications to offer superior diagnostics insights compared to conventional immunohistochemical detection methods.

XIII. Manufacturing

We are building a fully integrated biotechnology company, with operations spanning from research through clinical development, and manufacturing through sales and marketing. We operate three GMP-certified manufacturing facilities in Germany, where we manufacture mRNA therapeutics and engineered cell therapies for our own pipeline and for external customers. We operate a fourth facility in Germany where we manufacture custom peptides to support our extensive immunomonitoring activities within our development programs. Our subsidiary BioNTech Innovative Manufacturing Services GmbH, or BioNTech IMFS, has been manufacturing GMP-certified cellular products since 1999. It was granted its first GMP license for manufacturing mRNA in 2011 and has been manufacturing individualized mRNA products since 2014.

We have expanded our capability to produce and supply drug products to support clinical development of our, and our collaborators', product candidates. To date, we have manufactured over 500 drug substance batches in our manufacturing facilities.

Our approach has been to proactively build capacity in anticipation of demand from internal research and development, as well as from our collaborators. We have done so by continuing to make significant investments in manufacturing infrastructure and increasingly expanding our capacity to manufacture mRNA, viral vectors, cellular

products and peptides. We believe the development and optimization of our manufacturing processes in parallel to drug development is crucial to our success. We have also collaborated with Siemens to develop a process for a fully-automated, on-demand production of mRNA therapies.

Our Manufacturing Operations

mRNA. We believe scaling up manufacturing for mRNA can best be executed as part of a proprietary manufacturing approach, not as part of an outsourcing strategy. We believe this approach allows us to maintain control of our proprietary processes and gives us the flexibility we need for scheduling batch production for our drug substances to match our development plans as they evolve. Our mRNA manufacturing is currently conducted at our in-house BioNTech IMFS facility and our BioNTech East Wing facility, the latter being dedicated to iNeST manufacturing. Our mRNA manufacturing process involves standardized production of all mRNA constructs and minimal restrictions in construct length. We have the capacity to undertake sterile filtration and final filling in up to 1,200 vials of various sizes. Batch sizes range from a few milligrams for individualized applications (*i.e.*, iNeST) to 3g for standard mRNA applications (*i.e.*, FixVac and intratumoral immunotherapies), with batch sizes of up to 10g currently possible.

To date, we have produced more than 500 batches of mRNA drug substance to support our studies. We currently have infrastructure capable of producing more than 100 batches of mRNA drug substance and formulated drug product per month with a turnaround time of about 30 to 40 days from sequence identification to released product. We believe we currently have the capacity to supply needs of our product candidates in clinical trials up to registration.

In recent years, we have successfully decreased the time required to deliver individualized immunotherapy to patients. In 2014, it took us over three months to manually manufacture and deliver individualized immunotherapies to patients. Since December 2017, with the implementation of semiautomatic GMP manufacturing in collaboration with Siemens, we have been consistently manufacturing and delivering individualized immunotherapies in under six weeks. This advancement represents significant progress toward our target commercial manufacturing turnaround time of less than 28 days. We believe this is achievable, and we plan to continue to develop additional process improvements, which we expect will further reduce our turnaround times as we progress through clinical development.

Cell Therapy Products. We have end-to-end capabilities and over 20 years of experience in cell therapy manufacturing. Our manufacturing process for cellular products involves the isolation of primary human cells and subpopulations, including $CD34^+$ and $CD3^+$ cells. We engage in the culturing, expansion and genetic modification of primary human cells as well as mammalian cell lines. Our processes include vector production for transfection of cells with CARs, cell banking and cryopreservation.

We have set up a broad range of quality control assays for the characterization of cell therapy products that allow us to certify the manufactured drug products in a short time. We are a leader in the production of gamma retroviral vectors. To date, we have produced more than 50 different cell therapy products.

Peptides. Our custom peptide synthesis business has developed unique technologies to produce several million peptides during the past three years to support our growing clinical pipeline. These include fast small-scale manufacturing of peptides for target and epitope discovery as well as for neoepitope characterization and production of high content arrays. It is important to synthesize highly purified peptides in order to avoid false positives in immunomonitoring in our mRNA immunotherapy trials. We also use these peptides as starting material in our engineered cell therapies. We have developed know-how to produce highly complex and purified peptide pools that consist of overlapping peptides spanning entire antigens or neoepitopes. We plan to establish a new production facility, which will roughly double our current capacity.

Our Manufacturing Facilities

We operate four manufacturing and packaging facilities in Germany. In these facilities, we manufacture and package individualized mRNA, bulk mRNA, retroviral vectors, cellular products and peptides. In Mainz, we are currently constructing another facility for iNeST manufacturing at a commercial scale, which is planned to start manufacturing in 2022 and will supply markets mainly in Europe and the United States.

BioNTech IMFS. Our manufacturing operations for retroviral vectors, cell therapy products and mRNA are housed in our wholly owned subsidiary, BioNTech IMFS. Founded in 1997, BioNTech IMFS specializes in services for innovative therapeutic approaches. In 2009, BioNTech IMFS became our wholly owned subsidiary, giving us access to synergistic

platforms and complementary expertise for development, testing and manufacturing services. BioNTech IMFS and its predecessors have had GMP-certified cell and gene therapy manufacturing capabilities since 1999, and obtained GMP manufacturing authorization for mRNA production in 2011. In 2017, BioNTech IMFS began automated manufacturing of the iNeST product candidate and entered into its first commercial supply contract for retroviral vectors. Located near Mainz, the BioNTech IMFS facility occupies over 30,000 square feet. Two hundred and twenty staff members are employed at this facility, with collective expertise in molecular biology, cell biology and virology.

BioNTech iNeST Clinical Manufacturing (East Wing). We dedicate our GMP-certified manufacturing facility at our headquarters in Mainz, Germany to the production of iNeST immunotherapies. In 2015, our wholly owned subsidiary, BioNTech RNA Pharmaceuticals GmbH, or BioNTech RNA, and Siemens announced a collaboration for developing an automated, paperless and digitalized production site for individualized mRNA. We obtained our GMP manufacturing authorization for iNeST production at our East Wing facility in June 2018 and released our first drug product there the following month.

This facility contains approximately 17,000 square feet of laboratory and office space, including 4,300 square feet of GMP facilities. About 200 staff members are employed at this facility and operate it seven days per week. In its first year of operation the facility manufactured and released more than 250 batches of mRNA.

BioNTech Clinical Manufacturing. Our GMP-certified manufacturing facility in Kupferbergterrasse, Mainz, Germany is authorized to conduct secondary packing, labeling, storage and batch release of primary packed investigational medicinal products. This facility contains approximately 11,500 square feet of laboratory and office space, including 1,250 square feet of GMP facilities.

JPT. JPT, our peptide manufacturing facility, was established in 2004 and became a wholly owned subsidiary of BioNTech in 2008. JPT is located in Berlin, Germany and occupies over 16,000 square feet of clean rooms, laboratory and office space.

Other Certifications

BioNTech Diagnostics has a quality management system that is certified according to ISO 13485:2016 and JPT maintains a ISO 9001:2015 certified Quality Management System to allow production of European CE marked companion diagnostics.

Quality Assurance

We have implemented and maintain several Quality Assurance systems. BioNTech IMFS, BioNTech Clinical Manufacturing and BioNTech iNeST Clinical Manufacturing have implemented GMP-certified quality assurance systems. BioNTech Diagnostics has a quality management system that is certified according to ISO 13485:2016 and JPT maintains a ISO 9001:2015 certified Quality Management System.

XIV. Third-Party Collaborations

We have forged productive collaborations with pharmaceutical companies and academic research institutions with area expertise and resources in an effort to advance and accelerate our discovery and development programs in oncology, and also to leverage our drug classes into additional disease indications while minimizing our incremental costs.

Our collaborations include:

- Genentech for our iNeST platform in our mRNA drug class;
- Sanofi for our intratumoral therapy platform in our mRNA drug class;
- Genmab for our next-generation checkpoint immunomodulator platform in our antibodies drug class;
- Pfizer for our influenza vaccine program, which leverages technology from our infectious disease mRNA-based platform;
- Penn for up to 10 prophylactic indications in our infectious disease mRNA-based platform; and
- Genevant for our rare disease protein replacement therapy platform in our mRNA drug class.

We either wholly own or retain significant rights to all of our clinical stage programs, either in the form of a global share of profit and co-commercialization rights with our collaborators in certain markets or significant royalties and milestones. We plan to continue to identify potential collaborators who can contribute meaningful resources and insights to our programs and allow us to more rapidly expand our impact to broader patient populations.

Genentech—iNeST Collaboration

Collaboration Agreement

On September 20, 2016, we and BioNTech RNA entered into a Collaboration Agreement with Genentech and F. Hoffman-La Roche Ltd, which, as amended on June 1, 2018 and December 6, 2019, we refer to as the Genentech Collaboration Agreement, to jointly research, develop, manufacture and commercialize certain pharmaceutical products that comprise neoepitope RNAs, or the Genentech Collaboration Products, which include our iNeST development candidates, for any use worldwide. Under the Genentech Collaboration Agreement, we and Genentech agreed to perform joint research under a research plan to further improve our technology platform for the manufacturing of Genentech Collaboration Products. Under the terms of the Genentech Collaboration Agreement, Genentech paid us $310 million in upfront and near-term milestone payments.

We and Genentech must use commercially reasonable efforts to jointly develop one or more Genentech Collaboration Products in accordance with an agreed global development plan, with the costs of such development to be shared equally. We will continue certain clinical studies that were initiated prior to the execution of the Collaboration Agreement at our sole expense, and any future material changes in the operation of such clinical studies require Genentech's approval. Genentech may access and use any data generated in these ongoing clinical studies.

In addition to the clinical studies included in the global development plan, we may propose certain additional clinical studies for indications not included in the global development plan, and if the joint development committee formed by the parties does not elect to include the proposed studies in the global development plan, then we may conduct the study at our sole expense under certain conditions, and subject to certain restrictions. Genentech has the option to select any candidate in such studies for potential further joint development and/or commercialization by Genentech as a Genentech Collaboration Product. In the case that Genentech wishes to pursue the clinical development of a Genentech Collaboration Product in an indication that we are not interested in pursuing, then under certain conditions, we may opt out of the co-funding of such development and Genentech may continue do so at its own costs, except that we are obligated to repay Genentech's development costs in the event that such product subsequently receives regulatory approval.

Genentech has the sole right to commercialize the Genentech Collaboration Products on a worldwide basis, with all profits and losses from such commercialization to be split equally with us. If we exercise our right to opt out of sharing equally in future development costs for any Genentech Collaboration Products, then we will no longer split all such profits and losses for such Genentech Collaboration Products equally with Genentech and will instead receive a royalty on annual worldwide net sales of such Genentech Collaboration Products that are covered by a valid claim included in certain of our patents and certain joint patents that arise out of the collaboration. Furthermore, for certain Genentech Collaboration Products for which we share co-promotion rights with Genentech, we have the option to assume a percentage to be determined of the total sales force in the United States and certain other countries, including Germany and other major European markets. In addition, under certain regulatory and other circumstances, we have the right to independently commercialize Genentech Collaboration Products in indications that the joint development committee declines to pursue and that Genentech does not subsequently elect to commercialize, provided that we market such Genentech Collaboration Products under a separate brand and trademark that is approved by the joint commercialization committee established by the parties as not confusingly similar to the Genentech Collaboration Products being commercialized by Genentech. Our ability to research, develop, co-promote and/or independently commercialize Genentech Collaboration Products may be terminated or limited in the event we undergo a change of control.

We granted to Genentech an exclusive license under certain of our intellectual property, and our interest in any jointly-owned intellectual property developed under this agreement, to research, develop, make, sell and import any pharmaceutical products that comprise neoepitope RNA. Genentech granted to us an exclusive, non-transferable, sublicensable licenses under certain Genentech intellectual property, our intellectual property exclusively licensed to Genentech, and their interest in any jointly-owned intellectual property developed under this agreement for the performance of our ongoing clinical studies and the exercise of our rights and obligations under the Genentech Collaboration Agreement.

Until the first marketing approval for a Genentech Collaboration Product, we have granted Genentech the first right to negotiate an exclusive license to develop, manufacture and commercialize combination therapies involving pharmaceutical products based on neoepitope RNA and pharmaceutical products based on non-neoepitope RNA for the treatment of cancer in humans.

The Genentech Collaboration Agreement will remain in effect so as long as Genentech Collaboration Products are in development or commercialization, or until the date of the expiration of the last royalty term if BioNTech has exercised its option to opt-out of joint development of Genentech Collaboration Products. If the agreement expires, the licenses granted to Genentech become fully-paid up, royalty-free and irrevocable. Genentech may terminate the Collaboration Agreement if we fail to achieve certain milestone targets or at any time for convenience with or without reason upon 60 days' prior written notice. In the event of any such termination, all rights to the development and commercialization of Genentech Collaboration Products developed under the collaboration would revert to us and Genentech would grant us licenses under its intellectual property to further develop and commercialize Genentech Collaboration Products. We would be required to pay certain royalties to Genentech for such license(s). In addition, either party may terminate the agreement upon the other party's uncured material breach or insolvency.

Manufacturing Development and Supply Agreement

Concurrent with the Genentech Collaboration Agreement, we and BioNTech RNA entered into a Manufacturing Development and Supply Agreement with Genentech and F. Hoffman-La Roche Ltd, or the Genentech Manufacturing Agreement, which governs the manufacturing, related manufacturing development activities and supply of Genentech Collaboration Products. Pursuant to the Genentech Manufacturing Agreement, we are responsible for clinical manufacturing and supply, for developing and implementing manufacturing processes (including pursuant to specified target turnaround times), and for constructing, commissioning, qualifying and obtaining permits for the clinical facilities. We are permitted to subcontract certain steps in the clinical manufacturing process to our affiliate, BioNTech IMFS.

In addition, we are responsible for developing the commercial manufacturing process, which requires more stringent turnaround times than the clinical manufacturing process. Genentech will generally be responsible for commercial manufacturing. We are obligated to use commercially reasonable efforts to achieve certain predetermined clinical manufacturing capacity commitments.

Under the Genentech Manufacturing Agreement, we and Genentech will jointly develop a manufacturing network plan detailing the location, capacity, scale-out, associated timing and other appropriate details of the commercial manufacturing facilities. We may participate in commercial manufacturing through our right to include as part of the commercial manufacturing network one of our own facilities in the European Union or the United States and one of our own facilities in another region to be agreed upon with Genentech (provided that in each region our facility is not the first facility to be included in the commercial manufacturing network).

Sanofi—Intratumoral Therapy Collaboration

On November 2, 2015, BioNTech RNA entered into a Collaboration and License Agreement with Sanofi, which we refer to as the Sanofi Agreement. Pursuant to the Sanofi Agreement, we and Sanofi will collaborate on intratumorally administered mRNA-based therapeutics for the treatment of solid tumors in humans.

The Sanofi Agreement contemplates: (i) research, (ii) development and commercialization and (iii) possible co-development and co-commercialization activities with us.

During the research phase, the parties seek to identify, characterize and validate up to five "mixtures" of two or more mRNAs encoding different proteins administered together in the same solution. Sanofi at its sole discretion may select up to five mixtures created under the research plan for further development and commercialization, which we refer to as Sanofi Collaboration Products.

After selection of a Sanofi Collaboration Product, Sanofi would be responsible for all development and commercialization activities involving that product. We have the option, by payment of an exercise fee, to co-develop and co-commercialize up to two Sanofi Collaboration Products primarily in the United States and in some European countries, including the United Kingdom, France, Germany, Italy and Spain. If we exercise such an option, the costs for co-development and co-commercialization of the chosen Sanofi Collaboration Products would be allocated between the

parties. In turn, Sanofi has an option to co-develop and co-commercialize certain mixtures developed by us or with third parties that contain a certain amount of the mRNAs of a Sanofi Collaboration Product.

In March 2018, Sanofi selected the first Sanofi Collaboration Product for further development and commercialization and we exercised our option for co-development and co-commercialization of the Sanofi Collaboration Product. Effective as of March 2018, the parties entered into a separate development agreement for the co-development of this Sanofi Collaboration Product.

Under the Sanofi Agreement, Sanofi has paid upfront and near-term milestone payments of approximately €60 million. We are entitled to receive up to approximately €260 million per product upon achievement of certain development, regulatory and commercial milestones. If commercialized successfully, we would also be eligible for mid-single digit to very low double-digit tiered royalties on net sales on a country-by-country and product-by-product basis until the later of (i) expiration of the last relevant patent covering such product in such country, (ii) 10 years following first commercial sale of such product in such country, (iii) expiration of regulatory data exclusivity for such product in such country and (iv) the market entry of a generic biological product with a certain market share in relation to such product in such country.

The Sanofi Agreement will remain effective until the last-to-expire royalty term (or, when a co-development option has been exercised, the completion of all co-development and co-commercialization activities). The parties may terminate the Sanofi Agreement in its entirety or terminate certain co-development activities for convenience, with or without cause.

The Sanofi Agreement provides that we may not engage in certain research and development activities relating to the intratumoral injection of mRNAs.

Genmab—Next-generation Immunomodulator Collaboration

On May 19, 2015, we entered into a License and Collaboration Agreement with Genmab (together with all amendments and side letters thereto, collectively referred to as the Genmab Agreement) to jointly research, develop and commercialize polypeptide-based bispecific antibodies against certain target combinations for the treatment of cancer in humans worldwide, or the Genmab Agreement Field, using certain Genmab technology. In connection with our entry into the Genmab Agreement, Genmab paid us an upfront fee of $10 million.

Under the Genmab Agreement, we and Genmab must use commercially reasonable efforts to research and develop clinical candidates, including our next-generation checkpoint immunomodulators, with costs split equally during the research and evaluation phase. Our joint activities in this phase are governed by a research plan, which is subject to annual review and updates, and which specifies the clinical candidates to be developed. This research and evaluation phase is currently set to expire on May 31, 2021, but has in the past been extended.

During the research and evaluation phase, we and Genmab may propose clinical candidates for consideration by a joint research committee for further preclinical and clinical development. If a party, through the joint research committee, indicates that it is not interested in further development and commercialization of any clinical candidate, the other party may continue development and commercialization of such products on a unilateral basis, at its sole expense. The party that continues such development and commercialization is obligated to pay the other party certain development, regulatory and sales milestone payments and royalties on net sales of the applicable Unilateral Products. During either party's development and commercialization of a Unilateral Product, the other party must not develop or commercialize any bispecific antibody targeting the same target combination of such Genmab Unilateral Product if such bispecific antibody was generated as part of the collaboration under this agreement.

We and Genmab must use commercially reasonable efforts to develop candidates selected by the joint research committee, or the Genmab Collaboration Products, through preclinical and clinical development. In addition, the joint research committee may select an additional candidate, or the Genmab Back-up Candidate, as a back-up for each Genmab Collaboration Product and may decide at any time to replace the Genmab Collaboration Product with its Genmab Back-up Candidate. The preclinical and clinical development of the Genmab Collaboration Products would be performed pursuant to a development plan to be agreed upon by us and Genmab, with costs to be split equally. The joint steering committee may designate a third party as a manufacturer of a Genmab Collaboration Product or of any of its components.

We and Genmab must use commercially reasonable efforts to jointly commercialize all Genmab Collaboration Products and share equally all expenses and profits arising from such commercialization. We and Genmab, on a product-

by-product basis and at least 12 months prior to the anticipated start of a pivotal clinical trial for a Genmab Collaboration Product, will jointly designate between the two of us a lead party responsible for establishing the distribution and marketing operations in each geographical region. Each party would be entitled to equally co-promote the products pursuant to a separately negotiated global commercialization agreement that the parties agree to negotiate.

Unless otherwise agreed by the joint steering committee established under the agreement, Genmab is responsible for all regulatory actions and shall own all regulatory approvals obtained for the Genmab Collaboration Products. Genmab is obligated to provides regular updates to us on regulatory activities.

Each party grants to the other party a worldwide, co-exclusive, sublicensable, royalty-free license under certain of such first party's intellectual property, including certain patents and know-how, to perform the research under this agreement and to research, develop, make, import, use and sell Genmab Collaboration Products in the Genmab Agreement Field pursuant to the terms of the Genmab Agreement. These licenses shall continue on a country-by-country and product-by-product basis for as long as development or commercialization activities are contemplated under the Genmab Agreement.

During the research and evaluation phase prior to the selection of a Genmab Collaboration Product, neither we nor Genmab may engage in any research and development activity in the Genmab Agreement Field relating to the development of any bispecific antibody which targets any combination that is the subject of our joint research plan. During the preclinical and clinical development phase for any Genmab Collaboration Product, engagement in research and development activities in the Genmab Agreement Field unilaterally by a party relating to a Genmab Collaboration Product or its Genmab Back-up Candidate or any bispecific antibody which targets the same target combination for which such Genmab Collaboration Product or Genmab Back-up Candidate has been developed would require the other party's prior written consent.

Each party has the right to discontinue its participation in the further development and commercialization of a Genmab Collaboration Product at two points: (i) when an IND submission package has been agreed upon by the parties and (ii) when the draft clinical trial report from the first Phase 1/2 clinical trial becomes available. The party that wishes to opt out of such further development and commercialization may choose to permit the other party to continue the development and commercialization of the Genmab Collaboration Product or divest its interest in such Genmab Collaboration Product. If the opt-out party permits continued development and commercialization, the other party may elect to pursue development and commercialization of such Genmab Collaboration Product alone as a Unilateral Product, at its sole cost and subject to pre-defined milestone and royalty payments and certain additional pre-defined terms. If the other party wishes to not pursue such continued development and commercialization on such pre-defined payment and additional terms, then the parties will jointly divest their interest in such Genmab Collaboration Product to a third party, and if such divestiture fails, the parties will cease all development and commercialization of such Genmab Collaboration Product. Alternatively, if the opt-out party seeks to unilaterally divest its interest in the applicable Genmab Collaboration Product, the other party has the right of first exclusive negotiation to obtain exclusive, worldwide rights to develop and commercialize such Genmab Collaboration Product. If such unilateral divestiture fails after the other party's exercise of its right of first exclusive negotiation, the opt-out party may either continue development and commercialization of such Genmab Collaboration Product or offer the other party to continue such development and commercialization on such pre-defined payment and additional terms as set forth above.

The Genmab Agreement will remain in effect until the later of (i) the expiration of the last-to-expire royalty term for any Unilateral Product and (ii) the time when no Genmab Collaboration Products are being developed or commercialized under this agreement. Either party may terminate the agreement in its entirety or on a product-by-product basis with immediate effect upon the other party's uncured material breach or insolvency.

Eli Lilly TCR Therapy Collaboration

In May 2015, BioNTech C&GT entered into a drug discovery research, development and commercialization agreement with Eli Lilly regarding TCR-based therapeutics for the treatment of cancer. We refer to this agreement as the Lilly Agreement.

Under the Lilly Agreement, BioNTech C&GT is obligated to use commercially reasonable efforts to perform specified research and development activities relating to potential TCR targets. Additionally, BioNTech C&GT is obligated to work exclusively with Eli Lilly in the field of non-small cell lung cancer outside of certain permitted personalized TCR and RNA therapy activities. In consideration of these activities, Eli Lilly is obligated to pay to BioNTech C&GT an annual

research and development fee. Additionally, Eli Lilly made an upfront payment of $30 million to BioNTech C&GT in connection with entry into the Lilly Agreement and an additional $30 million equity investment in BioNTech C&GT. In March 2019, we agreed to exchange Eli Lilly's shares in BioNTech C&GT for our (BioNTech SE's) shares. Eli Lilly is obligated to pay up to an aggregate of approximately $300 million to BioNTech C&GT upon the occurrence of certain development, regulatory and commercial milestones. Finally, upon commercialization of a product, Eli Lilly would be obligated to pay tiered royalties on net sales of the product ranging from the low single-digit to very low double-digit percentages. BioNTech C&GT would be obligated to pay to Eli Lilly tiered royalties in the mid-single-digit percentages on net sales of certain products targeted at any new MHC peptide complexes, as well as up to an aggregate of $70 million upon the occurrence of commercial milestones.

BioNTech C&GT agreed to grant to Eli Lilly a worldwide, exclusive license to certain of its intellectual property necessary to exploit any selected targets and worldwide, non-exclusive licenses to BioNTech C&GT's background intellectual property and interest in collaboration intellectual property to exploit any selected targets, non-platform products, and small molecule and antibody products. Furthermore, BioNTech C&GT granted to Eli Lilly a worldwide, non-exclusive, sublicensable, royalty-free license to its background intellectual property and interest in collaboration intellectual property to exploit companion diagnostics for platform products and diagnostics generally.

In turn, Eli Lilly granted to BioNTech C&GT a worldwide exclusive, sublicensable license under its interest in collaboration intellectual property to exploit personalized RNA therapies and TCR therapies and a worldwide, non-exclusive, sublicensable license under its interest in collaboration intellectual property to exploit diagnostics and companion diagnostics.

Eli Lilly has the sole right to select targets investigated during the research term for development and commercialization. Upon selection of a target Eli Lilly is obligated to use commercially reasonable efforts to develop and commercialize at least one product in the United States and in one other country from a specified list of major countries. On September 5, 2019, Eli Lilly selected its first target under the Agreement, resulting in a $2 million milestone payment to us.

The Lilly Agreement may be terminated in its entirety or in part by either party upon an uncured material breach or insolvency of the other party. Eli Lilly may terminate the Lilly Agreement with or without reason by giving 30 days' advance written notice to BioNTech C&GT.

Pfizer—Influenza Collaboration

On July 20, 2018, we and BioNTech RNA entered into a Research Collaboration and License Agreement with Pfizer, or the Pfizer Agreement, for the research, development and Pfizer's commercialization of immunogenic compositions comprising modified RNA and/or replicon technology for prophylaxis against influenza in humans, which we refer to as the Pfizer Agreement Field.

We and Pfizer agreed to collaborate on the research in the Pfizer Agreement Field for an initial period of three years. The details of such research were set forth in a research plan that is governed by a joint steering committee, with Pfizer holding the final decision-making right. Each party will bear its own costs under the research plan. The research term will be extended automatically by a reasonable amount of time if the activities or deliverables under the research plan are delayed due to our material breach of our research obligations under the research plan. In addition, Pfizer may unilaterally extend the research term by up to a year by making an additional payment to us.

After the research term expires, Pfizer has the sole responsibility, authority and control of the development, manufacturing and commercialization of all candidates and products. Pfizer undertakes to use commercially reasonable efforts to seek regulatory approval for one product in the United States and in two countries out of France, Germany, Italy, Spain, the United Kingdom and Japan, and to commercialize such product in such countries where such product has received regulatory approval.

Under the Pfizer Agreement, we grant to Pfizer an exclusive, worldwide, sublicensable license under certain of our intellectual property, including our patents and know-how, relating to replicons and modified RNA in the Pfizer Agreement Field as well as certain intellectual property in-licensed by us from third parties, to use, research, develop, manufacture, commercialize and otherwise exploit candidates and products selected under the Pfizer Agreement. We also grant to Pfizer a non-exclusive, royalty-free, sublicensable license under all intellectual property controlled by us or our affiliates to use, develop, manufacture, commercialize and otherwise exploit candidates and products selected under the Pfizer Agreement in the Pfizer Agreement Field. We undertake to maintain in full effect all intellectual property licenses held by us at the time

we entered into the agreement and to not modify or amend any such license in a manner that would adversely affect any of the rights granted to Pfizer under the Pfizer Agreement. We are obligated to notify Pfizer of any breach of our current licenses and may be obligated to take steps to maintain Pfizer's access to any intellectual property licensed under such licenses.

We also granted Pfizer a right of first negotiation to acquire an exclusive worldwide license under certain intellectual property controlled by us for Pfizer to develop, manufacture and commercialize immunogenic products comprising RNA for prophylaxis against respiratory syncytial virus or human cytomegalovirus. The right of first negotiation may be exercised until the end of the research term.

In consideration of the rights granted to Pfizer under the agreement, Pfizer subscribed to shares in BioNTech AG under a separate investment agreement. In addition, under the Pfizer Agreement, Pfizer made an upfront payment of $50 million and agreed to potential payments of up to $325 million upon the achievement of specified development, regulatory and commercial milestones. Pfizer further agreed to a mid-single digit to very low double-digit tiered royalty on net sales if a product is commercialized. Royalties are subject to stacking provisions. The obligation of Pfizer to pay royalties ends, on a country-by-country and a product-by-product, basis upon the later of (i) the expiration of the last valid licensed patent right covering such product category in such country, (ii) 10 years after the first commercial sale of a product of such product category in such country and (iii) the lapse of regulatory data exclusivity for the first product in such product category in such country. There are only two product categories: one for modified RNA and a second for replicon products.

During the term of the Pfizer Agreement, we have committed not to research, develop, manufacture, commercialize or otherwise exploit immunogenic compositions compromising RNA in the Pfizer Agreement Field other than pursuant to the Pfizer Agreement.

The Pfizer Agreement ends on a country-by-country basis upon expiration of the last royalty term for any product in that country. Thereafter, the licenses granted to Pfizer with respect to such product in such country will convert into a perpetual, exclusive, fully paid-up and royalty-free license. In addition to termination rights granted to each party in the case of the other party's uncured material breach, Pfizer may terminate the agreement, in whole or in part, for convenience and with or without reason at any time upon 60 days' prior written notice. In addition, Pfizer is entitled to terminate the agreement and initiate a technology transfer of certain intellectual property if one of its key competitors acquires control over us.

Bill & Melinda Gates Foundation—HIV and Tuberculosis Collaboration

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

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

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

The primary objective of BMGF is to provide funding to accelerate the development of lifesaving, low-cost drugs to reduce the burden of diseases in developing countries. This objective is known as global access commitments, or GAC. The

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

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

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

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

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

The term of the letter agreement continues in perpetuity.

Genevant—Rare Disease Protein Replacement Therapy Strategic Collaboration

In July 2018, our wholly owned subsidiary BioNTech RNA Pharmaceuticals GmbH, or BioNTech RNA, entered into a license and co-development agreement with Genevant Sciences GmbH, or Genevant for the joint development of certain pharmaceutical products and the licensing of specified rights to Genevant's lipid nanoparticle delivery technology to BioNTech RNA. We refer to this agreement as the Genevant Agreement.

Under the Genevant Agreement, BioNTech RNA and Genevant have agreed to collaborate to develop pharmaceutical products that contain any of five mRNA payloads created by BioNTech RNA encapsulated within a Genevant (or, if the parties agree, a third party) LNP, or the Co-Development Products, for the treatment, prevention and diagnosis of liver diseases, excluding any oncology diseases, or the Co-Development Field. Each party granted to the other party a worldwide, co-exclusive license or sublicense, with limited sublicensing rights, under certain of its patents and know-how to research, develop, make, have made, use, distribute, sell, offer for sale, have sold, import, export and otherwise commercialize the Co-Development Products in the Co-Development Field as provided in development and commercialization plans approved by a joint steering committee and subject to certain restrictions under the Genevant Agreement.

In addition, BioNTech RNA obtained an exclusive, worldwide, royalty-bearing license or sublicense under Genevant's LNP delivery technology to research, develop, make, have made, use, distribute, sell, offer for sale, have sold, import, export and otherwise commercialize pharmaceutical products containing BioNTech mRNA payloads encapsulated within an LNP, or the BioNTech Products, for the treatment, prevention and diagnosis of illnesses in the field of oncology, or the BioNTech Field.

Each party retained certain rights to practice its intellectual property for all purposes outside of the Co-Development Field or in the Co-Development Field with any product that is not a Co-Development Product, subject to the next sentence as to BioNTech. During the term of the Genevant Agreement for each Co-Development Product or BioNTech Product, BioNTech RNA has agreed not to conduct or enable any clinical development, promotion or commercialization of any product involving the use of LNP with the BioNTech mRNA payload contained in the Co-Development Product or BioNTech Product other than in collaboration with Genevant pursuant to the Genevant Agreement. Genevant has also retained rights to practice its intellectual property for all purposes outside the BioNTech Field, or in the BioNTech Field with any product that is not a BioNTech Product.

The parties are jointly responsible for the development of, and must use commercially reasonable efforts to develop, the Co-Development Products in accordance with a development plan approved by a joint steering committee. Genevant is responsible for the preclinical, clinical and commercial manufacture of the Co-Development Products, and BioNTech RNA is obligated to supply the mRNA payloads for use in manufactured Co-Development Products. The parties share equally all costs for the development of Co-Development Products as well as any profits and losses. For each Co-Development Product, one or the other party will take the lead responsibility for commercialization of the Co-Development Product in the Co-Development Field. Each party must use commercially reasonable efforts to perform the commercialization activities allocated to it in a commercialization plan approved by a joint steering committee.

Each party may opt-out of the co-development of any Co-Development Product with 90 days' prior notice at any time after the filing of an IND or equivalent for the Co-Development Product. In such event, the other party may continue the development of the Co-Development Product on its own, at its sole cost and expense apart from specified obligations to support manufacturing and any ongoing clinical studies, but has to pay to the party that opted out pre-defined regulatory and sales milestones for the Co-Development Product of up to a low nine figure U.S. dollar amount in the aggregate and tiered low to mid-single digit percentage royalties on aggregate net sales of the Co-Development Product. In the event that a party opts out of the co-development of any Co-Development Product, the license granted by the party opting out to the other party shall become exclusive licenses, even as to the opting out party.

BioNTech RNA is solely responsible for the development and commercialization of the BioNTech Products, including the performance of preclinical and clinical trials, all regulatory activities, and marketing and sales, and bears all related costs. BioNTech RNA must use commercially reasonable efforts to develop and obtain regulatory approval for BioNTech Products in the BioNTech Field in the United States, Germany, United Kingdom, France, Spain and Italy. Genevant is responsible for the manufacturing of the BioNTech Products, and the details of such manufacturing are to be agreed in a separate manufacturing and supply agreement. BioNTech RNA is obligated to pay regulatory and sales milestone payments on each BioNTech Product, and royalties based on aggregate net sales of all BioNTech Products, to Genevant.

The Genevant Agreement continues until later of (i) the expiration of the last-to-expire royalty term for any BioNTech Product worldwide and (ii) the date on which all Co-Development Products cease being developed or commercialized. BioNTech RNA may terminate the agreement for convenience with respect to one or more BioNTech Products at any time with 90 or 180 days' prior notice, depending on whether regulatory approval has been granted. The Genevant Agreement grants each party termination rights: if the other party challenges the validity, enforceability or scope of any patents licensed to it under the Genevant Agreement; for uncured material breaches of the other party; for the other party's insolvency; or if the other party undergoes a change of control through which it is controlled by a competitor, if specified by the parties at the time of the Genevant Agreement, before the earlier of July 4, 2021 or when the other party undergoes an initial public offering.

Under certain scenarios, if BioNTech RNA terminates the Genevant Agreement with respect to a particular BioNTech Product, before granting a license to a third party for the BioNTech mRNA payload included in the BioNTech Product, Genevant has the right of negotiation with BioNTech. Under certain scenarios, if Genevant terminates the Genevant Agreement, Genevant keeps all licenses and have certain rights, but not the obligation, to continue the development and commercialization of Co-Development Products, and BioNTech RNA has certain obligations to provide assistance, documentation, and certain know-how and inventions to enable Genevant's continued development and commercialization of Co-Development Products.

XV. Government Regulation

Government authorities in the United States, at the federal, state and local levels, and in the European Union and other countries and jurisdictions, extensively regulate, among other things, the research, development, testing, manufacture,

quality control, approval, packaging, storage, record-keeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting and import and export of pharmaceutical products, including biological products. In addition, some jurisdictions regulate the pricing of pharmaceutical products. The processes for obtaining marketing approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other requirements of regulatory authorities, require the expenditure of substantial time and financial resources.

Regulation and Procedures Governing Approval of Drug and Biological Products in the United States

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and its implementing regulations and biologics under the FDCA, the Public Health Service Act, or the PHSA, and their implementing regulations. Both drugs and biologics also are subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state and local statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or following approval may subject a sponsor to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, license revocation, clinical hold, untitled or warning letters, voluntary or mandatory product recalls, market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

A sponsor seeking approval to market and distribute a new drug or biological product in the United States generally must satisfactorily complete each of the following steps:

- preclinical laboratory tests, animal studies and formulation studies all performed in accordance with applicable regulations, including the FDA's good laboratory practices, or GLP, regulations;
- submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials may begin;
- approval by the IRB representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials to establish the safety, potency and purity of the product candidate for each proposed indication, in accordance applicable regulations, including with GCP, regulations;
- preparation and submission to the FDA of a NDA for a drug product, or a BLA for a biological product requesting marketing approval for one or more proposed indications, including submission of detailed information on the manufacture and composition of the product in clinical development, evidence of safety, purity and potency from preclinical testing and clinical trials, and proposed labeling;
- review of the product by an FDA advisory committee, if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities, including those of third parties, at which the product, or components thereof, are produced to assess compliance with current GMP requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- satisfactory completion of any FDA audits of the clinical study sites to assure compliance with GCPs, and the integrity of clinical data in support of the NDA or BLA;
- payment of user fees and securing FDA approval of the NDA or BLA; and
- compliance with any post-approval requirements, including the potential requirement to implement a REMS and to conduct any post-approval studies required by the FDA.

The preclinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our investigational medicines and any future investigational medicines will be granted on a timely basis, or at all.

Preclinical Studies and Investigational New Drug Application

Before testing any drug or biological product candidate in humans, the product candidate must undergo preclinical testing. Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as animal studies to evaluate the potential for activity and toxicity. The conduct of the preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, are submitted to the FDA as part of an IND application. The IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about the product or conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks, and places the trial on a clinical hold. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns before the clinical trial can begin.

As a result, submission of the IND may result in the FDA not allowing the trial to commence or not be conducted on the terms originally specified by the sponsor in the IND. If the FDA raises concerns or questions either during this initial 30-day period, or at any time during the IND process, it may choose to impose a partial or complete clinical hold. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA. A clinical hold issued by the FDA may therefore delay either a proposed clinical study or cause suspension of an ongoing study, until all outstanding concerns have been adequately addressed and the FDA has notified the company that investigation may proceed. This could cause significant difficulties in completing planned clinical trials in a timely manner.

The FDA may impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance.

Human Clinical Trials in Support of an NDA or a BLA

Clinical trials involve the administration of the investigational product candidate to healthy volunteers or patients with the disease to be treated under the supervision of qualified principal investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent for their participation. Clinical trials are conducted under study protocols detailing, among other things, the objectives of the study, inclusion and exclusion criteria, the parameters to be used in monitoring safety, dosing procedures and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND.

A sponsor who wishes to conduct a clinical trial outside the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of the NDA or BLA so long as the clinical trial is well-designed and well-conducted in accordance with GCP, including review and approval by an independent ethics committee, and the FDA is able to validate the study data through an onsite inspection, if necessary.

Further, each clinical trial must be reviewed and approved by an IRB either centrally or individually at each institution at which the clinical trial will be conducted. The IRB will consider, among other things, clinical trial design, patient informed consent, ethical factors and the safety of human subjects. An IRB must operate in compliance with FDA regulations. The FDA, IRB, or the clinical trial sponsor may suspend or discontinue a clinical trial at any time for various reasons, including a finding that the clinical trial is not being conducted in accordance with FDA requirements or that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive GCP rules and the requirements for informed consent. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee, or DSMB. This group may recommend continuation of the study as planned, changes in study conduct, or cessation of the study at designated check points based on access to certain data from the study.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Additional studies may be required after approval.

- Phase 1 clinical trials (or Phase 1) are initially conducted in a limited population to test the product candidate for safety, including adverse effects, dose tolerance, absorption, metabolism, distribution, excretion and

pharmacodynamics in healthy humans or, on occasion, in patients, such as in the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers.

- Phase 2 clinical trials (or Phase 2) are generally conducted in a limited patient population to identify possible adverse effects and safety risks, preliminarily evaluate the efficacy of the product candidate for specific targeted indications and determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger Phase 3 clinical trials. When a drug is intended to treat life-threatening or severely debilitating illnesses, the FDA may accept well-controlled Phase 2 clinical trials as adequate to provide sufficient data on the drug's safety and effectiveness to support a decision on its approvability for marketing, in which case Phase 3 clinical trials would not be required.
- Phase 3 clinical trials (or Phase 3) proceed if the Phase 2 clinical trials demonstrate that a certain dose or dose range of the product candidate is potentially effective and has an acceptable safety profile. Phase 3 clinical trials are undertaken within an expanded patient population, often at geographically dispersed clinical trial sites, to gather additional information about safety and effectiveness necessary to evaluate the overall benefit-risk relationship of the product and to provide an adequate basis for product labeling.

In some cases, the FDA may approve an NDA or a BLA for a product candidate but require the sponsor to conduct additional clinical trials to further assess the product candidate's safety and effectiveness after approval. Such post-approval trials are typically referred to as Phase 4 clinical trials (or Phase 4). These studies may be used to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of biologics approved under accelerated approval regulations. If the FDA approves a product while a company has ongoing clinical trials that were not necessary for approval, a company may be able to use the data from these clinical trials to meet all or part of any Phase 4 clinical trial requirement or to request a change in the product labeling. Failure to exhibit due diligence with regard to conducting required Phase 4 clinical trials could result in withdrawal of approval for products.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events, any findings from other trials, tests in laboratory animals or *in vitro* testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. The FDA or the sponsor or its DSMB may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the new drug candidate or biological product candidate has been associated with unexpected serious harm to patients.

There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Sponsors of clinical trials of FDA-regulated products, including biologics, are required to register and disclose certain clinical trial information, which is publicly available at www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved.

Compliance with GMP Requirements

Before approving an NDA or a BLA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in full compliance with GMP requirements and adequate to assure consistent production of the product within required specifications. Among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final drug or biological product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug or biological product does not undergo unacceptable

deterioration over its shelf life. In particular, the PHSA emphasizes the importance of manufacturing control for products like biologics whose attributes cannot be precisely defined.

Manufacturers and others involved in the manufacture and distribution of drugs and biological products must also register their establishments with the FDA and certain state agencies. Both domestic and foreign manufacturing establishments must register and provide additional information to the FDA upon their initial participation in the manufacturing process.

The manufacturing facilities may be subject to periodic unannounced inspections by government authorities to ensure compliance with GMPs and other laws. Manufacturers may have to provide, on request, electronic or physical records regarding their establishments. Delaying, denying, limiting or refusing inspection by the FDA may lead to a product being deemed to be adulterated.

Review and Approval of an NDA or a BLA

The results of product candidate development, preclinical testing and clinical trials, including negative or ambiguous results as well as positive findings, are submitted to the FDA as part of an NDA or a BLA requesting a license to market the product. These applications must contain extensive manufacturing information and detailed information on the composition of the product and proposed labeling. The FDA adjusts the Prescription Drug User Fee Act, or PDUFA, user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs or BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA has 60 days after submission of the application to conduct an initial review to determine whether the NDA or BLA is sufficient to accept for filing based on the agency's threshold determination that it is substantially complete so as to permit substantive review. Once the submission has been accepted for filing, the FDA begins an in-depth review of the application. Under the goals and policies agreed to by the FDA under PDUFA, the FDA aims to complete its initial review of a standard application and respond to the sponsor within ten months of the 60-day filing date, and for a priority review application within six months. The FDA does not always meet its PDUFA goal dates for standard and priority NDA or BLA applications, and its review goals are subject to change from time to time. The review process may often be significantly extended by FDA requests for additional information or clarification. The review process and the PDUFA goal date may also be extended by three months if the FDA requests or if the sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

The FDA reviews NDA and BLA applications to determine, among other things, whether the proposed product is safe and potent, or effective, for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with GMP requirements to assure and preserve the product's identity, safety, strength, quality, potency and purity. On the basis of the FDA's evaluation of the application and accompanying information, including the results of the inspection of the manufacturing facilities and any FDA audits of clinical trial sites to assure compliance with GCPs, the FDA may issue an approval letter, denial letter or complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. Under the FDCA, the FDA may approve an NDA if it determines that the product is safe and effective for its intended use, the benefits of the drug outweigh any risks, and the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality and purity. Under the PHSA, the FDA may approve a BLA if it determines that the product is safe, pure and potent and the facility where the product will be manufactured meets standards designed to ensure that it continues to be safe, pure and potent. If the application is not approved, the FDA may issue a complete response letter, which will contain the conditions that must be met in order to secure final approval of the application, and when possible will outline recommended actions the sponsor might take to obtain approval of the application. If a complete response letter is issued, the sponsor may either resubmit the NDA or BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

Sponsors that receive a complete response letter who elect to address the deficiencies may submit to the FDA information that represents a complete response to the issues identified by the FDA in the response letter. Such resubmissions are classified under PDUFA as either Class 1 or Class 2, based on the information submitted by a sponsor in response to an action letter. Under the goals and policies agreed to by the FDA under PDUFA, the FDA aims to review and act on a Class 1 resubmission with two months of receipt and, with respect to a Class 2 resubmission, within six months of

receipt. The FDA will not approve an application until issues identified in the complete response letter have been addressed.

The FDA may also refer the application to an Advisory Committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. In particular, the FDA may refer applications for novel drug or biological products or drug or biological products that present difficult questions of safety or efficacy to an advisory committee. Typically, an Advisory Committee is a panel of independent experts, including clinicians and other scientific experts. The FDA is not bound by the recommendations of an Advisory Committee, but it considers such recommendations carefully when making decisions.

If the FDA approves a new product, it may limit the approved indications for use of the product, or limit the approval to specific dosages. It may also require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may call for post-approval studies, including Phase 4 clinical trials, to further assess the product's safety after approval. The agency may also require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including risk evaluation and mitigation strategies, or REMS, to help ensure that the benefits of the product outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patent registries. If the FDA concludes a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS; the FDA will not approve the NDA or BLA without a REMS, if required. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Fast Track, Breakthrough Therapy and Priority Review Designations

The FDA may designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs include fast track designation, breakthrough therapy designation and priority review designation.

The FDA may designate a product for fast track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug or biologic may request that the FDA designate the drug or biologic as a fast track product at any time during the clinical development of the product. For fast track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a fast track application does not begin until the last section of the application is submitted. Fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

In 2012, Congress enacted the Food and Drug Administration Safety and Innovation Act, or the FDASIA. This law established a new regulatory scheme allowing for expedited review of products designated as "breakthrough therapies." A product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to facilitate the design of clinical trials in an efficient manner.

The FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case-by-case basis, whether the proposed product represents a significant improvement when compared with other available therapies. Significant

improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application to six months (compared to 10 months under standard review).

Fast track designation, priority review and breakthrough therapy designation may expedite the development or approval process, but do not change the standards for approval.

Accelerated Approval Pathway

The FDA may grant accelerated approval to a product for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. Products granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a product, such as an effect on IMM. The FDA has stated that although it has limited experience with accelerated approvals based on intermediate clinical endpoints, such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a product.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a product. Thus, accelerated approval has been used extensively in the development and approval of products for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or to confirm a clinical benefit during post-marketing studies, may lead the FDA to withdraw the product from the market. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

Accelerated approval pathways are available for regenerative medicine therapies that meet certain conditions. Regenerative medicine therapies include cell therapies (both allogenic and autologous), therapeutic tissue engineering products, human cell and tissue products, and combination products using any such therapies or products, except those regulated under section 361 of the PHSA. Human gene therapies, including genetically modified cells, that lead to a sustained effect on cells or tissues, may also meet the definition of a regenerative medicine therapy, as may xenogeneic cell products.

Regenerative medicine therapies designed to treat, modify, reverse or cure serious conditions are eligible for FDA's expedited programs, including fast track designation, breakthrough therapy designation, priority review and accelerated approval, if they meet the criteria for such programs. They may also be eligible for Regenerative Medicine Advanced Therapy Designation, or RMAT designation.

An investigational drug is eligible for RMAT designation if it meets the definition of regenerative medicine therapy, it is intended to treat, modify, reverse or cure a serious condition, and preliminary clinical evidence indicates that the

regenerative medicine therapy has the potential to address unmet medical needs for such condition. An unmet medical need is a condition whose treatment or diagnosis is not addressed adequately by available therapy.

RMAT designation confers all the benefits of the fast track and breakthrough therapy designation programs, including early actions with the FDA. The FDA reviews each application on a case-by-case basis to determine whether the clinical evidence is sufficient to support RMAT designation, considering factors such as the rigor of data collection, the consistency and persuasiveness of the outcomes, the number of patients or subjects, and the severity, rarity or prevalence of the condition, among other factors. The FDA may decline to grant RMAT designation if it finds the clinical evidence insufficient.

RMAT designation may expedite the development or approval process, but it does not change the standards for approval.

Post-Approval Regulation

If regulatory approval for marketing of a product or for a new indication for an existing product is obtained, the sponsor will be required to comply with rigorous and extensive post-approval regulatory requirements as well as any post-approval requirements that the FDA has imposed on the particular product as part of the approval process. The sponsor will be required, among other things, to report certain adverse reactions and production problems to the FDA, provide updated safety and efficacy information and comply with requirements concerning advertising and promotional labeling. Manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including GMP regulations, which impose certain procedural and documentation requirements upon manufacturers. Accordingly, the BLA holder and its third-party manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with GMP regulations and other regulatory requirements. In addition, changes to the manufacturing process or facility generally require prior FDA approval before being implemented, and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market study requirements or clinical trial requirements to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, untitled letters or warning letters or holds on post-approval clinical trials;
- adverse publicity;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions, fines, debarment, disgorgement of profits or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Pharmaceutical products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

Orphan Drug Designation

Orphan drug designation in the United States is designed to encourage sponsors to develop products intended for rare diseases or conditions. In the United States, a rare disease or condition is statutorily defined as a disease or condition that

affects fewer than 200,000 individuals in the United States or that affects more than 200,000 individuals in the United States but for which there is no reasonable expectation that the cost of developing and making available the product for the disease or condition will be recovered from sales of the product in the United States.

Orphan drug designation qualifies a company for certain financial incentives, including tax advantages and, if the product receives the first FDA approval for the indication for which it has orphan designation, market exclusivity for seven years following the date of the product's marketing approval. An application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. Once a product receives orphan drug designation from the Office of Orphan Products Development at the FDA, the product must then go through the review and approval process like any other product.

In addition, a sponsor of a product that is otherwise the same product as an already approved orphan drug may seek and obtain orphan drug designation for the subsequent product for the same rare disease or condition if it can present a plausible hypothesis that its product may be clinically superior to the first product. More than one sponsor may receive orphan drug designation for the same product for the same rare disease or condition, but each sponsor seeking orphan drug designation must file a complete request for designation.

The period of exclusivity begins on the date that the marketing application is approved by the FDA and applies only to the indication for which the product has been designated. The FDA may approve a second application for the same product for a different use or a second application for a clinically superior version of the product for the same use. The FDA cannot, however, approve the same product made by another manufacturer for the same indication during the market exclusivity period unless it has the consent of the sponsor, the manufacturer makes a showing of clinical superiority over the product with orphan exclusivity, or the sponsor is unable to provide sufficient quantities.

Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

Pediatric Studies and Exclusivity

Under the Pediatric Research Equity Act of 2003, an NDA or a BLA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. Sponsors who are planning to submit a marketing application for a drug or biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must also submit pediatric study plans prior to the assessment data, and no later than 60 calendar days following an end-of-Phase 2 meeting with the FDA or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 study. Pediatric study plans must contain an outline of the proposed pediatric study or studies the sponsor plans to conduct, including study objectives and design, any deferral or waiver requests and other information required by regulation. The sponsor, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other and agree upon a final plan. The FDA or the sponsor may request an amendment to the plan at any time.

The FDA may, on its own initiative or at the request of the sponsor, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Additional requirements and procedures relating to deferral requests and requests for extension of deferrals are contained in FDASIA. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation.

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent and orphan exclusivity. This six-month exclusivity may be granted if an NDA or a BLA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

Biosimilars and Reference Product Exclusivity

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or the BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. To date, a number of biosimilars have been licensed under the BPCIA, and numerous biosimilars have been approved in Europe.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, recent government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate implementation and impact of the BPCIA is subject to significant uncertainty.

Regulation of Combination Products in the United States

Certain products may be comprised of components that would normally be regulated under different types of regulatory authorities and frequently by different centers at the FDA. These products are known as combination products. Specifically, under regulations issued by the FDA, a combination product may be:

- A product comprised of two or more regulated components that are physically, chemically or otherwise combined or mixed and produced as a single entity;
- Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products;
- A drug, or device or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device or biological product where both are required to achieve the intended use, indication or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, *e.g.*, to reflect a change in intended use, dosage form, strength, route of administration or significant change in dose; or
- Any investigational drug, device or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device or biological product where both are required to achieve the intended use, indication or effect.

Under the FDCA, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. That determination is based on the "primary mode of action" of the combination product. Thus, if the primary mode of action of a device-biologic combination product is attributable to the biological product, the FDA center responsible for premarket review of the biological product would have primary jurisdiction for the combination

product. The FDA has also established an Office of Combination Products to address issues surrounding combination products and provide more certainty to the regulatory review process. That office serves as a focal point for combination product issues for agency reviewers and industry. It is also responsible for developing guidance and regulations to clarify the regulation of combination products, and for assignment of the FDA center that has primary jurisdiction for review of combination products where the jurisdiction is unclear or in dispute.

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, an applicant will need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can initiate clinical trials or market and sell the product in those countries or jurisdictions.

Regulation and Procedures Governing Approval of Medicinal Products in the European Union

The process governing approval of medicinal products, including biological medicinal products and advanced therapy medicinal products, or ATMPs, which comprise gene therapy products, somatic cell therapy products and tissue-engineered products, in the European Union generally follows the same lines as in the United States. It entails satisfactory completion of pharmaceutical development, nonclinical and clinical studies to establish the safety and efficacy of the medicinal product for each proposed indication. Moreover, an applicant must also demonstrate the ability to manufacture the product to a suitable quality.

Clinical Trial Approval

Pursuant to the currently applicable Clinical Trials Directive 2001/20/EC and the Directive 2005/28/EC on GCP, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the member states.

Clinical trials must be conducted in accordance with European Union and national regulations and the International Conference on Harmonization, or ICH, guidelines on GCP. Additional GCP guidelines from the European Commission, focusing in particular on traceability, apply to clinical trials of advanced therapy medicinal products. If the sponsor of the clinical trial is not established within the European Union, it must appoint an entity within the European Union to act as its legal representative.

Under this system, a sponsor must obtain approval from the competent national authority of a European Union member state in which the clinical trial is to be conducted or in multiple member states if the clinical trial is to be conducted in a number of member states. Furthermore, the sponsor may only start a clinical trial at a specific study site after the independent ethics committee has issued a favorable opinion. The clinical trial application must be accompanied by a copy of the trial protocol and an investigational medicinal product dossier with supporting information prescribed by Directive 2001/20/EC and Directive 2005/28/EC and corresponding national laws of the member states and further detailed in applicable guidance documents. Moreover, the sponsor must take out a clinical trial insurance policy, and in most European Union countries the sponsor is liable to provide ‘no fault’ compensation to any study subject injured in the clinical trial.

In April 2014, the European Union adopted a new Clinical Trials Regulation (EU) No 536/2014, which is set to replace the current Clinical Trials Directive 2001/20/EC. It is expected that the new Clinical Trials Regulation will apply at earliest in 2020. It will overhaul the current system of approvals for clinical trials in the European Union. Specifically, the new regulation, which will be directly applicable in all member states, aims to simplify and streamline the approval of clinical trials in the European Union. For instance, the new Clinical Trials Regulation provides for a streamlined application procedure using a single entry point and strictly defined deadlines for the assessment of clinical trial applications. This means that one national authority takes the lead in reviewing the application and the other national authorities have only a limited involvement. Any substantial changes to the trial protocol or other information submitted with the clinical trial applications must be notified to or approved by the relevant competent authorities and ethics committees.

The sponsor of a clinical trial must register the clinical trial in advance, and information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial will be made public as part of the registration. The results of the clinical trial must be submitted to the competent authorities and, with the exception of non-pediatric Phase 1 trials, will be made public at the latest within 12 months after the end of the trial.

During the development of a medicinal product, the European Medicines Agency, or EMA, and national medicines regulators within the European Union provide the opportunity for dialogue and guidance on the development program. At the EMA level, this is usually done in the form of scientific advice, which is given by the Scientific Advice Working Party of the Committee for Medicinal Products for Human Use, or CHMP. A fee is incurred with each scientific advice procedure. Advice from the EMA is typically provided based on questions concerning, for example, quality (chemistry, manufacturing and controls testing), nonclinical testing and clinical studies, and pharmacovigilance plans and risk-management programs. Advice is not legally binding with regard to any future marketing authorization application of the product concerned.

Marketing Authorization

To obtain a marketing authorization for a product under the European Union regulatory system, a sponsor must submit a marketing authorization application, or MAA, either under a centralized procedure administered by the EMA or one of the procedures administered by competent authorities in European Union member states (decentralized procedure, national procedure or mutual recognition procedure).

All application procedures require an application in the common technical document, or CTD, format, which includes the submission of detailed information about the manufacturing and quality of the product, and nonclinical and clinical trial information. There is an increasing trend in the European Union toward greater transparency and, while the manufacturing or quality information is currently generally protected as confidential information, the EMA and national regulatory authorities are now liable to disclose much of the nonclinical and clinical information in marketing authorization dossiers, including the full clinical study reports, in response to freedom of information requests after the marketing authorization has been granted. In October 2014, the EMA adopted a policy under which clinical study reports would be posted on the agency's website following the grant, denial or withdrawal of a MAA, subject to procedures for limited redactions and protection against unfair commercial use. A similar requirement is contained in the new Clinical Trials Regulation that is currently expected to take effect at earliest in 2020.

A marketing authorization may be granted only to a sponsor established in the European Union. Regulation (EC) No. 1901/2006 on medicinal products for pediatric use provides that prior to obtaining a marketing authorization in the European Union in the centralized procedure, a sponsor must demonstrate compliance with all measures included in an EMA-approved Pediatric Investigation Plan covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, class waiver or deferral for one or more of the measures included in the Pediatric Investigation Plan.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all European Union member states. Pursuant to Regulation (EC) No. 726/2004, the centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy medicinal products and products with a new active substance indicated for the treatment of certain diseases, including products for the treatment of cancer. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional.

Under the centralized procedure, the CHMP established at the EMA is responsible for conducting the assessment of a product to define its risk/benefit profile. Under the centralized procedure, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions from the CHMP. Accelerated evaluation may be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health determined by three cumulative criteria: (i) the seriousness of the disease (*e.g.*, heavy disabling or life-threatening diseases) to be treated, (ii) the absence or insufficiency of an appropriate alternative therapeutic approach, and (iii) anticipation of high therapeutic benefit.

If the CHMP accepts such a request, the time limit of 210 days will be reduced to 150 days, but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that it is no longer appropriate to conduct an accelerated assessment.

The Committee for Advanced Therapies, or CAT, is responsible in conjunction with the CHMP for the evaluation of ATMPs. The CAT is primarily responsible for the scientific evaluation of ATMPs and prepares a draft opinion on the quality, safety and efficacy of each ATMP for which a MAA is submitted. The CAT's opinion is then taken into account by the CHMP when giving its final recommendation regarding the authorization of a product in view of the balance of benefits

and risks identified. Although the CAT's draft opinion is submitted to the CHMP for final approval, the CHMP may depart from the draft opinion if it provides detailed scientific justification. The CHMP and CAT are also responsible for providing guidelines on ATMPs and have published numerous guidelines, including specific guidelines on gene therapies and cell therapies. These guidelines, which are not legally binding, provide additional guidance on the factors that the EMA will consider in relation to the development and evaluation of ATMPs and include, inter alia, the preclinical studies required to characterize ATMPs, the manufacturing and control information that should be submitted in a MAA; and post-approval measures required to monitor patients and evaluate the long term efficacy and potential adverse reactions of ATMPs.

The European Commission may grant a so-called "marketing authorization under exceptional circumstances." Such authorization is intended for products for which the applicant can demonstrate that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use, because the indications for which the product in question is intended are encountered so rarely that the applicant cannot reasonably be expected to provide comprehensive evidence, or in the present state of scientific knowledge, comprehensive information cannot be provided, or it would be contrary to generally accepted principles of medical ethics to collect such information. Consequently, marketing authorization under exceptional circumstances may be granted subject to certain specific obligations, which may include the following:

- the applicant must complete an identified program of studies within a time period specified by the competent authority, the results of which form the basis of a reassessment of the benefit/risk profile;
- the medicinal product in question may be supplied on medical prescription only and may in certain cases be administered only under strict medical supervision, possibly in a hospital, and in the case of a radio-pharmaceutical, by an authorized person; and
- the package leaflet and any medical information must draw the attention of the medical practitioner to the fact that the particulars available concerning the medicinal product in question are as yet inadequate in certain specified respects.

A marketing authorization under exceptional circumstances is subject to annual review to reassess the risk-benefit balance in an annual re-assessment procedure. Continuation of the authorization is linked to the annual reassessment and a negative assessment could potentially result in the marketing authorization being suspended or revoked. The renewal of the marketing authorization of a medicinal product under exceptional circumstances follows the same rules as a "normal" marketing authorization. After five years, the marketing authorization will then be renewed under exceptional circumstances for an unlimited period, unless the EMA decides, on justified grounds, to proceed with one additional five-year renewal.

The European Commission may also grant a so-called "conditional marketing authorization" prior to obtaining the comprehensive clinical data required for an application for a full marketing authorization. Such conditional marketing authorizations may be granted for product candidates (including medicines designated as orphan medicinal products) if the CHMP finds that all the following requirements are met:

- the benefit-risk balance of the product is positive;
- it is likely that the applicant will be able to provide comprehensive data;
- unmet medical needs will be fulfilled; and
- the benefit to public health of the medicinal product's immediate availability on the market outweighs the risks due to need for further data.

A conditional marketing authorization may contain specific obligations to be fulfilled by the marketing authorization holder, including obligations with respect to the completion of ongoing or new studies, and with respect to the collection of pharmacovigilance data. Conditional marketing authorizations are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions and/or specific obligations. The timelines for the centralized procedure described above also apply with respect to the review by the CHMP of applications for a conditional marketing authorization. Once comprehensive data on the medicinal product have been obtained, the marketing authorization may be converted into a standard marketing authorization which is no longer subject to specific obligations. Initially, this is valid for five years, but can be renewed for unlimited validity.

The European Union medicines rules expressly permit the member states to adopt national legislation prohibiting or restricting the sale, supply or use of any medicinal products containing, consisting of or derived from a specific type of human or animal cell, such as embryonic stem cells.

Periods of Authorization and Renewals

A marketing authorization is valid for five years, in principle, and it may be renewed after five years on the basis of a reevaluation of the risk benefit balance by the EMA or by the competent authority of the authorizing Member State. To that end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal period. Any authorization that is not followed by the placement of the product on the European Union market (in the case of the centralized procedure) or on the market of the authorizing Member State within three years after authorization ceases to be valid.

Regulatory Requirements after Marketing Authorization

Following approval, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of the medicinal product. These include compliance with the European Union's stringent pharmacovigilance or safety reporting rules, pursuant to which post-authorization studies and additional monitoring obligations can be imposed. The holder of a marketing authorization must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs. All new MAAs must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the marketing authorization. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies. RMPs and PSURs are routinely available to third parties requesting access, subject to limited redactions.

In addition, the manufacturing of authorized products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the EMA's GMP requirements and comparable requirements of other regulatory bodies in the European Union, which mandate the methods, facilities and controls used in the manufacturing, processing and packing of products to assure their safety and identity. Specifically, medicinal products may only be manufactured in the European Union, or imported into the European Union from another country, by the holder of a manufacturing/import authorization from the competent national authority. The manufacturer or importer must have a qualified person who is responsible for certifying that each batch of product has been manufactured in accordance with European Union standards of good manufacturing practice, or GMP, before releasing the product for commercial distribution in the European Union or for use in a clinical trial. Manufacturing facilities are subject to periodic inspections by the competent authorities for compliance with GMP.

Finally, the marketing and promotion of authorized products, including industry-sponsored continuing medical education and advertising directed toward the prescribers of products and/or the general public, are strictly regulated in the European Union. In principle, all advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the European Union. Although general requirements for advertising and promotion of medicinal products are established under Directive 2001/83/EC, as amended, the details are governed by regulations in each member state and can differ from one country to another.

Human Cells and Tissues

Human cells and tissues that are intended for human applications but that do not fall within the scope of rules governing medicinal products or medical devices are not subject to premarket review and approval, nor do they require extensive preclinical and clinical testing. However, there are European Union rules governing the donation, procurement, testing and storage of human cells and tissues intended for human application, whether or not they are ATMPs. These rules also cover the processing, preservation and distribution of human cell and tissues that are not ATMPs. Establishments that conduct such activities must be licensed and are subject to inspection by regulatory authorities. Such establishments must implement appropriate quality systems and maintain appropriate records to ensure that cells and tissues can be traced from the donor to the recipient and vice versa. There are also requirements to report serious adverse events and reactions linked to the quality and safety of cells and tissues. More detailed rules may exist at the national level.

Named Patient Supplies

The European Union medicines rules allow individual member states to permit the supply of a medicinal product without a marketing authorization to fulfill special needs, where the product is supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of a healthcare professional and for use by an individual patient under his direct personal responsibility. This may in certain countries also apply to products manufactured in a country outside the European Union and imported to treat specific patients or small groups of patients.

Orphan Drug Designation and Exclusivity

Regulation (EC) No. 141/2000 and Regulation (EC) No. 847/2000 provide that a product can be designated as an orphan drug by the European Commission if its sponsor can establish: that the product is intended for the diagnosis, prevention or treatment of (i) a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union when the application is made, or (ii) a life-threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives it is unlikely that the marketing of the product in the European Union would generate sufficient return to justify the necessary investment. For either of these conditions, the sponsor must demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Union or, if such method exists, the product has to be of significant benefit compared to products available for the condition.

An orphan drug designation provides a number of benefits, including fee reductions, regulatory assistance and the possibility to apply for a centralized European Union marketing authorization. Marketing authorization for an orphan drug leads to a 10-year period of market exclusivity. During this market exclusivity period, neither the EMA nor the European Commission or the member states can accept an application or grant a marketing authorization for a "similar medicinal product." A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in a currently authorized orphan medicinal product, and which is intended for the same therapeutic indication. The market exclusivity period for the authorized therapeutic indication may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug designation because, for example, the product is sufficiently profitable not to justify market exclusivity.

European Data Collection and Data Protection Laws

We are required to comply with strict data protection and privacy legislation in the jurisdictions in which we operate, including the General Data Protection Regulation (EU) 2016/679, or GDPR. The GDPR governs our collection and use of personal data in the European Union relating to individuals (*e.g.*, patients). The GDPR imposes several requirements on organizations that process such data, including: to observe core data processing principles; to comply with various accountability measures; to provide more detailed information to individuals about data processing activities; to establish a legal basis to process personal data (including enhanced consent requirements); to maintain the integrity, security and confidentiality of personal data; and to report personal data breaches. The GDPR also restricts the transfer of personal data outside of the European Economic Area (*e.g.*, to the United States and other countries that are not deemed to provide adequate protection under their domestic laws). The GDPR may impose additional responsibility and liability in relation to personal data that we process, and require us to put in place additional mechanisms ensuring compliance with the new data protection rules. This may be onerous and adversely affect our business, financial condition, results of operations and prospects. Failure to comply with the requirements of the GDPR and related national data protection laws of European Union member states may result in a variety of enforcement measures, including significant fines and other administrative measures. The GDPR has introduced substantial fines for breaches of the data protection rules, increased powers for regulators, enhanced rights for individuals, and new rules on judicial remedies and collective redress. We may be subject to claims by third parties, such as patients or regulatory bodies, that we or our employees or independent contractors inadvertently or otherwise breached GDPR and related data protection rules. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we do not prevail, we could be required to pay substantial fines and/or damages and could suffer significant reputational harm. Even if we are successful, litigation could result in substantial cost and be a distraction to management and other employees.

Regulation of Diagnostic Products in the European Union

In the European Union, *in vitro* diagnostic products are regulated as *in vitro* diagnostic medical devices, or IVDs. The marketing of IVDs is subject to compliance with the In Vitro Diagnostic Medical Devices Directive 98/79/EC (IVD Directive). An IVD may be placed on the market within the European Union only if it conforms to certain "essential

requirements" and bears the CE Mark. The most fundamental and essential requirement is that an IVD must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. In addition, the IVD must achieve the performance(s) stated by the manufacturer and be designed and manufactured in a suitable manner.

Manufacturers must demonstrate that their IVDs conform to the relevant essential requirements through a conformity assessment procedure. The nature of the assessment depends upon the classification of the device. For IVDs intended to determine certain conditions or detect certain diseases, conformity assessment procedures involve a notified body. Notified bodies are often private entities and are authorized or licensed to perform such assessments by government authorities. Conformity assessment procedures require an assessment of available clinical evidence, literature data for the product and post-market experience in respect of similar products already marketed. Notified bodies also may review the manufacturer's quality systems. If satisfied that the product conforms to the relevant essential requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity and application of the CE Mark. For all other IVDs, the manufacturer performs its own conformity assessment procedure and self-declares conformity before applying the CE Mark. Application of the CE Mark allows the general commercializing of an IVD in the European Union. The manufacturer or, if the manufacturer is located outside the European Union, its authorized representative in the European Union must also register with the competent authority in the European Union member state in which it is located.

In May 2017, the European Union adopted a new In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746, or the IVD Regulation, which will apply in the European Union from May 26, 2022. The IVD Regulation does not set out a radically new system, but clearly envisages, among other things, stricter controls of IVDs, including the involvement of notified bodies in conformity assessments of many more categories of IVD and increased expectations as regards clinical data for IVDs. The IVD Regulation also envisages greater control over notified bodies and their standards, increased transparency, more robust device vigilance requirements and clarification of the rules for clinical investigations. Under transitional provisions, IVDs with notified body certificates issued under the IVD Directive prior to May 26, 2022 may continue to be placed on the market for the remaining validity of the certificate, until May 27, 2024 at the latest. After the expiry of any applicable transitional period, only IVDs that have been CE marked under the IVD Regulation may be placed on the market in the European Union.

Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we may obtain regulatory approval. Even if our product candidates are approved for marketing, sales of such product candidates will depend, in part, on the extent to which third-party payors, including government health programs in the United States (such as Medicare and Medicaid), commercial health insurers and managed care organizations, provide coverage and establish adequate reimbursement levels for such product candidates. In the United States, the member states of the European Union and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Reimbursement rules and levels are not harmonized in the European Union and therefore differ from member state to member state. Patients are unlikely to use any product candidates we may develop unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of such product candidates. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services and imposing controls to manage costs.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, and the cost of these studies would be in addition to the costs required to obtain FDA or other comparable marketing approvals. Even after pharmacoeconomic studies are conducted, product candidates may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover any product candidates we may develop could reduce physician utilization of such product candidates once approved and have a material adverse effect on our sales, results of operations and financial condition. Additionally, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. For example, the payor may require co-payments that patients find unacceptably high. Further, one payor's determination to provide coverage for a product does not assure that such coverage will continue or that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor. Third-party reimbursement and coverage

may not be adequate to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. The insurance coverage and reimbursement status of newly approved products for orphan diseases is particularly uncertain, and failure to obtain or maintain adequate coverage and reimbursement for any such product candidates could limit a company's ability to generate revenue.

The containment of healthcare costs also has become a priority of federal, state and foreign governments as well as other third-party payors such as statutory health insurance funds, and the prices of pharmaceuticals have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue from the sale of any approved products. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented or coverage may be ended in the future.

Outside the United States, we will face challenges in ensuring and obtaining adequate coverage and payment for any product candidates we may develop. Pricing of prescription pharmaceuticals is subject to governmental control in many countries, including in particular the member states of the European Union. Pricing negotiations with governmental authorities or other third-party payors such as statutory health insurance funds can extend well beyond the receipt of regulatory marketing approval for a product and may require us to conduct a clinical trial that compares the cost effectiveness of any product candidates we may develop to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in our commercialization efforts.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost effectiveness of a particular product candidate to currently available therapies (so called health technology assessments) in order to obtain reimbursement or pricing approval. Moreover, European Union member states may restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Member states may approve a specific price for a product or may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other member states allow companies to fix their own prices for products, but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the European Union have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the European Union. The downward pressure on health care costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products in the marketplace. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union Member States and parallel trade (arbitrage between low-priced and high-priced member states) can further reduce prices. Special pricing and reimbursement rules may apply to orphan drugs. Inclusion of orphan drugs in reimbursement systems tend to focus on the medical usefulness, need, quality and economic benefits to patients and the healthcare system as for any product. Acceptance of any medicinal product for reimbursement may come with cost, use and often volume restrictions, which again can vary by country. In addition, results based rules of reimbursement may apply. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products, if approved in those countries.

Healthcare Law and Regulation

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of pharmaceutical products that are granted marketing approval. Our current and future arrangements with providers, researchers, consultants, third-party payors and customers are subject to broadly applicable federal and state fraud and abuse, anti-kickback, false claims, transparency and patient privacy laws and regulations and other healthcare laws and regulations that may constrain our business and/or financial arrangements. Restrictions under applicable federal and state healthcare laws and regulations include, without limitation, the following:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in-cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of,

any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or a specific intent to violate it in order to have committed a violation. Moreover, the government may assert that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- the federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false, fictitious, or fraudulent or knowingly making, using, or causing to be made or used a false record or statement to avoid, decrease, or conceal an obligation to pay money to the federal government;
- HIPAA, which created additional federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or a specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without the appropriate authorization by entities subject to the law, such as healthcare providers, health plans and healthcare clearinghouses and their respective business associates;
- the federal transparency requirements known as the federal Physician Payments Sunshine Act, under the ACA, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services, or CMS, within the U.S. Department of Health and Human Services, information related to payments and other transfers of value made by that entity to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- federal government price reporting laws, which require us to calculate and report complex pricing metrics to government programs and which may be used in the calculation of reimbursement and/or discounts on marketed products;
- the Foreign Corrupt Practices Act, a U.S. law which regulates certain financial relationships with foreign government officials (which could include, for example, certain medical professionals);
- the national anti-bribery laws and laws governing interactions with healthcare professionals of European Union Member States;
- the U.K. Bribery Act 2010; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring pharmaceutical manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures and pricing information. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement

bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry.

Violations of these laws can subject us to criminal, civil and administrative sanctions including monetary penalties, damages, fines, disgorgement, individual imprisonment and exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, reputational harm, and we may be required to curtail or restructure our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to similar actions, penalties, and sanctions. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business. Moreover, we expect that there will continue to be federal and state laws and regulations, proposed and implemented, that could impact our future operations and business.

Current and Future Healthcare Reform Legislation

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our investigational medicines, restrict or regulate post-approval activities, and affect our ability to profitably sell any investigational medicines for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any collaborators, may receive for any approved products.

The ACA, for example, contains provisions that subject biological products to potential competition by lower-cost biosimilars and may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid-managed care plans, mandatory discounts for certain Medicare Part D beneficiaries, and annual fees based on pharmaceutical companies' share of sales to federal health care programs. With the current presidential administration and Congress, there may be additional administrative or legislative changes, including modification, repeal or replacement of all, or certain provisions of, the ACA, which may impact reimbursement for drugs and biologics. On January 20, 2017, an Executive Order was signed directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On October 13, 2017, an executive order was signed terminating the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. In addition, CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Further, each chamber of Congress has put forth multiple bills this year designed to repeal or repeal and replace portions of the ACA. While Congress has not passed repeal legislation, the TCJA includes a provision repealing the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Congress may consider other legislation to repeal and replace elements of the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

Additionally, other federal health reform measures have been proposed and adopted in the United States since the ACA was enacted:

- The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2025 unless additional Congressional action is taken.
- The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

- The Middle Class Tax Relief and Job Creation Act of 2012 required that CMS reduce the Medicare clinical laboratory fee schedule by 2% in 2013, which served as a base for 2014 and subsequent years. In addition, effective January 1, 2014, CMS also began bundling the Medicare payments for certain laboratory tests ordered while a patient received services in a hospital outpatient setting.

Further, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which have resulted in several recent Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. In addition, the federal government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs, including price-controls, restrictions on reimbursement, and requirements for substitution of generic products for branded prescription drugs to limit the growth of government-paid health care costs. For example, the federal government has passed legislation requiring pharmaceutical manufacturers to provide rebates and discounts to certain entities and governmental payors to participate in federal healthcare programs. Individual states in the United States have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation, from other countries and bulk purchasing.

Packaging and Distribution in the United States

If our products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The failure to comply with any of these laws or regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, exclusion from federal healthcare programs, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, or refusal to allow a firm to enter into supply contracts, including government contracts. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in regulations, statutes, or the interpretation of existing regulations could impact our business in the future by requiring, for example, (i) changes to our manufacturing arrangements, (ii) additions or modifications to product labeling, (iii) the recall or discontinuation of our products or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

Other U.S. Environmental, Health and Safety Laws and Regulations

We may be subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

We maintain workers' compensation employers' liability insurance to cover us for costs and expenses we may incur due to injuries to our employees, but this insurance may not provide adequate coverage against potential liabilities.

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

XVI. Intellectual Property

A. Introduction

We pursue a layered intellectual property strategy to protect our various technology platforms and their application to the treatment of cancer and other serious diseases. One focus of our intellectual property strategy is to provide protection for our platforms and product candidates currently in development. We also pursue intellectual property protection for assets that may be used in future development programs and/or that may be of interest to our collaborators, or otherwise may prove valuable in the field.

Various aspects of our technology platforms and our product candidates are claimed by patent filings. We also pursue other modalities of protection, including trademark and trade secret protection, as appropriate. Many of our intellectual property assets were developed and are owned solely by us, some have been developed via collaboration and are jointly owned, and some have been acquired by acquisition and/or licensed from third parties. We expect that we will continue to make additional patent application filings, and will continue to pursue opportunities to acquire and license additional intellectual property assets, technologies, platforms or product candidates, as developments arise or are identified.

Regardless, given the early stage of development of our product candidates, we cannot be certain that any of the patent filings or other intellectual property rights that we have pursued or obtained will provide protection for any product candidates that may ultimately be commercialized. Our most advanced product candidates are currently in clinical testing, with no certainty that they will be successful, or that significant modification or adjustment may not be required for successful commercialization.

Our future commercial success depends, in part, on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business; defend and enforce our patents and other intellectual property; preserve the confidentiality of our trade secrets; and operate without infringing, misappropriating or violating the valid and enforceable patents and other intellectual property rights of third parties. Our ability to stop third parties from making, using, selling, offering to sell or importing our products may depend on the extent to which we have rights under valid and enforceable patents, trade secrets or other intellectual property rights that cover these activities. With respect to both our owned and licensed intellectual property, we cannot be sure that patents will issue with respect to any of the owned or licensed pending patent applications or with respect to any patent applications that we, our co-owners or our licensors may file in the future, nor can we be sure that any of our owned or licensed patents or any patents that may be issued in the future to us or our licensors will be commercially useful in protecting any products that, we ultimately attempt to commercialize, or any method of making or using such products. Moreover, we may be unable to obtain patent protection for certain of our product candidates generally as well as with respect to certain indications. See “Risk Factors—Risks Related to our Intellectual Property” for a more comprehensive description of risks related to our intellectual property.

As of January 15, 2020, our overall owned and in-licensed patent portfolio included more than 200 patent families, each of which includes at least one filing in the United States or Europe, and several of which are pending or granted in multiple jurisdictions. The patent families include at least 100 patent families that are solely or jointly owned by BioNTech, including certain families acquired through our acquisitions of antibody assets and infrastructure from MabVax Therapeutics Holdings, Inc., and the rest that we have licensed from a third party.

An issued patent provides its owner (or possibly its licensee) with a right to exclude others from making, using or selling that which is claimed in the patent, for a specified period of time (the “term” of the patent), in the jurisdiction in which the patent is issued. In the United States, and in many other countries, patents have a presumptive term of 20 years from their effective filing date (which is the earliest non-provisional filing date to which the patent claims priority). However, many jurisdictions, including the United States, require the payment of periodic maintenance fees in order for patents to remain in force for the full 20-year term. The United States also has provisions that require a patent term to be shortened if its claims are too similar to another patent owned by the same party that has a shorter term. The United States and certain other jurisdictions also have provisions that permit extension of patent term for patents that claim a drug or drug product, or its approved use, if the patent was issued before clinical trials were completed and certain other requirements

were satisfied. In the United States, such extension is called a Patent Term Extension, or PTE, and it is limited to a period of not more than five years, or the total patent term including the PTE cannot exceed 14 years after the date of regulatory approval; only one patent can be extended per product approval. The United States also offers a different form of patent term extension, known as Patent Term Adjustment, or PTA, whereby a particular patent's term is automatically extended beyond the 20-year date if the United States Patent and Trademark Office, or the USPTO, caused delay during its examination; however, potentially available PTA is reduced by any amount of any delay caused by the patent applicant.

Below, we provide a summary of the contours of our current patent portfolio as it relates to different aspects of relevant technology, including noting ownership and 20-year terms for filings included in the portfolio that are directed to such aspects. Particularly given our pre-commercial state of development, we cannot be certain that any of the patent filings in our portfolio will provide meaningful protection for any product we ultimately attempt to commercialize.

B. Patent Portfolio

The patent portfolios for our most advanced programs are summarized below. Patent prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the USPTO and its foreign equivalents can be significantly narrowed by the time they issue, if they issue at all. We expect this could be the case with respect to some of our pending patent applications referred to below.

1. mRNA

The patent portfolio for our mRNA therapeutic platforms and product candidates includes patent filings directed to features of therapeutic mRNA structures, some of which are included in current development candidates. Our patent portfolio also includes patent filings directed to mRNA formulations, including the lipoplex formulations currently utilized with our FixVac and iNeST platforms, and the lipid nanoparticles currently utilized with our RiboMab and RiboCytokine platforms, as well as patent filings directed to mRNA manufacturing, and to uses of mRNA therapeutics. We provide more detail below regarding the patent filings directed to these features.

mRNA Structure

Our patent portfolio includes patent filings directed to various features of mRNA structure, which may, for example, contribute to increased immunogenicity (*e.g.*, antigen presentation), translation efficiency, and/or stability of mRNA constructs that include them. Such features include, for example, antigen-MHC fusions, 5' cap structures, 3' UTR structures, polyA tails and reduced-uracil content mRNAs. Filings directed to each of these features, or collectively, the mRNA Structure Filings, have been made in the United States and various foreign jurisdictions. Some such mRNA Structure Filings are owned solely by BioNTech SE or BioNTech RNA which are referred to collectively in this section as BioNTech, some jointly by BioNTech and one or more third parties, and some by BioNTech licensors, such as Louisiana State University, or LSU, and the terms of the applicable agreement with LSU, are further summarized below in "—C. In-Licensing." Issued existing mRNA Structure Filings have, and pending existing mRNA Structure Filings, if issued, would have, 20-year terms that extend into the mid-2020s to the mid-2030s.

mRNA Formulations

Our patent portfolio includes patent filings directed to various formulations for mRNA delivery, some of which are utilized with current development candidates. For example, our portfolio includes patent filings directed to lipoplex formulations, with 20-year terms that extend into 2038, if issued, or collectively, the mRNA Lipoplex Filings, although none of these filings is currently an issued patent. Such mRNA Lipoplex Filings are solely owned by BioNTech RNA.

In addition, our portfolio includes U.S. and foreign patent filings directed to lipid nanoparticles and polyplex technologies, which are jointly owned by BioNTech RNA and TRON, or collectively, the mRNA Lipid Nanoparticle/Polyplex Filings. Issued mRNA Lipid Nanoparticle/Polyplex Filings have, and pending mRNA Lipid Nanoparticle/Polyplex Filings, if issued, would have, 20 year terms that extend into the mid- to late-2030s. Some such mRNA Lipid Nanoparticle/Polyplex Filings were granted in certain foreign jurisdictions, but do not currently include any U.S. issued patents. The terms of the co-ownership of such patent filings with TRON are summarized below in "—C. In-Licensing."

mRNA Manufacturing

As discussed below, we utilize trade secret protection for many aspects of our mRNA manufacturing technologies, including as currently utilized for production of certain of our development candidates. In addition, our patent portfolio includes certain patent filings relevant to mRNA manufacturing, or collectively, the mRNA Manufacturing Filings, which we believe may provide commercial value to protect product candidates and/or support collaborations or other licensing arrangements. For example, our mRNA Manufacturing Filings include U.S. and foreign patent filings relating to certain aspects of mRNA purification and production. These mRNA Manufacturing Filings are either solely owned by BioNTech RNA, or jointly owned by BioNTech RNA and TRON and, if issued, would have 20-year terms that would extend into mid to late 2030s, although none is currently an issued patent.

mRNA Product Candidates

Our most advanced mRNA product candidate development programs are in oncology and involve various platforms. Our pipeline also includes mRNA product candidates for treatment of certain infectious diseases and mRNA product candidates for protein replacement therapy in certain rare diseases.

Oncology mRNA Product Candidates

Our current clinical programs are all in oncology. The most advanced involve iNeST immunotherapy product candidates being developed with our collaborator, Genentech. We also have FixVac product candidates in Phase 1 clinical trials, and have recently initiated Phase 1 clinical trials of our mRNA-based intratumoral immunotherapy developed through our collaboration with Sanofi.

FixVac

Our FixVac product candidates share many of the structural elements involved in our iNeST product candidates. Thus, some or all of the mRNA Structure Filings relevant to our iNeST product candidates and discussed above are also relevant to our FixVac product candidates. These patent filings, or the FixVac Platform Filings, include mRNA Structure Filings relating to antigen-MHC fusions, phosphorothioate stabilized 5’ cap structures, 3’ UTR structures containing a specific sequence element, and interrupted polyA tails, which are solely or jointly owned by BioNTech or BioNTech’s licensors. Issued FixVAC Platform Filings have, and pending FixVac Platform Filings, if issued, would have, 20-year terms extending into the mid-2020s to the mid-2030s. While we have pursued or obtained patent protection covering components of FixVac product candidates, manufacturing-related methods and/or formulations, we do not currently have any claims in our owned or in-licensed issued patents that cover the overall construct used in our FixVac product candidates.

Our patent portfolio further includes U.S. and foreign patent filings relating to combined uses of our FixVac and iNeST product candidates. Such issued patent filings have, and such pending patent filings, if issued, would have, 20-year terms that extend into 2033, and are jointly owned by BioNTech RNA and TRON.

Our current Phase 1 clinical trials for FixVac product candidates are studying such product candidates in treatment of advanced melanoma, head and neck cancer, and breast cancer (particularly triple negative breast cancer). While we do not currently have any claims in our owned or in-licensed issued patents that are directed to use of our FixVac product candidates in the indications of these clinical trials, certain FixVac Platform Filings include specific reference to treatment of each of these indications. Additionally, our patent portfolio relevant to FixVac product candidates further includes U.S. and foreign patent filings relating to use of particular tumor antigens for treatment of triple negative breast cancer included in Phase 1 clinical trials, or the Triple Negative Breast Cancer FixVAC Filings. Issued Triple Negative Breast Cancer FixVac Filings have, and pending Triple Negative Breast Cancer FixVac Filings, if issued, would have, 20-year terms that extend into 2034, and are jointly owned by BioNTech SE and TRON.

iNeST

Our patent filings relevant to our iNeST product candidates include mRNA Structure Filings relating to features for increasing antigen presentation (*e.g.*, antigen-MHC fusions) and features for increasing translation efficiency and/or stability of mRNA constructs (*e.g.*, phosphorothioate stabilized 5’ cap structures, 3’ UTR structures containing a specific sequence element, and polyA tails of a particular length or interrupted polyA tails); mRNA Lipoplex

Filings relating to negatively charged lipoplexes (*e.g.*, for spleen targeting); and mRNA Manufacturing Filings, or collectively, the iNeST mRNA Platform Filings. While we have pursued or obtained patent protection covering components of iNeST product candidates, manufacturing-related methods and/or formulations, we do not currently have any claims in our owned or in-licensed issued patents that cover the overall construct used in our iNeST product candidates.

Our patent portfolio further includes U.S. and foreign filings directed to the process of identifying neoantigens in patient samples and/or predicting those that will be immunoreactive in an iNeST immunotherapy product, or collectively, the Neoantigen Filings. Certain issued Neoantigen Filings have, and certain pending Neoantigen Filings, if issued, would have 20-year terms that extend into the mid- to late-2030s, although none is a U.S. issued patent. The Neoantigen Filings are solely owned by BioNTech RNA, or jointly owned by BioNTech RNA and TRON.

We are currently studying our iNeST product candidates for the treatment of metastatic melanoma in Phase 2 clinical trials and those for the treatment of various solid tumors in Phase 1 clinical trials. Certain iNeST mRNA Platform Filings and Neoantigen Filings cover treatment of each of these indications. However, we do not currently have any claims in our owned or in-licensed issued patents that are directed to use of iNeST product candidates in the indications of these clinical trials.

Intratumoral Immunotherapies

Certain of the mRNA Structure Filings (including some that are relevant to iNeST and/or FixVac product candidates, as discussed above) are also directed to one or more features of our intratumoral immunotherapies, including our most advanced intratumoral immunotherapy, which we are developing through our collaboration with Sanofi, and which has recently entered Phase 1 clinical trials. For example, mRNA Structure Filings relating to 3' UTR structures containing a specific sequence element, interrupted polyA tail structures, and reduced-uracil content mRNAs, which, as noted above are solely or jointly owned by BioNTech and, if issued, would have 20-year terms extending into the mid-2030s, provide protection to our current intratumoral immunotherapy development candidate. However, these filings do not currently include any issued patents.

We have also obtained third-party licenses to technologies relating to certain features of the mRNA structure relevant to the intratumoral immunotherapies. These include two non-exclusive sublicenses—one from mRNA RiboTherapeutics, Inc., or MRT, and one from its affiliate CellScript, LLC (these licenses, together, the MRT-CellScript Sublicenses). MRT-CellScript Sublicenses allow us to use, make and/or sell nucleoside-modified mRNA products that are covered by U.S. and European Patent Office patent filings owned by the Trustees of the University of Pennsylvania, or the Penn Modified RNA Patent Rights, which sublicenses are further summarized below in "—C. In-Licensing."

Additionally, certain patent filings have arisen from our collaboration relating to compositions including mRNAs encoding particular cytokines for treatment of solid tumors, or the mRNA Cytokine Filings. Such mRNA Cytokine Filings, if issued, would have 20-year terms that would extend into 2038. However, these filings do not currently include any issued patents.

RiboMabs and RiboCytokines

We own or license a number of patent filings directed to our RiboMab and RiboCytokine programs. Many are owned solely by us, some are jointly owned, and some have been acquired or licensed.

Patent filings relevant to our RiboMab and RiboCytokine programs include certain mRNA Structure Filings relevant to our iNeST and/or FixVac product candidates, specifically relating to 3' UTR structures containing a specific sequence element, interrupted polyA tail structures, and reduced-uracil content mRNAs; mRNA Lipid Nanoparticle/Polyplex Filings; and patent filings under the MRT-CellScript Sublicenses relating to nucleoside-modified mRNAs.

We have also recently acquired patent assets from MabVax Therapeutics, or the MabVax Filings, that relate to various antibodies, including certain antibodies targeting sialyl Lewis A and ganglioside GD2, as well as nucleic acid encoding them. Issued MabVax Filings have, and the pending MabVax Filings, if issued, would have, 20-year terms that extend into the mid-2030s.

Infectious Diseases

As is discussed elsewhere in this Annual Report, we have collaborated with third parties, including Pfizer, Penn and Fosun Pharma, to develop infectious disease mRNA vaccines.

Certain patent filings that might be useful to our infectious disease mRNA vaccines include certain of the mRNA Structure Filings and the mRNA Lipid Nanoparticle/Polyplex Filings.

Rare Diseases

We are developing mRNA-based protein replacement therapy for several rare disease indications through our collaboration with Genevant.

Certain of the mRNA Structure Filings (including some that are relevant to iNeST and/or FixVac product candidates, as discussed above) and patent filings under the CellScript Licenses include patent filings directed to nucleoside-modified mRNAs also provide protection for one or more features of mRNA-based protein replacement product candidates. For example, mRNA Structure Filings include patent filings directed to 3' UTR structures containing a specific sequence element, interrupted poly A tail structures and reduced-uracil content mRNAs, which, as noted above are solely or jointly owned by BioNTech, and, if issued, would have 20-year terms that would extend into the mid-2030s. However, these filings do not currently include any issued patents.

Our patent portfolio relating to our rare disease programs also include certain patent filings that we have licensed from Genevant, or the Genevant Filings. Specifically, the Genevant Filings are owned by Arbutus Biopharma Corporation, which is a Genevant affiliate, and relate primarily to lipid or non-liposomal formulations that might be useful in these programs, and have been filed primarily in the U.S. and Europe, with 20-year terms that extend into mid-2020s to mid-2030s for the issued Genevant Filings and the pending Genevant Filings, if issued.

2. Engineered Cell Therapy

Our engineered cell therapy product class features use of chimeric antigen receptor, or CAR-, T cell or individualized T cell receptors for oncology therapy. Our patent filings relevant to these platforms and product candidates, or the CAR-T/TCR Filings, are generally co-owned by BioNTech Cell & Gene Therapies GmbH, or BioNTech C&GT, and TRON. For example, the CAR-T/TCR Filings include patent filings directed to various CAR-T formats and methods of enhancing CAR-T cells by nucleic acid vaccination, as well as patent filings directed to processes of identifying and/or making individualized T cell receptors. The CAR-T/TCR Patent Filings, if issued, would have 20-year terms that would extend into the mid- to late-2030s. However, these filings do not currently include any issued patents.

Certain CAR-T programs involve CAR-T cell product candidates that target different members of the claudin family. Our patent portfolio includes certain patent filings specifically relevant to our claudin-specific CAR-T cell product candidates and are jointly owned by BioNTech C&GT, TRON and Ganymed, or the Claudin-Specific CAR-T Cell Filings. The issued Claudin-Specific CAR-T Cell Filings have, and the pending Claudin-Specific CAR-T Cell Filings, if issued, would have, 20-year terms extending into the mid-2030s. However, these filings do not currently include any U.S. issued patents. The terms of our co-ownership of such patent filings with TRON and Ganymed are summarized below in "—C. In-Licensing."

3. Antibodies

Our antibodies product class features bispecific checkpoint immunomodulators for oncology therapy, which are developed through collaboration with Genmab. Our development candidates include bispecific antibodies that are designed to activate 4-1BB upon simultaneous binding to PD-L1 or CD-40. Our patent portfolio includes certain patent filings relevant to such bispecific antibodies, or the Bispecific Checkpoint Modulator Filings, co-owned by us and Genmab. Such Bispecific Checkpoint Modulator Filings, if issued, would have 20-year terms that would extend into the late-2030s and do not currently include any issued patents.

4. Small Molecule Immunomodulators

Our small molecule therapeutics product class features oncology treatment using small molecule product candidates that activate the immune system via TLR7 agonism. Our patent portfolio includes patent filings relevant to these TLR7 agonists, or the TLR7 Agonist Filings. Certain TLR7 Agonist Filings are directed to substituted imidazoquinolines, and, if issued, would have 20-year terms that would extend into the late 2030s. However, these filings do not currently include any issued patents.

C. In-Licensing

Some of our intellectual property assets have been acquired by acquisition and/or in-licensing.

We have pursued a strategy of identifying and in-licensing third-party patents that we believe are complementary to or otherwise interact synergistically with our own intellectual property portfolio. We have entered into material intellectual property licensing or option arrangements with Penn, TRON, Louisiana State University and MRT-CellScript.

The key terms of these arrangements are summarized below.

Penn Agreement

In October 2018, BioNTech RNA entered into a collaboration and license agreement with the Trustees of the University of Pennsylvania regarding the development and commercialization of certain mRNA vaccines and mRNA diagnostics for the diagnosis, detection, evaluation, prophylaxis and treatment of infectious diseases. We refer to this agreement as the Penn Agreement.

Under the Penn Agreement, BioNTech RNA and Penn agree to collaborate with respect to research and development activities and are obligated to use commercially reasonable efforts to develop products that use formulated mRNAs encoding one or more immunogens for 10 disease indications in the field of infectious diseases (each, a Penn Product). Penn is responsible for all research and development work up to completion of studies enabling an IND as well as IND-supporting preclinical work, and BioNTech RNA is responsible for the manufacture of mRNA amounts to support the preclinical and IND-enabling studies. If a Penn Product developed under the research program achieves certain acceptance criteria for a specified indication, BioNTech RNA has the right to obtain an exclusive worldwide license under Penn's patent rights (and a non-exclusive license under Penn's know-how and materials) to research, develop, make, use or commercialize Penn Products in such indication. Under the Penn Agreement, Penn retains certain rights to conduct and authorize non-commercial third-party research, educational and patient care activities under any licensed intellectual property. Moreover, the license granted by Penn is subject to certain rights granted to the U.S. government in connection with government funding provided by the United States, including the requirement that products that result from intellectual property funded by the U.S. government that are sold in the United States be substantially manufactured in the United States.

BioNTech RNA has an obligation to use commercially reasonable efforts to clinically develop, obtain regulatory approval for and commercialize at least one Penn Product for each indication licensed under the Penn Agreement. Moreover, BioNTech RNA is obligated to achieve certain clinical and regulatory milestones within specified time periods, and its failure to do so would provide Penn the right to terminate the Penn Agreement on an indication-by-indication basis.

BioNTech RNA paid to Penn an upfront fee of $5 million to fund research activities and has agreed to pay Penn additional funds through quarterly payments, not to exceed an aggregate of $15 million, upon depletion of the previously advanced funds. Under the Penn Agreement, BioNTech RNA also agreed to pay Penn an annual alliance management fee. In addition, if any Penn Product is covered by a Penn patent, BioNTech RNA will pay to Penn development and commercialization milestone payments up to $44.4 million for each Penn Product licensed under this agreement and royalties in a low-single digit percentage on net sales of all Penn Products licensed under the Penn Agreement. Further, Penn will receive a percentage of any income from sublicenses BioNTech RNA grants to third parties, subject to certain caps set forth in the Penn Agreement.

BioNTech RNA has the sole responsibility for and decision-making authority over clinical development and commercialization activities relating to any Penn Product arising from the collaboration. BioNTech RNA is also responsible for the manufacture of mRNA to support clinical development and commercialization efforts.

The Penn Agreement remains in effect until the expiration of the last Penn patent covering any licensed Penn Product or developmental product candidate. BioNTech RNA may terminate the Penn Agreement for convenience in its entirety or on an indication-by-indication basis upon 90 days' prior notice to Penn. The Penn Agreement also grants both parties termination rights for uncured material breaches, including for BioNTech RNA's failure to achieve its obligations to achieve certain diligence milestones, and insolvency.

TRON Agreements

In 2015, we and our subsidiaries BioNTech RNA, BioNTech Diagnostics GmbH, BioNTech Protein Therapeutics GmbH, BioNTech Cell & Gene Therapies GmbH, Eufets GmbH and JPT Peptide Technologies GmbH entered into a Master Agreement for Research Services with TRON. Concurrently with this Master Agreement for Research Services, or the TRON Research Agreement, we entered into a License Agreement with Ganymed, TRON, Johannes Gutenberg-Universität Mainz 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 2019, we and our subsidiaries BioNTech RNA Pharmaceuticals GmbH, BioNTech Diagnostics GmbH, BioNTech Protein Therapeutics GmbH, BioNTech Cell & Gene Therapies GmbH, BioNTech Innovative Manufacturing Services GmbH and JPT Peptide Technologies GmbH, entered into a Framework Collaboration Agreement with TRON, or the TRON Collaboration Agreement.

TRON Research Agreement

Under the TRON Research Agreement, TRON from time to time performs certain services for us under work orders, which may comprise innovative applied research projects, pre-defined research and development or clinical research services. We and TRON meet at regular intervals, but no less than annually, to prepare an overall non-binding project plan, which sets the scope, period and costs for the relevant projects contemplated for that period. Individual work orders set the specific binding terms of each project or service. TRON is obligated to render services in accordance with the scientific standards, all applicable laboratory and legal provisions and with the care customary in the industry.

We are entitled to the exclusive rights to all inventions, methods, specifications, materials, documents, data, know-how and other results (together, the Results) developed or discovered by TRON or by us and TRON jointly under the TRON Research Agreement, except to the extent they constitute improvements of the technologies applied by TRON in the relevant projects. Under the TRON Research Agreement, TRON granted us a non-exclusive, royalty-free license to use TRON Improvements if such TRON Improvements are necessary for the continued development and exploitation of the Results or the manufacture or marketing of products which contain any of the Results and are covered by a patent claiming any of the Results.

Under the TRON Research Agreement, TRON's services rendered in the field of applied research are invoiced at cost. For other services, fixed prices are to be set forth in the individual work orders. TRON invoices us monthly and our payments are due no later than 10 days thereafter. Additionally, we are obligated to pay to TRON low single-digit tiered royalties on net sales of any product developed under the TRON Research Agreement that is covered by a patent claiming any of the Results.

The TRON Research Agreement limits each party's liability to the other to intentional and grossly negligent actions and, in the case of gross negligence, liability for indirect and consequential damages and lost profits is excluded. We are obligated to indemnify TRON for all product liability claims in connection with the products and for third-party claims asserting that the Results violate third-party intellectual property rights.

The TRON Research Agreement has an indefinite term, but may be terminated by either party on six months' notice. If one of our subsidiaries terminates its role in the TRON Research Agreement, the agreement will survive and continue without that subsidiary.

In November 2017, we and TRON entered into an agreement to include certain research and development activities regarding neoepitope RNA immunotherapies as work included in the TRON Research Agreement.

TRON License Agreement

The TRON License Agreement governs the ownership of and licenses under certain patents, inventions, know-how, technologies and other knowledge (together, the Development Results) filed and created before January 1, 2015 in the course of our collaboration with TRON, Johannes Gutenberg-Universität Mainz and Universitätsmedizin der Johannes Gutenberg-Universität Mainz (collectively, the University Parties) and Ganymed pursuant to the 2008 Cooperation Agreement.

The TRON License Agreement sets forth the parties' rights with respect to the Development Results, mainly depending on which parties have contributed to such Development Results. Ownership of the Development Results and any patents and other intellectual property in certain shares to TRON, on the one hand, and BioNTech and/or Ganymed, on the other hand included therein is allocated. Each party may assign its share in the co-owned Development Results to its affiliates provided that such party provide notice of the transfer and the identity of the new co-owner to the other co-owners. However, in case of an assignment of such share to a third party (except in case of a material asset sale), the assigning party must obligate the assignee to comply with the terms of the TRON License Agreement and the assigning party will remain bound by the obligations of the TRON License Agreement unless the other co-owners have consented to discharge the assigning party from such obligations.

The parties to the TRON License Agreement grant licenses to each other under their shares in the Development Results substantially as follows. Ganymed is exclusively entitled to use the Development Results for certain antibodies and antibody fragments that bind to certain defined targets, or the Ganymed Field of Use. We are exclusively entitled to use the Development Results in any other field of use (including immunological therapeutics, small molecule compounds, siRNA-based therapeutics, micro-proteins, antibody based *in vitro* (except for those in the Ganymed Field of Use), diagnostics and therapeutics based on long-chain RNA as well as other cell therapy applications, immune cells transgenized with recombinant directed against certain defined targets or chimeric antigene receptors and RNA-based pharmaceuticals). The University Parties may use the Development Results for internal research purposes only. We have an obligation to use reasonable efforts to develop and commercialize products in our field of use worldwide.

Under the TRON License Agreement, we and Ganymed must agree on which party will have the primary role in filing, prosecuting, maintaining and defending jointly owned patents. We and Ganymed each have the exclusive right to enforce the Development Results in our respective fields of use, subject to certain step-in rights of the other parties.

We are obligated to pay to the University Parties low single-digit tiered royalties on net sales on any product that is covered by certain of the patents including in the Development Results. If licenses are granted to third parties, we are obligated to pay to the University Parties a mid-single-digit share of all upfront payments, milestone payments and other remuneration we receive from such third parties in consideration for the license. Regarding upfront payments only, the University Parties' share will be offset against subsequent license fees on net sales. In addition, we are obligated to pay certain development and regulatory milestones up to a low seven-figure amount to Johannes Gutenberg-Universität Mainz.

The TRON License Agreement contains a limitation on liability as between the parties, wherein the parties will only be liable to each other for intentional and grossly negligent actions, and, in the case of gross negligence, liability for indirect and consequential damages and lost profits is excluded. We are obligated to indemnify the University Parties and Ganymed for third-party claims of product liability or violation of applicable law based on our distribution of our products or if we breach the TRON License Agreement or if we or one of our agents acts culpably.

The TRON License Agreement will remain in effect as long as there are any obligations on us or Ganymed to pay license fees. After expiry of the TRON License Agreement, each party will have a perpetual, non-exclusive, royalty-free license to use the Developments Results. The TRON License Agreement may be terminated by any party on six months' notice. The licenses granted between the parties will survive such termination. The TRON License Agreement also grants all parties termination rights for uncured material breaches. If only one party terminates its role in the Agreement, the Agreement will survive and continue between the other parties.

TRON Collaboration Agreement

Under the TRON Collaboration Agreement, TRON from time to time undertakes certain projects in collaboration with us under separate project specific agreements, comprising innovative non-clinical research and development projects. We and TRON meet regularly to review and update project plans, and no less than annually to agree the budget for the on-going projects for the coming calendar year. Individual project agreements set the specific binding terms of each project.

TRON is obligated to perform its obligations in accordance with the scientific standards, all applicable technical laboratory and legal provisions and with the care customary in the non-clinical biotechnology research industry.

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

Under the TRON Collaboration Agreement, TRON's activities are invoiced at cost. TRON invoices us monthly and our payments are due no later than 10 days thereafter. Additionally, we are obligated to pay to TRON low single-digit tiered royalties on net sales of any product developed under the TRON Collaboration Agreement that is covered by a patent claiming any of the Results or, in certain circumstances, by a patentable invention forming part of the Results which we elect to maintain as a trade secret. If licenses under Results are granted to third parties, we are obligated to pay to TRON a mid-single-digit share of all upfront payments, milestone payments and other remuneration we receive from such third parties in consideration for the license. In addition, we are obligated to pay a one-time only milestone of a low seven-figure amount to TRON the first time annual sales of a product developed under the TRON Collaboration Agreement reach a low nine-figure number.

The TRON Collaboration Agreement limits each party's liability to the other to cases of willful misconduct and gross negligence and, in the case of gross negligence, liability for indirect and consequential damages and lost profits is excluded. We are obligated to indemnify TRON for all product liability claims in connection with the products and for third-party claims asserting that the Results violate third-party intellectual property rights.

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

LSU License Agreement

In May 2015, we entered into a Patent License Agreement with the Board of Supervisors of Louisiana State University and Agricultural and Mechanical College, or LSU, and the University of Warsaw, or UW. The agreement (which we refer to as the LSU Agreement) replaces and supersedes the earlier license agreement between the parties.

Under the LSU Agreement, UW and LSU granted to us an exclusive royalty-bearing license under certain patent rights relating to mRNA cap analogs and the synthesis and use of anti-reverse phosphorothioate analogs of the mRNA cap in the United States, certain jurisdictions in the European Union and other countries. As consideration for the license granted, we are obligated to pay running royalties in the low single digits on all net sales of products utilizing the licensed patents and to pay annual maintenance fees to LSU.

We are obligated to use commercially reasonable efforts to develop one or more marketable products utilizing the licensed patents, upon which we would owe additional milestone payments to LSU.

The LSU Agreement remains in effect until expiration of the licensed patents. We have the right to terminate the LSU Agreement for convenience with 60 days' prior notice, and LSU and UW may terminate for our uncured material breach.

CellScript and mRNA Ribotherapeutics License Agreement

BioNTech RNA entered into the two MRT-CellScript Sublicenses discussed above. Together, the MRT-CellScript Sublicenses grant BioNTech RNA worldwide, non-exclusive sublicenses under the Penn Modified mRNA Patent Rights (as

defined in the MRT-CellScript Sublicenses) to research, develop, make, import, use and commercialize products for *in vivo* uses in humans and non-human animals, including therapeutic and prophylactic applications, and for certain uses in the diagnostic and prognostic field of use and certain laboratory research or screening uses. Under these sublicenses, BioNTech RNA has the right to grant sublicenses to affiliates and third parties.

BioNTech RNA must use reasonable efforts to develop and commercialize products under the sublicenses. Furthermore, BioNTech RNA is obliged to pay MRT and CellScript development milestone payments of up to approximately $26 million as well as royalties in the low to mid-single digits on net sales of licensed products, depending on the field of use.

The agreements continue until the expiration or abandonment of the last licensed patent to expire or be abandoned. BioNTech RNA may terminate the agreement for convenience with respect to all or certain patent rights with 60 days' prior written notice. MRT or CellScript may terminate the respective sublicense agreement for payment default, uncured material breach or the bankruptcy of BioNTech RNA.

D. Trademark Portfolio

Certain features of our business and our product candidates are protected by trademarks. Our trademark portfolio includes, but is not limited to, registrations for each of FixVac®, IVAC®, MammaTyper®, RiboCytokine® and RiboMab®.

E. Trade Secret Protection

Certain of our technologies, including in particular certain proprietary manufacturing processes or technologies and/or neoantigen prediction technologies, are protected as trade secrets.

In addition to patent protection, we rely upon unpatented trade secrets and confidential know-how and continuing technological innovation to develop and maintain our competitive position. We protect certain of our technologies, including, in particular, certain proprietary manufacturing processes and technologies and/or neoantigen prediction technologies, as trade secrets. However, trade secrets and confidential know-how are difficult to protect. We seek to protect our proprietary information, in part, by using confidentiality agreements with any future collaborators, scientific advisors, employees and consultants, and invention assignment agreements with our employees. We also have agreements requiring assignment of inventions with selected consultants, scientific advisors and collaborators. These agreements may not provide meaningful protection. These agreements may also be breached, and we may not have an adequate remedy for any such breach. In addition, our trade secrets and/or confidential know-how may become known or be independently developed by a third party, or misused by any collaborator to whom we disclose such information. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our products or to obtain or use information that we regard as proprietary. Although we take steps to protect our proprietary information, third parties may independently develop the same or similar proprietary information or may otherwise gain access to our proprietary information. As a result, we may be unable to meaningfully protect our trade secrets and proprietary information. See "Risk Factors—Risks Related to our Intellectual Property" for a more comprehensive description of risks related to our intellectual property.

XVII. Competition

We compete in an industry characterized by rapidly advancing technologies, intense competition and a complex intellectual property landscape. We face substantial competition from many different sources, including large and specialty pharmaceutical and biotechnology companies, academic research institutions and governmental agencies and public and private research institutions.

Below is a description of competition surrounding each of our technologies.

mRNA Therapies. mRNA therapies are a new medical frontier, and we expect competition in this space to be robust across diverse therapeutic areas. We compete with a number of companies focused on developing mRNA technologies for a wide range of applications, including Moderna, CureVac, eTheRNA immunotherapies, Translate Bio, Arcturus Therapeutics, ethris, Genevant and GlaxoSmithKline.

Oncology. The oncology therapeutics landscape in general is highly competitive and includes large and specialty pharmaceutical and biotechnology companies, academic research institutions and governmental agencies and public and

private research institutions. It includes both competition from marketed therapies as well as potential new therapeutics in development. We may compete with products with different mechanisms of action as well as against established standards of care. Companies such as AstraZeneca, Amgen, Bristol-Myers Squibb, Celgene, Eli Lilly, GlaxoSmithKline, Incyte, Janssen Pharmaceuticals, Merck & Co., Novartis, Pfizer, Roche and Sanofi are developing diversified immuno-oncology programs and have substantial resources. We expect our intratumoral immunotherapy candidates for the treatment of solid tumors to face direct competition from companies such as Moderna and CureVac.

We also expect our FixVac and iNeST candidates to face competition from smaller specialized oncology companies such as Agenus, Gritstone, Moderna in collaboration with Merck & Co., Aduro Biotech, Advaxis Immunotherapies, Achilles Therapeutics, NousCom, ISA Pharmaceuticals, CureVac in collaboration with Eli Lilly, Genocea Biosciences, Vaccibody, PACT Pharma and ZIOPHARM Oncology in the antigen-based therapy space.

Engineered Cell Therapy Drug Class. We compete with a number of companies focused on adoptive cell therapies, including Novartis Pharmaceuticals, Gilead Sciences, Celgene, Allogene Therapeutics, CRISPR Therapeutics, bluebird bio, Medigene, Adaptimmune Therapeutics, Amgen, Atara Biotherapeutics, Autolus Limited, Cellectis, PACT, Mustang Bio, Iovance Biotherapeutics, TCR2 Therapeutics, Editas Medicine, Celyad, Celularity, Unum Therapeutics, Intrexon, and Bellicum Pharmaceuticals and Precision Biosciences.

Antibodies Drug Class. We compete with a number of companies with operations focused on checkpoint immunomodulators, including AstraZeneca, Merck, Pfizer, Novartis, Roche and Bristol-Myers Squibb.

Small Molecule Immunomodulator Drug Class. We are aware of a number of other companies developing TLR agonists, including Checkmate Pharmaceuticals, Dynavax Technologies, Exicure, Gilead, GlaxoSmithKline, Hoffmann-La Roche, Mologen and Nektar Therapeutics.

Infectious Diseases. The infectious disease space includes general competition from well-established pharmaceutical companies such as AbbVie, Bayer, Gilead, Janssen Pharmaceuticals, Merck & Co. and Novartis. In addition, Seqirus UK, Sanofi Pasteur, GlaxoSmithKline, Biomedical Corp. of Quebec and AstraZeneca produce influenza vaccines.

Rare Diseases. We compete with a number of companies focused on rare diseases, including Roche, Alexion Pharmaceuticals, Novartis, Bristol-Myers Squibb, Sanofi Novo Nordisk and Pfizer.

Many of our competitors and potential competitors, either alone or with their collaborators, have greater scientific, research and product development capabilities as well as greater financial, marketing, sales and human resources and experience than we do. In addition, smaller or early-stage companies, including immunotherapy-focused therapeutics companies, may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Some of our collaborators, such as Genmab, Pfizer and Sanofi, may also be competitors within the same market or other markets. Accordingly, our competitors may be more successful than us in developing and potentially commercializing technologies and achieving widespread market acceptance. In addition, our competitors may design technologies that are more efficacious, safer or more effectively marketed than ours or have fewer side effects, or may obtain regulatory approvals more quickly than we are able, which could eliminate or reduce our commercial potential. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

We anticipate that the key competitive factors affecting our technologies will be efficacy, safety, cost and convenience, as well as our ability to build a fully-integrated biotechnology company. The availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our products. The timing of market introduction of our products and competitive products will also affect competition among products. We expect the relative speed with which we can develop our products, complete the clinical trials and approval processes, and supply commercial quantities of the products to the market to be important competitive factors. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

XVIII.Legal Proceedings

From time to time, we may be involved in legal proceedings in the ordinary course of business. We are currently not a party to any material legal or administrative proceedings. In addition, we are not aware of any material legal or

administrative proceedings contemplated to be brought against us. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

C. Organizational Structure

For a list of our subsidiaries that are included in the consolidated financial statements as of December 31, 2019 please refer to Item 18.

D. Property, Plants and Equipment

Our headquarters are located in Mainz, Germany, where we occupy:

- Approximately 9,416 square meters (equivalent to approximately 101,353 square feet) of laboratory, GMP manufacturing, storage and office space under a lease for the entire building located at An der Goldgrube 12, 55131 Mainz under a lease that has an initial term that expires on October 31, 2027, but which we have the option to extend until October, 2042.
- Approximately 1,069 square meters (equivalent to approximately 11,507 square feet) of office and GMP manufacturing space under a lease for part of the building located at Kupferbergterrasse 15, 17019, 44116 Mainz under a lease that expires in March 31, 2022.
- Approximately 4,882 square meters (equivalent to approximately 52,549 square feet) of flexible use space under a lease for the entire building at Adam-Opel-Strasse 10, 55129 Mainz-Hechtsheim that has an initial term that expires on December 31, 2024, but which we have the option to extend until December 31, 2027. If the lease has not been terminated prior to December 31, 2024, and the option has not been exercised prior to this date, the lease will convert to an unlimited period terminable by either party on 12 months' prior written notice.
- Approximately 82,881 square meters (equivalent to approximately 892,124 square feet) of office space and a further area of land associated with this office space of approximately 12,600 square meters (equivalent to approximately 135,625 square feet), which is owned by BioNTech.
- Approximately 4,025 square meters (equivalent to 43,324 square feet) of office space under a lease for the entire building at Hechtsheimer Strasse 2,55131 Mainz-Hechtsheim, which commenced on July 1, 2019. The initial term of the lease expires on June 30, 2029, which we have the option to extend until June 30, 2034 and again until June 30, 2039.
- We also own a plot of land of approximately 8,753 square meters (equivalent to 94,216 square feet) at Hechtsheimer Strasse, 55131 Mainz.

In addition, our BioNTech IMFS facility in Idar-Oberstein, Germany, occupies approximately 2,800 square meters (equivalent to approximately 30,140 square feet). This includes 650 square meters (approximately 7,000 square feet) of clean room area, and 700 square meters (approximately 7,500 square feet) of development and quality control laboratories. We occupy approximately 575 square meters (equivalent to approximately 6,200 square feet) of this space, which is used primarily for storage, under a lease that has an initial expiry date of October 1, 2021, but which we have the right to extend by an additional five years. We occupy approximately 100 square meters (equivalent to approximately 1,075 square feet) of this space, which is used primarily for storage, under a lease that can be terminated by either party on six months' written notice (but not earlier than May 1, 2020). We occupy approximately 80 square meters (equivalent to approximately 860 square feet) of this space, which is used as office space, under a lease that can be terminated by either party on three months' written notice. The rest of this facility, including the GMP-certified manufacturing suites, is owned by BioNTech. We also recently purchased a building of approximately 802 square meters (equivalent to 8,632 square feet) near our IMFS facility in Idar-Oberstein, which will be used as office space.

At our JPT facility in Berlin, Germany, we occupy approximately 1,794 square meters (equivalent to approximately 19,299 square feet) of office, laboratory and other space. Approximately 250 square meters of that space (equivalent to approximately 2,690 square feet) is occupied under a lease which has an expiry date of June 20, 2020 and will continue for further six-month periods, unless terminated by either party on three months' prior written notice. Approximately 1,523 square meters (equivalent to approximately 16,199 square feet) are occupied under a lease for an indeterminate period of time but which may be terminated by either party on 12 months' prior written notice. The remaining approximately 20 square meters (equivalent to approximately 215 square feet) of storage space is occupied under a lease on a monthly basis and can be terminated by either party giving two weeks' written notice.

In Martinsried, Germany, outside Munich, Germany, we occupy approximately 1,681 square meters (equivalent to approximately 18,100 square feet) under a lease that has an initial term that expires on December 31, 2020, but which we have the option to extend until December 31, 2022.

In Neuried, Germany, outside Munich, Germany, we occupy approximately 725 square meters (equivalent to approximately 7,800 square feet) of laboratory and office space under a lease that expires on December 31, 2021, but which we have the option to extend until December 31, 2026. If the lease is not terminated before December 31, 2021 (where the option is not exercised) or December 31, 2026 (where the option is exercised) the lease will renew automatically for an additional one-year period until terminated by either party on 12 months' prior written notice.

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

In San Diego, we occupy approximately 14,971 square feet of laboratory and office space under a lease to part of a building located at 11535 Sorrento Valley Road, San Diego, California, that expires on February 28, 2022.

We intend to expand our capacity as follows:

- In the third quarter of 2020, we anticipate completing the construction of two new buildings at our BioNTech IMFS facility in Idar-Oberstein, Germany, which we will own, and as a result of which we will occupy an additional 780 square meters (equivalent to approximately 8,395 square feet) of clean room space and 550 square meters (equivalent to approximately 5,900 square feet) of laboratory space, expanding our capacity for GMP cell therapy manufacturing and 650 square meters (equivalent to approximately 7,000 square feet) of office space.
- We anticipate completing the construction of a new complex of building for our JPT business in Berlin, Germany, possibly as early as 2023. Upon completion of the construction project we will occupy up to approximately 5,000 additional square meters (equivalent to approximately 53,820 square feet) of useable floor space split between laboratories, offices and storage.

We are committed to the continued development of world-class laboratory as well as manufacturing operations to support our research and development as well as clinical manufacturing needs, to prepare for commercial scale manufacturing of our product candidates, and to realize external commercial opportunities. We expect to commit approximately an additional €250 million through 2023. Our planned laboratory and manufacturing investments include:

- two new buildings at our BioNTech IMFS facility, including three floors each of clean rooms and additional development and quality control laboratories;
- our planned commercial scale facility in Mainz, which will occupy more than 100,000 square feet and will house cleanrooms, laboratories and offices;
- an expansion of our JPT facility, which is designed to more than double our capacity; and
- an expansion of our laboratory space for research and development on our Mainz campus.

Item 4A. Unresolved Staff Comments

There are no written comments from the staff of the U.S. Securities and Exchange Commission which remain unresolved before the end of the fiscal year to which the Annual Report relates.

Item 5. Operating and Financial Review and Prospects

The following "Operating and Financial Review and Prospects" should be read together with the information in "Selected Consolidated Financial Data" and 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 the International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB, which may differ in material respects from generally accepted accounting principles in other jurisdictions, including U.S. GAAP. The following discussion includes forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including but not limited to those described in "Risk Factors" and elsewhere in this 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 operations for each period presented:

	Years ended December 31,		
(in thousands)	**2019**	**2018**	**2017**
Revenues from contracts with customers	108,589	€127,575	€61,598
Cost of sales	(17,361)	(13,690)	(9,318)
Gross profit	**€91,228**	**€113,885**	**€52,280**
Research and development expenses	(226,466)	(143,040)	(85,496)
Sales and marketing expenses	(2,718)	(3,041)	(6,603)
General and administrative expenses	(45,547)	(26,334)	(23,520)
Other operating income	2,724	5,396	2,349
Other operating expenses	(739)	(720)	(288)
Operating loss	**€(181,518)**	**€(53,854)**	**€(61,277)**
Finance income	4,122	8,046	2,133
Finance expenses	(326)	(48)	(26,007)
Interest expense related to lease liability	(1,718)	(1,721)	(676)
Share of loss of equity method investees	-	(84)	(78)
Loss before tax	**€(179,440)**	**€(47,662)**	**€(85,905)**
Income taxes	268	(600)	(45)
Loss for the period	**€(179,172)**	**€(48,262)**	**€(85,950)**

Revenue

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

The following is a summary of revenue recognized for the periods indicated:

	Years ended December 31,		
(in thousands)	**2019**	**2018**	**2017**
Revenues from contracts with customers			
Revenues resulting from collaboration and license agreements	€84,428	€101,837	€42,333
Revenues from other sales transactions	24,161	25,738	19,265
Total revenues from contracts with customers	**€108,589**	**€127,575**	**€61,598**

The following table summarizes our collaboration revenue for the periods indicated:

	Years ended December 31,		
(in thousands)	**2019**	**2018**	**2017**
Revenues resulting from collaboration and license agreements			
Genentech Inc.	€64,026	€49,536	€27,829
Pfizer Inc.	14,348	7,174	-
Sanofi S.A.	4,233	41,712	5,665
Genmab A/S	-	2,740	6,765
Eli Lilly and Company	1,821	676	2,074
Total revenues resulting from collaboration and license agreements	**€84,428**	**€101,837**	**€42,333**

Our collaboration revenue consists of milestone payments, upfront licensing payments and reimbursement of development expenses. Certain of these payments are initially recorded on our statement of financial position and are subsequently recognized as revenue in accordance with our accounting policy as described further in "—Critical Accounting Policies and Use of Estimates" and Note 2.3.4 to our consolidated financial statements included elsewhere in this Annual Report. From the year ended December 31, 2018 to the year ended December 31, 2019 the total revenues resulting from collaboration and license agreements decreased from €101.8 million to €84.4 million. From the year ended December 31, 2017 to the year ended December 31, 2018 the total revenues resulting from collaboration and license agreements increased from €42.3 million to €101.8 million. The revenue recognized in the year ended December 31, 2018 included an amount of €33.2 million collaboration revenue from our Sanofi collaboration for a reimbursement of 50% of CellScript sublicense costs pursuant to a separate sub-sublicense agreement dated December 22, 2018. This transaction only occurred in the year ended December 31, 2018. Our collaborations with Bayer and Genevant did not result in any revenue in the years ended December 31, 2019, December 31, 2018 and December 31, 2017.

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

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

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

Cost of Sales

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

The following table summarizes our cost of sales for the periods indicated:

	Years ended December 31,		
(in thousands)	**2019**	**2018**	**2017**
Cost of sales			
Wages, benefits and social security expense	€7,206	€6,726	€6,105
Laboratory supplies	3,845	1,368	2,849
Purchased services	1,986	2,514	-
Depreciation and amortization	1,467	1,367	-
Other	2,857	1,715	364
Total cost of sales	**€17,361**	**€13,690**	**€9,318**

Research and Development Expenses

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

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

The costs above comprise the following categories:

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

The following table summarizes our research and development expenses for the periods indicated:

	Years ended December 31,		
(in thousands)	**2019**	**2018**	**2017**
Research and development expenses			
Wages, benefits and social security expense	€83,213	€45,668	€31,970
Purchased services	65,552	42,079	22,686
Laboratory supplies	37,218	22,921	15,762
Depreciation and amortization	27,533	18,312	9,859
Lease and lease related cost	2,527	2,404	3,475
IT costs	3,800	1,572	366
Travel costs	1,546	1,281	776
Transport costs	1,081	668	396
Job advertisement expenses	1,040	352	-
Other	2,956	7,783	206
Total research and development expenses	**€226,466**	**€143,040**	**€85,496**

The largest component of our total operating expenses has historically been our investment in research and development activities, including development of our platforms and manufacturing technologies. We cannot reasonably estimate the nature, timing and amount of research and development expenses required to complete the development of the product candidates we are currently developing or may develop in the future. A change in expectations or outcomes of any of the known or unknown risks and uncertainties may materially impact our expected research and development expenditures.

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

Research and development expenses increased from €143.0 million during the year ended December 31, 2018 to €226.5 million during the year ended December 31, 2019 mainly due to an increase in wages, benefits and social security expenses due to an increase in headcount and the full-year reflection of the ESOP program expenses during the year ended December 31, 2019 as well as higher development expenses spent on purchased services and laboratory supplies.

Research and development expenses increased from €85.5 million during the year ended December 31, 2017 to €143.0 million during the year ended December 31, 2018 which was mainly due to an increase in wages, benefits and social security expenses and higher development expenses spent especially on purchased services and laboratory supplies.

Sales and Marketing Expenses

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

Sales and marketing expenses amounted to €2.7 million in the year ended December 31, 2019, €0.2 million of which constituted expenses for purchased services. Sales and marketing expenses amounted to €3.0 million in the year ended December 31, 2018, €0.8 million of which constituted expenses for purchased services.

Our sales and marketing expenses amounted to €6.6 million in the year ended December 31, 2017, €2.8 million of which constituted expenses for purchased services.

General and Administrative Expenses

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

The following table summarizes our general and administrative expenses for the periods indicated:

	Years ended December 31,		
(in thousands)	**2019**	**2018**	**2017**
General and administrative expenses			
Wages, benefits and social security expense	€19,122	€8,582	€9,861
Purchased services	6,419	5,177	3,544
IT and office equipment	4,573	3,774	2,706
Depreciation and amortization	4,855	2,284	630
Lease and lease related cost	1,715	1,012	1,611
Travel costs	1,391	1,043	247
Insurance premiums	1,061	145	99
Laboratory supplies	785	456	63
Job advertisement expenses	548	861	719
Other	5,078	3,000	4,039
Total general and administrative expenses	**€45,547**	**€26,334**	**€23,520**

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

General and administrative expenses increased from €26.3 million during the year ended December 31, 2018 to €45.5 million during the year ended December 31, 2019. This increase was mainly influenced by an increase in headcount and the full-year reflection of the ESOP program expenses during the year ended December 31, 2019 as well as a charge of €2.6 million in connection with certain withholding tax payments for intellectual property licenses related to prior years that was recorded during the year ended December 31, 2019 but not during the year ended December 31, 2018.

General and administrative expenses increased from €23.5 million during the year ended December 31, 2017 to €26.3 million during the year ended December 31, 2018. The relatively small increase is influenced by offsetting effects. Whereby the costs for purchased services as well as IT and office equipment increased, the costs of wages, benefits and social security expenses as well as office costs decreased.

Other Operating Income (Expenses)

Our other operating income consists primarily of government grants. In the year ended December 31, 2019, our other operating income amounted to €2.7 million, €1.5 million of which constituted government grants. In the year ended December 31, 2018, our other operating income amounted to €5.4 million, €4.2 million of which constituted government grants. In the year ended December 31, 2017, our other operating income amounted to€2.3 million, most all of which was attributable to government grants.

Finance Income (Expenses)

Our finance income consists of interest income on cash and foreign exchange gains. In the year ended December 31, 2019, our finance income amounted to €4.1 million, €2.3 million of which were attributable to unrealized foreign exchange gains. In the year ended December 31, 2018, our finance income amounted to €8.0 million, €6.1 million of which were attributable to unrealized foreign exchange gains. In the year ended December 31, 2017, no foreign exchange gains were reported under finance income and our finance income amounted to €2.1 million.

In the year ended December 31, 2019, our finance expense amounted to €0.3 million. In the year ended December 31, 2018, our finance expense amounted to €48 thousand. In both years, no foreign exchange losses were reported under finance expense. In the year ended December 31, 2017, our finance expense amounted to €26.0 million, most of which was attributable to unrealized foreign exchange losses resulting from unhedged U.S. dollar cash accounts.

Tax Losses

We have accumulated tax losses with respect to corporate tax and trade tax. As at December 31, 2019, our accumulated tax losses amounted to €356.0 million with respect to corporate tax and €352.3 million with respect to trade tax. We had accumulated tax losses of €179.3 million with respect to corporate tax and €176.4 million with respect to trade tax as at December 31, 2018. We had accumulated tax losses of €178.5 million with respect to corporate tax and €176.0 million with respect to trade tax as at December 31, 2017.

Deferred tax assets on tax losses have not been capitalized as there is not sufficient probability in terms of IAS 12 that there will be future taxable profits available against which the unused tax losses can be utilized. The accumulated tax losses as at December 31, 2019 relate to Germany and the United States (as at December 31, 2018 and December 31, 2017: Germany). There is no expiration date for any of the accumulated tax losses under German or US tax law.

Information About Our Business Units and Operating Segments

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

- The **Clinical** segment contains all development activities relating to clinical programs. Clinical trials include testing the product candidates on humans. Clinical trials are an essential part of the development and licensing of the pharmaceutical products and are performed before the respective product can be placed on the market. We are actively engaged in many collaborations and licensing deals with leading pharmaceutical companies and academic collaborators.
- The **Technology Platform** segment contains all development activities relating to preclinical programs. Preclinical development is the stage of research that begins before clinical trials. It is performed to determine the desired pharmacological effects and to identify any unwanted effects that may cause adverse reactions during human exposure.
- The **Manufacturing** segment is an essential part of the research and development process as it includes the manufacturing unit of mRNA and engineered cell therapies. All of the medical substances and tools that form the basis for the research studies performed by BioNTech are manufactured in this segment (*i.e.*, the Manufacturing segment contains only internally produced substances and tools).

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

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

Biotech Business Unit

The following table summarizes the statements of operations of our biotech business unit, consisting of the Clinical, Technology Platform and Manufacturing segments and the associated business services operations for each period presented:

	Years ended December 31,		
(in thousands)	**2019**	**2018**	**2017**
Revenues	€85,122	€108,662	€42,657
Cost of sales	-	(40)	-
Gross profit	**€85,122**	**€108,622**	**€42,657**
Research and development expenses	(226,305)	(142,448)	(83,583)
Sales and marketing expenses	(1,302)	(2,106)	(4,904)
General and administrative expenses	(42,577)	(23,791)	(21,094)
Other result	1,514	4,065	1,598
Operating loss	**€(183,548)**	**€(55,659)**	**€(65,326)**

Comparison of the year ended December 31, 2019 and year ended December 31, 2018

Revenue

The following table summarizes the revenue of our biotech business unit by segment for each period presented:

	Years ended December 31,		Change	
(in thousands)	**2019**	**2018**	**€**	**%**
Revenues				
Clinical	€33,493	€36,750	€(3,257)	(9)
Technology Platform	2,839	46,235	(43,396)	(94)
Manufacturing	48,790	25,635	23,155	90
Business Service	-	42	(42)	(100)
Total unit revenues	**€85,122**	**€108,662**	**€(23,540)**	**(22)**

Revenue of our biotech business unit decreased by €23.5 million, or 22%, to €85.1 million in the year ended December 31, 2019 from €108.7 million in the year ended December 31, 2018. The decrease was primarily driven by the decline of revenues of the Technology Platform segment which was partially offset by the increase in collaboration revenue generated in the Manufacturing segment.

The decrease in revenue in our Clinical segment of €3.3 million from €36.8 million in the year ended December 31, 2018, to €33.5 million in the year ended December 31, 2019, was due to decreased collaboration revenue with Genmab due to the fact that the remaining upfront payments received were completely recognized as revenue during the year ended December 31, 2018 with an amount of €2.7 million. The collaboration revenue generated from the Pfizer agreement increased by €7.2 million in the year ended December 31, 2019 compared to the year ended December 31, 2018 given that twelve months compared to six months straight-line allocation of revenue were generated from the upfront payment received under this collaboration. Nevertheless, this increase was offset by a decrease in collaboration revenue generated with Genentech of €8.7 million.

The decrease in revenue in our Technology Platform segment of €43.4 million from €46.2 million in the year ended December 31, 2018, to €2.8 million in the year ended December 31, 2019, was primarily due to a reimbursement of 50% of CellScript sublicense costs in 2018 (€33.2 million) pursuant to a separate sub-sublicense agreement dated December 22, 2018 and the occurrence of the Transfer and License Agreement with Ganymed for Bispecific Antibodies in the year ended December 31, 2018 (€3.9 million), which both did not reoccur in the year ended December 31, 2019.

The increase in revenue in our Manufacturing segment of €23.2 million from €25.6 million in the year ended December 31, 2018, to €48.8 million in the year ended December 31, 2019, was driven by our collaboration agreement with Genentech. Given that the respective revenues are recognized based on costs the increase is due to higher manufacturing costs of the investigational medicinal product that correlate with higher patient enrollment in the ongoing clinical trials.

Research and Development Expenses

The following table summarizes the research and development expenses of our biotech business unit by segment for each period presented:

	Years ended December 31,		Change	
(in thousands)	**2019**	**2018**	**€**	**%**
Research and development expenses				
Clinical	€91,516	€48,641	€42,875	88
Technology Platform	79,119	60,320	18,799	31
Manufacturing	50,478	31,508	18,970	60
Business Service	5,192	1,979	3,213	162
Total unit research and development expenses	**€226,305**	**€142,448**	**€83,857**	**59**

Research and development expenses of our biotech business unit increased by €83.9 million, or 59%, to €226.3 million in the year ended December 31, 2019 from €142.4 million in the year ended December 31, 2018. This increase was due to an increase in headcount, the full-year reflection of the ESOP program and higher expenses incurred in our collaboration agreements.

The following table summarizes our clinical research and development expenses, broken down by drug class and selected platforms, for each period presented:

	Years ended December 31,		Change	
(in thousands)	**2019**	**2018**	**€**	**%**
Clinical research and development expenses				
mRNA				
FixVac	€11,025	€3,018	€8,007	265
iNeST	23,730	13,335	10,395	78
Other mRNA	25,110	9,441	15,669	166
Total mRNA	59,865	25,794	34,071	132
Engineered Cell Therapies	1,616	653	963	147
Antibodies	18,010	14,353	3,657	25
Small Molecule Immunomodulators	2,303	1,497	806	54
Other	9,722	6,344	3,378	53
Total clinical research and development expenses	**€91,516**	**€48,641**	**€42,875**	**88**

The €15.7 million increase in other mRNA clinical research and development expenses mainly relates to collaboration agreements and license programs with partners that were initiated in the fourth quarter of 2018 and therefore affected the year ended December 31, 2019 for twelve months compared to three months in the year ended December 31, 2018. Other mRNA expenses for the year ended December 31, 2019 was primarily comprised of €7.0 million RiboCytokines project costs, €4.8 million Infectious Disease Vaccines costs, €4.7 million Intratumoral Immunotherapy costs, €3.5 million RiboMabs platforms costs and €2.0 million Protein Replacement Therapy costs. Other mRNA expenses for the year ended December 31, 2018 was primarily comprised of €2.8 million Intratumoral Immunotherapy costs, €2.6 million RiboCytokines project costs, €2.1 million RiboMabs platforms costs.

Other clinical research and development expenses primarily consist of share-based compensation, which is not directly related to individual drug classes and platforms.

Sales and Marketing Expenses

Sales and marketing expenses of our biotech business unit decreased by €0.8 million, or 38%, to €1.3 million in the year ended December 31, 2019 from €2.1 million in the year ended December 31, 2018. This decrease was primarily due to a reduction of purchased sales and marketing services.

General and Administrative Expenses

General and administrative expenses of our biotech business unit increased by €18.8 million, or 79%, to €42.6 million in the year ended December 31, 2019 from €23.8 million in the year ended December 31, 2018. This increase was due to an increase in headcount, the full-year reflection of expenses recognized from the granting of options under the ESOP program, expense for withholding tax related to prior years, increased purchased administrative services and insurance premiums as well as increased depreciation.

Other Result

The other result of our biotech business unit decreased by €2.6 million, or 63%, to €1.5 million in the year ended December 31, 2019 from €4.1 million in the year ended December 31, 2018. This decrease was primarily attributable to a decrease in government grants.

Comparison of the year ended December 31, 2018 and December 31, 2017

Revenue

The following table summarizes the revenue of our biotech business unit by segment for each period presented:

	Years ended December 31,		**Change**	
(in thousands)	**2018**	**2017**	**€**	**%**
Revenues				
Clinical	€36,750	€25,721	€11,029	43
Technology Platform	46,235	14,828	31,407	212
Manufacturing	25,635	2,108	23,527	1,116
Business Service	42	-	42	-
Total unit revenues	**€108,662**	**€42,657**	**€66,005**	**155**

Revenue of our biotech business unit increased by €66.0 million, or 155%, to €108.7 million in the year ended December 31, 2018 from €42.7 million in the year ended December 31, 2017. This increase was due to a significant increase in the revenue recognition of our collaboration revenue, particularly with respect to our collaborations with Genentech (in the Clinical and Manufacturing segments) and Sanofi, as well as revenue from our collaboration with Pfizer, which was entered into in 2018. In the Technology Platform segment, the revenue recorded during the year ended December 31, 2018 included €3.9 million for outlicensing patents and know-how to a third party. No further payments are due.

Research and Development Expenses

The following table summarizes the research and development expenses of our biotech business unit by segment for each period presented:

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

Research and development expenses of our biotech business unit increased by €58.9 million, or 70%, to €142.4 million in the year ended December 31, 2018 from €83.6 million in the year ended December 31, 2017. This increase was primarily due to increase in clinical development activities, manufacturing for the iNeST clinical study supply and increased headcount.

The following table summarizes our clinical research and development expenses, broken down by drug class and selected platforms, for each period presented:

	Years ended December 31,		Change	
(in thousands)	**2018**	**2017**	**€**	**%**
Clinical research and development expenses				
mRNA				
FixVac	€3,018	€2,539	€479	19
iNeST	13,335	17,223	(3,888)	(23)
Other mRNA	9,441	3,124	6,317	202
Total mRNA	25,794	22,886	2,908	13
Engineered Cell Therapies	653	2,213	(1,560)	(70)
Antibodies	14,353	-	14,353	-
Small Molecule Immunomodulators	1,497	-	1,497	-
Other	6,344	-	6,344	-
Total clinical research and development expenses	**€48,641**	**€25,099**	**€23,542**	**94**

Other clinical research and development expenses primarily consist of share-based compensation, which is not directly related to individual drug classes and platforms.

Sales and Marketing Expenses

Sales and marketing expenses of our biotech business unit decreased by €2.8 million, or 57%, to €2.1 million in the year ended December 31, 2018 from €4.9 million in the year ended December 31, 2017. This decrease was primarily due to a reduction of purchased sales and marketing services.

General and Administrative Expenses

General and administrative expenses of our biotech business unit increased by €2.7 million, or 13%, to €23.8 million in the year ended December 31, 2018 from €21.1 million in the year ended December 31, 2017. This increase was primarily due to increased purchased administrative services, information technology and office equipment as well as increased depreciation.

Other Result

The other result of our biotech business unit increased by €2.5 million, or 154%, to €4.1 million in the year ended December 31, 2018 from €1.6 million in the year ended December 31, 2017. This increase was primarily attributable to an increase in government grants.

External Services Business Unit

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

	Years ended December 31,		
(in thousands)	**2019**	**2018**	**2017**
Revenues	€23,467	€18,914	€18,941
Cost of sales	(16,923)	(13,358)	(9,318)
Gross profit	**€6,544**	**€5,556**	**€9,623**
Research and development expenses	(600)	(884)	(1,912)
Sales and marketing expenses	(1,415)	(935)	(1,698)
General and administrative expenses	(2,970)	(2,542)	(2,427)
Other result	468	559	463
Operating income	**€2,027**	**€1,753**	**€4,049**

Our external services business unit's operating income increased by €0.2 million, or 11%, to €2 million in the year ended December 31, 2019 from €1.8 million in the year ended December 31, 2018. This increase was mainly due to an increase in revenues. Our external services business unit's operating income decreased by €2.2 million, or 55%, to €1.8 million in the year ended December 31, 2018 from €4.0 million in the year ended December 31, 2017. The decrease in operating income was primarily attributable to an increase in cost of sales by €4.1 million, or 44%, partially offset by a decrease in research and development and sales and marketing expenses in 2018 by €1.8 million, or 50%.

Related Party Transactions

Related party transactions that occurred during the years ended December 31, 2019 and December 31, 2018 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.

Definitive Merger Agreement with Neon Therapeutics, Inc.

On January 16, 2020, BioNTech and Neon Therapeutics, Inc. (listed on the Nasdaq) have entered into a definitive merger agreement, under which BioNTech will acquire Neon in an all-stock transaction valued at approximately $67.0 million (also referred to as “Merger”). Neon is a biotechnology company developing novel neoantigen-based T cell therapies. The transaction will combine two organizations with a common culture of pioneering translational science and a shared vision for the future of cancer immunotherapy. The Merger is conditioned upon, among other things, the approval of the Merger Agreement by the shareholders of Neon and other customary closing conditions. At closing, BioNTech will issue, and Neon shareholders will receive, 0.063 of BioNTech’s American Depositary Shares, or ADSs, in exchange for each of their shares of Neon. This exchange ratio will not be adjusted for changes in the market price of either our ADSs or Neon common stock between the date the Merger Agreement was signed and completion of the Merger. As a result, changes in the price of our ADSs prior to the completion of the Merger will affect the value of our ADSs delivered upon completion of the Merger.

Impact of COVID-19

We are closely monitoring the potential impact of COVID-19 on our business. The COVID-19 pandemic could affect our ability to enroll patients in clinical studies and complete clinical trials on the timelines we currently anticipate. In

addition, our suppliers, licensors, CROs and collaborators could also be disrupted by conditions related to COVID-19, possibly resulting in disruption to our supply chain, clinical trials, partnerships or operations. Our operations, including research and manufacturing, could also be disrupted due to the potential of the impact of staff absences as a result of self-isolation procedures or extended illness. It is not possible at this time to predict the likelihood, timing or severity of the aforementioned direct and indirect impacts of COVID-19 on our business.

Critical Accounting Policies and Use of Estimates

Our consolidated financial statements for the years ended December 31, 2019 and December 31, 2018have been prepared in accordance with IFRS, as issued by the IASB.

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

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

Revenue Recognition

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

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

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

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

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

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

Share-Based Compensation

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

The cost of equity-settled transactions is determined by the fair value at the grant date. These costs are recognized in 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), over the period in which the service is provided (the vesting period). The cumulative expense recognized for equity-settled transactions at each reporting date until the vesting date reflects the extent to which the vesting period has expired and our best estimate of the number of equity instruments that will ultimately vest. The expenses or credits in the statement of operations for a period represent the movement in cumulative expense recognized as at the beginning and end of that period.

Fair Value of Share-Based Awards

Employee Stock Ownership Plan

On November 15, 2018, we established a share option program that grants selected employees options to receive shares in the Company. The program is designed as an Employee Stock Ownership Plan and option grants are classified as share-based equity-settled remuneration. As at December 31, 2019, we had options outstanding representing 11,796,894 ordinary shares with a weighted-average exercise price of €10.23.

The following share options outstanding as per December 31, 2019 have been issued to the management board:

	Share options outstanding	Number of Ordinary Shares underlying options	Weighted average exercise price (€)
Prof. Dr. Ugur Sahin, M.D.	101,686	1,830,348	10.14
Sean Marett	33,895	610,110	10.14
Dr. Sierk Poetting, Ph.D.	33,895	610,110	10.14
Dr. Özlem Türeci, M.D.	108,463	1,952,334	10.14

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

The option rights generally fully vest after four years (except that Dr. Türeci's option vested on March 16, 2019 and except for one similar arrangement in the case of one other senior employee) and can only be exercised if: (i) the waiting period of four years has elapsed; and (ii) at the time of exercise, the average closing price of the shares of the Company or the average closing price of the right or certificate to be converted into an amount per share in the ten trading days preceding the exercise of the option right exceeds the strike price by a minimum of 32%, with this percentage increasing by eight percentage points as of the fifth anniversary of the respective issue date and as of each subsequent anniversary date. The option rights will be forfeited without compensation if not exercised within eight years after the allocation date. Both of these conditions have been incorporated into the fair value at grant date.

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

	Grant date 15 November 2018	Grant dates between February 21 - April 3, 2019	Grant dates between April 29 - May 31, 2019	Grant date December 1, 2019
Weighted average fair value	€7.41	€6.93	€7.04	€9.49
Weighted average share price	€14.40	€15.72	€16.03	€19.84
Exercise price	€10.14	€15.03	€15.39	€15.82
Expected volatility (%)	46.0%	46.0%	46.0%	46.0%
Expected life (years)	5.84	6.00	6.00	5.50
Risk-free interest rate (%)	0.05%	0.05%	0.05%	0.05%

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

2019 Chief Executive Officer Grant

In September 2019, we agreed to grant Prof. Ugur Sahin, M.D. an option to purchase 4,374,963 of our ordinary shares, subject to Prof. Sahin's continuous employment with us.

The options' per share exercise price is the Euro translation of the public offering price from our initial public offering, €13.60 ($15.00). The option will vest annually in equal installments after four years commencing on the first anniversary of our initial public offering and will be exercisable four years after our initial public offering. The option will be subject to the terms, conditions, definitions and provisions of our ESOP and the applicable option agreement thereunder. The vested option rights can only be exercised if and to the extent that each of the following performance criteria has been achieved: (i) at the time of exercise, the current price is equal to or greater than the threshold amount (that is, the exercise price, provided that such amount increases by seven percentage points on each anniversary of the allocation date); (ii) at the time of exercise, the current price is at least equal to the target price (that is, (a) for the twelve-month period starting on the fourth anniversary of the allocation date, $8.5 billion divided by the total number of the shares outstanding immediately following the initial public offering (other than shares owned by us), and (b) for each twelve-month period starting on the fifth or subsequent anniversary of the allocation date, 107% of the target share price applicable for the prior twelve-month period); and (iii) the closing price for the fifth trading day prior to the start of the relevant exercise window is higher than the exercise price by at least the same percentage by which the Nasdaq Biotechnology Index or a comparable successor index as of such time is higher than such index was as of the last trading day before the allocation date. The Option Rights can be exercised at the latest ten years after the Allocation Date. If they have not been exercised by that date, they will lapse without compensation.

A Monte-Carlo simulation model has been used to measure the fair value at grant date of the 2019 Employee Stock Ownership Plan. This model incorporates the impact of the performance criteria regarding share price and index development described above in the calculation of the award's fair value at grant date. The inputs used in the measurement of the fair value at grant date of the 2019 Employee Stock Ownership Plan were as follows:

	Grant date October 10, 2019
Weighted average fair value	€5.63
Weighted average share price	€13.60
Exercise price	€13.60
Expected volatility (%)	41.4%
Expected life (years)	5.37
Risk-free interest rate (%)	1.52 %

The options' per share exercise price is the Euro translation of the public offering price from BioNTech's initial public offering on October 10, 2019. Expected volatility was based on an evaluation of the historical volatilities of comparable companies over the historical period commensurate with the expected term. The expected term was based on general option holder behavior for employee options.

Taxes

Deferred tax assets are recognized for unused tax losses only to the extent that it is probable that taxable profit will be available against which the losses can be utilized. Significant management judgement is required to determine the amount of deferred tax assets that can be recognized, based upon the likely timing and the level of future taxable profits, together with future tax planning strategies.

The Group has tax losses carried forward and these losses relate to subsidiaries that have a history of losses. The subsidiaries neither have any taxable temporary difference nor any tax planning opportunities available that could partly support the recognition of these losses as deferred tax assets.

On this basis, the Group has determined that it cannot recognize deferred tax assets on the tax losses carried forward.

For further disclosures relating to deferred taxes, see Note 8 of our consolidated financial statements included elsewhere in this Annual Report.

B. 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.

C. Trend Information

See the description of "Operating Results" in this Item 5 within this Annual Report.

D. Liquidity and Capital Resources

We have historically funded our operations primarily from private placements of our ordinary shares, proceeds from collaborators and services and proceeds from secured bank loans. As of December 31, 2019, we had cash and cash equivalents of €519.1 million. Cash and cash equivalents are invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation, and consist primarily of cash in banks and on hand and short-term deposits with an original maturity of three months or less, which are stated at fair value.

We maintain two secured loans with Deutsche Bank AG, or Deutsche Bank, to finance the buildout of our JPT Peptide Technologies GmbH facility and Innovative Manufacturing Services GmbH (IMFS) facility. Our €10.0 million secured credit facility, entered into with Deutsche Bank by our subsidiary BioNTech Innovative Manufacturing Services GmbH, bears interest at a rate of 2.15% and matures on December 30, 2027. We have drawn €9.0 million under this facility as of December 31, 2019. The loan is repayable in equal quarterly installments of €312.5 thousand commencing on March 31, 2020. Our €9.45 million secured credit facility, entered into with Deutsche Bank by our subsidiary JPT Peptide Technologies GmbH, bears interest at a rate of 2.08% and matures on September 30, 2028. We have drawn €7.6 million as of December 31, 2019. The loan is repayable by quarterly installments of €286.4 thousand commencing on September 30, 2020. The loan is drawn on predetermined dates. Each of these facilities is secured by liens over our property.

In December 2019, we have signed a financing arrangement with The European Investment Bank, or the EIB, to partially support the implementation of certain technical aspects of our investment in the development of patient-tailored therapeutic vaccines for cancer in Germany, or the Investment. Under this arrangement, the EIB has agreed to provide BioNTech with a credit in an amount of up to €50 million to partially finance the Investment, provided that the amount of credit does not exceed 50% of the cost of the Investment. The credit consists of (i) a term loan in the amount of €25 million that may be drawn in a single tranche upon the achievement of certain milestone events, not all of which have been achieved (Credit A), and (ii) a term loan in the amount of €25 million that may be drawn in a maximum of four tranches each of which must be for a minimum of €5 million or the balance of the remaining facility (Credit B). Tranches under Credit B may only be drawn after Credit A has been drawn down and upon the achievement of certain milestone events. Each tranche under Credit A and Credit B must be repaid within six years from the date on which the tranche is disbursed

to us. Interest is payable on the outstanding balance of Credit A at the cash interest fixed rate of 1% per annum quarterly in arrears, plus deferred interest at fixed rate of 5% per annum. We pay interest on the outstanding balance of Credit B at the cash interest fixed rate of 2% per annum quarterly in arrears. In addition, we are obligated to pay the EIB a tiered proportion of drug product revenues received by us ranging from less than single-digit to low single-digit percentages. The profit participation right will end at the end of a six-year period beginning in 2023 or when the EIB has received €15 million in profit participation payments, whichever occurs first. The financing arrangement is to be secured by way of liens over certain of our property.

Cash Flow

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

	Years ended December 31,		
(in thousands)	**2019**	**2018**	**2017**
Net cash flows from (used in):			
Operating activities	€(198,537)	€(58,877)	€(52,562)
Investing activities	(77,115)	(66,452)	(52,549)
Financing activities	383,290	365,177	(1,643)
Exchange rate differences	16	(459)	(24,820)
Total cash inflow	**€107,654**	**€239,389**	**€(131,574)**

Operating Activities

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

Net cash used in operating activities for the year ended December 31, 2019 was €198.5 million, comprising a loss before tax of €179.4 million, non-cash adjustments of €65.0 million, and a net negative change in assets and liabilities of €83.4 million. Non-cash items primarily included depreciation and amortization as well as share-based compensation expenses. The net negative change in assets and liabilities was primarily due to a decrease in contract liabilities and trade payables.

Net cash used in operating activities for the year ended December 31, 2018 was €58.9 million, comprising a loss before tax of €47.7 million, non-cash adjustments of €29.9 million, and a net negative change in assets and liabilities of €41.1 million. Non-cash items primarily included depreciation and amortization as well as share-based compensation expenses. The net negative change in assets and liabilities was primarily due to an increase in trade receivables and a decrease in payables and liabilities.

The increase in net cash used in operating activities from the year ended December 31, 2018 to the year ended December 31, 2019 was primarily due to an increase in amounts spent for wages, benefits and social security expenses as headcount increases and higher research and development expenditures.

Net cash used in operating activities for the year ended December 31, 2017 was €52.6 million, comprising a loss before tax of €85.9 million, non-cash adjustments of €39.9 million, and a net negative change in assets and liabilities of €8.0 million. Non-cash items primarily included depreciation and amortization as well as share-based compensation expenses. The net negative change in assets and liabilities was primarily due to a decrease in payables and liabilities.

Investing Activities

Net cash used in investing activities for the year ended December 31, 2019 was €77.1 million, of which €32.5 million was attributable to the purchase of intangible assets, including the final installment payment for the license agreement for the CellScript patent, €38.6 million was attributable to the purchase of property, plant and equipment, partially offset by

proceeds from the sale of property, plant and equipment amounting to k€21and €6.1 million were attributable to the acquisition of MAB Discovery GmbH's operational antibody generation unit based near Munich, Germany.

Net cash used in investing activities for the year ended December 31, 2018 was €66.5 million, of which €37.3 million was attributable to the purchase of intangible assets, including payment for the license agreement for the CellScript patent, and €29.9 million was attributable to the purchase of property, plant and equipment, partially offset by proceeds from the sale of property, plant and equipment amounting to k€705.

Net cash used in investing activities for the year ended December 31, 2017 was €52.5 million, of which €33.4 million was attributable to the purchase of intangible assets, including payment for the license agreement for the CellScript patent, and €24.3 million was attributable to the purchase of property, plant and equipment, partially offset by proceeds from the sale of property, plant and equipment amounting to €5.2 million.

Financing Activities

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

During the year ended December 31, 2019, we generated cash from financing activities of €383.3 million, primarily from proceeds from the issuance of shares in the amount of €375.4 million and proceeds from loans and borrowings in the amount of €11.0 million, partially offset by the payment of finance lease liabilities in the amount of €3.1 million.

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

We had insignificant financing activities during the year ended December 31, 2017.

Operation and Funding Requirements

Since our inception, we have incurred significant losses and negative cash flows from operations due to our significant research and development expenses and our investment in our manufacturing capabilities. We have accumulated losses of €424.8 million as of December 31, 2019 and €245.8 million as of December 31, 2018. We expect to continue to incur significant losses in the foreseeable future and expect our expenses to increase in connection with our ongoing activities, particularly as we continue research and development and clinical activities for our product candidates. Our expenses will also increase if, and as, we:

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

- seek to identify and validate additional product candidates;
- acquire or in-license other product candidates and technologies;
- make milestone or other payments under any in-license agreements;
- maintain, protect, defend, enforce and expand our intellectual property portfolio; and
- experience any delays or encounter issues with any of the above.

We are subject to all of the risks related to the development and commercialization of pharmaceutical products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. We believe that our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements into the third quarter of 2021.

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

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

E. Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

F. Tabular Disclosure of Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2019 and the effects that such obligations are expected to have on our liquidity and cash flows in future periods:

Year ended December 31, 2019

(in thousands)	**Less than 1 year**	**1 to 3 years**	**3 to 5 years**	**More than 5 years**	**Total**
Interest bearing loans and borrowings	€2,220	€5,448	€5,245	€8,355	€21,268
Lease liabilities	5,176	9,712	8,170	55,852	78,910
Total	**€7,396**	**€15,160**	**€13,415**	**€64,207**	**€100,178**

We have lease agreements for land and buildings in all of our locations, which will expire from 2021 to 2042. In addition, we have various leases for equipment and cars which will expire from 2020 to 2022. The amounts in the table above represent our fixed undiscounted contractual lease obligations and do not include the optional extensions.

G. Safe Harbor

See the beginning of this Item as well as also see “Cautionary Statement Regarding Forward-Looking Statements” included elsewhere in this Annual Report.

Item 6. Directors, Senior Management and Employees

A. Directors and Senior Management

Management Board and Supervisory Board

Management Board (*Vorstand*)

The following table sets forth the names and functions of the current members of our Management Board, their ages as of January 12, 2020 and their terms:

Name	Age	Term Expires	Position
Prof. Ugur Sahin, M.D.	54	2022	Chief Executive Officer
Sean Marett	54	2022	Chief Business Officer and Chief Commercial Officer
Dr. Sierk Poetting	46	2022	Chief Financial Officer and Chief Operating Officer
Dr. Özlem Türeci	52	2022	Chief Medical Officer
Ryan Richardson	40	2022	Chief Strategy Officer

The business address of the members of our Management Board is the same as our business address: An der Goldgrube 12, D-55131 Mainz, Germany.

The following is a brief summary of the business experience of the members of our Management Board:

Prof. Ugur Sahin, M.D. co-founded BioNTech in 2008 and has served as our Chief Executive Officer since that time. Prof. Sahin also served as the head of the Scientific Advisory Board of Ganymed Pharmaceuticals AG from 2008 until the company was acquired by Astellas Pharma Inc., or Astellas, in 2016. In 2010, Prof. Sahin co-founded TRON, and served as a Managing Director from 2010 until 2019. Prof. Sahin has also been a professor (W3) at the Mainz University Medical Center since 2014. Prof. Sahin co-founded the Ci3, the German Cluster Initiative of Individualized ImmunIntervention (Ci3), a non-profit organization. Prof. Sahin earned an M.D. in 1990 from the University of Cologne. Prof. Sahin is married to Dr. Özlem Türeci.

Sean Marett joined BioNTech in 2012. Prior to joining BioNTech, he worked in global strategic and regional marketing and sales roles at GlaxoSmithKline in the United States and Pfizer in Europe before taking business development executive roles at Evotec and Lorantis, the latter of which he helped to successfully sell to Celldex Therapeutics, Inc. He has successfully executed complex licensing transactions with large pharmaceutical companies, negotiated M&A transactions and raised finance from investors. Mr. Marett built and ran a contract clinical manufacturing organization with operations across Europe and the United States for over half a decade for the contract manufacturer, NextPharma. Mr. Marett has been Chairman of PHMR Ltd, a company specializing in market access and pharmaceutical reimbursement, since 2017. He previously held non-executive directorship of KWS BioTest Ltd (successfully sold to Charles River) from 2011 until 2018 and was a member of the investment committee of Mann BioInvest Ltd, a fund dedicated to biotechnology and pharmaceutical company investments from 2013 until 2016. He holds a BSc (Hons) in Biochemistry from Kings College London and an MBA from Manchester Business School.

Dr. Sierk Poetting is our Chief Financial Officer and Chief Operating Officer. Dr. Poetting joined BioNTech in September 2014 from Novartis, where he served from May 2012 to August 2014 as Vice President and Chief Financial Officer for the Sandoz Division in North America. Dr. Poetting started his career as a consultant with McKinsey & Company. A German citizen, Dr. Poetting holds a Master of Science in Optical Sciences from the University of Arizona and a Ph.D. in Physics from the Ludwig-Maximilians University in Munich.

Dr. Özlem Türeci is our Chief Medical Officer. Dr. Türeci joined BioNTech in 2008 as a clinical and scientific advisory board member, before becoming our Chief Medical Officer in 2018. Dr. Türeci co-founded Ganymed Pharmaceuticals, now a subsidiary of Astellas, in 2001 as Chief Scientific Officer and became its Chief Executive Officer in 2008. Dr. Türeci is chairman and co-initiator of Ci3. Dr. Türeci is also President of the Association for Cancer Immunotherapy (CIMT). Dr. Türeci earned her M.D. from Saarland University Faculty of Medicine, Homburg. Dr. Türeci is married to Prof. Ugur Sahin, M.D.

Ryan Richardson is our Chief Strategy Officer. Mr. Richardson joined BioNTech in September 2018 from J.P. Morgan Securities LLC, where he served from June 2010 to September 2018 in various roles, including as Executive Director, Healthcare Investment Banking. Prior to his time at J.P. Morgan Securities LLC, Mr. Richardson served in various roles in the healthcare economics and consulting field, including as co-founder of Quantitative Insights. Mr. Richardson earned an MBA from the University of Chicago Booth School of Business, a MSc from the London School of Economics and Political Science and a B.S. in Biology from the University of Kansas.

Supervisory Board (*Aufsichtsrat*)

The following table sets forth the names and functions of the current members of our Supervisory Board, their ages as of December 31, 2019, 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	Principal Occupation
Helmut Jeggle	49	2023	Chief Executive Officer and Chief Operating Officer of ATHOS Service GmbH
Michael Motschmann	62	2023	Member of the Board of Management and Head of Equity Investments of MIG Verwaltungs AG
Prof. Christoph Huber, M.D.	75	2023	Chairman Emeritus at the Johannes-Gutenberg University Mainz
Dr. Ulrich Wandschneider	58	2023	Independent consultant to life sciences companies

The business address of the members of our Supervisory Board is the same as our business address: An der Goldgrube 12, D-55131 Mainz, Germany.

The following is a brief summary of the prior business experience of the members of our Supervisory Board:

Helmut Jeggle has served as the Chairman of our Supervisory Board since 2008. Mr. Jeggle has served as the Chief Executive Officer and Chief Operating Officer of ATHOS Service GmbH since 2015. From 2007 until 2015, Mr. Jeggle served as the Head of Direct Investments of ATHOS Service GmbH. From 2002 until 2007, Mr. Jeggle held various positions with Hexal AG, including Head of Business Planning & Analyses. Mr. Jeggle is currently the Chief Executive Officer of each of Salvia GmbH (since 2014), Neula Holding GmbH (since 2010) and AT-Gruppe (since 2008) and a manager of Santo Group (since 2011). Mr. Jeggle is a member of numerous supervisory boards, including 4SC AG. Mr. Jeggle has a degree in business administration from the University of Applied Sciences Neu-Ulm and earned his Master of Business Administration from the Stuttgart Institute of Management and Technology.

Michael Motschmann has served as a member of our Supervisory Board since 2008. Mr. Motschmann co-founded MIG Verwaltungs AG, or MIG, in 2004, where he serves on the Management Board and as Head of Equity Investments. In his role with MIG, Mr. Motschmann currently serves on the supervisory boards of several private portfolio companies.

Prof. Christoph Huber, M.D. is a co-founder of BioNTech and has served as a member of our Supervisory Board since 2008. Prof. Huber has more than 50 years of professional experience in hematology, oncology and translational immunology. Prof. Huber has since 2014 served as Chairman Emeritus of the Department of Hematology and Oncology at the Johannes-Gutenberg University Mainz. Prof. Huber was a co-founder of Ganymed, now a subsidiary of Astellas Pharma Inc. He is an executive board member of CIMT and a board member of Ci3. From 2018 to April 2019, Prof. Huber served as a member of the supervisory board of TRON. Prof. Huber earned his M.D. at the University of Innsbruck.

Dr. Ulrich Wandschneider, Ph.D. has served as a member of our Supervisory Board since 2018. Dr. Wandschneider has more than 20 years of experience in the healthcare sector as a manager in the operative business and as a member of boards and committees. From 2004 to 2016 Dr. Wandschneider served as Chief Executive Officer first of Mediclin AG later of Asklepios Kliniken GmbH & Co. KGaA. Dr. Wandschneider currently serves on various supervisory and advisory boards.

B. Compensation

Remuneration of Supervisory Board Members

Our Articles of Association provide for a fixed annual remuneration for each member of the Supervisory Board of €50,000 per year. However, the chairman is entitled to receive €150,000 per year and the vice chairman €75,000 per year. In addition, the chairman of the audit committee is entitled to be paid €20,000 per year. All members of the Supervisory Board are reimbursed for their expenses.

(in thousands)	**Helmut Jeggle**	**Michael Motschmann**	**Prof. Dr. Christian Huber, M.D.**	**Dr. Ulrich Wandschneider**
2019	**€150**	**€50**	**€50**	**€95**
2018	**€31**	**€16**	**€46**	**€7**

A member of the Supervisory Board who serves for only a portion of a given fiscal year or who holds the position of chairman or vice chairman of the Supervisory Board or of chairman of the Audit Committee for only a portion of a given fiscal year shall only be remunerated pro rata. The same is true if the clause of the Articles of Association regarding the remuneration of the members of the Supervisory Board becomes ineffective (e.g., because it is repealed) during the course of a year.

In case any remuneration or reimbursement of expenses is subject to value added tax, such amount shall be paid additionally by the Company.

There are no arrangements or understandings between us and any member of our Supervisory Board providing for benefits upon termination of their service as director.

Remuneration of the Members of Our Management Board

We have entered into agreements with all current members of our Management Board.

We believe that the agreements between us and the members of our Management Board provide for payments and benefits (including upon termination of employment) that are in line with customary market practice.

The following sets forth the end dates of the current service agreements of our Management Board:

- Prof. Ugur Sahin: December 31, 2022
- Sean Marett: September 30, 2022
- Dr. Sierk Poetting: September 30, 2022
- Dr. Özlem Türeci: May 31, 2022
- Ryan Richardson: December 31, 2022

From January 1, 2019 until August 31, 2019, the annual base salaries for our Management Board members, Prof. Ugur Sahin, Sean Marett, Dr. Sierk Poetting and Dr. Özlem Türeci, were €210,000, €360,000, €300,000 and €300,000, respectively. Effective September 1, 2019 the annual base salaries for Prof. Ugur Sahin, Sean Marett, Dr. Sierk Poetting and Dr. Özlem Türeci are €360,000, €400,000, €360,000 and €360,000, respectively. Effective January 1, 2020 the annual base salary for Ryan Richardson is €320,000. In December 2019, the Management Board members, Prof. Ugur Sahin, Sean Marett, Dr. Sierk Poetting and Dr. Özlem Türeci, were each awarded a cash bonus of €50,000, to be paid in 2020.

Our current service agreements with our Management Board provide for short-term incentive compensation of up to a maximum of 50% of the annual base salary. The amount of such short-term incentive compensation will depend on the achievement of certain company goals in a particular fiscal year, which goals will be set uniformly for all members of the Management Board. Half of the incentive compensation will be paid promptly upon achievement of the applicable company goals, with the remaining amount payable one year later, subject to adjustment relative to our share price

performance during that year. The provisions in relation to the short-term incentive compensation will take effect from the beginning of the first year after the year in which BioNTech Shares or ADSs of the Company are listed on a stock exchange or other multilateral trading system, e.g., from the first year following the completion of our initial public offering.

The service agreements of our Management Board provide for long-term incentive compensation in terms of a yearly grant of options to purchase BioNTech Shares. The options granted each year will be subject to the terms, conditions, definitions and provisions of our ESOP and the applicable option agreement thereunder. The number of options to be granted each year to Prof. Ugur Sahin, Sean Marett, Dr. Sierk Poetting, Dr. Özlem Türeci and Ryan Richardson is to be calculated based on a value of €750,000, €300,000, €300,000, €300,000 and €260,000, respectively, in each case divided by the amount by which a certain target share price exceeds the exercise price (which in the case of each grant is equal to the stock price as of the time of that grant). These provisions in relation to the long-term incentive compensation took effect from January 1, 2020.

There are no arrangements or understandings between us and any member of our Management Board providing for benefits upon termination of their service as director.

In the years ended December 31, 2019 and December 31, 2018, the members of our Management Board received aggregate remuneration of €19.6 million and €7.2 million, respectively.

(in thousands)	**Prof. Ugur Sahin, M.D.**	**Sean Marett**	**Dr. Sierk Poetting**	**Dr. Özlem Türeci** (1)
Fixed and Variable Compensation				
2019	€311	€423	€370	€370
2018	€210	€315	€283	€175
Fringe Benefits (2)				
2019	5	12	11	-
2018	1	12	11	-
ESOP Plan Granted (3)				
2019	6,748	1,180	1,180	9,043
2018	442	147	147	5,426
Total				
2019	**€7,064**	**€1,615**	**€1,561**	**€9,413**
2018	**€653**	**€474**	**€441**	**€5,601**

(1) Dr. Özlem Türeci commenced employment with us on June 1, 2018

(2) Includes social security, health and additional insurance, company bike and travel expenses.

(3) The fair value was determined pursuant to the regulations of IFRS 2 “Share-based Payments.” This table shows the pro-rata share of personnel expenses resulting from stock-based compensation for the respective financial year.

The table below provides an overview of the share options granted to our Management Board in the years ended December 31, 2019 and December 31, 2018.

	Grant Date [1]	Number of Ordinary Shares Underlying Share Options [4]	Option Exercise Price (€)	Option Expiration Date
Prof. Ugur Sahin, M.D.	11/15/2018	1,830,348	10.14	09/17/2026
	10/10/2019 [2]	4,374,963	13.60	10/11/2029
Sean Marett	11/15/2018	610,110	10.14	09/17/2026
Dr. Sierk Poetting	11/15/2018	610,110	10.14	09/17/2026
Dr. Özlem Türeci	11/15/2018 [3]	1,952,334	10.14	09/17/2026

(1) Except as otherwise indicated, all options fully vest on September 16, 2022.

(2) Options vest in four equal installments on October 10 of 2020, 2021, 2022 and 2023.

(3) Options fully vested on March 16, 2019, however these options will not become exercisable until September 16, 2022.

(4) Share amounts reflect an 18-for-1 stock split of our ordinary shares which became effective on September 18, 2019, upon registration with the commercial register (*Handelsregister*).

Employee Stock Ownership Plan

Based on a pertinent authorization of the general meeting on August 18, 2017, we have established a share option program under which we grant selected employees options to receive our shares. The program is designed as an Employee Stock Ownership Plan, or ESOP. We have offered the participants a certain number of rights by explicit acceptance of the participants. The exercise of the option rights in accordance with the agreement gives the participants the right to obtain shares against payment of the exercise price. The option rights (other than Dr. Türeci's options referred to above and one other senior employee's options) generally fully vest after four years and can only be exercised if: (i) the waiting period of four years has elapsed; and (ii) at the time of exercise, the average closing price of the shares of the Company or the average closing price of the right or certificate to be converted into an amount per share on the previous ten trading days preceding the exercise of the option right exceeds the strike price by a minimum of 32%, with this percentage increasing by eight percentage points as of the fifth anniversary of the respective issue date and as of each subsequent anniversary date. The option rights can be exercised at the latest eight years after the allocation date. If they have not been exercised by that date, they will forfeit without compensation.

By way of shareholders' resolution of the general meeting on August 19, 2019, the authorization to issue such option rights was amended such, that, in order for the options to be exercisable, the average closing price of the Company's shares or the average closing price of the right or certificate to be converted into an amount per share on the ten trading days immediately preceding the exercise must exceed the strike price by a minimum of 28%, with this percentage increasing by seven percentage points as of the fifth anniversary of the issue date and as of each subsequent anniversary date. Also, in addition to the aforementioned requirements, the exercise is only possible if the share price (calculated by reference to the price of the ordinary share underlying the ADS) has performed similar to or better than the Nasdaq Biotechnology Index. The changes made do not affect option rights already issued.

Chief Executive Officer Grant

In September 2019, we agreed to grant Prof. Ugur Sahin, M.D., our co-founder and Chief Executive Officer, an option to purchase 4,374,963 of our ordinary shares, subject to Prof. Sahin's continuous employment with us. The options' per share exercise price is the Euro translation of the public offering price from our initial public offering, €13.60 ($15.00). The option will vest annually in equal installments after four years commencing on the first anniversary of our initial public offering and will be exercisable four years after our initial public offering. The option will be subject to the terms, conditions, definitions and provisions of our ESOP and the applicable option agreement thereunder.

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 structure. Hence, our corporate bodies are the Management Board (*Vorstand*), the Supervisory Board (*Aufsichtsrat*) and the shareholders' meeting (*Hauptversammlung*). Our Management and Supervisory Boards are entirely separate, and, as a rule, no individual may simultaneously be a member of both boards.

Our Management Board is responsible for the day-to-day management of our business in accordance with applicable laws, our Articles of Association (*Satzung*) and the Management Board's internal rules of procedure (*Geschäftsordnung*). Our Management Board represents us in our dealings with third parties.

The principal function of our Supervisory Board is to supervise our Management Board. The Supervisory Board is also responsible for appointing and removing the members of our Management Board, representing us in connection with transactions between a current or former member of the Management Board and us, and granting approvals for certain significant matters.

Our Management Board and our Supervisory Board are solely responsible for and manage their own areas of competency (*Kompetenztrennung*); therefore, neither board may make decisions that, pursuant to applicable law, our Articles of Association or the internal rules of procedure are the responsibility of the other board. Members of both boards owe a duty of loyalty and care to us. In carrying out their duties, they are required to exercise the standard of care of a prudent and diligent businessperson. If they fail to observe the appropriate standard of care, they may become liable to us.

In carrying out their duties, the members of both boards must take into account a broad range of considerations when making decisions, including our interests and the interests of our shareholders, employees, creditors and, to a limited extent, the general public, while respecting the rights of our shareholders to be treated on equal terms. Additionally, the Management Board is responsible for implementing an internal monitoring system for risk management purposes.

Our Supervisory Board has comprehensive monitoring responsibilities. To ensure that our Supervisory Board can carry out these functions properly, our Management Board must, among other duties, regularly report to our Supervisory Board regarding our current business operations and future business planning (including financial, investment and personnel planning). In addition, our Supervisory Board or any of its members is entitled to request special reports from the Management Board on all matters regarding the Company, our legal and business relations with affiliated companies and any business transactions and matters at such affiliated companies that may have a significant impact on our position at any time.

Under German law, our shareholders have, 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 four members.

As we are not subject to co-determination, the members of our Supervisory Board are all elected by the shareholders' meeting in accordance with the provisions of the SE Regulation and the German Stock Corporation Act (*Aktiengesetz*). German law does not require the majority of our Supervisory Board members to be independent and neither our Articles of

Association (*Satzung*) nor the rules of procedure for our Supervisory Board provide otherwise. However, the rules of procedure for our Supervisory Board provide that the Supervisory Board should have an independent member with expertise in the field of accounting, internal control processes and auditing.

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 Mr. Helmut Jeggle as chairperson and Dr. Ulrich Wandschneider as deputy chairperson, each for the term of their respective membership on our Supervisory Board.

The Supervisory Board meets at least twice each calendar half-year. Our Articles of Association provide that a quorum of the Supervisory Board members is present if at least three of its members participate in the vote. Members of our Supervisory Board are deemed present if they attend the meeting via telephone or other (electronic) means of communication (including via video conference) or submit their written vote through another member. Additionally, our Articles of Association allow for resolutions to be taken via telephone or other (electronic) means of communications (including via video conference).

Resolutions of our Supervisory Board are passed by the vote of a simple majority of the votes cast unless otherwise required by law, our Articles of Association or the rules of procedure of our Supervisory Board. In the 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;
- creating or holding any interest in businesses (except wholly owned subsidiaries) or disposing of shares in businesses (except for a sale of JPT);
- issuing shares from authorized capital, unless the shares are issued pursuant to a redemption of stock appreciation rights; and
- acquiring treasury shares in return for valuable consideration.

Supervisory Board Practices

Decisions are generally made by our Supervisory Board as a whole, however decisions on certain matters may be delegated to committees of our Supervisory Board to the extent permitted by law. The chairperson, or if he or she is prevented from doing so, the deputy chairperson, chairs the meetings of the Supervisory Board and determines the order in which the agenda items are discussed, the method and order of voting, as well as any adjournment of the discussion and passing of resolutions on individual agenda items after a due assessment of the circumstances. Our Supervisory Board may designate further types of actions as requiring its approval.

In addition, each member of the Supervisory Board is obliged to carry out his or her duties and responsibilities personally, and such duties and responsibilities cannot be generally and permanently delegated to third parties. However, the Supervisory Board and its committees have the right to appoint independent experts for the review and analysis of specific circumstances in accordance with its control and supervision duties under applicable European and German law. We would bear the costs for any such independent experts that are retained by the Supervisory Board or any of its committees.

Pursuant to Section 107 para. 3 of the German Stock Corporation Act (*Aktiengesetz*), the supervisory board may form committees from among its members and charge them with the performance of specific tasks. The committees' tasks, authorizations and processes are determined by the supervisory board. Where permissible by law, important powers of the supervisory board may also be transferred to committees.

By resolution, the Supervisory Board has established an Audit Committee, a Remuneration, Nominating and Governance Committee and a Capital Markets Committee. Set forth in the table below are the current members of the Audit Committee, the Remuneration, Nominating and Corporate Governance Committee and the Capital Markets Committee.

Name of Committee	**Current Members**
Audit Committee	Dr. Ulrich Wandschneider, Michael Motschmann and Helmut Jeggle
Remuneration, Nominating and Corporate Governance Committee	Michael Motschmann, Prof. Christoph Huber, M.D. and Dr. Ulrich Wandschneider
Capital Markets Committee	Helmut Jeggle, Michael Motschmann

Audit Committee

Our Audit Committee consists of Dr. Ulrich Wandschneider, Michael Motschmann and Helmut Jeggle. Dr. Ulrich Wandschneider is the chair of the Audit Committee. The Audit Committee assists the Supervisory Board in overseeing the accuracy and integrity of our financial statements, our accounting and financial reporting processes and audits of our financial statements, the effective functioning of our internal control system, our risk management system, our compliance with legal and regulatory requirements, our independent auditor's qualifications and independence, the performance of the independent auditor and the effective functioning of our internal audit functions, and, subject to certain limitations, 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:

- considering the commissioning of the audit engagement, as well as the compensation, retention and oversight of the independent auditor;
- evaluating the qualifications, independence and performance of the independent auditor;
- reviewing and pre-approving the audit and non-audit services to be performed by the independent auditor;
- reviewing and discussing with the independent auditor and management the annual audit plan, as well as critical accounting policies and practices to be used;
- reviewing and discussing with the independent auditor and management the adequacy and effectiveness of our internal accounting controls and critical accounting policies;
- reviewing and discussing with the independent auditor and management the results of our annual audit;
- reviewing and discussing with the independent auditor and management any quarterly or annual earnings announcements;
- reviewing any related party transactions and reviewing and monitoring potential conflict of interest situations on an ongoing basis for compliance with our policies and procedures;
- overseeing procedures for the receipt, retention and treatment of complaints received regarding accounting, internal accounting controls or auditing matters; and
- reviewing and evaluating the performance of the Audit Committee and its members.

Within the limits of applicable European and German law, the Audit Committee shall have the resources and authority appropriate to discharge its duties and responsibilities, including the authority to select, retain, terminate, and approve the fees and other engagement terms of special or independent counsel, accountants or other experts and advisors, as it deems necessary or appropriate for so discharging its duties and responsibilities, without seeking approval of the Management Board or Supervisory Board. The Audit Committee has legal power to enter into the contract on our behalf and we will be bound to these and will be obliged to discharge any obligations as the Audit Committee may incur on our behalf for these purposes.

Dr. Wandschneider and Mr. Motschmann qualify as "independent directors" as such term is defined in Rule 10A-3 under the Exchange Act and Nasdaq Rule 5605. We intend to have a fully independent audit committee within one year from effectiveness of our initial public offering registration statement, as permitted by Rule 10A-3. Additionally, our Supervisory Board has determined that Dr. Ulrich Wandschneider qualifies as an "audit committee financial expert" as that term is defined under the Exchange Act.

Remuneration, Nominating and Corporate Governance Committee

Our Remuneration, Nominating and Corporate Governance Committee consists of Michael Motschmann, Prof. Christoph Huber, M.D. and Dr. Ulrich Wandschneider. Mr. Motschmann is the chair of the committee. The Remuneration, Nominating and Corporate Governance Committee's duties and responsibilities to carry out its purpose include, among others:

- preparing and discussing with management policies relating to the remuneration of the members of our Management Board;
- reviewing and supervising corporate goals and objectives for the remuneration of the members of the Management Board, including evaluation of the performance of the members of the Management Board in light of these goals and proposals to the Supervisory Board for remuneration based on such evaluations;
- 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;
- overseeing the evaluation of the Supervisory Board and reporting on its performance and effectiveness; and
- reviewing and evaluating the performance of the Remuneration, Nominating and Corporate Governance Committee and its members.

Capital Markets Committee

Our Capital Markets Committee consists of Helmut Jeggle and Michael Motschmann. Mr. Jeggle is the chair of the committee. The Capital Markets Committee advises 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.

Management Board and Senior Management

Our Management Board consists of at least two members. Our Supervisory Board determines the exact number of members of our Management Board. Pursuant to this amendment to the Articles, the Supervisory Board may also appoint a chairperson or a spokesman of the Management Board. Prof. Ugur Sahin, M.D. has been appointed chairman of the Management Board.

The members of our Management Board are appointed by our Supervisory Board for a term of up to five years. They are eligible for reappointment or extension, including repeated re-appointment and extension, after the completion of their

term in office, in each case again for up to an additional five years. Under certain circumstances, such as a serious breach of duty or a vote of no confidence by the shareholders in a shareholders' meeting, a member of the Management Board may be removed from office by our Supervisory Board prior to the expiration of his or her term.

The members of our Management Board conduct the daily business of our company in accordance with applicable laws, our Articles of Association and the rules of procedure for the Management Board adopted by our Supervisory Board. They are generally responsible for the management of our company and for handling our daily business relations with third parties, the internal organization of our business and communications with our shareholders.

A member of the management board of an SE governed by German law may not deal with or vote on matters relating to proposals, arrangements or contractual agreements between himself or herself and our company, and a member of our Management Board may be liable to us if he or she has a material interest in any contractual agreement between our company and a third party which is not disclosed to and approved by our Supervisory Board.

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 20 of each year;
- reporting to the Supervisory Board;
- all measures and transactions that require the Supervisory Board's approval;
- all measures and transactions relating to a business area that is of extraordinary importance to the us or involving an extraordinary economic risk;
- taking on new lines of business or discontinuing existing lines of business;
- investments with a total value above €100,000;
- acquisitions or sales of interests or holdings; and
- certain large transactions.

Code of Conduct and Conflicts of Interest Policy

We have adopted a Code of Business Conduct & Ethics, or Code of Conduct, which outlines the principles of legal and ethical business conduct under which we do business. The Code of Conduct applies to all of our Supervisory Board members, Management Board members, directors of our subsidiaries and our affiliates and employees. The full text of the Code of Conduct is available on our website at https://www.biontech.de. The information and other content appearing on our website are not 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 Conduct for members of our Supervisory or Management Boards will be made only after approval by our Supervisory Board and will be disclosed on our website promptly following the date of such amendment or waiver.

We have also adopted a Conflicts of Interest Policy which sets forth the procedures by which we manage potential and actual conflicts of interest. Under the Conflicts of Interest Policy, which applies to all of our Supervisory Board Members, Management Board members, directors of our subsidiaries and our affiliates and employees, an actual, potential or perceived conflict of interest must be disclosed as soon as a Board member, director or employee discovers the conflict. If the conflict is transactional in nature and involves a member of the Management Board or the Supervisory Board, the Management or Supervisory Board, as the case may be, with the abstention of the conflicted member, shall decide whether to approve the transaction.

In addition, we have implemented compliance policies that describe the compliance management systems that have been implemented for us and our subsidiaries. Our compliance policies are designed to ensure compliance with applicable legal requirements, while at the same time implementing high ethical standards that are mandatory for both management and each employee. The overall responsibility for the compliance management system lies with the Management Board. The Audit Committee will receive regular reports on the operation of the compliance management system.

D. Employees

As of December 31, 2019, we had 1,310 full-time equivalent employees working for BioNTech, of whom 316 hold a doctoral degree or higher. The following tables provide breakdowns of our full-time equivalent employees as of December 31, 2019 by function and by region:

Function	**2019**
Clinical Research & Development	89
Scientific Research & Development	454
Operations	412
Quality	141
Supporting Functions	138
Commercial & Business Development	76
Total	**1,310**

Region	**2019**
Mainz, Germany (Headquarters)	952
Munich, Germany	42
Idar-Oberstein, Germany	212
Berlin, Germany	101
United States	3
Total	**1,310**

None of our employees have engaged in any labor strikes. We have no collective bargaining agreements with our employees, but we maintain a company agreement (*Betriebsvereinbarungen*) with respect to certain topics at our Idar-Oberstein site. We have a workers' council at our Idar-Oberstein and Mainz sites. However, we consider our relationship with our employees to be positive and have not experienced any major labor disputes.

E. Share Ownership

The share ownership information with respect to Management Board and Supervisory Board members is presented in Item 7 below.

Item 7. Major Shareholders and Related Party Transactions

A. Major Shareholders

The following table presents information, as of February 14, 2020, 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 February 14, 2020 through the exercise of any option, warrant or other right. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all ordinary shares held by that person. 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 226,779,744 ordinary shares outstanding as of February 14, 2020. This amount excludes 5,524,506 shares held in treasury. Unless otherwise indicated, the address for each beneficial owner is An der Goldgrube 12, D-55131 Mainz, Germany.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage Beneficially Owned
5% Shareholders		
AT Impf GmbH (1)	114,141,520	50.33%
Medine GmbH (2)	41,690,970	18.38%
MIG Verwaltungs AG (3)	13,556,106	5.98%
Entities affiliated with FMR LLC	12,718,257	5.61%
Members of the Supervisory Board and the Management Board		
Prof. Ugur Sahin, M.D. (4)	41,690,970	18.38%
Sean Marett (5)	1,091,502	(10)
Dr. Sierk Poetting (6)	711,828	(10)
Dr. Özlem Türeci	-	-
Ryan Richardson	-	-
Helmut Jeggle (7)	116,798,941	51.50%
Michael Motschmann	-	-
Prof. Christoph Huber, M.D. (8)	2,552,040	1.13%
Dr. Ulrich Wandschneider (9)	4,680	(10)
All members of our Supervisory Board and Management Board, as a group	**162,849,961**	**71.81%**

(1) Information herein is based upon a Schedule 13G jointly filed with the SEC on February 12, 2020 by ATHOS KG, AT Impf GmbH, Helmut Jeggle and Thomas Maier. Consists of 114,141,520 ordinary shares held by AT Impf GmbH. The sole member of AT Impf GmbH is ATHOS KG, and, as a result, ATHOS KG is deemed to be the beneficial owner of the securities held by AT Impf GmbH. Helmut Jeggle and Thomas Maier are each general partners (*Komplementär*) of ATHOS KG and may be deemed to be beneficial owners of the securities held by AT Impf KG. Each of Messrs. Jeggle and Maier disclaim beneficial ownership of such shares except to the extent of their pecuniary interest therein.

(2) Information herein is based upon a Schedule 13G jointly filed with the SEC on February 13, 2020 by Medine GmbH and Prof. Sahin. The sole shareholder of Medine GmbH is Prof. Sahin, and, as a result, Prof. Sahin is deemed to be the beneficial owner of the securities held by Medine GmbH.

(3) Information herein is based upon a Schedule 13G jointly filed with the SEC on February 14, 2020 by MIG Verwaltungs AG, MIG GmbH & Co. Fonds 7 KG, MIG GmbH & Co. Fonds 8 KG and MIG GmbH & Co. Fonds 9 KG, Munich. Consists of (a) 5,495,148 ordinary shares held by MIG GmbH & Co. Fonds 7 KG, Munich, (b) 1,780,002 ordinary shares held by MIG GmbH & Co. Fonds 8 KG, Munich and (c) 6,280,956 ordinary shares held by MIG GmbH & Co. Fonds 9 KG, Munich.

(4) Consists of the shares described in note 2 above. Prof. Sahin is the sole shareholder of Medine GmbH.

(5) Consists of 1,091,502 ordinary shares held by RLG GmbH. Mr. Marett is the sole shareholder of RLG GmbH.

(6) Consists of 711,828 shares held by Tofino GmbH. Does not include 487,800 shares held on behalf of other beneficial owners in his capacity as trustee of Tofino GmbH.

(7) Consists of (a) the shares described in note 1 above, (b) 332,316 ordinary shares held directly by Mr. Jeggle, (c) 2,273,886 ordinary shares held by Salvia GmbH and (d) 51,219 ordinary shares held by Nils GmbH. Mr. Jeggle has no voting or dispositive power with regard to such shares described in note 1 above and disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein.

(8) Consists of 2,552,040 ordinary shares held by CHuber 2008 GmbH. Prof. Huber is the sole shareholder of CHuber 2008 GmbH.

(9) Consists of 4,680 shares held by Tofino GmbH.

(10) Less than one percent

Holdings by U.S. Shareholders

We estimate that as of February 14, 2020, approximately 14.24% of our outstanding ordinary shares are held by 29 U.S. record holders.

B. Related Party Transactions

Agreements with TRON

We have a longstanding relationship with Translational Oncology at the University Medical Center of the Johannes Gutenberg University Mainz (*Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH*), or TRON. TRON is a non-profit limited liability company engaged in biopharmaceutical research. Prof. Ugur Sahin, M.D., our co-founder and Chief Executive Officer, co-founded TRON and served as Managing Director for Science and Research at TRON, until his resignation September 10, 2019. Additionally, Prof. Christoph Huber, a member of our Supervisory Board, served on TRON's supervisory board until his resignation in April 2019. Prof. Ugur Sahin, M.D., our co-founder and Chief Executive Officer, owns a significant amount of shares in TRON.

On January 1, 2015, we and certain of our subsidiaries entered into both a Master Agreement for Research Services and a License Agreement with TRON. During the year ended December 31, 2019, the aggregate value of transactions related to these agreements with TRON amounted to €10.0 million pursuant to these agreements (€6.6 million during the year ended December 31, 2018).

Agreements with Santo Service GmbH

We have several agreements with Santo Service GmbH, or Santo Service, pursuant to which Santo Service provides us with certain real property and custodial services. Santo Service is wholly owned by AT Impf GmbH, which is wholly owned by our controlling shareholder. During the year ended December 31, 2019, the aggregate value of transactions with Santo Service amounted to €2.0 million pursuant to these agreements (€1.2 million during the year ended December 31, 2018).

Agreement with Medine GmbH

On August 29, 2019, we entered into an agreement with Medine GmbH, or Medine, pursuant to which we acquired all of the outstanding shares of reBOOST Management GmbH, or reBOOST, which owns certain intellectual property, in exchange for total consideration of approximately €0.3 million. reBOOST and Medine are wholly owned by Prof. Ugur Sahin, M.D., our co-founder and Chief Executive Officer, who is also the Managing Director of reBOOST and Medine.

Series A 2018 Financing

In February 2018, we issued an aggregate of 22,587,912 of our ordinary shares to certain new and existing shareholders at a price of $11.99 per share for aggregate proceeds of $270.9 million.

The following table sets forth the aggregate number of ordinary shares that we issued and sold in this transaction to our related parties and the aggregate purchase price for such shares:

Participant	Number of Ordinary Shares	Aggregate Purchase Price ($)
AT Impf GmbH (1)	5,002,812	59,997,612.58

(1) See "Major Shareholders" under this Item 7 for additional information about shares held by this entity or the parent company of this entity.

Series B 2019 Financing

In June and August 2019, we issued an aggregate of 12,465,288 ordinary shares (excluding 5,524,506 ordinary shares which were issued to a Hong Kong-based investor and subsequently transferred to us for no consideration) to certain new and existing shareholders at a price of $18.10 per share for aggregate proceeds of €198.6 million ($225.6 million).

The following table sets forth the aggregate number of ordinary shares that we issued and sold in this transaction to our related parties and the aggregate purchase price for such shares:

Participant	Number of Ordinary Shares	Aggregate Purchase Price ($)
AT Impf GmbH (1)	1,657,332	29,999,550.68

(1) See "Major Shareholders" under this Item 7 for additional information about shares held by this entity or the parent company of this entity.

Initial Public Offering

In October 2019, we sold 10,517,408 ADSs representing 10,517,408 of our ordinary shares to certain new and existing shareholders at a price of $15.00 per ADS for proceeds of €135.4 ($149.1 million) in our initial public offering. The following table sets forth the aggregate number of ADSs that we issued and sold in this transaction to our related parties and the aggregate purchase price for such shares:

Participant	Number of Ordinary Shares	Aggregate Purchase Price ($)
AT Impf GmbH (1)	2,800,000	42,000,000.00
Helmut Jeggle (1)	51,219	768,285.00

(1) See "Major Shareholders" under this Item 7 for additional information about shares held by this entity, the parent company of this entity or Supervisory Board member.

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 Listing Details

Not applicable.

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*) will be publicly available from the commercial register (*Handelsregister*) at the local court of Mainz, Germany, electronically at www.unternehmensregister.de and as an exhibit to this Annual Report.

Share Capital

We have share capital registered in the commercial register (*Handelsregister*) in the amount of €232,304,250, which is divided into 232,304,250 registered shares (*Namensaktien*). All shares are shares with no par value (*Stückaktien ohne Nennbetrag*) with a notional amount attributable to each ordinary share of €1. Each issued ordinary share is fully paid.

Form, Certification and Transferability of Shares

The form and contents of our share certificates, collective share certificates and global share certificates are determined by our Management Board. A shareholder's right to certification of its shares is excluded, to the extent permitted by law and to the extent that certification is not required by the stock exchange on which the shares or rights or certificates representing them are admitted to trading. We are permitted to issue collective share certificates and global share certificates that represent multiple or all of our shares.

Our shares are freely transferable under German law.

Changes in Our Share Capital During the Last Three Fiscal Years

Our share capital as registered with the commercial register (*Handelsregister*) amounts to €232,304,250, including an amount of €5,524,506 relating to 5,524,506 ordinary shares held in treasury. Since January 1, 2017, (up until and including the capital increase of August 16, 2019, without giving effect to the 18-to-1 stock split which became effective on September 18, 2019), our share capital has changed as follows:

- On September 14, 2017, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 9,083,000 shares;
- On February 1, 2018, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 1,254,884 shares;
- On September 12, 2018, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 32,373 shares;
- On October 18, 2018, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 186,715 shares;
- On January 29, 2019, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 282,678 shares;
- On April 24, 2019, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 131,933 shares against contributions in kind (swap of shares in our company against shares in one of our subsidiary companies);
- On June 26, 2019, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 666,123 shares;
- On August 16, 2019, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 333,310 shares;

- On September 18, 2019, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 206,595,492 shares by way of a capital increase from our funds; thus, no contribution by investors was made;
- On August 30, 2019, we entered into an agreement with BMGF pursuant to which BMGF agreed to purchase up to 3,038,674 of our ordinary shares. This capital increase from our authorized capital was resolved upon by our Management Board (*Vorstand*) with the consent of the Supervisory Board (*Aufsichtsrat*) on September 18, 2019 and came into effect upon registration with the commercial register (*Handelsregister*);
- On October 14, 2019, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 10,000,000 shares; and
- On November 6, 2019, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 517,408 shares.

Anti-takeover Provisions of Our Charter Documents

Our Articles of Association (*Satzung*) do not include any provisions that would have a direct effect of delaying, deferring or preventing a change of control. However, in the event of a hostile takeover, we could use our authorized capital to increase our share capital to issue new shares to an investor at a premium. An increase in the number of shares outstanding could have a negative effect on a party's ability to carry out a hostile takeover. The provisions of German law relating to public bids and takeovers that require any such bids to be carried out in a manner designed to safeguard equal and fair treatment to all shareholders and give them a right to be bought out at an adequate compensation where a party acquires "control" (as such term is defined in such provisions) over the relevant company do not apply.

Future Changes to the Share Capital

Authorized Capital

Under the relevant law, the general meeting of a European stock corporation (*Societas Europaea*) governed by German law can authorize the Management Board to, with the consent of the Supervisory Board, issue shares in a specified aggregate nominal amount of up to 50% of the issued share capital of such company at the time the resolution becomes effective. The shareholders' authorization becomes effective upon registration in the commercial register (*Handelsregister*) and may extend for a period of no more than five years thereafter. Under § 4(5) of our Articles of Association (*Satzung*), the Management Board is authorized to increase our share capital, on one or more occasions, by a total of up to €105,818,002 by issuing, on one or more occasions, up to 105,818,002 new, registered shares with no par value (*Genehmigtes Kapital*), in each case with consent of the Supervisory Board. This authorization expires on August 18, 2024.

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

Conditional Capital

Pursuant to § 4(6) of our Articles of Association (*Satzung*), our share capital is conditionally increased by €21,874,806 through issuance of new, registered shares with no par value (*Bedingtes Kapital ESOP 2017/2019*). The conditional capital may only be used to issue shares to the holders of option rights granted under our ESOP to members of our Management Board and to certain of our employees.

The conditional capital increase will only be implemented to the extent that stock options under our ESOP are exercised and said stock options are not serviced by our providing treasury shares or through cash payments. Any new shares issued under the conditional capital pursuant to the said § 4(6) of our Articles of Association (*Satzung*) shall be entitled to dividends from the beginning of the previous financial year in case they are created by the exercise of subscription rights until the start of the annual general meeting of the Company and otherwise from the beginning of the financial year in which they are created as a result of the exercise of the stock options.

Pursuant to § 4(7) of our Articles of Association (*Satzung*), our share capital is conditionally increased by €87,499,260 through issuance of new, registered shares with no par value (*Bedingtes Kapital WSV 2019*). The conditional

capital may only be used to issue shares to the holders or creditors of option rights or conversion rights or those under an obligation to convert under warrant-linked or convertible bonds avail of their option rights or conversion rights or where they are under an obligation to convert, to the extent they satisfy their obligation to convert, or to the extent that we exercise a right to choose to grant our shares, in whole or in part instead of paying a monetary amount due, and to the extent cash compensation is not granted in each relevant case or treasury shares or shares of another stock-listed company are not utilized for servicing.

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

Preemptive Rights

German law generally provides shareholders with preemptive rights when new shares convertible bonds, bonds with warrants, profit participation rights or participating bonds are issued. This requirement, however, may also be satisfied by way of a credit institution subscribing for the securities and then offering them to the shareholders for purchase (*mittelbares 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 to be issued and in relation to the authorized capital, *i.e.,* an authorization to the Management Board to, with the consent of the Supervisory Board, resolve on the issuance of new securities; provided, however, that in each case the exclusion or the authorization to so exclude preemptive rights, respectively, must be justified by specific facts, in accordance with established case law of the German Federal Court of Justice (*BGH*). The German Federal Court of Justice (*BGH*) considers the exclusion of subscription rights justified if it (i) serves a purpose in the company's interests, (ii) is suitable for attaining such purpose, and (iii) is necessary and appropriate. Additionally, the management board must submit a written report to the shareholders' meeting in which it presents the reasons for the exclusion of the subscription rights.

Accordingly, under our Articles of Association (*Satzung*), the Management Board may, with the consent of the Supervisory Board, exclude such preemptive rights in a capital increase from the authorized capital in the following circumstances:

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

- in case shares are to be issued to a member of our Management Board or to another person who is employed by us or one of our affiliates and a minimum holding period of at least one year and the obligation to transfer back the shares in the event that the beneficiary is not employed by us or one of our affiliated companies for the entire duration of the holding period or any other agreed period is agreed upon. Additional restrictions with regard to the shares issued may be agreed upon;
- after listing on Nasdaq, if excluding subscription rights, according to the written declaration of an internationally renowned investment bank, is expedient to the shares' successful placement in view of the requirements of eligible investors and if the discount by which the issue price of the shares may be below the current stock exchange price at the time the Management Board adopts the resolution on using authorized capital, according to such declaration, does not exceed the extent necessary for a successful placement; and
- in order to be able to satisfy an option to acquire additional ordinary shares or American Depositary Shares that has been agreed with the issuing banks in connection with a public offering of our shares in the form of American Depositary Shares.

The total number of new shares issued from the authorized capital and under exclusion of subscription rights pursuant to bullets one through three and eight above may not exceed 20% of the share capital, either at the time this authorization becomes effective or, if lower, at the time it is utilized. To be counted against the aforementioned 20% limit are: (i) those shares issued or to be issued to service conversion or option rights or conversion or option obligations or tender rights of the issuer under bonds, if the bonds have been issued during the term of this authorization up to the time of its exercise, excluding the subscription rights of shareholders, as well as, to a certain extent (ii) treasury shares that have been disposed under exclusion of subscription rights during the term of this authorization (except in the case of certain exceptions of the resolution to item no. 8 of the general meeting of August 19, 2019).

Corporate Purpose of our Company

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

Shareholders' Meetings and Voting Rights

Pursuant to our Articles of Association (*Satzung*), shareholders' meetings may be held at our seat or in any municipality in Germany with more than 500,000 inhabitants. Generally, shareholders' meetings are convened by our Management Board, or our Supervisory Board. Shareholders representing in the aggregate at least five percent of our ordinary shares may, subject to certain formal prerequisites, request that a shareholders' meeting be convened. Shareholders representing in the aggregate at least five percent of our ordinary shares or owning shares with an aggregate nominal value of at least €500,000 may request the addition of one or several items to the agenda of any shareholders' meeting. Invitations to shareholders' meetings must be published in the German Federal Gazette (*Bundesanzeiger*) at least 36 days before the meeting.

Shareholders may participate in and vote in the shareholders' meeting if they are registered as a shareholder with the Company's share register. A shareholder who wishes to attend the shareholders' meeting—either in person or by proxy, which may also be appointed by us (*Stimmrechtsvertreter*)—must register for the meeting, which registration must occur no later than six days before the meeting (or at a later date, if so determined by our Management Board).

Each share carries one vote at a shareholders' meeting. Resolutions are, in accordance with our Articles of Association (*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 fiscal year are generally determined by a process in which the Management Board and Supervisory Board submit a proposal to the company's annual general shareholders' meeting held in the subsequent fiscal year and such annual general shareholders' meeting adopts a resolution.

German law provides that a resolution concerning dividends and distribution thereof may be adopted only if the company's unconsolidated financial statements prepared in accordance with German law show net retained profits. In determining the profit available for distribution, the result for the relevant year must be adjusted for profits and losses brought forward from the previous year and for withdrawals from or transfers to reserves. Certain reserves are required by law and must be deducted when calculating the profit available for distribution.

Shareholders generally participate in profit distributions in proportion to the number of shares they hold. Dividends on shares resolved by the general shareholders' meeting are paid annually, shortly after the general shareholders' meeting, in compliance with the rules of the respective clearing system. Dividend payment claims are subject to a three-year statute of limitation in the company's favor.

Authorization to Purchase and Sell Our Own Shares

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

Squeeze-Out of Minority Shareholders

Under German law, the shareholders' meeting of a stock corporation may resolve, upon request of a shareholder that holds at least 95% of the share capital, that the shares held by any remaining minority shareholders be transferred to the majority shareholder against payment of "adequate cash compensation" (*Ausschluss von Minderheitsaktionären*). This

amount must take into account the full value of the company at the time of the resolution, which is generally determined using the future earnings value method (*Ertragswertmethode*).

A squeeze-out in the context of a merger (*umwandlungsrechtlicher Squeeze-Out*) only requires a majority shareholder to hold at least 90% of the share capital.

Liquidation Rights

Apart from liquidation, e.g., as a result of insolvency proceedings, we may be liquidated with a vote of the holders of at least three-quarters of the share capital represented at the shareholders' meeting at which such a vote is taken. If we are liquidated, any assets remaining after all of our liabilities have been paid off would be distributed among our shareholders in proportion to their holdings in accordance with German statutory law. The German Stock Corporation Act provides certain protections for creditors which must be observed in the event of liquidation.

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, Congo, Egypt, Eritrea, Guinea, Guinea-Bissau, Iran, Iraq, Lebanon, Libya, North Korea, Somalia, South Sudan, Sudan, Syria, Tunisia and Zimbabwe.

For statistical purposes, there are, however, limited notification requirements regarding transactions involving cross-border monetary transfers. With some exceptions, every corporation or individual residing in the Federal Republic of Germany must report to the German Central Bank (*Deutsche Bundesbank*) (i) any payment received from, or made to, a non-resident corporation or individual that exceeds €12,500 (or the equivalent in a foreign currency) and (ii) in case the sum of claims against, or liabilities payable to, non-residents or corporations exceeds €5,000,000 (or the equivalent in a foreign currency) at the end of any calendar month. Payments include cash payments made by means of direct debit, checks and bills, remittances denominated in euros and other currencies made through financial institutions, as well as netting and clearing arrangements.

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 our ADSs.

This discussion is based on domestic German tax laws, including, but not limited to, circulars issued by German tax authorities, which are not binding on the German courts, and the Treaty (defined below). It is based upon tax laws in effect at the time of filing of this 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 and when introduced, may also be applicable on sales and/or transfer of ADSs. In addition, in Germany, for example, there are currently ongoing discussions on the raise of the top tax rate, which may also have an effect on the German tax consequences of acquiring, owning and disposing of the ADSs. There is no assurance that German tax authorities will not challenge one or more of the tax consequences described in this discussion.

In addition, this discussion is based upon the assumption that each obligation in the deposit agreement and any related agreement will be performed in accordance with its terms. It does not purport to be a comprehensive or exhaustive

description of all German tax considerations that may be of relevance in the context of acquiring, owning and disposing of ADSs.

The tax information presented in this 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 represent a beneficial ownership interest in the underlying shares of BioNTech and qualify as ADRs for the purpose of the ADR Tax Circular. If the ADSs qualify as ADRs under the ADR Tax Circular, dividends would accordingly be attributable to holders of the ADSs for German tax purposes, and not to the legal owner of the ordinary shares (*i.e.*, the financial institution on behalf of which the ordinary shares are stored at a domestic depository for the ADS holders). Furthermore, holders of the ADSs should be treated as beneficial owners of the capital of BioNTech with respect to capital gains (see below in section "—German Taxation of Capital Gains of the U.S. Treaty Beneficiaries of the ADSs"). However, investors should note that circulars published by the German tax authorities (including the ADR Tax Circular) are not binding on German courts, including German tax courts, and it is unclear whether a German court would follow the ADR Tax Circular in determining the German tax treatment of the ADSs. For the purpose of this German tax section, it is assumed that the ADSs qualify as ADRs within the meaning of the ADR Tax Circular.

Taxation of Holders Not Tax Resident in Germany

The following discussion describes the material German tax consequences for a holder that is a U.S. treaty beneficiary of acquiring, owning and disposing of the ADSs. For purposes of this discussion, a "U.S. treaty beneficiary" is a resident of the United States for purposes of the Agreement between the Federal Republic of Germany and United States of America for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income and on Capital as of June 4, 2008 (*Abkommen zwischen der Bundesrepublik Deutschland und den Vereinigten Staaten von Amerika zur Vermeidung der Doppelbesteuerung und zur Verhinderung der Steuerverkürzung auf dem Gebiet der Steuern vom Einkommen und vom Vermögen und einiger anderer Steuern in der Fassung vom 4. Juni 2008*), hereinafter referred to as the "Treaty," who is fully eligible for benefits under the Treaty.

A holder will be a U.S. treaty beneficiary entitled to full Treaty benefits in respect of the ADSs if it is, inter alia:

- the beneficial owner of the ADSs (and the dividends paid with respect thereto);
- a U.S. holder;
- not also a resident of Germany for German tax purposes; and
- not subject to the limitation on benefits (i.e., anti-treaty shopping) article of the Treaty that applies in limited circumstances.

Special rules apply to pension funds and certain other tax-exempt investors.

This discussion does not address the treatment of ADSs that are (i) held in connection with a permanent establishment or fixed base through which a U.S. treaty beneficiary carries on business or performs personal services in Germany or (ii) part of business assets for which a permanent representative in Germany has been appointed.

General Rules for the Taxation of Holders Not Tax Resident in Germany

Non-German resident holders of ADSs are subject to German taxation with respect to German source income (*beschränkte Steuerpflicht*). According to the ADR Tax Circular, income from the shares should be attributed to the holder

of the ADSs for German tax purposes. As a consequence, income from the ADSs should be treated as German source income.

German Withholding Taxation of Dividends of the U.S. Treaty Beneficiaries of the ADSs

Generally, the full amount of a dividend distributed by BioNTech to a non-German resident holder which does not maintain a permanent establishment or other taxable presence in Germany is subject to (final) German withholding tax at an aggregate rate of 26.375%. German withholding tax is withheld and remitted to the German tax authorities by (i) the disbursing agent (*i.e.*, the German credit institution, financial services institution, securities trading enterprise or securities trading bank (each as defined in the German Banking Act (*Kreditwesengesetz*) and in each case including a German branch of a foreign enterprise, but excluding a foreign branch of a German enterprise)) that holds or administers the underlying shares in custody and (a) disburses or credits the dividend income from the underlying shares, (b) disburses or credits the dividend income from the underlying shares on delivery of the dividend coupons or (c) disburses such dividend income to a foreign agent; or (ii) the central securities depository (*Wertpapiersammelbank*) in terms of the German Depositary Act (*Depotgesetz*) holding the underlying shares in a collective deposit, if such central securities depository disburses the dividend income from the underlying shares to a foreign agent, regardless of whether a holder must report the dividend for tax purposes and regardless of whether or not a holder is a resident of Germany. Dividend payments, to the extent funded from BioNTech's tax-recognized contribution account (*steuerliches Einlagekonto*), do not, subject to certain prerequisites, form part of the taxable dividend income but lower the holder's acquisition costs for the ADSs.

Pursuant to the Treaty, the German withholding tax may generally not exceed (i) 15% of the gross amount of the dividends received by a U.S. treaty beneficiary other than a company holding ADSs which represent 10% or more of the voting shares in BioNTech, and (ii) 5% of the gross amount of the dividends received by a U.S. treaty beneficiary that is a company holding ADSs which represent 10% or more of the voting shares in BioNTech. The excess of the total withholding tax, including the solidarity surcharge, over the maximum rate of withholding tax permitted by the Treaty is refunded to U.S. treaty beneficiaries upon application. For example, for a declared dividend of 100, a U.S. treaty beneficiary initially receives 73.625 (100 minus the 26.375% withholding tax including solidarity surcharge). The U.S. treaty beneficiary is entitled to a partial refund from the German tax authorities in the amount of 11.375% of the gross dividend (of 100). As a result, the U.S. treaty beneficiary ultimately receives a total of 85 (85% of the declared dividend) following the refund of the excess withholding. However, investors should note that it is unclear how the German tax authorities will apply the refund process to dividends on the ADSs with respect to non-German resident holders of the ADSs. Further, such refund is subject to the German anti-avoidance treaty shopping rule (as described below in "—Withholding Tax Refund for U.S. Treaty Beneficiaries").

German Withholding Taxation of Capital Gains of the U.S. Treaty Beneficiaries of the ADSs

The capital gains from the disposition of the ADSs realized by a non-German resident holder which does not maintain a permanent establishment or other taxable presence in Germany would be treated as German source income and be subject to German tax if the ADSs qualify as a Qualified Participation. A Qualified Participation is given if a holder at any time during the five years preceding the disposition, directly or indirectly, owned 1% or more of BioNTech's share capital, irrespective of whether through the ADSs or shares of BioNTech. If such holder had acquired the ADSs without consideration, the previous owner's holding period and quota would be taken into account.

Pursuant to the Treaty, capital gains from the disposition of a Qualified Participation realized by a U.S. treaty beneficiary are, however, generally exempt from German taxation. Pursuant to the Treaty, U.S. treaty beneficiaries are not subject to German tax in relation to capital gains from the disposition of a Qualified Participation even under the circumstances described in the preceding paragraph and therefore should not be subject to German taxation on capital gains from the disposition of the ADSs.

German statutory law requires the 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 1% or more of the share capital of a German company. While circulars issued by the German Federal Ministry of Finance are only binding on the German tax authorities but not on the German courts, in practice, the disbursing agents nevertheless typically rely on guidance contained in such circulars. Therefore, a disbursing agent would only withhold tax at 26.375% on capital gains derived by a U.S. treaty beneficiary from the sale of ADSs held in a custodial account in Germany in the event that the disbursing agent did not follow the abovementioned guidance. In this case, the U.S. treaty beneficiary may be entitled to claim a refund of the withholding tax from the German tax authorities under the Treaty, as described below in "—Withholding Tax Refund for U.S. Treaty Beneficiaries." A refund of taxes withheld on capital gains from the disposition of the ADSs which do not qualify as Qualified Participations may also be claimed based on German statutory domestic law.

Withholding Tax Refund for U.S. Treaty Beneficiaries

U.S. treaty beneficiaries are generally eligible for treaty benefits under the Treaty, as described above in "—Taxation of Holders Not Tax Resident in Germany." Accordingly, U.S. treaty beneficiaries are in general entitled to claim a refund of (i) the portion of the otherwise applicable 26.375% German withholding tax (*Kapitalertragsteuer*) on dividends that exceeds the applicable Treaty rate and (ii) the full amount of German withholding tax (*Kapitalertragsteuer*) on capital gains from the disposition of ADSs. The application for such claim is generally to be filed with the Federal Central Office of Taxation (*Bundeszentralamt für Steuern*).

However, in respect of dividends, the refund described in the preceding paragraph is only possible if, due to special rules on the restriction of withholding tax credit, the following three cumulative requirements are met: (i) the holder must qualify as beneficial owner of the ADSs for an uninterrupted minimum holding period of 45 days within a period starting 45 days prior to and ending 45 days after the due date of the dividends, (ii) the holder has to bear at least 70% of the change in value risk related to the ADSs during the minimum holding period as described under (i) of this paragraph and has not entered into (acting by itself or through a related party) hedging transactions which lower the change in value risk by more than 30%, and (iii) the holder must not be obliged to fully or largely compensate directly or indirectly the dividends to third parties. If these requirements are not met, then for a holder not being tax-resident in Germany who applied for a full or partial refund of the withholding tax pursuant to a double taxation treaty, no refund is available. This restriction generally does only apply if (a) the tax underlying the refund application is below a tax rate of 15% based on the gross amount of the dividends and (b) the holder does not directly own 10% or more of the shares of BioNTech and is subject to income taxes in its state of residence, without being tax-exempt. The restriction of the withholding tax credit does not apply if the holder has beneficially owned the ADSs for at least one uninterrupted year until receipt (*Zufluss*) of the dividends.

In general, as previously discussed, investors should note that it is unclear how the German tax administration will apply the refund process to dividends on the ADSs. Further, such refund is subject to the German anti-avoidance treaty shopping rule. Generally, this rule requires that the U.S. treaty beneficiary (in case it is a non-German resident company) maintains its own administrative substance and conducts its own business activities. In particular, a foreign company has no right to a full or partial refund to the extent persons holding ownership interests in BioNTech would not be entitled to the refund if they derived the income directly and the gross income realized by the foreign company is not caused by the business activities of the foreign company, and there are either no economic or other considerable reasons for the interposition of the foreign company, or the foreign company does not participate in general commerce by means of a business organization with resources appropriate to its business purpose. However, this shall not apply if the foreign company's principal class of stock is regularly traded in substantial volume on a recognized stock exchange, or if the foreign company is subject to the provisions of the German Investment Tax Act (*Investmentsteuergesetz*). Whether or not and to which extent the anti-avoidance treaty shopping rule applies to the ADSs has to be analyzed on a case by case basis taking into account all relevant tests. In addition, the interpretation of these tests is disputed and to date no published decisions of the German Federal Finance Court exist in this regard.

Due to the legal structure of the ADSs, only limited guidance of the German tax authorities exists on the practical application of this procedure with respect to the ADSs.

Taxation of Holders Tax Resident in Germany

This subsection provides an overview of dividend taxation and of capital gains taxation with regard to the general principles applicable to ADS's holders that are tax resident in Germany. A holder is a German tax resident if, in case of an individual, he or she maintains a domicile (*Wohnsitz*) or a usual residence (*gewöhnlicher Aufenthalt*) in Germany or if, in case of a corporation, it has its place of management (*Geschäftsleitung*) or registered office (Sitz) in Germany.

The German dividend and capital gains taxation rules applicable to German tax residents require a distinction between ADSs held as private assets (*Privatvermögen*) and ADSs held as business assets (*Betriebsvermögen*).

ADSs as Private Assets (Privatvermögen)

If the ADSs are held as private assets by a German tax resident, dividends and capital gains (other than capital gains from the disposition of a Qualified Participation) are taxed as investment income and are principally subject to 25% German flat income tax on capital income (*Abgeltungsteuer*) (plus a 5.5% solidarity surcharge (*Solidaritätszuschlag*) thereon, resulting in an aggregate rate of 26.375%), which is levied in the form of withholding tax (*Kapitalertragsteuer*). In other words, once deducted, the holder's income tax liability on the dividends will be settled. Dividend payments to the extent funded from BioNTech's tax-recognized contribution account (*steuerliches Einlagekonto*), do not, subject to certain prerequisites, form part of the taxable dividend income but lower the holder's acquisition costs for the ADSs.

Holders of ADSs may apply to have their capital investment income assessed in accordance with the general rules and with an individual's personal income tax rate if this would result in a lower tax burden in which case actually incurred expenses are not deductible. The holder would be taxed on gross personal investment income (including dividends or gains with respect to ADSs), less the saver's allowance of €801 for an individual or €1,602 for a married couple and a registered civil union (*eingetragene Lebenspartnerschaft*) filing taxes jointly. The deduction of expenses related to the investment income (including dividends or gains with respect to ADSs) is generally not possible for private investors.

Losses resulting from the disposal of ADSs can only be offset against capital gains from the sale of any shares (*Aktien*) and other ADSs. If, however, a holder holds a Qualifying Participation, 60% of any capital gains resulting from the sale and transfer are taxable at the holder's personal income tax rate (plus 5.5% solidarity surcharge thereon). Conversely, 60% of any capital losses are recognized for tax purposes.

Church tax generally has to be withheld, if applicable, based on an automatic data access procedure, unless the holder of ADSs has filed a blocking notice (*Sperrvermerk*) with the Federal Central Tax Office. Where church tax is not levied by way of withholding, it is determined by means of income tax assessment.

ADSs as Business Assets (Betriebsvermögen)

In case the ADSs are held as business assets, the taxation depends on the legal form of the holder (*i.e.*, whether the holder is a corporation or an individual).

Irrespective of the legal form of the holder, dividends are subject to the aggregate withholding tax rate of 26.375%. The withholding tax is generally creditable against the respective holder's corporate income tax or income tax liability. Due to special rules on the restriction of withholding tax credits in respect of dividends, a full withholding tax credit requires that the following three cumulative requirements are met: (i) the holder must qualify as beneficial owner of the ADSs for an uninterrupted minimum holding period of 45 days occurring within a period starting 45 days prior to and ending 45 days after the due date of the dividends, (ii) the holder has to bear at least 70% of the change in value risk related to the ADSs during the minimum holding period as described under (i) of this paragraph and has not entered into (acting by itself or through a related party) hedging transactions which lower the change in value risk for more than 30%, and (iii) the holder must not be obliged to fully or largely compensate directly or indirectly the dividends to third parties. If these requirements are not met, three-fifths of the withholding tax imposed on the dividends must not be credited against the holder's corporate income tax or income tax liability, but may, upon application, be deducted from the holder's tax base for the relevant tax assessment period. A holder that is generally subject to German income tax or corporate income tax and that has received gross dividends without any deduction of withholding tax due to a tax exemption without qualifying for a full tax credit under the aforementioned requirements has to notify the competent local tax office accordingly and has to make a payment in the amount of the omitted withholding tax deduction. The special rules on the restriction of withholding tax credit do not apply to a holder whose overall dividend earnings within an assessment period do not exceed €20,000 or that has been the beneficial owner of the ADSs for at least one uninterrupted year 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.

With regard to holders in the legal form of a corporation, capital gains are in general effectively 95% tax exempt from corporate income tax (including solidarity surcharge). Dividends are also generally 95% tax exempt from corporate income tax (including solidarity surcharge), inter alia, if the holder held at least 10% of the registered share capital (*Grundkapital oder Stammkapital*) of BioNTech at the beginning of the calendar year ("Qualifying Dividends"). Five percent of the capital gains and five percent of the Qualifying Dividends are treated as non-deductible business expenses, respectively, and, as such, are subject to corporate income tax (including solidarity surcharge); actual business expenses incurred to generate dividends may be deducted. The acquisition of a participation of at least 10% in the course of a calendar year is deemed to have occurred at the beginning of such calendar year for the determination of whether a dividend is a Qualifying Dividend. Participations in the share capital of BioNTech held through a partnership, including co-entrepreneurships (*Mitunternehmerschaften*), are attributable to the respective partner only on a pro rata basis at the ratio of its entitlement to the profits of the partnership.

Further, capital gains and dividend income of a German tax resident corporation are generally subject to German trade tax. The aforementioned 95% exemption for capital gains generally applies also for trade tax purposes.

However, the amount of any dividends after deducting business expenses related to the dividends is not subject to trade tax if the corporation held at least 15% of BioNTech's registered share capital at the beginning of the relevant tax assessment period. In the latter case, the aforementioned exemption of 95% of the dividend income also applies for trade tax purposes. Losses from the sale of ADSs are generally not tax deductible for corporate income tax and trade tax purposes.

With regard to individuals holding ADSs as business assets, 60% of dividends and capital gains are taxed at the individual's personal income tax rate (plus 5.5% solidarity surcharge thereon). Correspondingly, only 60% of business expenses related to the dividends and capital gains as well as losses from the sale of ADSs are principally deductible for income tax purposes. The dividend income and 60% of the capital gains are generally subject to trade tax, which is fully or partly creditable against the individual's personal income tax by a lump-sum method. Dividends (after deduction of business expenses economically related thereto) are exempt from trade tax if the holder held at least 15% of BioNTech's registered share capital at the beginning of the relevant tax assessment period.

German Inheritance and Gift Tax (Erbschaft- und Schenkungsteuer)

The transfer of ADSs to another person by inheritance or gift should be generally subject to German inheritance and gift tax only if:

(i) the decedent or donor or heir, beneficiary or other transferee (a) maintained his or her domicile or a usual residence in Germany, (b) had its place of management or registered office in Germany at the time of the transfer, (c) is a German citizen who has spent no more than five consecutive years outside of Germany without maintaining a domicile in Germany or (d) is a German citizen who serves for a German entity established under public law and is remunerated for his or her service from German public funds (including family members who form part of such person's household, if they are German citizens) and is only subject to estate or inheritance tax in his or her country of domicile or usual residence with respect to assets located in such country (special rules apply to certain former German citizens who neither maintain a domicile nor have their usual residence in Germany);

(ii) at the time of the transfer, the ADSs are held by the decedent or donor as business assets forming part of a permanent establishment in Germany or for which a permanent representative in Germany has been appointed; or

(iii) the ADSs subject to such transfer form part of a portfolio that represents at the time of the transfer 10% or more of the registered share capital of BioNTech and that has been held directly or indirectly by the decedent or donor, either alone or together with related persons.

The Agreement between the Federal Republic of Germany and the United States of America for the avoidance of double taxation with respect to taxes on inheritances and gifts as of December 21, 2000 (*Abkommen zwischen der Bundesrepublik Deutschland und den Vereinigten Staaten von Amerika zur Vermeidung der Doppelbesteuerung auf dem Gebiet der Nachlass-, Erbschaft- und Schenkungssteuern in der Fassung vom 21. Dezember 2000*), hereinafter referred to as the "United States-Germany Inheritance and Gifts Tax Treaty," provides that the German inheritance tax or gift tax can, with certain restrictions, only be levied in the cases of (i) and (ii) above. Special provisions apply to certain German citizens living outside of Germany and former German citizens.

Other Taxes

No German transfer tax, value-added tax, stamp duty or similar taxes are assessed on the purchase, sale or other transfer of ADSs. Provided that certain requirements are met, an entrepreneur may, however, opt for value- added tax on transactions that are otherwise tax-exempt. Net wealth tax (*Vermögensteuer*) is currently not imposed in Germany. Certain member states of the European Union and also Germany on a standalone basis are considering introducing a financial transaction tax (*Finanztransaktionssteuer*) which, if and when introduced, may also be applicable on sales and/or transfer of ADSs.

Material United States Federal Income Tax Considerations

The following discussion describes material U.S. federal income tax considerations relating to the acquisition, ownership and disposition of ADSs by a U.S. Holder (as defined below) that acquires our ADSs and holds them as a capital asset. This discussion is based on the tax laws of the United States, including the Internal Revenue Code of 1986, as amended, or the Code, Treasury regulations promulgated or proposed thereunder, and administrative and judicial interpretations thereof, all as in effect on the date hereof. These tax laws are subject to change, possibly with retroactive effect, and subject to differing interpretations that could affect the tax consequences described herein. This section does not address the treatment of a non-U.S. holder, nor does it address the tax treatment under the laws of any state, local or foreign taxing jurisdiction.

For purposes of this discussion, a "U.S. Holder" is a beneficial owner of our ADSs that, for U.S. federal income tax purposes, is:

- an individual who is a citizen or resident of the United States;
- a domestic corporation (or other entity taxable as a corporation);
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust if (i) a court within the United States is able to exercise primary supervision over the trust's administration and one or more U.S. persons have the authority to control all substantial decisions of the trust or (ii) a valid election under the Treasury regulations is in effect for the trust to be treated as a U.S. person.

This discussion does not address all aspects of U.S. federal income taxation that may be applicable to U.S. Holders in light of their particular circumstances or status (including, for example, banks and other financial institutions, insurance companies, broker and dealers in securities or currencies, traders that have elected to mark securities to market, regulated investment companies, real estate investment trusts, partnerships or other pass- through entities, corporations that accumulate earnings to avoid U.S. federal income tax, tax-exempt organizations, pension plans, persons that hold our shares as part of a straddle, hedge or other integrated investment, persons subject to alternative minimum tax or whose "functional currency" is not the U.S. dollar).

If a partnership (including any entity or arrangement treated as a partnership for U.S. federal income tax purposes) holds our ADSs, the tax treatment of a person treated as a partner in the partnership for U.S. federal income tax purposes generally will depend on the status of the partner and the activities of the partnership. Partnerships (and other entities or arrangements so treated for U.S. federal income tax purposes) and their partners should consult their own tax advisors.

In general, and taking into account the earlier assumptions, for U.S. federal income and German tax purposes, a holder of ADSs will be treated as the owner of the shares represented by those ADSs. Exchanges of shares for ADSs, and ADSs for shares, generally will not be subject to U.S. federal income or to German tax.

This discussion addresses only U.S. Holders and does not discuss any tax considerations other than U.S. federal income tax considerations. Prospective investors are urged to consult their own tax advisors regarding the U.S. federal, state and local, and foreign tax consequences of the purchase, ownership, and disposition of ADSs.

Dividends

Under the U.S. federal income tax laws, and subject to the passive foreign investment company, or PFIC, rules discussed below, the gross amount of any dividend we pay out of our current or accumulated earnings and profits (as determined for U.S. federal income tax purposes) is includible in income for a U.S. Holder and subject to U.S. federal income taxation. Dividends paid to a noncorporate U.S. Holder that constitute qualified dividend income will be taxable at a preferential tax rate applicable to long-term capital gains, provided that the U.S. Holder holds the ADSs for more than 60 days during the 121-day period beginning 60 days before the ex-dividend date and meets other holding period requirements. Dividends we pay with respect to the ADSs generally will be qualified dividend income.

A U.S. Holder must include any German tax withheld from the dividend payment, as described above under "—German Taxation—General Rules for the Taxation of Holders Not Tax Resident in Germany," in the gross amount of dividend paid even though the holder does not in fact receive it. The dividend is taxable to the holder when the depositary receives the dividend, actually or constructively. Because we are not a U.S. corporation, the dividend will not be eligible for the dividends-received deduction generally allowed to U.S. corporations in respect of dividends received from other U.S. corporations. The amount of the dividend distribution includible in U.S. Holder's income will be the U.S. dollar value of the Euro payments made, determined at the spot Euro/U.S. dollar rate on the date the dividend distribution is includible in income, regardless of whether the payment is in fact converted into U.S. dollars. Generally, any gain or loss resulting from currency exchange fluctuations during the period from the date the dividend payment is included in income to the date the payment is converted into U.S. dollars will be treated as ordinary income or loss and will not be eligible for the special tax rate applicable to qualified dividend income. The gain or loss generally will be income or loss from sources within the United States for foreign tax credit limitation purposes.

To the extent a distribution with respect to ADSs exceeds our current or accumulated earnings and profits, as determined under U.S. federal income tax principles, the distribution will be treated, first, as a tax-free return of the U.S. Holder's investment, up to the holder's adjusted tax basis in its ADSs, and, thereafter, as capital gain, which is subject to the tax treatment described below in "—Gain on Sale, Exchange or Other Taxable Disposition."

Subject to certain limitations, the German tax withheld in accordance with the Treaty and paid over to the German taxing authority will be creditable or deductible against a U.S. Holder's U.S. federal income tax liability. To the extent a refund of the tax withheld is available to a U.S. Holder under German law or under the Treaty, the amount of tax withheld that is refundable will not be eligible for credit against a U.S. Holder's U.S. federal income tax liability. See "—German Taxation—Withholding Tax Refund for U.S. Treaty Beneficiaries" above for the procedures for obtaining a tax refund.

Gain On Sale, Exchange or Other Taxable Disposition

Subject to the PFIC rules described below under "—Passive Foreign Investment Company Considerations", a U.S. Holder that sells, exchanges or otherwise disposes of ADSs in a taxable disposition generally will recognize capital gain or loss for U.S. federal income tax purposes equal to the difference between the U.S. dollar value of the amount realized and the holder's tax basis, determined in U.S. dollars, in the ADSs. Gain or loss recognized on such a sale, exchange or other disposition of ADSs generally will be long-term capital gain if the U.S. Holder's holding period in the ADSs exceeds one year. Long-term capital gains of non-corporate U.S. Holders are generally taxed at preferential rates. The gain or loss generally will be income or loss from sources within the United States for foreign tax credit limitation purposes. A U.S. Holder's ability to deduct capital losses is subject to limitations.

Passive Foreign Investment Company Considerations

We do not believe that we should be treated as, and do not expect to become, a PFIC. Because the determination of our PFIC status is made annually based on the factual tests described below, however, we cannot provide any assurances regarding our PFIC status for the current or future taxable years or that the IRS will agree with our conclusion regarding our PFIC status.

If we were classified as a PFIC in any taxable year, a U.S. Holder would be subject to special rules with respect to distributions on and sales, exchanges and other dispositions of the ADSs. We will be treated as a PFIC for any taxable year

in which at least 75% of our gross income is "passive income" or at least 50% of our gross assets during the taxable year (based on the average of the fair market values of the assets determined at the end of each quarterly period) are assets that produce or are held for the production of passive income. Passive income for this purpose generally includes, among other things, dividends, interest, rents, royalties, gains from commodities and securities transactions, and gains from assets that produce passive income. However, rents and royalties received from unrelated parties in connection with the active conduct of a trade or business are not considered passive income for purposes of the PFIC test. In determining whether we are a PFIC, a pro rata portion of the income and assets of each corporation in which we own, directly or indirectly, at least a 25% interest (by value) is taken into account.

If we were a PFIC with respect to a U.S. Holder, then unless such U.S. Holder makes one of the elections described below, a special tax regime would apply to the U.S. Holder with respect to (i) any "excess distribution" (generally, aggregate distributions in any year that are greater than 125% of the average annual distribution received by the holder in the shorter of the three preceding years or the holder's holding period for the ADSs) and (ii) any gain realized on the sale or other disposition of the ADSs. Under this regime, any excess distribution and realized gain will be treated as ordinary income and will be subject to tax as if (a) the excess distribution or gain had been realized ratably over the U.S. Holder's holding period, (b) the amount deemed realized in each year had been subject to tax in each year of that holding period at the highest marginal rate for such year (other than income allocated to the current period or any taxable period before we became a PFIC, which would be subject to tax at the U.S. Holder's regular ordinary income rate for the current year and would not be subject to the interest charge discussed below), and (c) the interest charge generally applicable to underpayments of tax had been imposed on the taxes deemed to have been payable in those years. If we were determined to be a PFIC, this tax treatment for U.S. Holders would apply also to indirect distributions and gains deemed realized by U.S. Holders in respect of stock of any of our subsidiaries determined to be PFICs. In addition, dividend distributions would not qualify for the lower rates of taxation applicable to long-term capital gains discussed above under "—Taxation of Dividends."

A U.S. Holder that holds the ADSs at any time during a taxable year in which we are classified as a PFIC generally will continue to treat such ADSs as ADSs in a PFIC, even if we no longer satisfy the income and asset tests described above, unless the U.S. Holder elects to recognize gain, which will be taxed under the excess distribution rules as if such ADSs had been sold on the last day of the last taxable year for which we were a PFIC.

Certain elections by a U.S. Holder would alleviate some of the adverse consequences of PFIC status and would result in an alternative treatment of the ADSs, as described below.

If we were a PFIC, the rules above would not apply to a U.S. Holder that makes an election to treat ADSs as stock of a "qualified electing fund" or QEF. However, we do not expect that a U.S. Holder would be able to make this election because we do not intend to provide to U.S. Holders the required information to make a valid QEF election.

If we were a PFIC, the rules above also would not apply to a U.S. Holder that makes a "mark-to-market" election with respect to the ADSs, but this election will be available with respect to the ADSs only if they meet certain minimum trading requirements to be considered "marketable stock" for purposes of the PFIC rules. Generally, shares of ADSs will be treated as marketable stock if they are "regularly traded" on a "qualified exchange" within the meaning of applicable U.S. Treasury Regulations. ADSs generally will be considered regularly traded during any calendar year during which they are traded, other than in *de minimis* quantities, on at least 15 days during each calendar quarter. Any trades that have as their principal purpose meeting this requirement will be disregarded. Our ADSs will be marketable stock as long as they remain listed on the Nasdaq Global Select Market and are regularly traded.

A U.S. Holder that makes a valid mark-to-market election for the first tax year in which the holder holds (or is deemed to hold) ADSs and for which we are a PFIC will be required to include each year an amount equal to the excess, if any, of the fair market value of such ADSs the holder owns as of the close of the taxable year over the holder's adjusted tax basis in such ADSs. The U.S. Holder will be entitled to a deduction for the excess, if any, of the holder's adjusted tax basis in the ADSs over the fair market value of such ADSs as of the close of the taxable year, but only to the extent of any net mark-to-market gains with respect to such ADSs included by the U.S. Holder under the election for prior taxable years. The U.S. Holder's basis in such ADSs will be adjusted to reflect the amounts included or deducted pursuant to the election. Amounts included in income pursuant to a mark-to-market election, as well as gain on the sale, exchange or other taxable disposition of such ADSs, will be treated as ordinary income. The deductible portion of any mark-to-market loss, as well as loss on a sale, exchange or other disposition of ADSs to the extent that the amount of such loss does not exceed net mark-to-market gains previously included in income, will be treated as ordinary loss.

The mark-to-market election applies to the taxable year for which the election is made and all subsequent taxable years, unless the shares cease to be treated as marketable stock for purposes of the PFIC rules or the IRS consents to its revocation. The excess distribution rules described above generally will not apply to a U.S. Holder for tax years for which a mark-to-market election is in effect. However, if we were a PFIC for any year in which the U.S. Holder owns the ADSs but before a mark-to-market election is made, the interest charge rules described above would apply to any mark-to-market gain recognized in the year the election is made.

A U.S. Holder of PFIC shares must generally file an annual information return on IRS Form 8621 (Information Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund). The failure to file IRS Form 8621 could result in the imposition of penalties and the extension of the statute of limitations with respect to U.S. federal income tax.

U.S. Holders are urged to consult their tax advisors as to our status as a PFIC, and the tax consequences to them if we were a PFIC, including the reporting requirements and the desirability of making, and the availability of, a QEF election or a mark-to-market election with respect to the ADSs.

Medicare Tax

Non-corporate U.S. Holders that are individuals, estates or trusts and whose income exceeds certain thresholds generally are subject to a 3.8% tax on all or a portion of their net investment income, which may include their gross dividend income and net gains from the disposition of ADSs. A U.S. person that is an individual, estate or trust is encouraged to consult its tax advisors regarding the applicability of this Medicare tax to its income and gains in respect of any investment in ADSs.

Information Reporting with Respect to Foreign Financial Assets

Individual U.S. Holders may be subject to certain reporting obligations on IRS Form 8938 (Statement of Specified Foreign Financial Assets) with respect to the ADSs for any taxable year during which the U.S. Holder's aggregate value of these and certain other "specified foreign financial assets" exceed a threshold amount that varies with the filing status of the individual. This reporting obligation also applies to domestic entities formed or availed of to hold, directly or indirectly, specified foreign financial assets, including the ADSs. Significant penalties can apply if U.S. Holders are required to make this disclosure and fail to do so.

U.S. Holders who acquire ADSs for cash may be required to file IRS Form 926 (Return by a U.S. Transferor of Property to a Foreign Corporation) with the IRS and to supply certain additional information to the IRS if (i) immediately after the transfer, the U.S. Holder owns directly or indirectly (or by attribution) at least 10% of our total voting power or value or (ii) the amount of cash transferred to us in exchange for ADSs, when aggregated with all related transfers under applicable regulations, exceeds $100,000. Substantial penalties may be imposed on a U.S. Holder that fails to comply with this reporting requirement.

Information Reporting and Backup Withholding

In general, information reporting, on IRS Form 1099, will apply to dividends in respect of ADSs and the proceeds from the sale, exchange or redemption of ADSs that are paid to a holder of ADSs within the United States (and in certain cases, outside the United States), unless such holder is an exempt recipient such as a corporation. Backup withholding (currently at a 24% rate) may apply to such payments if a holder of ADSs fails to provide a taxpayer identification number (generally on an IRS Form W-9) or certification of other exempt status or fails to report in full dividend and interest income.

Backup withholding is not an additional tax. A U.S. Holder generally may obtain a refund of any amounts withheld under the backup withholding rules that exceed the U.S. Holder's income tax liability by filing a refund claim with the IRS.

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.

I. Subsidiary Information

Not applicable.

Item 11. Quantitative and Qualitative Disclosures About Market Risk

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

Currency Risk

We are subject to currency risk, as our income and expenditures are denominated in Euro and the U.S. dollar. As such, we are exposed to exchange rate fluctuations between these currencies. Cash inflows denominated in U.S. dollar occurred in the course of our initial public offering on the Nasdaq Global Select Market in October 2019, or our IPO, and from our Genentech collaboration agreement. We aim to match U.S. dollar cash inflows with U.S. dollar cash outflows where possible, and we do not hedge this exposure. If we increase sales of our products in the United States, we would expect to have significant increases in cash balances, revenues and sales and marketing expenses denominated in U.S. dollars, while we would expect the majority of our development and operating expenses to remain denominated in Euro.

We publish our consolidated financial statements in Euro. Revenue and expenses incurred in U.S. dollars will be translated into Euro when they are reported in our consolidated financial statements. As a result, any substantial future appreciation or decline of the U.S. dollar against the Euro could have a material effect on our revenue and profitability. As an example, if the U.S. dollar weakens by 5% against the Euro, cash and cash equivalents as of December 31, 2019 would decrease by €10.2 million, or 2%.

For additional information about our quantitative and qualitative 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, it will, if appropriate, reduce the number of ADSs to reflect the sale and pay to ADS holders any proceeds, or send to ADS holders any property, remaining after it has paid the taxes.

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 evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. 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 chief executive officer and our chief financial officer have concluded that, as of December 31, 2019, our disclosure controls and procedures were not effective due to the material weakness in our internal control over financial reporting primarily related to (i) a lack of sufficient accounting and supervisory personnel who have the appropriate level of technical accounting experience and training, (ii) a lack of supervision over external consultants providing technical accounting services and (iii) a lack of consistent application of accounting processes and procedures by our accounting personnel.

Management's Annual Report on Internal Control over Financial Reporting

This Annual Report does not include a report of management's assessment regarding internal control over financial reporting due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

Attestation Report of the Registered Public Accounting Firm

This Annual Report does not include an attestation report of the company's registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies and because BioNTech is an emerging growth company under the JOBS Act.

Changes in Control over Financial Reporting

This Annual Report does not include disclosure of changes in control over financial reporting due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

Item 16A. Audit Committee Financial Expert

Our Audit Committee consists of Dr. Ulrich Wandschneider, Michael Motschmann and Helmut Jeggle. Dr. Ulrich Wandschneider is the chair of the Audit Committee. Dr. Wandschneider and Mr. Motschmann qualify as "independent directors" as such term is defined in Rule 10A-3 under the Exchange Act and Nasdaq Rule 5605. We intend to have a fully independent audit committee within one year from effectiveness of our IPO registration statement, as permitted by Rule 10A-3. Additionally, our Supervisory Board has determined that Dr. Ulrich Wandschneider qualifies as an "audit committee financial expert" as that term is defined under the Exchange Act.

Item 16B. Code of Ethics

We have adopted a Code of Business Conduct & Ethics, or Code of Conduct, which outlines the principles of legal and ethical business conduct under which we do business. The Code of Conduct applies to all of our Supervisory Board members, Management Board members, directors of our subsidiaries and our affiliates and employees. The full text of the Code of Conduct is available on our website at https://www.biontech.de. The information and other content appearing on our website are not part of this 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 Conduct for members of our Supervisory or Management Boards will be made only after approval by our Supervisory Board and will be disclosed on our website promptly following the date of such amendment or waiver.

Item 16C. Principal Accountant Fees and Services

Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft, or EY, has served as our independent registered public accounting firm for the years ended December 31, 2019, December 31, 2018 and December 31, 2017 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 thousands)	**2019**	**2018**
Audit fees	€578	€550
Audit-related fees	721	-
Tax fees	132	41
All other fees	49	32
Total fees for professional audit services and other services	**€1,480**	**€623**

Audit fees relate to the audit of the financial statements as set out in this Annual Report, certain procedures on our quarterly results and services related to our statutory and regulatory filings for our subsidiaries.

Audit-related fees billed for assurance and related services that are related to the issuance of a comfort letter in connection with our IPO in October 2019 and fees for other services relate to the IPO.

Tax service fees were billed for services in conjunction with transactions, especially with our IPO in October 2019.

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 year ended December 31, 2019 were approved by the Audit Committee. The external audit plan and fees for professional audit services and other services rendered by EY for the year ended December 31, 2018 were approved by the Supervisory Board. 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 in 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 December 16, 2019, was published in the German Federal Gazette (*Bundesanzeiger*) on March 20, 2020. The Corporate Governance Code contains recommendations (*Empfehlungen*) and suggestions (*Anregungen*) relating to the management and supervision of German companies that are listed on a stock exchange. It follows internationally and nationally recognized standards for good and responsible corporate governance. The purpose of the Corporate Governance Code is to make the German system of corporate governance transparent for investors. The Corporate Governance Code includes corporate governance recommendations and suggestions with respect to shareholders and shareholders' meetings, the management and supervisory boards, transparency, accounting policies and auditing.

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.

While in our opinion it is doubtful whether the above legal requirements and hence the Corporate Governance Code will apply following our listing on the Nasdaq Global Select Market, we intend to issue the annual declaration described above on a voluntary basis. Therefore, our Management Board and Supervisory Board will comply with the Corporate Governance Code except for such provisions which are explicitly listed in the annual declaration and for which they provide an explanation of non-compliance.

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***

	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.

	European Union/Federal Republic of Germany	*Delaware*
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 his removal would be sufficient to elect him if then cumulatively voted at an election of the entire board of directors, or, if there are classes of directors, at an election of the class of directors of which he is a part.
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 by-laws of the corporation or (ii) the certificate of incorporation directs that a particular class of stock is to elect such director, in which case a majority of the other directors elected by such class, or a sole remaining director elected by such class, will fill such vacancy.

	European Union/Federal Republic of Germany	*Delaware*
Annual General Meeting	A European stock corporation which is governed by German law must hold an annual shareholders' meeting within six months of the end of its fiscal year. The annual shareholders' meeting must be held at a location determined by the articles of association. If the articles of association do not provide for a specific location, the shareholders' meeting shall be held at the company's seat or, if applicable, at the venue (in Germany) where its shares are listed.	Under Delaware law, the annual meeting of stockholders shall be held at such place, on such date and at such time as may be designated from time to time by the board of directors or as provided in the certificate of incorporation or by the bylaws.
General Meeting	Under the law, extraordinary shareholders' meetings, in addition to the annual shareholders' meetings, may be called by either the Management Board, or by the Supervisory Board. Shareholders holding at least 5% of the company's share capital are entitled to request that an extraordinary shareholders' meeting be convened. In the event that the meeting is not then so convened, 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	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.

voting by issuing a written vote to another Supervisory Board member or any third party entitled to attend the Supervisory Board meeting.

	European Union/Federal Republic of Germany	*Delaware*
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.

	European Union/Federal Republic of Germany	*Delaware*
Liability of Directors and Officers	Under German law, any provision, whether contained in the company's articles of association or any contract or otherwise, that purports to exempt a Management or Supervisory Board member from any liability that would otherwise attach to such board member in connection with any negligence, default, breach of duty or breach of trust in relation to the company is void. Under German law, members of both the Management Board and members of the Supervisory Board are liable to the company, and in certain cases to third parties or shareholders, for any damage caused to them due to a breach of such member's duty of care. Apart from insolvency or special circumstances, only the company has the right to claim damages from members of either board. The company may waive claims for damages against a negligent Management or Supervisory Board member only after the expiry of three years.	Under Delaware law, a corporation's certificate of incorporation may include a provision eliminating or limiting the personal liability of a director to the corporation and its stockholders for damages arising from a breach of fiduciary duty as a director. However, no provision can limit the liability of a director for: • any breach of the director's duty of loyalty to the corporation or its stockholders; • acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law; • intentional or negligent payment of unlawful dividends or stock purchases or redemptions; or • any transaction from which the director derives an improper personal benefit.
Voting Rights	Under the relevant European and German law, each share, except for statutory non-voting preferred shares (*nicht stimmberechtigte Vorzugsaktien*), entitles its holder to vote at the shareholders' meeting with, in the case of no-par value shares, each share conferring one vote. While German law does not provide for a minimum attendance quorum for 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.

	European Union/Federal Republic of Germany	*Delaware*
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 Supervisory 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 himself of all material information reasonably available regarding a significant transaction. The duty of loyalty requires that a director act in a manner he reasonably believes to be in the best interests of the corporation. He must not use his corporate position for personal gain or advantage. In general, but subject to certain exceptions, actions of a director are presumed to have been made on an informed basis, in good faith and in the honest belief that the action taken was in the best interests of the corporation. However, this presumption may be rebutted by evidence of a breach of one of the fiduciary duties. Delaware courts have also imposed a heightened standard of conduct upon directors of a Delaware corporation who take any action designed to defeat a threatened change in control of the corporation. In addition, under Delaware law, when the board of directors of a Delaware 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.

	European Union/Federal Republic of Germany	*Delaware*
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 plaintiffs shares thereafter devolved on the plaintiff by operation of law; and • either (i) allege with particularity the efforts made by the plaintiff to obtain the action the plaintiff desires from the directors and the reasons for the plaintiff's failure to obtain the action, or (ii) or state the reasons for not making the effort. Additionally, the plaintiff must remain a stockholder through the duration of the derivative suit. The action will not be dismissed or compromised without the approval of the Delaware Court of Chancery.

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 Section 16 rules regarding sales of ordinary shares by insiders, which will provide less data in this regard than the data provided to shareholders of U.S. companies that are subject to the Exchange Act; and
- exemption from the Nasdaq rules applicable to domestic issuers requiring disclosure within four business days of any determination to grant a waiver of the code of business conduct and ethics to directors and officers. Although we will require board approval of any such waiver, we may choose not to disclose the waiver in the manner set forth in the Nasdaq rules, as permitted by the foreign private issuer exemption.

Furthermore, Nasdaq Rule 5615(a)(3) provides that a foreign private issuer, such as we, may rely on home country corporate governance practices in lieu of certain of the rules in the Nasdaq Rule 5600 Series and Rule 5250(d), provided that we nevertheless comply with Nasdaq's Notification of Noncompliance requirement (Rule 5625) and the Voting Rights requirement (Rule 5640) and that we have an audit committee that satisfies Rule 5605(c)(3), consisting of committee members that meet the independence requirements of Rule 5605(c)(2)(A)(ii). Although we are permitted to follow certain corporate governance rules that conform to German requirements in lieu of many of the Nasdaq corporate governance rules, we 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.

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
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)
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 IVAC Developments to the Master Agreement for Research Services by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH, BioNTech Diagnostics GmbH, BioNTech Protein Therapeutics GmbH, BioNTech Cell & Gene Therapies GmbH, BioNTech Innovative Manufacturing Services GmbH (f/k/a Eufets GmbH), JPT Peptide Technologies GmbH and TRON-Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH, dated November 28, 2017 (incorporated herein by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
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	Amended Patent License Agreement by and among the Registrant, the Board of Supervisors of Louisiana State University and Agricultural and Mechanical College and Uniwersytet Warszawski, dated May 12, 2015 (incorporated herein by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.7	License and Collaboration Agreement by and between the Registrant and Genmab A/S, dated May 19, 2015 (incorporated herein by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.8	Amendment No. 1 to License and Collaboration Agreement by and between the Registrant and Genmab A/S, dated May 18, 2017 (incorporated herein by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.9	Amendment No. 2 to License and Collaboration Agreement by and between the Registrant and Genmab A/S, dated August 4, 2017 (incorporated herein by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.10	Amendment No. 3 to License and Collaboration Agreement by and between the Registrant and Genmab A/S, dated May 18, 2018 (incorporated herein by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.11	Collaboration and License Agreement by and between Sanofi S.A. and BioNTech RNA Pharmaceuticals GmbH, dated November 2, 2015 (incorporated herein by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.12	Amendment to Collaboration and License Agreement by and between Sanofi S.A. and BioNTech RNA Pharmaceuticals GmbH, dated December 22, 2018 (incorporated herein by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.13	Development Agreement by and between Sanofi S.A. and BioNTech RNA Pharmaceuticals GmbH, dated March 29, 2018 (incorporated herein by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.14	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)
4.15*	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
4.16*	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
4.17	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)
4.18	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)

4.19	License and Co-Development Agreement by and between Genevant Sciences GmbH and BioNTech RNA Pharmaceuticals GmbH, dated July 4, 2018 (incorporated herein by reference to Exhibit 10.17 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.20	Research Collaboration and License Agreement by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH and Pfizer, Inc., dated July 20, 2018 (incorporated herein by reference to Exhibit 10.18 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.21	Collaboration and License Agreement by and between the Trustees of the University of Pennsylvania and BioNTech RNA Pharmaceuticals GmbH, dated October 9, 2018 (incorporated herein by reference to Exhibit 10.19 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.22	Sublease Agreement by and among the Registrant and Universitätsmedizin der Johannes Gutenberg-Universität Mainz, dated January 14, 2013 (incorporated herein by reference to Exhibit 10.21 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.23	Amendment to Sublease Agreement by and among the Registrant and Universitätsmedizin der Johannes Gutenberg-Universität Mainz, dated July 5, 2014 (incorporated herein by reference to Exhibit 10.22 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.24	Amendment to Sublease Agreement by and among the Registrant and Universitätsmedizin der Johannes Gutenberg-Universität Mainz, dated June 8, 2015 (incorporated herein by reference to Exhibit 10.23 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.25	Amendment to Sublease Agreement by and among the Registrant and Universitätsmedizin der Johannes Gutenberg-Universität Mainz, dated January 18, 2017 (incorporated herein by reference to Exhibit 10.24 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.26	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)
4.27	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)
4.28	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)
4.29	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)
4.30	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)

4.31	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)
4.32	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)
4.33	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)
4.34	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)
4.35*	Amendment to Lease Agreement by and among the Registrant and Wista-Management GmbH, dated October 24, 2019
4.36	Loan Agreement by and between BioNTech Innovative Manufacturing Services GmbH and Deutsche Bank AG dated November 21, 2017 (incorporated herein by reference to Exhibit 10.34 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.37	Loan Agreement by and between JPT Peptides Technologies GmbH and Deutsche Bank AG dated July 18, 2018 (incorporated herein by reference to Exhibit 10.35 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.38	Investment Agreement by and between the Registrant and the Bill & Melinda Gates Foundation, dated August 30, 2019 (incorporated herein by reference to Exhibit 10.36 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.39	Letter Agreement by and between the Registrant and the Bill & Melinda Gates Foundation, dated August 30, 2019 (incorporated herein by reference to Exhibit 10.37 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.40	Drug Discovery Research, Development and Commercialization Agreement by and between the Registrant and Eli Lilly and Company, dated May 11, 2015 (incorporated herein by reference to Exhibit 10.38 to the Registrant's Registration Statement on Form F-1/A (File No. 333-233688), filed with the SEC on September 24, 2019)
4.41*	Finance Contract by and between the Registrant and the European Investment Bank, dated December 12, 2019
4.42*	Finance Fee Letter by and between the Registrant and the European Investment Bank, dated December 12, 2019
8*	List of Subsidiaries of the Registrant
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
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.

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 31, 2020

By: /s/ Prof. Ugur Sahin, M.D.
Prof. Ugur Sahin, M.D.
Chief Executive Officer

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Management and the 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, 2019 and 2018, the related consolidated statements of operations, comprehensive loss, changes in equity and cash flows for each of the three years in the period ended December 31, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, in conformity with International Financial Reporting Standards as issued by the International Accounting Standard Board.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/Titus Zwirner	/s/Andreas Weigel
Wirtschaftsprüfer	Wirtschaftsprüfer
(German Public Auditor)	(German Public Auditor)

Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft

We have served as the Company's auditor since 2018

Cologne, Germany
March 31, 2020

Consolidated Statements of Financial Position

(in thousands)		As of December 31, 2019	As of December 31, 2018
Assets	***Note***		
Non-current assets			
Intangible assets	11	€89,434	€88,042
Property, plant and equipment	10	93,044	66,200
Right-of-use assets	19	55,018	49,766
Other financial assets	12	-	18
Total non-current assets		**€237,496**	**€204,025**
Current assets			
Inventories	13	11,722	5,789
Trade receivables	14	11,913	18,938
Other financial assets	12	1,680	336
Other assets	15	9,069	9,164
Income tax assets		756	891
Deferred expense		5,862	2,348
Cash and cash equivalents	12	519,149	411,495
Total current assets		**€560,151**	**€448,961**
Total assets		**€797,647**	**€652,986**
Equity and liabilities			
Equity			
Share capital*	16	232,304	193,296
Capital reserve*	16	686,714	344,115
Treasury shares*	16	(5,525)	-
Accumulated losses		(424,827)	(245,771)
Other reserves	17	4,826	(25,487)
Equity attributable to equity holders of the parent		**€493,492**	**€266,153**
Non-controlling interest		-	847
Total equity		**€493,492**	**€267,000**
Non-current liabilities			
Financial liabilities	12	68,904	54,218
Contract liabilities	4	97,109	205,647
Total non-current liabilities		**€166,013**	**€259,865**
Current liabilities			
Tax provisions		150	297
Provisions		762	710
Financial liabilities		1,823	-
Trade payables	12	20,498	41,721
Contract liabilities	4	93,583	66,027
Other financial liabilities	12	13,836	8,266
Other liabilities	18	7,490	9,100
Total current liabilities		**€138,142**	**€126,121**
Total liabilities		**€304,155**	**€385,986**
Total equity and liabilities		**€797,647**	**€652,986**

* Numbers have been adjusted to reflect capital increase due to 1:18 share split which occurred on September 18, 2019.

The accompanying notes form an integral part of these consolidated financial statements.

Consolidated Statements of Operations

(in thousands, except per share data)	Note	Years ended December 31, 2019	2018	2017
Revenues from contracts with customers	4	€108,589	€127,575	€61,598
Cost of sales	7.1	(17,361)	(13,690)	(9,318)
Gross profit		**€91,228**	**€113,885**	**€52,280**
Research and development expenses	7.2	(226,466)	(143,040)	(85,496)
Sales and marketing expenses	7.3	(2,718)	(3,041)	(6,603)
General and administrative expenses	7.4	(45,547)	(26,334)	(23,520)
Other operating income	7.5	2,724	5,396	2,349
Other operating expenses		(739)	(720)	(288)
Operating loss		**€(181,518)**	**€(53,854)**	**€(61,277)**
Finance income	7.6	4,122	8,046	2,133
Finance expenses	7.7	(326)	(48)	(26,007)
Interest expense related to lease liability	19	(1,718)	(1,721)	(676)
Share of loss of equity method investees		-	(84)	(78)
Loss before tax		**€(179,440)**	**€(47,662)**	**€(85,905)**
Income taxes	8	268	(600)	(45)
Loss for the period		**€(179,172)**	**€(48,262)**	**€(85,950)**
Attributable to:				
Equity holders of the parent		(179,056)	(48,019)	(85,653)
Non-controlling interests		(116)	(243)	(297)
		€(179,172)	**€(48,262)**	**€(85,950)**
Earnings per share				
in EUR				
Basic & diluted, loss per share for the year attributable to ordinary equity holders of the parent	9	€(0.85)	€(0.25)	€(0.51)

The accompanying notes form an integral part of these consolidated financial statements.

Consolidated Statements of Comprehensive Loss

		Years ended December 31,		
(in thousands)	**Note**	**2019**	**2018**	**2017**
Loss for the period		**€(179,172)**	**€(48,262)**	**€(85,950)**
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		77	10	(23)
Net other comprehensive income that may be reclassified to profit or loss in subsequent periods		**77**	**10**	**(23)**
Other comprehensive income for the period, net of tax		**77**	**10**	**(23)**
Comprehensive loss for the period, net of tax		**€(179,095)**	**€(48,252)**	**€(85,973)**
Attributable to:				
Equity holders of the parent		(178,979)	(48,009)	(85,677)
Non- controlling interests		(116)	(243)	(297)
Comprehensive loss for the period, net of tax		**€(179,095)**	**€(48,252)**	**€(85,973)**

The accompanying notes form an integral part of these consolidated financial statements.

Consolidated Statements of Changes in Stockholders' Equity

		Year ended December 31, 2019								
		Equity attributable to equity holders of the parent								
(in thousands)	Note	Share capital*	Capital reserve*	Treasury shares*	Accumulated losses	Other reserves	Foreign currency translation reserve	Total	Non-controlling interest	Total equity
As of January 1, 2019		**€193,296**	**344,115**	**-**	**(245,771)**	**(25,474)**	**(13)**	**266,153**	**847**	**267,000**
Loss for the period		-	-	-	(179,056)	-	-	**(179,056)**	(116)	**(179,172)**
Other comprehensive income		-	-	-	-	-	77	**77**	-	**77**
Total comprehensive income		**-**	**-**	**-**	**(179,056)**	**-**	**77**	**(178,979)**	**(116)**	**(179,095)**
Issuance of share capital	16	8,126	41,748	-	-	-	-	**49,874**	-	**49,874**
Capital increase Series B	16	17,990	186,390	(5,525)	-	-	-	**198,855**	-	**198,855**
Capital increase initial public offering (referred to as IPO)	16	10,517	132,743	-	-	-	-	**143,260**	-	**143,260**
Acquisition of non-controlling interest	16	2,375	(1,644)	-	-	-	-	**731**	(731)	**-**
Transaction costs	16	-	(16,638)	-	-	-	-	**(16,638)**	-	**(16,638)**
Share-based payments	17	-	-	-	-	30,236	-	**30,236**	-	**30,236**
As of December 31, 2019		**€232,304**	**686,714**	**(5,525)**	**(424,827)**	**4,762**	**64**	**493,492**	**-**	**493,492**

* Numbers have been adjusted to reflect capital increase due to 1:18 share split which occurred on September 18, 2019.

		Year ended December 31, 2018								
		Equity attributable to equity holders of the parent								
(in thousands)	Note	Share capital*	Capital reserve*	Treasury shares*	Accumulated losses	Other reserves	Foreign currency translation reserve	Total	Non-controlling interest	Total equity
As of January 1, 2018		**€166,764**	**8,922**	**-**	**(197,753)**	**(27,206)**	**(23)**	**(49,296)**	**1,090**	**(48,206)**
Loss for the period		-	-	-	(48,019)	-	-	**(48,019)**	(243)	**(48,262)**
Other comprehensive income		-	-	-	-	-	10	**10**	-	**10**
Total comprehensive income		**-**	**-**	**-**	**(48,019)**	**-**	**10**	**(48,009)**	**(243)**	**(48,252)**
Issuance of share capital	16	25,949	329,867	-	-	-	-	**355,816**	-	**355,816**
Share based payments	17	-	-	-	-	7,641	-	**7,641**	-	**7,641**
Settlement of share-based payment plan		583	5,326	-	-	(5,909)	-	**-**	-	**-**
As of December 31, 2018		**€193,296**	**344,115**	**-**	**(245,771)**	**(25,474)**	**(13)**	**266,153**	**847**	**267,000**

* Numbers have been adjusted to reflect capital increase due to 1:18 share split which occurred on September 18, 2019.

		Year ended December 31, 2017								
		Equity attributable to equity holders of the parent								
(in thousands)	**Note**	**Share capital***	**Capital reserve***	**Treasury shares***	**Accumulated losses**	**Other reserves**	**Foreign currency translation reserve**	**Total**	**Non-controlling interest**	**Total equity**
As of January 1, 2017		**€3,270**	**172,416**	**-**	**(112,100)**	**(33,115)**	**-**	**30,471**	**1,387**	**31,858**
Loss for the period		-	-	-	(85,653)	-	-	**(85,653)**	(297)	**(85,950)**
Other comprehensive income		-	-	-	-	-	(23)	**(23)**	-	**(23)**
Total comprehensive income		**-**	**-**	**-**	**(85,653)**	**-**	**(23)**	**(85,676)**	**(297)**	**(85,973)**
Issuance of share capital	16	163,494	(163,494)	-	-	-	-	**-**	-	**-**
Share based payments	17	-	-	-	-	5,909	-	**5,909**	-	**5,909**
As of December 31, 2017		**€166,764**	**8,922**	**-**	**(197,753)**	**(27,206)**	**(23)**	**(49,296)**	**1,090**	**(48,206)**

* Numbers have been adjusted to reflect capital increase due to 1:18 share split which occurred on September 18, 2019.

The accompanying notes form an integral part of these consolidated financial statements.

Consolidated Statements of Cash Flows

(in thousands)	Years ended December 31, 2019	2018	2017
Operating activities			
Loss for the period	€(179,172)	€(48,262)	€(85,950)
Income taxes	(268)	600	45
Loss before tax	**€(179,440)**	**€(47,662)**	**€(85,905)**
Adjustments to reconcile loss before tax to net cash flows:			
Depreciation and amortization of property, plant, equipment and intangible assets	33,896	21,984	10,529
Share-based payment expense	30,235	7,641	5,909
Net foreign exchange differences	70	459	24,820
(Gain)/Loss on disposal of property, plant and equipment	542	(14)	15
Finance income	(1,782)	(1,996)	(2,133)
Interest on lease liability	1,718	1,721	676
Finance expense	326	48	53
Share of loss of an associate and a joint venture	-	84	78
Working capital adjustments:			
Decrease/(Increase) in trade receivable and contract assets	2,939	(18,732)	(2,816)
Decrease/(Increase) in inventories	(5,798)	(1,253)	(574)
(Decrease)/Increase in trade and other payables, contract liabilities and provisions	(80,577)	(21,080)	(4,574)
Interest received	1,256	1,996	2,133
Interest paid	(2,044)	(1,769)	(729)
Income tax received (paid), net	122	(304)	(45)
Net cash flows used in operating activities	**€(198,537)**	**€(58,877)**	**€(52,562)**
Investing activities			
Purchase of property, plant and equipment	(38,592)	(29,901)	(24,320)
Proceeds from sale of property, plant and equipment	21	705	5,193
Purchase of intangibles assets	(32,488)	(37,256)	(33,422)
Acquisition of subsidiaries and businesses, net of cash acquired	(6,056)	-	-
Net cash flows used in investing activities	**€(77,115)**	**€(66,452)**	**€(52,549)**
Financing activities			
Proceeds from issuance of share capital, net of costs	375,351	361,725	-
Proceeds from loans and borrowings	11,000	5,600	-
Payment of finance lease liabilities	(3,061)	(2,148)	(1,643)
Net cash flows from/(used in) financing activities	**€383,290**	**€365,177**	**€(1,643)**
Net increase/(decrease) in cash and cash equivalents	107,638	239,848	(106,753)
Change in cash resulting from exchange rate differences	16	(459)	(24,820)
Cash and cash equivalents at January 1	411,495	172,106	303,680
Cash and cash equivalents at December 31	**€519,149**	**€411,495**	**€172,106**

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 Depository Shares (ADS) representing BioNTech's shares are publicly traded on Nasdaq Global Select Market since October 10, 2019. The registered office is located in Mainz, An der Goldgrube 12, 55131 Germany. The accompanying International Financial Reporting Standards (IFRS) consolidated financial statements present the financial position and the results of operation of BioNTech SE and its subsidiaries, hereinafter also referred to as "BioNTech" or the "Group".

Effective March 8, 2019, BioNTech AG changed its name and legal form to BioNTech SE. The Group is principally engaged in developing innovative immunotherapies for the individualized treatment of cancer and other infectious diseases.

During the year ended December 31, 2019 the following changes to the Group structure occurred:

- Two entities were founded in the United States: BioNTech USA Holding, LLC and BioNTech Research & Development, Inc. Both are wholly-owned subsidiaries of BioNTech SE.
- reBOOST Management GmbH, was acquired through a share purchase which represents a related party transaction.

All entities listed above are included in the Group's consolidated financial statements.

Information on the Group's structure is provided in Note 5.

The consolidated financial statements of the Group for the year ended year ended December 31, 2019 were authorized for issue in accordance with a resolution of the directors on March 31, 2020.

2 Significant Accounting Policies

2.1 Basis of Preparation

The consolidated financial statements have been prepared on a going concern basis in accordance with the IFRS as issued by the International Accounting Standards Board (IASB).

BioNTech prepares and publishes its consolidated financial statements in Euros. Unless otherwise stated, the numbers are rounded to thousands of Euros. Accordingly, numerical figures shown as totals in some tables may not be exact arithmetic aggregations of the figures that preceded them.

2.2 Basis of Consolidation

The consolidated financial statements comprise the financial statements of the Company 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.

The Group re-assesses whether it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control. Consolidation of a subsidiary begins when the Group obtains control over the subsidiary and ceases when the Group loses control of the subsidiary.

The statement of operations and each component of other comprehensive income are attributed to the equity holders of the parent of the Group and to the non-controlling interests, even if this results in the non-controlling interests having a deficit balance. When necessary, adjustments are made to the financial statements of subsidiaries to bring their accounting policies in line with the Group's accounting policies. All intra-group assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated on consolidation.

A change in the ownership interest of a subsidiary, without a loss of control, is accounted for as an equity transaction.

If the Group loses control over a subsidiary, it derecognizes the related assets (including goodwill), liabilities, non-controlling interests and other components of equity, while any resultant gain or loss is recognized in the statement of operations. Any investment retained is recognized at fair value.

2.3 Summary of Significant Accounting Policies

2.3.1 Business combinations and Goodwill

Business combinations are accounted for using the acquisition method. The cost of an acquisition is measured as the aggregate of the consideration transferred, which is measured at acquisition date fair value, and the amount of any non-controlling interests in the acquiree.

Goodwill is initially measured at cost as the excess of the aggregate of the consideration transferred and the amount recognized for non-controlling interests and any previous interest held over the net identifiable assets acquired and liabilities assumed.

After initial recognition, goodwill is tested at least annually or when there is an indication for impairment. See Note 2.3.13.

2.3.2 Current versus Non-Current Classifications

The Group presents assets and liabilities in the consolidated statements of financial position based on current or non-current classification. An asset is current when it is either: (i) expected to be realized within 12 months after the reporting period or (ii) cash or cash equivalents, unless it is restricted from being exchanged or used to settle a liability for at least 12 months after the reporting period. All other assets are classified as non-current. A liability is current when it is due to be settled within 12 months after the reporting period. The Group classifies all other liabilities as non-current.

Deferred tax assets and liabilities are classified as non-current assets and liabilities, respectively.

2.3.3 Fair Value Measurement

Fair value is a market-based measurement. For some assets and liabilities, observable market transactions or market information is available. For other assets and liabilities, observable market transactions or market information might not be available. When a price for an identical asset or liability is not observable, another valuation technique is used. To increase consistency and comparability in fair value measurements, there are three levels of the fair value hierarchy:

- Level 1 contains the use of quoted prices in active markets for identical assets or liabilities.
- Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability either directly or indirectly.
- Level 3 inputs are unobservable.

Within this hierarchy, estimated values are made by management based on reasonable assumptions, including other fair value methods.

For assets and liabilities that are recognized in the financial statements at fair value on a recurring basis, the Group determines whether transfers have occurred between levels in the fair value hierarchy by re-assessing categorization (based on the lowest level input that is significant to the fair value measurement as a whole) at the end of each reporting period.

For the purpose of fair value disclosures, the Group has determined classes of assets and liabilities on the basis of the nature, characteristics and risks of the asset or liability and the level of the fair value hierarchy, as explained above.

2.3.4 Revenue from Contracts with Customers

Revenue Recognition

Revenue from contracts with customers is recognized when control of the goods or services are transferred to the customer at an amount that reflects the consideration to which BioNTech expects to be entitled in exchange for those goods or services. If a contract with a customer contains more than one performance obligation, the transaction price is allocated to each performance obligation on a relative-stand-alone selling price basis. BioNTech has generally concluded that it acts as the principal in its revenue arrangements because it typically controls the goods or services before transferring them to the customer. The following is a description of these activities.

Revenue from Collaboration and License Agreements

BioNTech generates revenues from collaboration and license agreements under which BioNTech grants licenses to use, research, develop, manufacture and commercialize product candidates and products. If the grant of a license is bundled together with the rendering of services, it is assessed whether these agreements are comprised of more than one performance obligation. A performance obligation is only accounted for as the grant of a license if the grant of a license is the sole or the predominant promise of the performance obligation. For each promise to grant a license that is a separate performance obligation, it is considered whether control is transferred to a licensee either at a point in time or over time. Under the terms of its licensing arrangements, BioNTech provides the licensee with a right to access BioNTech's intellectual property as it exists throughout the license period (as BioNTech's intellectual property is still subject to further research). Therefore, the promise to grant a license is accounted for as a performance obligation satisfied over time, as the licensee simultaneously receives and consumes the benefits of BioNTech's performance.

If the consideration in an agreement includes a variable amount, BioNTech estimates the amount of consideration to which BioNTech will be entitled in exchange for transferring the goods to the customer. At contract inception, the variable consideration is estimated based on the most likely amount of consideration expected from the transaction and constrained until it is highly probable that a significant revenue reversal in the amount of cumulative revenue recognized will not occur when the associated uncertainty with respect the variable consideration is subsequently resolved. The estimated deferred revenue is updated at each reporting date to reflect the current facts and circumstances.

Rendering of Services

BioNTech provides development and manufacturing services to customers and recognizes revenue over time using an input-based method to measure progress toward complete satisfaction of the services because the customer simultaneously receives and consumes the benefits provided by BioNTech. If BioNTech has a right to consideration from a customer in the amount that corresponds directly with the value to the customer of BioNTech's performance completed to date (for example, service contracts in which BioNTech bills a fixed amount for each hour or day of service provided), BioNTech recognizes revenue in the amount for which BioNTech has a right to invoice the customer.

Sale of Products

Revenue from the sale of medical products (*e.g.*, peptides and retroviral vectors for clinical supply) is recognized when BioNTech transfers control of the product to the customer. Control of the product normally transfers when the customer gains physical possession and BioNTech has not retained any significant risks of ownership or future obligations with respect to the product. A receivable is recognized, as the consideration is unconditional and only the passage of time is required before payment is due. The transaction price is quoted in the relevant price lists in force at the date of customer placing the respective order for such products. Payments from customers are due within 20 days (Europe) or 30 days (non-Europe) after invoice.

Contract Balances

Contract Assets

A contract asset is the right to consideration in exchange for goods or services transferred to the customer. If BioNTech performs by transferring goods or services to a customer before the customer pays consideration or before payment is due, a contract asset is recognized for the earned consideration that is conditional.

Trade Receivables

A receivable represents BioNTech's right to an amount of consideration that is unconditional (*i.e.*, only the passage of time is required before payment of the consideration is due).

Contract Liabilities

A contract liability is the obligation to transfer goods or services to a customer for which BioNTech has received consideration (or an amount of consideration is due) from the customer. If a customer pays consideration before BioNTech transfers goods or services to the customer, a contract liability is recognized when the payment is made or when the payment is due (whichever is earlier). Contract liabilities are recognized as revenue when BioNTech performs under the contract.

2.3.5 Government Grants

Government grants are recognized where there is reasonable assurance that the grant will be received and all attached conditions will be complied with. When the grant relates to an expense item, it is recognized as income on a systematic basis over the periods that the related costs, for which the grant is intended to compensate, are expensed. When the grant relates to an asset, it is recognized as deduction in calculating the carrying amount of the asset and thus in the statement of operations over the life of the depreciable asset as a reduced depreciation expense.

2.3.6 Taxes

Current Income Tax

Current income tax assets and liabilities are measured at the amount expected to be recovered from or paid to the taxation authorities. The tax rates and tax laws used to compute the amount are those that are enacted or substantively enacted at the reporting date in the countries where the Group operates and generates taxable income.

Management periodically evaluates positions taken in the tax returns with respect to situations in which applicable tax regulations are subject to interpretation and establishes provisions where appropriate.

Deferred Tax

Deferred tax is provided using the liability method on temporary differences between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes at the reporting date.

Deferred tax liabilities are recognized for all taxable temporary differences, except:

- when the deferred tax liability arises from the initial recognition of goodwill or an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss; or
- in respect of taxable temporary differences associated with investments in subsidiaries, associates and interests in joint arrangements, when the timing of the reversal of the temporary differences can be controlled and it is probable that the temporary differences will not reverse in the foreseeable future.

Deferred tax assets are recognized for all deductible temporary differences, the carry forward of unused tax credits and any unused tax losses. Deferred tax assets are recognized to the extent that it is probable that taxable profit will be available against which the deductible temporary differences, the carry forward of unused tax credits and unused tax losses can be utilized, except:

- when the deferred tax asset relating to the deductible temporary difference arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss; or
- in respect of deductible temporary differences associated with investments in subsidiaries, associates and interests in joint arrangements, deferred tax assets are recognized only to the extent that it is probable that the temporary differences will reverse in the foreseeable future and taxable profit will be available against which the temporary differences can be utilized.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply in the year in which the asset is realized, or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted at the reporting date.

Recognition of Taxes

Current and deferred tax items are recognized similar to the underlying transaction either in profit or loss, other comprehensive income or directly in equity.

The Group offsets current tax assets and current tax liabilities if, and only if, it has a legally enforceable right to set off the recognized amounts and intends 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 the Group has a legally enforceable right to set off current tax assets and current tax liabilities and the deferred tax assets and deferred tax liabilities relate to income taxes levied by the same taxation authority on either (i) the same taxable entity or (ii) different taxable entities which intend either to settle current tax liabilities and assets on a net basis, or to realize the assets and settle the liabilities simultaneously, in each future period in which significant amounts of deferred tax liabilities or assets are expected to be settled or recovered.

Sales Tax

Expenses and assets are recognized net of sales tax, except when the sales tax incurred on a purchase of assets or services is not recoverable from the taxation authority.

The net amount of sales tax recoverable from, or payable to, the taxation authority is included as part of receivables or payables in the statement of financial position.

2.3.7 Foreign Currencies

The Group's consolidated financial statements are presented in Euros, which is also the parent company's functional currency. For each entity, the Group determines the functional currency, and items included in the financial statements of such entity are measured using that functional currency. The Group uses the direct method of consolidation and on disposal of a foreign operation, the gain or loss that is reclassified to the statement of operations reflects the amount that arises from using this method.

Transactions and Balances

Transactions in foreign currencies are initially recorded by the Group's entities at their respective functional currency spot rates at the date the transaction first qualifies for recognition.

Monetary assets and liabilities denominated in foreign currencies are translated at the functional currency spot rates of exchange at the reporting date.

Non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rates at the dates of the initial transactions.

In determining the spot exchange rate to use on initial recognition of the related asset, expense or income (or part of it) on the derecognition of a non-monetary asset or non-monetary liability relating to advance consideration, the date of the transaction is the date on which the Group initially recognizes the non-monetary asset or non-monetary liability arising from the advance consideration. If there are multiple payments or receipts in advance, the Group determines the transaction date for each payment or receipt of advance consideration.

Foreign Currency Translation

On consolidation, the assets and liabilities of foreign operations are translated into Euros at the rate of exchange prevailing at the reporting date and their statements of operations are translated at exchange rates prevailing at the dates of the transactions.

The exchange differences arising on translation for consolidation are recognized in other comprehensive income. On disposal of a foreign operation, the component of other comprehensive income relating to that particular foreign operation is reclassified to profit or loss.

Any goodwill arising on the acquisition of a foreign operation and any fair value adjustments to the carrying amounts of assets and liabilities arising upon the acquisition are treated as assets and liabilities of the foreign operation and translated at the spot rate of exchange at the reporting date.

2.3.8 Property, Plant and Equipment

Construction in progress is stated at cost, net of accumulated impairment losses, if any. Property, plant and equipment are stated at cost, net of accumulated depreciation and accumulated impairment losses, if any. Such cost includes the cost of replacing part of the property, plant and equipment if the recognition criteria are met. All other repair and maintenance costs are expensed as incurred.

Depreciation is calculated on a straight-line basis over the estimated useful lives of the assets, as follows:

Property, plant and equipment	**Useful life (Years)**
Buildings	7-33
Equipment, tools and installations	3-15

An item of property, plant and equipment initially recognized is derecognized upon disposal (*i.e.*, at the date the recipient obtains control) or when no future economic benefits are expected from its use or disposal. Any gain or loss arising on derecognition of the asset (calculated as the difference between the net disposal proceeds and the carrying amount of the asset) is included in the statement of operations when the asset is derecognized.

The residual values, useful lives and methods of depreciation of property, plant and equipment are reviewed at each financial year end and adjusted prospectively, if appropriate.

2.3.9 Leases

The Group early adopted IFRS 16 Leases for annual periods beginning on January 1, 2017.

At the inception of a contract, the Group assesses whether the contract is, or contains, a lease. A contract is, or contains, a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. To assess whether a contract conveys the right to control the use of an identified asset, the Group assesses whether:

- the contract involves the use of an identified asset—this may be specified explicitly or implicitly and should be physically distinct or represent substantially all of the capacity of a physically distinct asset. If the supplier has a substantive substitution right, then the asset is not identified;
- the Group has the right to obtain substantially all of the economic benefits from use of the asset throughout the period of use; and
- the Group has the right to direct the use of the asset. The Group has this right when it has the decision-making rights that are most relevant to changing how and for what purpose the asset is used. In rare cases where the decision about how and for what purpose the asset is used is predetermined, the Group has the right to direct the use of the asset if either:
  - the Group has the right to operate the asset; or
  - the Group designed the asset in a way that predetermines how and for what purpose it will be used.

At inception or on reassessment of a contract that contains a lease component, the Group allocates the consideration in the contract to each lease component on the basis of their relative stand-alone prices. However, for the leases of land and buildings in which it is a lessee, the Group has elected not to separate non-lease components, and instead accounts for the lease and non-lease components as a single lease component.

The Group recognizes a right-of-use asset and a lease liability at the lease commencement date. The right-of-use asset is initially measured at cost, which comprises the initial amount of the lease liability adjusted for any lease payments made at or before the commencement date, plus any initial direct costs incurred and an estimate of the costs to dismantle and remove the underlying asset or to restore the underlying asset or the site on which it is located, less any lease incentives received by the Group.

The right-of-use asset is subsequently depreciated using the straight-line method from the commencement date to the earlier of the end of the useful life of the right-of-use asset and the end of the lease term. The estimated useful lives of right-of-use assets are determined on the same basis as those of property and equipment. In addition, the right-of-use asset is periodically reduced by impairment losses, if any, and adjusted for certain remeasurements of the lease liability.

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 Group uses its incremental borrowing rate as the discount rate.

Lease payments included in the measurement of the lease liability comprise the following:

- fixed payments, including in-substance fixed payments;
- variable lease payments that depend on an index or a rate, initially measured using the index or rate as of the commencement date;
- amounts expected to be payable under a residual value guarantee; and
- the exercise price under a purchase option that the Group is reasonably certain to exercise, lease payments in an optional renewal period if the Group is reasonably certain to exercise an extension option, and penalties for early termination of a lease unless the Group is reasonably certain not to terminate early.

The lease liability is subsequently measured at amortized cost using the effective interest method. It is remeasured when there is a change in future lease payments arising from a change in an index or rate, if there is a change in the Group's estimate of the amount expected to be payable under a residual value guarantee, or if the Group changes its assessment of whether it will exercise a purchase, extension or termination option. When the lease liability is remeasured, a corresponding adjustment is made to the carrying amount of the right-of-use asset or is recorded in the statement of operations if the carrying amount of the right-of-use asset has been reduced to zero.

The Group presents right-of-use assets separately and lease liabilities in 'financial liabilities' in the statement of financial position.

Depreciation is calculated on a straight-line basis over the estimated useful lives of the assets or shorter lease term, as follows:

Right-of-use assets	**Useful life (Years)**
Buildings	2-25
Equipment, tools and installations	2-5
Automobiles	3-4

Short-Term Leases and Leases of Low-Value Assets

The Group has elected not to recognize right-of-use assets and lease liabilities for short-term leases of machinery that have a lease term of 12 months or less or leases of low-value assets. The Group recognizes the lease payments associated with these leases as an expense in the statement of operations on a straight-line basis over the lease term.

2.3.10 Intangible Assets

Intangible assets acquired separately are measured on initial recognition at cost. The cost of intangible assets acquired in a business combination is their fair value at the date of acquisition. Following initial recognition, intangible assets are carried at cost less any accumulated amortization and accumulated impairment losses.

The useful lives of intangible assets are assessed as either finite or indefinite.

Intangible assets with finite lives are amortized generally on a straight-line basis over the useful economic life and assessed for impairment whenever there is an indication that the intangible asset may be impaired. The amortization period and the amortization method for an intangible asset with a finite useful life are at least reviewed at the end of each reporting period. The amortization expense on intangible assets with finite lives is recognized in the statement of operations 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	10-20
Licenses	3-20

Intangible assets with indefinite useful lives are not amortized, but 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 2.3.13 for further details). The assessment of indefinite life is reviewed annually to determine whether the indefinite life continues to be supportable. If not, the change in useful life from indefinite to finite is made on a prospective basis.

The group has classified advanced payments on intangible assets as intangible assets which 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 statement of operations.

Research and Development Costs

Research costs are expensed as incurred. Development expenditures on an individual project are recognized as an intangible asset if, and only if, all of the following six criteria can be demonstrated by the Group:

- the technical feasibility of completing the intangible asset so that the asset will be available for use or sale;
- its intention to complete the project;
- the ability and intention to use or sell the asset;
- how the asset will generate future economic benefits;
- the availability of resources to complete the asset; and
- the ability to reliably measure the expenditure during development.

Owing to the high risks up to the time that pharmaceutical products are approved, these criteria are not met in the Biotech business sector until regulatory approval has been provided. Therefore, the Group has not yet capitalized any development expenditures. The related expenditure is reflected in the statement of operations in the period in which the expenditure is incurred.

2.3.11 Financial Instruments – Initial Recognition and Subsequent Measurement

A financial instrument is any contract that gives rise to a financial asset of one entity and a financial liability or equity instrument of another entity.

i) Financial Assets

Initial recognition and Measurement

Financial assets are initially measured at fair value, after the initial measurement the financial assets are subsequently classified as either measured at amortized cost, fair value through other comprehensive income, or fair value through profit or loss.

The classification of financial assets at initial recognition depends on the financial asset's contractual cash flow characteristics and the Group's business model for managing them. With the exception of trade receivables that do not contain a significant financing component or for which the Group has applied the practical expedient, the Group initially measures a financial asset at its fair value plus, in the case of a financial asset not at fair value through profit or loss, transaction costs. Trade receivables that do not contain a significant financing component or for which the Group has applied the practical expedient are measured at the transaction price determined under IFRS 15. Refer to the accounting policies in Note 2.3.4.

In order for a financial asset to be classified and measured at amortized cost or fair value through OCI, it needs to give rise to cash flows that are 'solely payments of principal and interest (SPPI)' on the principal amount outstanding. This assessment is referred to as the SPPI test and is performed at an instrument level.

Financial Assets at Amortized Cost (Debt Instruments)

The Group measures financial assets at amortized cost if both of the following conditions are met:

- the financial asset is held within a business model with the objective to hold financial assets in order to collect contractual cash flows; and
- the contractual terms of the financial asset give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding.

Financial assets at amortized cost are subsequently measured using the effective interest rate (EIR) method, and are subject to impairment. Gains and losses are recognized in the statement of operations when the asset is derecognized, modified or impaired.

Derecognition

A financial asset (or, where applicable, a part of a financial asset or part of a group of similar financial assets) is primarily derecognized (i.e., removed from the Group's consolidated statement of financial position) when the rights to receive cash flows from the asset have expired or have been transferred in terms of fulfilling the derecognition criteria.

Impairment of Financial Assets

An allowance for expected credit losses (ECLs) is recognized for all debt instruments not held at fair value through profit or loss. ECLs are based on the difference between the contractual cash flows due in accordance with the contract and all of the cash flows that the Group expects to receive, discounted at an approximation of the original effective interest rate. The expected cash flows will include cash flows from the sale of collateral held or other credit enhancements that are integral to the contractual terms.

For trade receivables and contract assets, the Group applies a simplified approach in calculating ECLs. Therefore, the Group does not track changes in credit risk, but instead recognizes a loss allowance based on lifetime ECLs at each reporting date. The Group has established a provision matrix that is based on its historical credit loss experience, adjusted for forward-looking factors specific to the debtors and the economic environment.

ii) Financial Liabilities

Initial Recognition and Measurement

Financial liabilities are classified, at initial recognition, as financial liabilities at fair value through profit or loss, loans and borrowings or as payables.

All financial liabilities are recognized initially at fair value and, in the case of loans and borrowings and payables, net of directly attributable transaction costs.

The Group's financial liabilities include trade payables and other financial liabilities.

Subsequent Measurement

The measurement of financial liabilities depends on their classification, as described below.

Financial Liabilities at Fair Value through Profit or Loss

The Group has no financial liabilities measured at fair value through profit or loss.

Loans, Borrowings, Trade Payables and Other Financial Liabilities

After initial recognition, interest-bearing loans and borrowings, trade payables and other financial liabilities are subsequently measured at amortized cost using the EIR method. Gains and losses are recognized in the statement of operations when the liabilities are derecognized as well as through the EIR amortization process.

Amortized cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the EIR. The EIR amortization is included as finance costs in the statement of operations.

This category generally applies to interest-bearing loans and borrowings.

Derecognition

A financial liability is derecognized when the obligation under the liability is discharged or cancelled or expires. When an existing financial liability is replaced by another from the same lender on substantially different terms, or the terms of an existing liability are substantially modified, such an exchange or modification is treated as the derecognition of the original liability and the recognition of a new liability. The difference in the respective carrying amounts is recognized in the statement of operations.

2.3.12 Inventories

Inventories are valued at the lower of cost and net realizable value.

Costs incurred in bringing each product to its present location and condition are accounted for as follows:

- raw materials and supplies: purchase cost on a first-in/first-out basis; or
- unfinished goods and finished goods: cost of direct materials and labor and a proportion of manufacturing overheads based on the normal operating capacity, but excluding borrowing costs.

Net realizable value is the estimated selling price in the ordinary course of business, less estimated costs of completion and the estimated costs necessary to make the sale.

2.3.13 Impairment of Non-Financial Assets

The Group assesses, at each reporting date, whether there is an indication that an asset may be impaired. If any indication exists, or when annual impairment testing for an asset is required, the Group estimates the asset's recoverable amount. An asset's recoverable amount is the higher of an asset's or cash generating unit's (CGU) fair value less costs of disposal and its value in use. The recoverable amount is determined for an individual asset, unless the asset does not generate cash inflows that are largely independent of those from other assets or groups of assets. When the carrying amount of an asset or cash generating unit exceeds its recoverable amount, the asset is considered impaired and is written down to its recoverable amount.

In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset. In

determining fair value less costs of disposal, recent market transactions are taken into account. If no such transactions can be identified, an appropriate valuation model is used. These calculations are corroborated by valuation multiples, quoted share prices for publicly traded companies or other available fair value indicators.

The Group bases its impairment calculation on detailed budgets and forecast calculations, which are prepared separately for each of the Group's cash generating units to which the individual assets are allocated. These budgets and forecast calculations generally cover a period of five years. A long-term growth rate is calculated and applied to project future cash flows after the fifth year.

Impairment losses of continuing operations are recognized in the statement of operations in expense categories consistent with the function of the impaired asset.

For assets excluding goodwill, an assessment is made at each reporting date to determine whether there is an indication that previously recognized impairment losses no longer exist or have decreased. If such indication exists, the Group estimates the asset's or cash generating unit's recoverable amount. A previously recognized impairment loss is reversed only if there has been a change in the assumptions used to determine the asset's recoverable amount since the last impairment loss was recognized. The reversal is limited so that the carrying amount of the asset does not exceed its recoverable amount, nor exceed the carrying amount that would have been determined, net of depreciation, had no impairment loss been recognized for the asset in prior years. Such reversal is recognized in the statement of operations unless the asset is carried at a revalued amount, in which case, the reversal is treated as a revaluation increase.

2.3.14 Cash and Cash Equivalents

Cash and cash equivalents comprise cash in banks and on hand and short-term deposits with an original maturity of three months or less, which are subject to an insignificant risk of changes in value.

2.3.15 Provisions

Provisions are recognized when the Group has a present obligation (legal or constructive) as a result of a past event, it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation and a reliable estimate can be made of the amount of the obligation. When the Group expects some or all of a provision to be reimbursed, for example, under an insurance contract, the reimbursement is recognized as a separate asset, but only when the reimbursement is virtually certain. The expense relating to a provision is presented in the statement of operations net of any reimbursement.

2.3.16 Share-Based Payments

Employees (and others providing similar services) receive remuneration in the form of share-based payments, which are settled in equity instruments (equity-settled transactions).

Equity-Settled Transactions

The cost of equity-settled transactions is determined by the fair value at the date when the grant is made using an appropriate valuation model, further details of which are given in Note 17.

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), over the period in which the service is provided (the vesting period). The cumulative expense recognized for equity-settled transactions at each reporting date until the vesting date reflects the extent to which the vesting period has expired and the Group's best estimate of the number of equity instruments that will ultimately vest.

2.4 Standards applied for the First Time

In 2019 several new and amended standards and interpretations became effective. These were applied for the first time, but did not have an impact on the consolidated financial statements of the Group.

Standards/Interpretations	Date of application
IFRIC 23 Uncertainty over income tax treatment	January 1, 2019
Amendments to IFRS 9 Prepayment Features with Negative Compensation	January 1, 2019
Amendments to IAS 19 Plan Amendment, Curtailment or Settlement	January 1, 2019
Amendments to IAS 28 Long-term interests in associates and joint ventures	January 1, 2019
Annual improvement cycle to IFRS 2015-2017	January 1, 2019

2.5 Standard issued but not yet effective

The new and amended standards and interpretations that are issued, but not yet effective, up to the date of issuance of the Group's financial statements and that might have an impact on the Group's financial statements are disclosed below. The Group has not early adopted any standards and intends to adopt these new and amended standards and interpretations, if applicable, when they become effective.

Standards/Interpretations	Date of application
Amendments to IFRS 3 Business Combinations	January 1, 2020
Amendments to IFRS 9, IAS 39 and IFRS 7 Interest Rate Benchmark Reform	January 1, 2020
Amendments to IAS 1 and IAS 8 Definition of Material	January 1, 2020
Amendments to References to the Conceptual Framework in IFRS Standards	January 1, 2020
Amendments to IAS 1 Presentation of Financial Statements: Classification of Liabilities as Current or Non-current	January 1, 2022

The Group does not expect a significant impact of the application of any of these amendments.

3 Significant Accounting Judgments, Estimates and Assumptions Continued

The preparation of the Group's consolidated financial statements requires management to make judgements, estimates and assumptions that affect the reported amounts of revenues, expenses, assets and liabilities, the accompanying disclosures, and the disclosure of contingent liabilities. Uncertainty about these assumptions and estimates could result in outcomes that require a material adjustment to the carrying amount of assets or liabilities affected in future periods.

Judgments

In the process of applying the Group's accounting policies, management has made the following judgments, which have the most significant effect on the amounts recognized in the consolidated financial statements:

Revenue from Contracts with Customers

BioNTech applied the following judgements that significantly affect the determination of the amount and timing of revenue from contracts with customers:

Identification and Determination of the Nature of Performance Obligations in Collaboration and License Agreements

BioNTech generates revenues from collaboration and license agreements under which BioNTech grants licenses to use, research, develop, manufacture and commercialize candidates and products. As these agreements comprise several promises, it must be assessed whether these promises are capable of being distinct within the context of the contract. If these promises are not distinct, they have to be combined until the bundle of promised goods and services is distinct. For some agreements, this results in BioNTech accounting for all goods and services promised in a collaboration and license agreement as a single performance obligation with a single measure of progress.

For these combined performance obligations, it must be assessed which of these promises is the predominant promise to determine the nature of the performance obligation. BioNTech determined that the grant of the license is the predominant promise within the (combined) performance obligation to grant a license to the customers. It was assessed that BioNTech grants their customers a right to access or a right to use BioNTech's intellectual property due to the collaboration and license agreements.

Consequently, the promise to grant a license is accounted for as a performance obligation satisfied over time as BioNTech's customer simultaneously receive and consumes the benefits from BioNTech's performance.

Estimation of Variable Consideration and Assessment of the Constraint when Determining the Deferred Revenue

BioNTech's collaboration and license agreements comprise variable considerations which are contingent on the occurrence or non-occurrence of a future event *(i.e.*, reaching a certain milestone). When determining the deferred revenue of a collaboration and license agreement, BioNTech is required to estimate the amount of consideration to which it will be entitled in exchange for transferring the promised goods or services to the customer.

As there are usually only two possible outcomes (*i.e.*, milestone is reached or not), BioNTech has assessed that the method of the most likely amount is the best method to predict the amount of consideration to which BioNTech will be entitled.

The most likely amount of these milestone payments *(i.e.*, the full milestone payment) is only included in the transaction price if the occurrence of reaching future milestone is highly probable. BioNTech has assessed that the likelihood of achieving the respective milestone decreases depending on how far the expected date of achieving the milestone lies in the future.

BioNTech has concluded that future milestone payments are fully constrained at the end of the current fiscal year.

Future milestone payments would become unconstrained at the satisfaction of the milestone event, specifically a development event, a regulatory approval or achievement of a sales milestone.

For the carrying amounts of the revenue recognition-related contract balances, see Note 4.

Estimates and Assumptions

The key assumptions concerning the future and other key sources of estimation uncertainty at the reporting date that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year are described below. The Group based its assumptions and estimates on parameters available when the consolidated financial statements were prepared. Existing circumstances and assumptions about future developments, however, may change due to market changes or circumstances arising that are beyond the control of the Group. Such changes are reflected in the assumptions when they occur.

Share-Based Payments

Determining the fair value of share-based payment transactions requires the most appropriate valuation for the specific program, which depends on the underlying terms and conditions.

This estimate also requires the determination of the most appropriate inputs to the valuation model when calculating the fair value of the share option.

The Group has used an external appraisal for the measurement of the cash- and equity-settled transactions' fair value at the grant date considering certain assumption relating to, *e.g.*, the volatility of stock price, the determination of an appropriate risk-free interest rate, expected dividends and the probability of reaching a minimum hurdle to exercise the relevant options. 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 post the initial public offering, the grant date's share prices on the Nasdaq Global Select Market were included in the valuation.

For further disclosures relating to share-based payments, see Note 17.

Leases

Right-of-use assets are measured at the amount equal to the lease liability, adjusted by the amount of any prepaid or accrued lease payments relating to that lease.

Significant accounting judgments are required for the determination of the appropriate incremental borrowing rate, which is to be used in the calculation of the asset and liability that are recognized in the financial statements regarding the lease contracts.

For the carrying amounts of right-of-use assets and the related lease liability, see Note 19.

Taxes

Deferred tax assets are recognized for unused tax losses only to the extent that it is probable that taxable profit will be available against which the losses can be utilized. Significant management judgement is required to determine the amount of deferred tax assets that can be recognized, based upon the likely timing and the level of future taxable profits, together with future tax planning strategies.

The Group has tax losses carried forward and these losses relate to subsidiaries that have a history of losses. The subsidiaries neither have any taxable temporary difference nor any tax planning opportunities available that could partly support the recognition of these losses as deferred tax assets.

On this basis, the Group has determined that it cannot recognize deferred tax assets on the tax losses carried forward.

For further disclosures relating to deferred taxes, see Note 8.

4 Revenue from contracts with customers

4.1 Disaggregated revenue information

Set out below is the disaggregation of the Group's revenue from contracts with customers:

	Years ended December 31,		
(in thousands)	**2019**	**2018**	**2017**
Revenues resulting from collaboration and license agreements	€84,428	€101,837	€42,333
Genentech Inc.	*64,026*	*49,536*	*27,829*
Pfizer Inc.	*14,348*	*7,174*	-
Sanofi S.A.	*4,233*	*41,712*	*5,665*
Genmab A/S	-	*2,740*	*6,765*
Eli Lilly and Company	*1,821*	*676*	*2,074*
Revenues from other sales transactions	24,161	25,738	19,265
Total	**€108,589**	**€127,575**	**€61,598**

Through December 31, 2019, BioNTech received k€279,542 in upfront fees from Genentech under the Genentech Collaboration Agreement. Such amounts are initially deferred and subsequently recognized as revenue as the Company performs under the agreement and measured based on the costs incurred under the respective research programs. Of these upfront fees, k€64,026 was recognized as revenue in the year ended December 31, 2019 (k€49,536 in 2018; k€27,829 in 2017). As of December 31, 2019, k€131,556 upfront fees is recognized as deferred revenue within contract liabilities in the statement of financial position (as of December 31, 2018: k€195,582).

Through December 31, 2019, BioNTech received k€59,560 in upfront and near-term milestone payments from Sanofi under the Sanofi Agreement. Such amounts are initially deferred and subsequently recognized as revenue as the Company performs under the agreement and measured based on the costs incurred under the respective research programs. Of these upfront fees, k€4,233 was recognized as revenue in the year ended December 31, 2019 (k€8,535 in 2018; k€5,665 in 2017). As of December 31, 2019, k€34,483 upfront fees is recognized as deferred revenue within contract liabilities in the statement of financial position (as of December 31, 2018: k€38,716). During the year ended December 31, 2018, BioNTech

recognized k€33,177 of revenue from Sanofi for reimbursement of 50% of Cellscript sublicense costs pursuant to a separate sub-sublicense agreement dated December 22, 2018.

Through December 31, 2019, BioNTech received k€43,044 in upfront fees from Pfizer under the Pfizer Collaboration Agreement. Such amounts are initially deferred and subsequently recognized as revenue as BioNTech performs under the agreement and measured based on the time elapsed under the respective research programs. Of these upfront fees, k€14,348 was recognized as revenue in the year ended December 31, 2019 (k€7,174 in 2018). As of December 31, 2019, k€21,522 upfront fees is recognized as deferred revenue within contract liabilities in the statement of financial position (as of December 31, 2018: k€35,870).

The transactions resulting from product sales that are included within the revenue from other sales transactions are as follows:

	Years ended December 31,		
(in thousands)	**2019**	**2018**	**2017**
Product sales of JPT Peptide Technologies GmbH	€12,111	€10,748	€10,652

During the year ended December 31, 2019, BioNTech recognized revenue of k€1,059 under a bill-and-hold transaction for which the customer already had obtained control. The bill-and-hold arrangement is substantive since the request to retain the product in BioNTech's facilities until January 2020 was initiated by the customer.

4.2 Contract Balances

(in thousands)	**December 31, 2019**	**December 31, 2018**
Trade receivables	€11,913	€18,938
Contract liabilities	190,692	271,674

Trade receivables are non-interest bearing and are generally settled within 20 to 30 days.

Contract assets are recognized for revenue earned from sales and services based on individual customer contracts of BioNTech Innovative Manufacturing Services GmbH. However, the customers' advance payments exceeded BioNTech's transferred goods and services for which a conditional right to consideration exists. Therefore, only contract liabilities net of contract assets are presented as per December 31, 2019 and December 31, 2018, respectively.

Contract liabilities include mainly upfront fees received from BioNTech's major collaboration and license agreements. The outstanding balances of these accounts decreased during the year ended December 31, 2019 as revenues resulting from these agreements exceeded further payments received from the collaborators due to the achievement of milestones. During the year ended December 31, 2019, BioNTech did not receive upfront fees or an unconditional right of consideration from the collaboration and license agreements (year ended December 31, 2018: k€41,120) and recognized revenues resulting from collaboration and license agreements of k€82,607 (during the year ended December 31, 2018: k€65,068), which reduced the contract liabilities. In addition, during the year ended December 31, 2019, a milestone payment of k€1,821 was received from the Eli Lilly and Company collaboration agreement and recorded as revenue.

Set out below is the amount of revenue recognized for the periods indicated:

	Years ended December 31,		
(in thousands)	**2019**	**2018**	**2017**
Amounts included in contract liabilities at the beginning of the year	€82,607	€65,068	€40,428

4.3 Performance Obligations

Information about BioNTech's performance obligations is summarized below:

Collaboration and License Agreements

BioNTech accounts for its promises to grant licenses as performance obligations satisfied over time as the customers simultaneously receive and consume the benefit of BioNTech's performance of providing access to its intellectual property as the performance occurs. BioNTech recognizes revenue over time by measuring the progress toward complete satisfaction of that performance obligation according to the method that demonstrates BioNTech's performance towards complete satisfaction. In contracts in which the costs vary based on the stage of research, an input-based measure considering cost incurred depicts most reliably the progress of the related research activities. In other contracts, revenue recognition on a straight-line basis most reliably depicts BioNTech's performance toward complete satisfaction. In case the contractual activities progress, the achievement of development milestones will be used to measure the progress toward complete satisfaction.

The deferred revenue allocated to the remaining performance obligations (unsatisfied or partially unsatisfied) as at year-end are as follows:

(in thousands)	**December 31, 2019**	**December 31, 2018**
Within one year	€90,453	€64,522
More than one year	97,109	205,647
Total	**€187,562**	**€270,169**

The deferred revenue allocated to the remaining performance obligations does not contain deferred revenues of performance obligations which are part of contracts that have an original expected duration of one year or less or of performance obligations for which the consideration from the customer corresponds directly to the value to the customer of BioNTech's performance to date at an amount of k€3,130 (December 31, 2018: k€1,505).

5 Group information

Information about Subsidiaries

The consolidated financial statements of the Group include the following subsidiaries:

			% equity interest	
Name	**Country of incorporation**	**Registered office**	**December 31, 2019**	**December 31, 2018**
BioNTech RNA Pharmaceuticals GmbH	Germany	Mainz	100%	100%
BioNTech Delivery Technologies GmbH (previously BioNTech Protein Therapeutics GmbH)	Germany	Halle (previously Mainz)	100%	100%
BioNTech Diagnostics GmbH	Germany	Mainz	100%	100%
BioNTech Small Molecules GmbH	Germany	Mainz	100%	100%
BioNTech IVAC GmbH (previously BioNTech Business Services GmbH)	Germany	Mainz	100%	100%
BioNTech Austria Beteiligungen GmbH	Austria	Vienna	100%	100%
BioNTech Innovative Manufacturing Services GmbH	Germany	Idar- Oberstein	100%	100%
reBOOST Management GmbH	Germany	Mainz	100%	n/a
JPT Peptide Technologies GmbH	Germany	Berlin	100%	100%
JPT Inc. (previously TheraCode JPT Inc.)	United States	Acton	100%	100%
BioNTech USA Holding LLC	United States	New York	100%	n/a
BioNTech Research and Development Inc.	United States	New York	100%	n/a
BioNTech Cell & Gene Therapies GmbH	Germany	Mainz	100%	94.50%
BioNTech Real Estate Holding GmbH (previously Apta IT GmbH)	Germany	Holzkirchen	100%	100%
BioNTech Real Estate Verwaltungs GmbH	Germany	Holzkirchen	100%	100%
BioNTech Real Estate GmbH & Co. KG	Germany	Holzkirchen	100%	100%

During the year ended December 31, 2019, two entities were founded in the United States: BioNTech USA Holding, LLC and BioNTech Research & Development, Inc. Both are wholly-owned subsidiaries of BioNTech SE. Additionally, reBOOST Management GmbH, was acquired through a share purchase which represents a related party transaction.

During the year ended December 31, 2018, BioNTech Real Estate Verwaltungs GmbH and BioNTech Real Estate GmbH & Co. KG were established.

Parent Company

ATHOS KG, Holzkirchen, Germany owns 100% of shares in AT Impf GmbH, Munich, Germany and is the beneficiary owner of BioNTech. AT Impf GmbH, Munich, Germany is the parent company of the Group and 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, 2019**	**December 31, 2018**
AT Impf GmbH	Germany	Munich	50.33%	54.16%

Entity with significant Influence over the Group

Medine GmbH, Mainz 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, 2019**	**December 31, 2018**
Medine GmbH	Germany	Mainz	18.38%	21.57%

6 Business Combinations

MAB Discovery GmbH

In January 2019, BioNTech entered into an agreement to acquire MAB Discovery GmbH's operational antibody generation unit based near Munich, Germany (hereinafter also referred to as "MAB Discovery"), for a total consideration of k€6,050. The employees of MAB Discovery were transferred automatically to BioNTech with effect as of the closing date. The acquisition closed on April 1, 2019.

The Group has acquired MAB Discovery because it intends to adopt and pursue the unit's current business into its own.

The fair values of the identifiable net assets of MAB Discovery as at the date of acquisition were:

	Fair value recognized on acquisition
(in thousands)	MAB Discovery GmbH
Assets	
Goodwill	€2,205
Other intangible assets	2,711
Property, plant and equipment	999
Inventories	135
Total identifiable net assets at fair value	**€6,050**

(in thousands)	**Cash flow on acquisition** MAB Discovery GmbH
Net cash acquired	-
Cash paid	€6,050
Net cash flow on acquisition	**€(6,050)**

The consolidated financial statements include the results of MAB Discovery since the acquisition date. From the date of acquisition, MAB Discovery contributed k€4,299 to loss before tax in the Technology Platform business segment from continuing operations of the Group. If the transaction would have occurred at the beginning of the reporting period, an estimated amount of k€5,232 would have contributed to loss before tax in the Technology Platform business segment. From the date of acquisition, MAB Discovery did not generate any revenue and no revenue would have been generated if the transaction would have occurred at the beginning of the reporting period. Goodwill recognized is primarily attributed to the expected synergies and other benefits from combining the assets and activities of MAB Discovery with those of the Group.

Transaction costs of k€91 relating to the acquisition have been expensed and are included in the general and administrative expenses within the condensed consolidated statement of operations and are part of operating cash flows in the statement of cash flows.

reBOOST Management GmbH

On August 29, 2019, BioNTech entered into an agreement to purchase all of the outstanding shares of reBOOST Management GmbH (hereinafter also referred to as "reBOOST") from Medine GmbH, which is wholly owned by BioNTech's Chief Executive Officer, Ugur Sahin. The k€279 purchase price consists of k€31 cash consideration and assumption of liabilities of up to k€248. The related party acquisition closed on September 2, 2019.

The consolidated financial statements include the results of reBOOST since the acquisition date. From the date of acquisition, reBOOST contributed k€213 to loss before tax in the Technology Platform business segment from continuing operations of the Group. If the transaction would have occurred at the beginning of the reporting period, an estimated amount of k€237 would have contributed to loss before tax in the Technology Platform business segment. From the date of acquisition, reBOOST did not generate any revenue and no revenue would have been generated if the transaction would have occurred at the beginning of the reporting period. The Group acquired reBOOST because it expects to lift synergies and other benefits arising from the ongoing collaborations of reBOOST with different co-operations.

7 Income and Expenses

7.1 Costs of Sales

	Years ended December 31,		
(in thousands)	**2019**	**2018**	**2017**
Wages, benefits and social security expense	€7,206	€6,726	€6,105
Laboratory supplies	3,845	1,368	2,849
Purchased services	1,986	2,514	-
Depreciation and amortization	1,467	1,367	-
Other	2,857	1,715	364
Total	**€17,361**	**€13,690**	**€9,318**

7.2 Research and Development Expenses

	Years ended December 31,		
(in thousands)	**2019**	**2018**	**2017**
Wages, benefits and social security expense	€83,213	€45,668	€31,970
Purchased services	65,552	42,079	22,686
Laboratory supplies	37,218	22,921	15,762
Depreciation and amortization	27,533	18,312	9,859
Lease and lease related cost	2,527	2,404	3,475
IT costs	3,800	1,572	366
Travel costs	1,546	1,281	776
Transport costs	1,081	668	396
Job advertisement expenses	1,040	352	-
Other	2,956	7,783	206
Total	**€226,466**	**€143,040**	**€85,496**

7.3 Sales and Marketing Expenses

	Years ended December 31,		
(in thousands)	**2019**	**2018**	**2017**
Wages, benefits and social security expense	€1,938	€1,728	€1,631
Purchased services	247	794	2,771
Travel costs	88	267	260
Other	445	252	1,940
Total	**€2,718**	**€3,041**	**€6,603**

7.4 General and Administrative Expenses

	Years ended December 31,		
(in thousands)	**2019**	**2018**	**2017**
Wages, benefits and social security expense	€19,122	€8,582	€9,861
Purchased services	6,419	5,177	3,544
IT and office equipment	4,573	3,774	2,706
Depreciation and amortization	4,855	2,284	630
Lease and lease related cost	1,715	1,012	1,611
Travel costs	1,391	1,043	247
Insurance premiums	1,061	145	99
Laboratory supplies	785	456	63
Job advertisement expenses	548	861	719
Other	5,078	3,000	4,039
Total	**€45,547**	**€26,334**	**€23,520**

7.5 Other Operating Income

	Years ended December 31,		
(in thousands)	**2019**	**2018**	**2017**
Government grants	€1,547	€4,228	€2,266
Other	1,177	1,168	83
Total	**€2,724**	**€5,396**	**€2,349**

7.6 Finance Income

	Years ended December 31,		
(in thousands)	**2019**	**2018**	**2017**
Interest income	€1,781	€1,996	€2,133
Foreign exchange gains (net)	2,341	6,050	-
Total	**€4,122**	**€8,046**	**€2,133**

Finance income results from BioNTech's interests on short-term deposits. In the years ended December 31, 2019 and December 31, 2018 results from BioNTech's unhedged USD cash accounts were recorded as foreign exchange gains.

7.7 Finance Expense

	Years ended December 31,		
(in thousands)	**2019**	**2018**	**2017**
Financial instruments measured at amortized cost	€326	€48	€53
Foreign exchange loss (net)	-	-	25,955
Total	**€326**	**€48**	**€26,007**

In the year ended December 31, 2017, foreign exchange losses as a result from BioNTech's unhedged USD cash accounts were recorded as finance expenses.

8 Income Tax

Tax expense for the years ended December 31, 2019, December 31, 2018 and December 31, 2017 are comprised of current income taxes and other taxes.

The following table illustrates the reconciliation of tax expense to the estimated tax rate for the periods indicated. The reconciliation for the year ended December 31, 2019 excludes an amount of k€28 for property tax expenses.

	Years ended December 31,		
(in thousands)	**2019**	**2018**	**2017**
Loss before tax	**€(179,440)**	**€(47,662)**	**€(85,905)**
Expected tax benefit (based on BioNTech`s statutory tax rate of 30.78%, 2018: 30.99%, 2017: 30.86%)	55,240	14,776	26,517
Effects			
Government grants exempted from taxes	48	28	17
Non-deductible expenses	(58)	(18)	(22)
Add-back for trade tax purposes	(110)	(96)	(70)
Non-recognition of tax-effect on share-based payment expenses	(9,308)	-	-
Tax-effective equity transaction costs	5,121	-	-
Utilization of tax losses	-	1,165	-
Non-recognition of deferred taxes on tax losses and temporary differences	(51,197)	(13,634)	(26,015)
Deviation valuation allowance prior year due to change tax rate	192	-	-
Effect from lower foreign income tax rate	(102)	-	-
Adjustment prior year tax	316	-	-
Other effects	154	(2,821)	(472)
Income tax expense	**€296**	**€(600)**	**€(45)**

Deferred Taxes

Deferred taxes for the periods indicated relate to the following:

Year ended December 31, 2019

(in thousands)	**January 1, 2019**	**Recognized in P&L**	**December 31, 2019**
Fixed assets	€(90)	€(565)	€(655)
Inventories	-	596	596
Leases	306	206	512
Contract liabilities (prior year revenues)	28,441	(4,898)	23,543
Provisions	134	53	187
Other (incl. deferred expenses)	161	1,926	2,087
Deferred Tax Assets Net (before valuation)	**€28,951**	**€(2,681)**	**€26,270**
Valuation Adjustment	**(28,951)**	**2,681**	**(26,270)**
Deferred Tax Assets Net (after valuation)	**-**	**-**	**-**

Year ended December 31, 2018

(in thousands)	**January 1, 2018**	**Recognized in P&L**	**December 31, 2018**
Fixed assets	€(877)	€787	€(90)
Inventories	83	(83)	-
Leases	83	223	306
Contract liabilities (prior year revenues)	16,631	11,810	28,441
Provisions	73	61	134
Other	684	(523)	161
Deferred Tax Assets Net (before valuation)	**€16,676**	**€12,275**	**€28,951**
Valuation Adjustment	**(16,676)**	**(12,275)**	**(28,951)**
Deferred Tax Assets Net (after valuation)	**-**	**-**	**-**

Accumulated tax losses of the Group for the periods indicated amount to the following:

	Years ended December 31,		
(in thousands)	**2019**	**2018**	**2017**
Corporate Tax	€356,044	€179,264	€178,491
Trade Tax	352,341	176,425	176,024

Deferred tax assets on tax losses have not been capitalized as there is not sufficient probability in terms of IAS 12 that there will be future taxable profits available against which the unused tax losses can be utilized. The accumulated tax losses as at December 31, 2019 relate to Germany and the United States (as at December 31, 2018: Germany). There is no expiration date for any of the accumulated tax losses under German or US tax law.

9 Earnings per Share

Basic earnings per share (EPS) is calculated by dividing the loss for the year attributable to ordinary equity holders of the parent by the weighted average number of ordinary shares outstanding during the year.

Diluted EPS is calculated by dividing the profit attributable to ordinary equity holders of the parent by the weighted average number of ordinary shares outstanding during the year plus the weighted average number of ordinary shares that would be issued on conversion of all the dilutive potential ordinary shares into ordinary shares.

On September 18, 2019, BioNTech effected a 1:18 share split by issuing 206,595,492 shares by way of a capital increase from its own funds; thus, no outside proceeds were received. This capital increase came into effect upon

registration with the commercial register (*Handelsregister*). The accompanying financial statements and notes to the financial statements including the EPS information below give retroactive effect to the share split for all periods presented.

The following table reflects the income and share data used in the basic and diluted EPS calculations:

	Years ended December 31,		
(in thousands)	**2019**	**2018**	**2017**
Loss attributable to ordinary equity holders of the parent for basic earnings	**€(179,056)**	**€(48,019)**	**€(85,653)**
Weighted average number of ordinary shares for basic EPS	**211,499**	**190,710**	**166,764**
Effects of dilution from share options	-	-	-
Weighted average number of ordinary shares adjusted for the effect of dilution	**211,499**	**190,710**	**166,764**

There have been no other transactions involving ordinary shares or potential ordinary shares between the reporting date and the date of authorization of these financial statements. Stock options were not included in the calculation of diluted EPS because they are antidilutive for the periods presented.

10 Property, Plant and Equipment

(in thousands) **Acquisition and production costs**	**Land and buildings**	**Equipment, tools and installations**	**Construction in progress and advance payments**	**Total**
As of January 1, 2018	**€13,077**	**€58,080**	**€6,153**	**€77,310**
Additions	8,925	11,322	6,154	26,401
Disposals	-	(858)	-	(858)
Reclassifications	145	5,069	(5,216)	-
As of December 31, 2018	**€22,147**	**€73,613**	**€7,091**	**€102,853**
As of January 1, 2019	**€22,147**	**€73,613**	**€7,091**	**€102,853**
Additions	7,269	8,700	22,623	38,592
Disposals	-	(105)	(10)	(115)
Reclassifications	53	-	(53)	-
Currency differences	-	(1)	1	-
Acquisition of subsidiaries and businesses, net of cash acquired	-	999	-	999
As of December 31, 2019	**€29,469**	**€83,206**	**€29,652**	**€142,329**

(in thousands) **Cumulative depreciation and impairment charges**	**Land and buildings**	**Equipment, tools and installations**	**Construction in progress and advance payments**	**Total**
As of January 1, 2018	**€5,690**	**€22,013**	**-**	**€27,703**
Depreciation	782	8,349	-	**9,131**
Disposals	-	(182)	-	**(182)**
As of December 31, 2018	**€6,472**	**€30,180**	**-**	**€36,652**
As of January 1, 2019	**€6,472**	**€30,180**	**-**	**€36,652**
Depreciation	1,854	10,861	-	12,715
Disposals	-	(79)	-	(79)
Currency differences	-	(3)	-	(3)
As of December 31, 2019	**€8,326**	**€40,959**	**-**	**€49,285**

(in thousands) **Carrying amount**	**Land and buildings**	**Equipment, tools and installations**	**Construction in progress and advance payments**	**Total**
As of January 1, 2018	**€7,387**	**€36,067**	**€6,153**	**€49,606**
As of December 31, 2018	**€15,675**	**€43,433**	**€7,091**	**€66,200**
As of December 31, 2019	**€21,143**	**€42,247**	**€29,652**	**€93,044**

11 Intangible Assets

(in thousands) **Acquisition costs**	**Goodwill**	**Concessions, licenses and similar rights**	**Advance payments**	**Total**
As of January 1, 2018	**€534**	**€85,271**	**€3,565**	**€89,370**
Additions	-	12,150	3,128	15,278
Disposals	-	-	(765)	(765)
Reclassifications	-	4,431	(4,431)	-
As of December 31, 2018	**€534**	**€101,853**	**€1,497**	**€103,883**
As of January 1, 2019	**€534**	**€101,853**	**€1,497**	**€103,883**
Additions	-	11,744	1,529	13,273
Disposals	-	(133)	(477)	(610)
Reclassifications	-	146	(146)	-
Currency differences	-	(23)	-	(23)
Acquisition of subsidiaries and businesses, net of cash acquired	2,444	2,726	-	5,170
As of December 31, 2019	**€2,978**	**€116,313**	**€2,403**	**€121,693**

(in thousands) **Cumulative depreciation and impairment charges**	**Goodwill**	**Concessions, licenses and similar rights**	**Advance payments**	**Total**
As of January 1, 2018	**-**	**€5,833**	**-**	**€5,833**
Depreciation	-	10,009	-	10,009
As of December 31, 2018	**-**	**€15,842**	**-**	**€15,842**
As of January 1, 2019	**-**	**€15,842**	**-**	**€15,842**
Depreciation	-	16,502	-	16,502
Disposals	-	(81)	-	(81)
Currency differences	-	(3)	-	(3)
As of December 31, 2019	**-**	**€32,260**	**-**	**€32,260**

(in thousands) **Carrying amount**	**Goodwill**	**Concessions, licenses and similar rights**	**Advance payments**	**Total**
As of January 1, 2018	**€534**	**€79,438**	**€3,565**	**€83,537**
As of December 31, 2018	**€534**	**€86,011**	**€1,497**	**€88,042**
As of December 31, 2019	**€2,978**	**€84,053**	**€2,403**	**€89,434**

Contractual Commitments

Contractual commitments for the acquisition of intangible assets amounts to Nil as of December 31, 2019 (as of December 31, 2018: k€19,482).

Goodwill

For impairment testing, goodwill acquired through business combinations and intangible assets not yet in use have been allocated to the respective cash-generating units (CGU).

The goodwill acquired in the respective business combinations for the dates indicated is presented in the following table:

	MAB Discovery		JPT Peptide Technologies		reBOOST		Total	
(in thousands)	As of December 31, 2019	As of December 31, 2018	As of December 31, 2019	As of December 31, 2018	As of December 31, 2019	As of December 31, 2018	**As of December 31, 2019**	**As of December 31, 2018**
Goodwill	€2,205	-	€534	€534	€239	-	**€2,978**	**€534**

The Group performs its annual goodwill impairment test for the respective year as per October 1.

The recoverable amount was determined on a value in use calculation using cash flow projections from budgets approved by senior management covering at least a five-year period.

Management concluded that no reasonable possible change of key assumptions on which the calculation of the recoverable amount is based would cause the carrying amount of the CGU to exceed its recoverable amount.

The pre-tax discount rate applied to cash flow projections for the year ended December 31, 2019 is 9.0% (for the year ended December 31, 2018: 12.2%) and cash flows beyond the five-year period are extrapolated using a 1.8% growth rate (for the year ended December 31, 2018: 1.0%).

As the recoverable amount exceeded the carrying amount of the CGU for every balance sheet date, no impairment charge was required.

Intangible Assets not yet Available for Use

Intangible assets not yet available for use did not exist in the years ended December 31, 2019 and December 31, 2018.

12 Financial Assets and Financial Liabilities

12.1 Capital Risk Management

The objective of the capital management of BioNTech is primarily designed to finance the Group's growth strategy.

The Group's controlling committee reviews the total amount of cash of the Group on a weekly basis. As part of this review, the committee considers the total cash and cash equivalents, the cash outflow, currency translation differences and refinancing activities. The Group monitors cash using a burn rate. The cash burn rate is defined as the average monthly net cash flow from operating and investing activities during a financial year.

(in thousands)	**December 31, 2019**	**December 31, 2018**
Cash and cash equivalents at banks and on hand	€519,149	€411,495
Total	**€519,149**	**€411,495**

In meeting its financing objectives, the Group negotiates and enters into research cooperation agreements. In general, the aim is to maximize the financial resources available for further research and development projects.

BioNTech is not subject to externally imposed capital requirements. The objectives of BioNTech's capital management were achieved in the reporting year.

No changes were made in the objectives, policies or processes for managing cash during the years ended December 31, 2019 and December 31, 2018.

12.2 Categories of Financial Instruments

Financial assets at amortized cost

(in thousands)	December 31, 2019	December 31, 2018
Trade receivables	€11,913	€18,938
Other financial assets and receivables	1,680	354
Total	**€13,593**	**€19,292**
Total current	13,593	19,273
Total non-current	-	18

Financial liabilities: Financial liabilities at amortized cost (including interest-bearing loans and borrowings)

(in thousands)	Maturity	December 31, 2019	December 31, 2018
Trade payables		€19,909	€41,721
Lease liabilities		56,683	50,752
2.15% € 10,000,000 secured bank loan	12/30/2027	9,000	4,000
2.08% € 9,450,000 secured bank loan	09/30/2028	7,600	1,600
Other financial liabilities		11,551	6,132
Total		**€104,743**	**€104,205**
Total current		35,699	49,987
Total non-current		69,044	54,218

2.15% Secured Loan

The loan is secured by a lien over land and buildings with a carrying value of k€10,000 as at December 31, 2019 (December 31, 2018: k€10,000). Additionally, the loan is secured by a permanent guarantee (*Höchstbetragsbürgschaft*) of the Company to the bank to the amount of k€10,000. The loan is repayable in equal quarterly instalments of k€312.5 commencing on March 31, 2020. As at December 31, 2019, the undrawn available amount is k€1,000.

2.08% Bank Loan

The loan is secured by a lien over land and buildings to the amount of k€9,450. Additionally, the loan is secured by a permanent guarantee (*Höchstbetragbürgschaft*) of the Company to the bank to the amount of k€9,450 as at December 31, 2019 (December 31, 2018: k€9,450). The loan is repayable by quarterly instalments of k€286.4 commencing on September 30, 2020. As at December 31, 2019, the available undrawn amount of k€1,850 will be drawn on a predetermined date.

12.3 Fair Values

Fair values of cash and cash equivalents, trade receivables, trade payables and other current liabilities approximate their carrying amounts largely due to the short-term maturities of these instruments.

The liabilities include two fixed-interest rate loans. The fair value of the two fixed-interest rate loans is calculated based on significant observable inputs (Level 2). As of December 31, 2019 and December 31, 2018, the carrying value approximates their fair values as there have been no significant changes in relevant interest rates since inception of the respective loans.

12.4 Financial Instruments Risk Management Objectives and Policies

The Group’s financial liabilities comprise of bank loans, lease liabilities, trade and other payables. The main purpose of these financial liabilities is to enable the Group’s operations. The Group’s principal financial assets include mainly cash and trade receivables that derive directly from its operations.

The Group is exposed to market risk, credit risk and liquidity risk. The Group's senior management oversees the management of these risks.

The controlling committee provides assurance to the Group's senior management that the Group's financial risk activities are governed by appropriate policies and procedures and that financial risks are identified, measured and managed in accordance with the Group's policies and risk objectives. The Board of Directors reviews and agrees policies for managing each of these risks, which are summarized below.

12.5 Market Risk

Market risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate due to changes in market prices. Market risk comprises of three types of risk: interest risk, foreign currency risk and other price risk. Financial instruments affected by market risk include cash and cash equivalents. Interest risk as well as other price risk are not considered as risks for the Group.

The sensitivity analysis in the following sections relate to the position as at December 31, 2019 and December 31, 2018.

There were no material changes in the Group's market risk exposures or changes in the way risk was managed and valued during the periods.

Foreign Currency Risk

Foreign currency risk is the risk that the fair value or future cash flows of an exposure will fluctuate because of changes in foreign exchange rates. The Group's exposure to the risk of changes in foreign currency rates relates primarily to the Group's operating activities (when revenue or expense is denominated in a foreign currency).

In order to reduce exchange rate risk, BioNTech makes every effort to generate expenses and income in the same functional currency. The Group does not hedge exchange rate risks.

The carrying amount of the monetary assets (the Group's cash and cash equivalents) of BioNTech denominated in foreign currencies at the dates indicated are as follows:

(in thousands)	**December 31, 2019**	**December 31, 2018**
USD Bank accounts	€213,913	€176,376
Total	**€213,913**	**€176,376**

The following tables demonstrate the sensitivity to a reasonably possible change in USD exchange rates, with all other variables held constant. The impact on the Group's profit before tax is due to changes in the fair value of monetary assets. The Group's exposure to foreign currency changes for all other currencies is not material.

		1 € =	**Closing rate**		**Average rate**	
Currency	**Country**		**2019**	**2018**	**2019**	**2018**
USD	United States		1.1234	1.1450	1.1195	1.1810

(in thousands)	**Change in USD rate**	**Effect on loss before tax**	**Effect on pre-tax equity**
2019	+5 %	€(10,186)	€(10,186)
2019	-5%	€11,259	€11,259
2018	+5 %	€(8,399)	€(8,399)
2018	-5%	€9,283	€9,283

12.6 Credit Risk Management

Credit risk is the risk that a counterparty will not meet its obligations under a financial instrument or customer contract, leading to a financial loss. The Group is exposed to credit risk from its operating activities, including deposits with banks and financial institutions, foreign exchange transactions and trade accounts receivable.

Trade Receivables and Contract Assets

The Group's exposure to credit risk of trade receivables and contract assets is primarily on transactions with corporate customers in the biopharma/biotech industry that operate in Germany or in the United States. An analysis of the aging of receivables and the creditworthiness of customers is used to evaluate this risk at each reporting date. The Group follows risk control procedures to assess the credit quality of the customers taking into account their financial position, past experience and other factors. The compliance with credit limits by corporate customers is regularly monitored by management.

The credit risk on trade receivables and contract assets is very low as the customer portfolio of BioNTech mainly consists of medical universities, other public institutions and peers in the biopharma industry, which all have a very high credit rating and the group has not incurred bad debt expense. BioNTech does not expect that its customer portfolio will change.

Generally, trade receivables are written off if past due for more than one year and are not subject to enforcement activity. The maximum exposure to credit risk at the reporting date is the carrying value of each class of financial assets disclosed in Note 12.2. The Group does not hold collateral as security.

Cash Deposits

Credit risk from balances with banks and financial institutions is managed by the Group's controlling department in accordance with the Group's policy. Investments of surplus funds are made only with banks.

Credit risk stemming from cash and deposits is very low.

The Group's maximum exposure to credit risk for the components of the statements of financial position at December 31, 2019 and December 31, 2018 are the carrying amounts as illustrated in Note 12.1.

12.7 Liquidity Risk

Generally, BioNTech has relied on the financing from shareholders and collaborators in order to ensure sufficient liquidity. Lack of external financial support could pose a risk of going concern. The liquidity management of BioNTech ensures the availability of cash and cash equivalents for operational activities and further investments through appropriate budget planning. In addition, a sufficient level of cash and cash equivalents, which is managed centrally, is always maintained to finance the operational activities.

The Group monitors liquidity risks using a liquidity planning tool.

Ultimately, the responsibility for liquidity risk management lies with the management, which has established an appropriate approach to managing short-, medium- and long-term financing and liquidity requirements. BioNTech manages liquidity risks by holding appropriate reserves, as well as by monitoring forecasted and actual cash flows and reconciling the maturity profiles of financial assets and liabilities.

Risk Concentration

Concentrations arise when a number of counterparties are engaged in similar business activities, or activities in the same geographical region, or have economic features that would cause their ability to meet contractual obligations to be similarly affected by changes in economic, political or other conditions. Concentrations indicate the relative sensitivity of the Group's performance to developments affecting a particular industry.

In order to avoid concentrations of risk, the Group's policies and procedures include specific guidelines to focus on the maintenance of an effective diversification in the sources of funding and distribution of cash deposits. Identified concentrations of credit risks are controlled and managed accordingly.

The maturity profile of the Group's financial liabilities based on contractual undiscounted payments is summarized as follows:

Year ended December 31, 2019

(in thousands)	**Less than 1 year**	**1 to 5 years**	**More than 5 years**	**Total**
Interest bearing loans and borrowings	€2,220	€10,693	€8,355	**€21,268**
Trade and other payables	€20,498	-	-	**€20,498**
Lease liabilities	€5,176	€17,882	€55,852	**€78,910**
Other financial liabilities	€10,351	-	-	**€10,351**
Total	**€38,245**	**€28,575**	**€64,207**	**€131,027**

Year ended December 31, 2018

(in thousands)	**Less than 1 year**	**1 to 5 years**	**More than 5 years**	**Total**
Interest bearing loans and borrowings	-	€5,600	-	**€5,600**
Trade and other payables	41,721	-	-	**41,721**
Lease liabilities	3,822	13,346	56,524	**73,692**
Other financial liabilities	6,132	-	-	**6,132**
Total	**€51,675**	**€18,946**	**€56,524**	**€127,145**

12.8 Changes in Liabilities arising from Financing Activities

Year ended December 31, 2019

(in thousands)	**January 1, 2019**	**Cash flows**	**New leases and disposals**	**Reclassification**	**December 31, 2019**
Current obligations under lease contracts	€2,134	€(3,061)	€1,484	€2,928	**€3,485**
Non-current obligations under lease contracts	48,618	-	8,437	(2,928)	**54,127**
Interest-bearing loans and borrowings	5,600	11,000	-	-	**16,600**
Total	**€56,352**	**€7,939**	**€9,921**	**-**	**€74,212**

Year ended December 31, 2018

(in thousands)	**January 1, 2018**	**Cash flows**	**New leases and disposals**	**Reclassification**	**December 31, 2018**
Current obligations under lease contracts	€1,832	€(2,126)	€296	€2,132	**€2,134**
Non-current obligations under lease contracts	50,349	-	401	(2,132)	**48,618**
Interest-bearing loans and borrowings	-	5,600	-	-	**5,600**
Total	**€52,182**	**€3,474**	**€697**	**-**	**€56,352**

13 Inventories

(in thousands)	**December 31, 2019**	**December 31, 2018**
Raw materials and supplies	€8,201	€4,475
Unfinished goods	2,888	80
Finished goods	633	1,234
Total	**€11,722**	**€5,789**

During the year ended December 31, 2019, inventories of k€2,182 (during the year ended December 31, 2018: k€1,789) were recognized as an expense and recognized in cost of sales.

BioNTech has not pledged any inventories as securities for liabilities.

14 Trade Receivables

(in thousands)	December 31, 2019	December 31, 2018
Trade receivables	€11,913	€18,938
Total	**€11,913**	**€18,938**

Trade receivables are non-interest bearing and are generally due on terms of 20 to 30 days. As described in Note 12.6, expected credit loss for trade receivables is immaterial.

15 Other Assets

(in thousands)	December 31, 2019	December 31, 2018
Sales tax receivable	€7,536	€8,611
Prepayments on inventories	351	155
Other	1,182	398
Total	**€9,069**	**€9,164**

As at December 31, 2019, other assets mainly comprised interest income of k€529 and receivables from withholding taxes of k€310 (as at December 31, 2018, other assets were mainly comprised of interest income of k€270).

16 Issued Capital and Reserves

Year ended December 31, 2019

On September 18, 2019, BioNTech effected a 1:18 share split by issuing 206,595,492 shares by way of a capital increase from its own funds; thus, no outside proceeds were received. This capital increase came into effect upon registration with the commercial register (*Handelsregister*). The accompanying financial statements and notes to the financial statements give retroactive effect to the share split for all periods presented.

The financing transactions that occurred during the year ended December 31, 2019 were as follows:

Issuance of Share Capital

In January 2019, BioNTech issued 5,088,204 shares and increased its share capital by k€5,088. The cash investment of k€80,006 was received in 2018 (k€79,997).

On August 30, 2019, BioNTech entered into agreements with the Bill & Melinda Gates Foundation (BMGF). BMGF agreed to purchase 3,038,674 ordinary shares with nominal amount of k€ 3,039 of BioNTech for a total of k€49,864 (k$55,000). These agreements require BioNTech to perform certain research and development activities to advance the development of products for the prevention and treatment of HIV and tuberculosis. In the event of a breach of the underlying conditions, including such research and development activities, BMGF has the right to sell its shares back to BioNTech at the initial share price or fair market value, whichever is higher, subject to certain conditions. BioNTech's ability to pay dividends is also limited under the terms of these agreements.

Capital Increase Series B

In June and August 2019, BioNTech issued an aggregate of 12,465,288 of ordinary shares (excluding 5,524,506 ordinary shares which were issued to a Hong Kong-based investor and subsequently transferred to BioNTech for no consideration; these shares are held as treasury shares) to certain new and existing shareholders at a price of USD 18.10 per share for aggregate proceeds of k€198,548 (k$225,622). These share issuances led to an increase of share capital of k€ 17,990 and capital reserve of k€ 186,390 and recognition of a treasury share balance of k€ 5,525.

Initial Public Offering (IPO)

On October 10, 2019, BioNTech increased its share capital by k€10,000 in conjunction with the Initial Public Offering. American Depositary Shares which represent ordinary shares were offered on the Nasdaq Global Select Market at a price of $15.00. On November 6, 2019, BioNTech increased its share capital by k€517 upon the execution of the underwriter´s option. American Depositary Shares which represent ordinary shares were issued at a price of $15.00 (under both issuances). The gross proceeds were k€143,260 (k$157,761) including k€10,517 increase in share capital and k€132,743 increase in capital reserve.

Acquisition of Non-Controlling Interest

As of March 14, 2019, BioNTech acquired the remaining 5.5% of non-controlling interests in BioNTech Cell & Gene Therapies GmbH held by Eli Lilly Nederland B.V. in exchange of issuing 2,374,794 new ordinary shares with an imputed share in the share capital of €1.00 each. This acquisition was recognized within equity and resulted in the derecognition of the non-controlling interest of k€731 as well as an increase to the share capital of k€2,375. The net effect of the transaction of k€1,644 was recognized as a decrease in the capital reserve.

Year ended December 31, 2018

During the year ended December 31, 2018, the issued capital increased by k€26,532. The increase was mainly related to k€22,588 issued during the Series A financing round, k€3,361 issued as share capital and k€583 issued in the course of settling the share-based payment plan. As a result of the financing transactions the capital reserve increased during the year ended December 31, 2018, by k€335,193.

Year ended December 31, 2017

During the year ended December 31, 2017, a capital increase from company funds increased the issued capital and decreased the capital reserve by k€163,494.

17 Share-Based Payments

On September 18, 2019, BioNTech effected a 1:18 share split by issuing 206,595,492 shares by way of a capital increase from its own funds; thus, no outside proceeds were received. This capital increase came into effect upon registration with the commercial register (*Handelsregister*). The accompanying financial statements and notes to the financial statements including share-based payment information below give retroactive effect to the share split for all periods presented.

During the years ended December 31, 2019, December 31, 2018 and December 31, 2017, the Group had the following share-based arrangements.

17.1 Chief Executive Officer Grant (Equity-Settled)

Description of Share-Based Payments

In September 2019, BioNTech agreed to grant Prof. Ugur Sahin, M.D. an option to purchase 4,374,963 ordinary shares, subject to Prof. Sahin’s continuous employment with BioNTech. The options’ per share exercise price is the Euro translation of the public offering price from BioNTech’s initial public offering, €13.60 ($15.00). The option will vest annually in equal installments after four years commencing on the first anniversary of the initial public offering and will be exercisable four years after the initial public offering. The option will be subject to the terms, conditions, definitions and provisions of the Employee Stock Ownership Plan (ESOP) and the applicable option agreement thereunder. The vested option rights can only be exercised if and to the extent that each of the following performance criteria has been achieved: (i) at the time of exercise, the current price is equal to or greater than the Threshold Amount (that is, the exercise price, provided that such amount increases by seven percentage points on each anniversary of the Allocation Date); (ii) at the time of exercise, the current price is at least equal to the Target Price (that is, (a) for the twelve-month period starting on the fourth anniversary of the Allocation Date, $8.5 billion divided by the total number of the shares outstanding immediately following the initial public offering (other than shares owned by BioNTech), and (b) for each twelve-month period starting on the fifth or subsequent anniversary of the Allocation Date, 107% of the target share price applicable for the prior twelve-month period); and (iii) the closing price for the fifth trading day prior to the start of the relevant exercise window is higher than the exercise price by at least the same percentage by which the Nasdaq Biotechnology Index or a comparable

successor index as of such time is higher than such index was as of the last trading day before the Allocation Date. The Option Rights can be exercised at the latest ten years after the Allocation Date. If they have not been exercised by that date, they will lapse without compensation.

Measurement of Fair Values

A Monte-Carlo simulation model has been used to measure the fair value at grant date of the Chief Executive Officer Grant. This model incorporates the impact of the performance criteria regarding share price and index development described above in the calculation of the award's fair value at grant date. The inputs used in the measurement of the fair value at grant date of the Chief Executive Officer Grant were as follows:

	Grant date October 10, 2019
Weighted average fair value	€5.63
Weighted average share price	€13.60
Exercise price	€13.60
Expected volatility (%)	41.4%
Expected life (years)	5.37
Risk-free interest rate (%)	1.52 %

The options' per share exercise price is the Euro translation of the public offering price from BioNTech's initial public offering on October 10, 2019. Expected volatility was based on an evaluation of the historical volatilities of comparable companies over the historical period commensurate with the expected term. The expected term was based on general optionholder behavior for employee options.

Reconciliation of Outstanding Share-Options

The number and weighted-average exercise price of share options under the Chief Executive Officer Grant during the year ended December 31, 2019 were as follows:

	Share options outstanding	**Number of Ordinary Shares underlying options**	**Weighted average exercise price (€)**
As of January 1, 2019	-	-	-
Granted	4,374,963	4,374,963	13.60
As of December 31, 2019	**4,374,963**	**4,374,963**	**13.60**

The options outstanding at December 31, 2019 have a weighted-average expected life of 5.12 years.

Expense recognized in the Statement of Operations

The expense recognized for employee services received during the year ended December 31, 2019 is shown in the following table:

(in thousands)	**Year ended December 31, 2019**
Research and development expenses	€3,208
Total	**€3,208**

There were no cancellations or modifications to the awards in the year ended December 31, 2019.

17.2 Employee Stock Ownership Plan (Equity-Settled)

Description of Share-Based Payments

On November 15, 2018, the Group established a share option program that grants selected employees options to receive shares in the company. The program is designed as an Employee Stock Ownership Plan (ESOP). The Group has offered the participants a certain number of rights (Option Rights) by explicit acceptance of the participants. The exercise of the Option Rights in accordance with the terms of the ESOP, gives the participants the right to obtain shares against payment of the exercise price. The Option Rights vest over four years, can only be exercised if the company has executed a public offering in the United States (IPO) and when meeting the Threshold Amount. Threshold Amount means the exercise price provided that such price increases by eight percentage points on the first and then each subsequent anniversary of the Allocation Date (September 26, 2018). The Option Rights can be exercised at the latest eight years after the Allocation Date. If they have not been exercised by that date, they will forfeit without compensation.

Measurement of Fair Values

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 greater to the Threshold Amount as defined in the arrangement. Moreover, the option rights can only be exercised if the IPO has occurred. Both conditions have been incorporated into the fair value at grant date.

The inputs used in the measurement of the fair values at grant date of the ESOP was as follows:

	Grant date 15 November 2018	Grant dates between February 21 - April 3, 2019	Grant dates between April 29 - May 31, 2019	Grant date December 1, 2019
Weighted average fair value	€7.41	€6.93	€7.04	€9.49
Weighted average share price	€14.40	€15.72	€16.03	€19.84
Exercise price	€10.14	€15.03	€15.39	€15.82
Expected volatility (%)	46.0%	46.0%	46.0%	46.0%
Expected life (years)	5.84	6.00	6.00	5.50
Risk-free interest rate (%)	0.05%	0.05%	0.05%	0.05%

Expected volatility has been based on an evaluation of the historical and the implied volatilities of comparable companies over the historical period commensurate with the expected term. The expected term has been based on general option holder behavior for employee options.

Reconciliation of Outstanding Share-Options

The number and weighted-average exercise prices of share options under the ESOP during the years ended December 31, 2019 and December 31, 2018 were as follows:

	Share options outstanding	Number of Ordinary Shares underlying options	Weighted average exercise price (€)
As of January 1, 2018	-	-	-
Granted	658,109	11,845,962	10.14
As of December 31, 2018	**658,109**	**11,845,962**	**10.14**
As of January 1, 2019	658,109	11,845,962	10.14
Granted	14,511	261,198	15.17
Forfeited	(17,237)	(310,266)	10.85
As of December 31, 2019	**655,383**	**11,796,894**	**10.23**

The options outstanding at December 31, 2019 have a weighted-average expected life of 4.73 years.

Expense recognized in the Statement of Operations

The expense recognized for employee services received during the years ended December 31, 2019 and December 31, 2018 is shown in the following table:

	Years ended December 31,	
(in thousands)	**2019**	**2018**
Cost of sales	€896	€114
Research and development expenses	20,016	6,786
Sales and marketing expenses	108	13
General and administrative expenses	6,008	728
Total	**€27,028**	**€7,641**

There were no cancellations or modifications to the awards in the years ended December 31, 2019 and December 31, 2018.

17.3 Share appreciation rights (Equity-Settled)

Description of Share-Based Payments

On December 1, 2017, the Group granted 582,714 shares to selected employees under the share appreciation rights (SAR) program. The shares vested immediately at the grant date (December 2017) as there were no vesting conditions.

There were no other SARs granted during the years ended December 31, 2019 and December 31, 2018.

Measurement of Fair Values

The fair value of the SARs has been determined using a discounted cash flow (DCF) model as of December 2017.

The inputs used in the measurement of the fair values at grant date of the SARs were as follows:

	Grant date 1 December 2017
Fair value	10.13€
Exercise price	10.13€
WACC	8.2%
Tax rate	31.2%
Debt free net working capital (in % of sales)	5.5%
Risk-free interest rate (%)	1.2%
Long-term growth rate (%)	1.8%

Growth rate estimates are based on epidemiology data for different indications in focus geographies. The average market growth rates per indication and stage have been extrapolated with data derived from published industry research.

The expected life of the SARs is based on historical data and current expectations and is not necessarily indicative of exercise patterns that may occur.

Expected dividends were not incorporated into the measurement of fair value.

Expense recognized in the Statement of Operations

The expense recognized for employee services received during the year ended December 31, 2017 is shown in the following table:

(in thousands)	**Year ended December 31, 2017**
Cost of sales	-
Research and development expenses	3,620
Sales and marketing expenses	14
General and administrative expenses	2,275
Total	**€5,909**

17.3 Net Settlement Feature for Withholding Tax Obligation

Under the agreement, BioNTech must withhold an amount for an employee's tax obligation associated with the share-based payment and transfer that amount in cash to the tax authority on the employee's behalf. BioNTech does not withhold shares in order to settle the employee's tax obligations. The Group withheld an amount of k€7,761 that was paid to the taxation authority in relation to the SARs in the year ended December 31, 2018.

18 Other Liabilities

(in thousands)	**December 31, 2019**	**December 31, 2018**
Liabilities employees	€6,710	€5,236
Other	780	3,864
Total	**€7,490**	**€9,100**

Other liabilities comprise accruals for outstanding invoices in the amount of k€715 as at December 31, 2019 (as at December 31, 2018: k€3,739) and several other non-material positions.

19 Leases

19.1 Amounts Recognized in the Statement of Financial Positions

Right-of-Use Assets

The following amounts are presented as right-of-use assets within the statement of financial positions as of the dates indicated:

	December 31, 2019	**December 31, 2018**
Buildings	€54,956	€49,718
Equipment, tools and installations	7	21
Automobiles	55	27
Total	**€55,018**	**€49,766**

Additions to the right-of-use assets during the year ended December 31, 2019 were k€10,040 (during the year ended December 31, 2018: k€723).

Lease Liability

The following amounts are included in other financial liabilities as of the dates indicated:

(in thousands)	**December 31, 2019**	**December 31, 2018**
Current	€3,485	€2,134
Non-current	54,127	48,618
Total	**€57,612**	**€50,752**

19.2 Amounts Recognized in the Statement of Operations

Depreciation Charge of Right-of-Use Assets

	Years ended December 31,		
(in thousands)	**2019**	**2018**	**2017**
Buildings	€4,614	€2,751	€1,759
Equipment, tools and installations	25	60	111
Automobiles	40	35	39
Total depreciation charge	**€4,679**	**€2,846**	**€1,909**
Interest on lease liabilities	€1,718	€1,721	€676
Expense related to short-term leases (included in other expenses)	442	431	442
Expense relating to leases of low-value assets that are not short-term leases (included in other expenses)	90	90	95
Total amounts recognized in profit or loss	**€6,929**	**€5,088**	**€3,122**

19.3 Amounts recognized in the Statements of Cash Flows

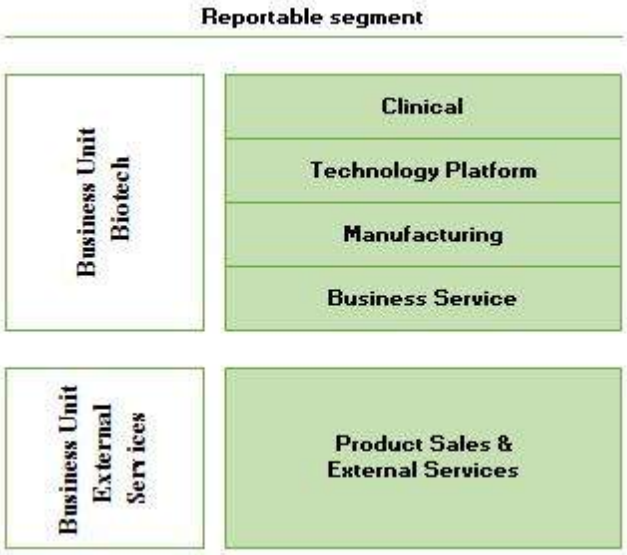
During the year ended December 31, 2019, the total cash outflow for leases amounted to k€4,779 (during the year ended December 31, 2018: k€3,847; during the year ended December 31, 2017: k€2,319).

20 Segment Information

BioNTech develops individualized treatments for cancer patients and improved therapeutics to treat infectious and rare diseases. This activity, together with research and development activities, forms the core of the company. External services provide the interface where medical products are sold to third parties.

BioNTech's business is managed in two business units, the biotech business unit and the external services business unit. The biotech business unit is comprised of three operation segments, which are individually monitored by the Chief Operating Decision Maker (CODM). Four operating segments have been identified in accordance with IFRS 8. No aggregation of operating segments was performed.

Resource allocation and performance assessment is performed at the level of the Management Board. The Management Board members are jointly responsible for the management and strategic decision making. Consequently, the Management Board has been identified as the CODM. BioNTech's business consist of the following reportable segments:



Research and Development activities form the Biotech Business Unit and are divided in the segments Clinical, Technology Platform and Manufacturing.

The **Clinical** segment subsumes all development activities relating to clinical programs. Clinical studies include testing the product candidates on humans. Clinical trials are an essential part of the development and licensing of the medicinal products and are performed before the respective product can be placed on the market. BioNTech is actively engaged in many collaborations and licensing deals with reputable pharmaceutical companies and academic partners.

Technology Platform contains all development activities relating to preclinical programs. Preclinical development is the stage of research that begins before clinical trials. It is performed to determine the desired pharmacological effects and to identify any unwanted effects that may cause adverse reactions during human exposure.

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

Product Sales & External Services comprises the legal entities JPT Peptide Technology GmbH and Innovative Manufacturing Services GmbH (IMFS), which form the interface to third parties. External services and medicinal products (*e.g.*, peptides and retroviral vectors) that are in the areas of molecular immunotherapies and biomarker-based diagnostic approaches for individualized treatment of cancer and other infectious diseases are sold to customers worldwide.

Business Service contains the Group's central administrative functions (*e.g.*, Finance, Procurement, Human Resources, Legal and Intellectual Property) and overarching projects. Business Service does not fulfil the requirements for an operating segment according to IFRS 8, as it will never generate more than incidental revenues. However, financial information about Business Service is disclosed, as it contributes to the understanding of the company.

The table below reconciles segment figures to Group figures for the periods indicated:

	Business Unit BioNTech				External Services Business Unit			
(in thousands)	**Clinical**	**Technology Platform**	**Manufacturing**	**Business Service**	**Product Sales & External Services**	**Total**	**Adjustments**	**Group**
Year ended December 31, 2019								
Revenues								
Collaboration Revenues	€33,493	€2,147	€48,788	-	-	€84,428		€84,428
Revenues from other sales transactions	-	692	2	-	23,467	24,161		24,161
Cost of sales	-	-	-	-	(16,923)	(16,923)	(438)	(17,361)
Gross profit	**€33,493**	**€2,839**	**€48,790**	**-**	**€6,544**	**€91,666**	**€(438)**	**€91,228**
Income / Expenses								
Research and development expenses	(91,516)	(79,119)	(50,478)	(5,192)	(600)	(226,905)	439	(226,466)
Sales and marketing expenses	-	-	-	(1,302)	(1,415)	(2,717)	(1)	(2,718)
General and administrative expenses	-	-	(3,821)	(38,756)	(2,970)	(45,547)	-	(45,547)
Other result	1,125	307	59	23	468	1,982	3	1,985
Segment operating income / (loss)	**€(56,898)**	**€(75,973)**	**€(5,450)**	**€(45,227)**	**€2,027**	**€(181,521)**	**€3**	**€(181,518)**

	Business Unit BioNTech				External Services Business Unit			
(in thousands)	**Clinical**	**Technology Platform**	**Manufacturing**	**Business Service**	**Product Sales & External Services**	**Total**	**Adjustments**	**Group**
Year ended December 31, 2018								
Revenues								
Collaboration Revenues	€36,750	€39,452	€25,635	-	-	€101,837		€101,837
Revenues from other sales transactions	-	6,783	-	42	18,914	25,738		25,738
Cost of sales	-	-	-	(40)	(13,358)	(13,398)	(292)	(13,690)
Gross profit	**€36,750**	**€46,235**	**€25,635**	**€2**	**€5,556**	**€114,177**	**€(292)**	**€113,885**
Income / Expenses								
Research and development expenses	(48,641)	(60,320)	(31,508)	(1,979)	(884)	(143,332)	292	(143,040)
Sales and marketing expenses	-	-	-	(2,106)	(935)	(3,041)	-	(3,041)
General and administrative expenses	-	-	(2,558)	(21,233)	(2,542)	(26,334)	-	(26,334)
Other result	3,772	178	30	85	559	4,624	52	4,676
Segment operating income / (loss)	**€(8,119)**	**€(13,908)**	**€(8,401)**	**€(25,231)**	**€1,753**	**€(53,906)**	**€52**	**€(53,854)**

	Business Unit BioNTech				External Services Business Unit			
(in thousands)	**Clinical**	**Technology Platform**	**Manufacturing**	**Business Service**	**Product Sales & External Services**	**Total**	**Adjustments**	**Group**
Year ended December 31, 2017								
Revenues								
Collaboration Revenues	€25,721	€14,504	€2,108	-	-	€42,333	-	€42,333
Revenues from other sales transactions	-	324	-	-	18,941	19,265	-	19,265
Cost of sales	-	-	-	-	(9,318)	(9,318)	-	(9,318)
Gross profit	**€25,721**	**€14,828**	**€2,108**	**-**	**€9,623**	**€52,280**	**-**	**€52,280**
Income / Expenses								
Research and development expenses	(25,099)	(37,019)	(14,764)	(6,701)	(1,912)	(85,496)	-	(85,496)
Sales and marketing expenses	-	-	-	(4,904)	(1,698)	(6,603)	-	(6,603)
General and administrative expenses	-	-	(785)	(20,309)	(2,427)	(23,520)	-	(23,520)
Other result	-	777	-	820	463	2,061	-	2,061
Segment operating income / (loss)	**€623**	**€(21,414)**	**€(13,441)**	**€(31,094)**	**€4,049**	**€(61,277)**	**-**	**€(61,277)**

The segments are managed based on external sales and operating profit/loss, which represents the operating profit earned by each segment. Segment figures are reported consolidated, which reflects the way management steers the business.

BioNTech's internal reporting is generally in accordance with IFRS and in line with the Group's accounting policies, except for minor deviations in classification between cost of sales and research and development cost. Whenever revenues are attributable to different segments, these revenues are split based on the incurred cost. Internal overhead costs are allocated to segments based on revenues when they are directly attributable to a service rendered. Sales and marketing expenses, general and administrative expenses and the other result that are not directly attributable to one of the segments are allocated to Business Service.

To reconcile the segment figures to the Group's financial statements for the year ended December 31, 2019, the presentation of k439 of research and development cost was adjusted (for the year ended December 31, 2018: k292).

Revenue at BioNTech can be differentiated between revenues resulting from collaboration and license agreements and revenues from other sales. The Company collaborates with reputable pharmaceutical and healthcare companies and several global academic collaborators. During the year ended December 31, 2019, the revenue generated from the Genentech and Pfizer collaboration agreements represent each more than 10% of BioNTech's overall revenue resulting from collaboration and license agreements. The revenues were partly recorded in the Clinical as well as Manufacturing segment. During the year ended December 31, 2018, the revenue generated from the Genentech and Sanofi collaboration agreements represent each more than 10% of BioNTech's overall revenue resulting from collaboration and license agreements. The revenues were partly recorded in the Clinical, Technology Platform as well as Manufacturing segment. During the year ended December 31, 2017, the revenue generated from the Genentech, Genmab and Sanofi collaboration agreements represent each more than 10% of BioNTech's overall revenue resulting from collaboration and license agreements. The revenues were partly recorded in the Clinical, Technology Platform as well as Manufacturing segment. The total amounts of revenues generated with these customers in the periods presented are disclosed in Note 4.

Revenues from other sales result from the sale of medical products (*e.g.*, peptides and retroviral vectors) for clinical supply. Research and development activities are managed on a worldwide basis but the operative manufacturing facilities and sales offices are located and managed in Germany. External sales are originated in Germany.

21 Related Party Disclosures

21.1 Parent and Ultimate Controlling Party

ATHOS KG, Holzkirchen, Germany owns 100% of shares in AT Impf GmbH, Munich, Germany and is the beneficiary owner of BioNTech. AT Impf GmbH, Munich, Germany is the parent company of the Group.

21.2 Transactions with Key Management Personnel

Key Management Personnel Compensation

Key management personnel at BioNTech has been defined as the members of the Management Board and of the Supervisory Board. Key management personnel compensation is comprised of the following:

Compensation of key management personnel of the Group

(in thousands)	**December 31, 2019**	**December 31, 2018**	**December 31, 2017**
Short-term employee benefits	€1,847	€1,161	€880
Share-based payment transactions	18,151	6,163	1,855
Total compensation paid to key management personnel	**€19,998**	**€7,324**	**€2,735**

In September 2019, BioNTech agreed to grant Prof. Ugur Sahin, M.D., BioNTech's co-founder and Chief Executive Officer, an option to purchase 4,374,963 ordinary shares (see Note 17).

Executive officers also participate in the Group's ESOP and SAR program (see Note 17).

Key Management Personnel Transactions

A number of key management personnel, or their related parties, hold positions in other companies that results in them having control or significant influence over these companies. A number of these companies have had transactions with the Group during the year.

The Group purchases various goods and services from research institutes where Prof. Ugur Sahin, M.D., our co-founder and Chief Executive Officer, co-founded TRON and served as Managing Director at TRON until 2019 and currently serves as a Professor of Medicine at the University of Mainz. Prof. Sahin resigned from this position with TRON, effective September 10, 2019. Additionally, Prof. Christoph Huber, M.D., a member of our Supervisory Board, served on TRON's supervisory board until his resignation in April 2019. Prof. Ugur Sahin, M.D., our co-founder and Chief Executive Officer, owns a significant amount of shares in TRON.

The aggregate value of transactions related to key management personnel were as follows for the periods indicated:

(in thousands)	**December 31, 2019**	**December 31, 2018**	**December 31, 2017**
Consulting services / patent assignment	€56	€25	€25
Purchases of various goods and services from TRON	9,968	11,160	6,553
Total	**€10,024**	**€11,185**	**€6,578**

The outstanding balances of transactions related to key management personnel were as follows as at the periods indicated:

(in thousands)	**December 31, 2019**	**December 31, 2018**
TRON	€1,843	€2,160
Total	**€1,843**	**€2,160**

21.3 Other Related Party Transactions

The total amount of transactions with ATHOS KG or entities controlled by them was as follows for the periods indicated:

(in thousands)	December 31, 2019	December 31, 2018	December 31, 2017
Purchases of various goods and services from entities controlled by ATHOS KG	€2,071	€2,431	€1,240
Purchases of property and other assets from entities controlled by ATHOS KG	-	4,748	-
Total	**€2,071**	**€7,179**	**€1,240**

The outstanding balances of transactions with ATHOS KG or entities controlled by them were as follows as at the periods indicated:

(in thousands)	December 31, 2019	December 31, 2018
ATHOS KG	€51	€587
Total	**€51**	**€587**

None of the balances are secured and no bad debt expense has been recognized in respect of amounts owed by related parties.

22 Events After the Reporting Period

22.1 In December 2019, BioNTech Delivery Technologies GmbH (previously BioNTech Protein Therapeutics GmbH; also referred to as "BioNTech Delivery Technologies"), a wholly owned subsidiary of BioNTech SE, entered into an agreement to acquire all assets, employees and proprietary know-how of Lipocalyx GmbH and its related parties (also referred to as "Lipocalyx") in exchange for a total consideration of cash at an amount of k€6,516 and additional contingent consideration provisionally estimated at an amount of k€572. Current assets and non-current assets before purchase price allocation accounted for in accordance with German GAAP at an amount of k€139 and k€77 (unaudited amounts) were acquired. No liabilities were assumed as part of this asset deal. The operational drug delivery business of Lipocalyx is based in Halle (Saale), Germany. The employees of Lipocalyx were transferred automatically to BioNTech Delivery Technologies with effect as of the closing date. The acquisition closed on January 6, 2020.

22.2 On January 12, 2020, BioNTech's Supervisory Board appointed Ryan Richardson to the Management Board as Chief Strategy Officer (CSO) and Managing Director. In his new role he will support and contribute to the creation and implementation of the Company's long-term growth strategy in collaboration with the management team. Ryan has previously served as Senior Vice President, Corporate Development & Strategy after joining the Company in 2018.

22.3 On January 16, 2020, BioNTech and Neon Therapeutics, Inc. (listed on the Nasdaq) have entered into a definitive merger agreement, under which BioNTech will acquire Neon in an all-stock transaction initially valued at approximately $67.0 million, based on the closing price of BioNTech's ADSs of $34.55 on Wednesday, January 15, 2020 (also referred to as "Merger"). At closing, BioNTech will issue, and Neon shareholders will receive, 0.063 of BioNTech's American Depositary Shares, or ADSs, in exchange for each of their shares of Neon. This exchange ratio will not be adjusted for changes in the market price of either our ADSs or Neon common stock between the date the Merger Agreement was signed and completion of the Merger. As a result, changes in the price of our ADSs prior to the completion of the Merger will affect the value of our ADSs delivered upon completion of the Merger. Neon is a biotechnology company developing novel neoantigen-based T cell therapies. The transaction will combine two organizations with a common culture of pioneering translational science and a shared vision for the future of cancer immunotherapy. The Merger is conditioned upon, among other things, the approval of the Merger Agreement by the shareholders of Neon and other customary closing conditions.

22.4 On March 16, 2020 BioNTech announced further details on the Company's R&D effort, "Project Lightspeed", to develop a potential vaccine to induce immunity and prevent COVID-19 infection in response to the growing global health threat posed by the disease. BioNTech's product candidate, BNT162, is a potential first-in-class mRNA vaccine in the worldwide effort against COVID-19. BioNTech intends to initiate clinical testing for BNT162 in late April 2020, subject to regulatory approval, as part of a global clinical development program in Europe (commencing in Germany), the United States and China. The Company has been in close contact with regulatory and scientific authorities around the world and is in ongoing discussions with research organizations to make a vaccine available to the public as quickly as possible worldwide.

As part of its global development program, BioNTech announced a strategic alliance with Shanghai Fosun Pharmaceutical (Group) Co., Ltd ("Fosun Pharma"; Stock Symbol: 600196.SH, 02196.HK) to jointly develop its COVID-19 vaccine in China. Under the agreement, both companies will collaborate to conduct clinical trials in China, leveraging Fosun Pharma's clinical development, regulatory, and commercial capabilities in the country. Upon regulatory approval, Fosun Pharma will commercialize the vaccine in China, while BioNTech retains the full rights to develop and commercialize the vaccine in the rest of the world. Fosun Pharma will pay BioNTech up to $135 million (€120 million) in upfront and potential future investment and milestone payments, including an equity investment of $50 million (€44 million) for 1,580,777 ordinary shares in BioNTech, subject to execution of share subscription documentation and approval from regulatory authorities in China. Future gross profits from the sale of the vaccine in China will be shared by the two companies.

On March 17, 2020 BioNTech and Pfizer Inc. (NYSE: PFE, "Pfizer") announced that the companies have agreed to a letter of intent regarding the co-development and distribution (excluding China) of a potential mRNA-based coronavirus vaccine aimed at preventing COVID-19 infection. The companies have executed a Material Transfer and Collaboration Agreement to enable the parties to immediately start working together.