UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934

FOR THE MONTH OF NOVEMBER 2020

COMMISSION FILE NUMBER 001-39081

BioNTech SE

(Translation of registrant's name into English)

An der Goldgrube 12
D-55131 Mainz
Germany
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(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F: Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

DOCUMENTS INCLUDED AS PART OF THIS FORM 6-K

On November 10, 2020, BioNTech SE (the "Company") provided a development update and reported its financial results for the three and nine months ended September 30, 2020. The interim condensed consolidated financial statements as well as the operating and financial review and prospects of the Company, for the three and nine months ended September 30, 2020, are attached hereto as Exhibit 99.1 and shall be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and incorporated by reference herein.

On May 6, 2020, the Company acquired Neon Therapeutics, Inc., a biotechnology company developing novel neoantigen-based T-cell therapies. Certain unaudited pro forma condensed combined financial information is attached hereto as Exhibit 99.2.

The information contained in Exhibit 99.2 is furnished only and shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or incorporated by reference in any filing under the Securities Act of 1933, as amended, or under the Exchange Act, unless expressly set forth by specific reference in such a filing.

SIGNATURE

Pursuant to the requirements of s the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BioNTech SE

By: /s/ Dr. Sierk Poetting
Name: Dr. Sierk Poetting
Title: Chief Financial Officer

Date: November 10, 2020

EXHIBIT INDEX

Exhibit	Description of Exhibit
99.1	Quarterly Report for the Three and Nine Months Ended September 30, 2020.
99.2	Unaudited pro forma condensed combined financial information for the year ended December 31, 2019 and the nine months ended September 30, 2020.

BioNTech SE

Quarterly Report for the Three and Nine Months ended September 30, 2020

BioNTech SE

Quarterly Report for the Three and Nine Months ended September 30, 2020

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Interim Condensed Consolidated Financial Statements

Interim Condensed Consolidated Statements of Financial Position

(in thousands)		September 30, 2020	December 31, 2019
Assets	**Note**	*(unaudited)*	
Non-current assets			
Intangible assets	8	€168,733	€89,434
Property, plant and equipment	9	127,739	93,044
Right-of-use assets		55,764	55,018
Other assets	11	5,177	-
Total non-current assets		**€357,413**	**€237,496**
Current assets			
Inventories		12,368	11,722
Trade receivables	10	7,170	11,913
Other financial assets	10	17,843	1,680
Other assets	11	54,146	9,069
Income tax assets		724	756
Deferred expense		9,127	5,862
Cash and cash equivalents		990,461	519,149
Total current assets		**€1,091,839**	**€560,151**
Total assets		**€1,449,252**	**€797,647**
Equity and liabilities			
Equity			
Share capital	12	246,310	232,304
Capital reserve	12	1,441,631	686,714
Treasury shares	12	(5,525)	(5,525)
Accumulated losses		(776,541)	(424,827)
Other reserves	13	21,808	4,826
Total equity		**€927,683**	**€493,492**
Non-current liabilities			
Financial liabilities	10	175,621	68,904
Other liabilities		695	-
Contract liabilities		76,773	97,109
Total non-current liabilities		**€253,089**	**€166,013**
Current liabilities			
Tax provisions		150	150
Provisions		817	762
Financial liabilities	10	3,021	1,823
Trade payables	10	41,912	20,498
Contract liabilities		70,250	93,583
Other financial liabilities	10	132,157	13,836
Other liabilities		20,173	7,490
Total current liabilities		**€268,480**	**€138,142**
Total liabilities		**€521,569**	**€304,155**
Total equity and liabilities		**€1,449,252**	**€797,647**

The accompanying notes form an integral part of these interim condensed consolidated financial statements.

Interim Condensed Consolidated Statements of Operations

		Three months ended September 30,		Nine months ended September 30,	
		2020	**2019**	**2020**	**2019**
(in thousands, except per share data)	**Note**	*(unaudited)*		*(unaudited)*	
Revenues from contracts with customers	4	€67,458	€28,662	€136,883	€80,601
Cost of sales		(6,840)	(4,230)	(18,344)	(12,925)
Gross profit		**€60,618**	**€24,432**	**€118,539**	**€67,676**
Research and development expenses	6	(227,706)	(50,396)	(388,017)	(161,039)
Sales and marketing expenses		(4,268)	(670)	(7,808)	(1,908)
General and administrative expenses		(23,324)	(10,582)	(57,952)	(34,481)
Other operating income		8,764	347	9,962	1,340
Other operating expenses		(466)	(5)	(1,325)	(163)
Operating loss		**€(186,382)**	**€(36,874)**	**€(326,601)**	**€(128,575)**
Finance income*		474	7,294	1,067	9,170
Finance expenses*		(21,081)	(82)	(24,455)	(233)
Interest expense related to lease liability		(552)	(433)	(1,432)	(1,283)
Loss before tax		**€(207,541)**	**€(30,095)**	**€(351,421)**	**€(120,921)**
Income taxes	7	(2,491)	(8)	(293)	(28)
Loss for the period		**€(210,032)**	**€(30,103)**	**€(351,714)**	**€(120,949)**
Attributable to:					
Equity holders of the parent		(210,032)	(30,103)	(351,714)	(120,833)
Non-controlling interests		-	-	-	(116)
		€(210,032)	**€(30,103)**	**€(351,714)**	**€(120,949)**
Earnings per share					
in EUR					
Basic & diluted, loss per share for the period attributable to equity holders of the parent**		€(0.88)	€(0.14)	€(1.51)	€(0.59)

* Foreign exchange differences on a cumulative basis are either shown as finance income or expenses and might switch between those two positions during the year-to-date reporting periods.
** Numbers of shares for calculating the earnings per share for the three and nine months ended September 30, 2019 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 interim consolidated financial statements.

Interim Condensed Consolidated Statements of Comprehensive Loss

		Three months ended September 30,		Nine months ended September 30,	
		2020	**2019**	**2020**	**2019**
(in thousands)	**Note**	*(unaudited)*		*(unaudited)*	
Loss for the period		**€(210,032)**	**€(30,103)**	**€(351,714)**	**€(120,949)**
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		(3,673)	(8)	(7,166)	(2)
Net other comprehensive income that may be reclassified to profit or loss in subsequent periods		**(3,673)**	**(8)**	**(7,166)**	**(2)**
Other comprehensive income for the period, net of tax		**(3,673)**	**(8)**	**(7,166)**	**(2)**
Comprehensive loss for the period, net of tax		**€(213,705)**	**€(30,111)**	**€(358,880)**	**€(120,951)**
Attributable to:					
Equity holders of the parent		(213,705)	(30,111)	(358,880)	(120,835)
Non-controlling interests		-	-	-	(116)
Comprehensive loss for the period, net of tax		**€(213,705)**	**€(30,111)**	**€(358,880)**	**€(120,951)**

The accompanying notes form an integral part of these interim condensed consolidated financial statements.

Interim Condensed Consolidated Statements of Changes in Stockholders' Equity

		Nine months ended September 30, 2020							
		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, 2020		**€232,304**	**686,714**	**(5,525)**	**(424,827)**	**4,762**	**64**	**493,492**	**-**	**493,492**
Loss for the period		-	-	-	(351,714)	-	-	**(351,714)**	-	**(351,714)**
Other comprehensive loss		-	-	-	-	-	(7,166)	**(7,166)**	-	**(7,166)**
Total comprehensive loss		**-**	**-**	**-**	**(351,714)**	**-**	**(7,166)**	**(358,880)**	**-**	**(358,880)**
Issuance of share capital	12	14,006	785,150	-	-	-	-	**799,156**	-	**799,156**
Transaction costs	12	-	(30,233)	-	-	-	-	**(30,233)**	-	**(30,233)**
Share-based payments	13	-	-	-	-	24,148	-	**24,148**	-	**24,148**
As of September 30, 2020 *(unaudited)*		**€246,310**	**1,441,631**	**(5,525)**	**(776,541)**	**28,910**	**(7,102)**	**927,683**	**-**	**927,683**

		Nine months ended September 30, 2019							
		Attributable to the 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		-	-	-	(120,833)	-	-	**(120,833)**	(116)	**(120,949)**
Other comprehensive income		-	-	-	-	-	(2)	**(2)**	-	**(2)**
Total comprehensive income / (loss)		**-**	**-**	**-**	**(120,833)**	**-**	**(2)**	**(120,835)**	**(116)**	**(120,951)**
Issuance of share capital	12	8,126	41,748	-	-	-	-	**49,874**	-	**49,874**
Capital increase Series B	12	17,990	186,390	(5,525)	-	-	-	**198,855**	-	**198,855**
Acquisition of non-controlling interest	12	2,375	(1,644)	-	-	-	-	**731**	(731)	-
Transaction costs	12	-	(858)	-	-	-	-	**(858)**	-	**(858)**
Share based payments	13	-	-	-	-	22,485	-	**22,485**	-	**22,485**
As of September 30, 2019 *(unaudited)*		**€221,787**	**569,751**	**(5,525)**	**(366,604)**	**(2,989)**	**(15)**	**416,405**	**-**	**416,405**

* Numbers as of January 1, 2019 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 interim condensed consolidated financial statements.

Interim Condensed Consolidated Statements of Cash Flows

	Nine months ended September 30,	
	2020	**2019**
(in thousands)	*(unaudited)*	
Operating activities		
Loss for the period	€(351,714)	€(120,949)
Income taxes	293	28
Loss before tax	**€(351,421)**	**€(120,921)**
Adjustments to reconcile loss before tax to net cash flows:		
Depreciation and amortization of property, plant, equipment and intangible assets	26,202	24,087
Share-based payment expense	24,148	22,485
Net foreign exchange differences	80	(170)
Loss on disposal of property, plant and equipment	716	11
Finance income	(1,068)	(1,102)
Interest on lease liability	1,432	1,283
Finance expense	7,275	233
Movements in government grants	(8,500)	-
Other non-cash income	(151)	-
Working capital adjustments:		
Decrease/(Increase) in trade receivable and contract assets	(54,881)	4,575
Decrease/(Increase) in inventories	(508)	(4,945)
(Decrease)/Increase in trade payables, other liabilities, contract liabilities and provisions	95,058	(60,003)
Interest received	784	1,102
Interest paid	(1,643)	(1,517)
Income tax received (paid), net	(261)	(28)
Net cash flows used in operating activities	**€(262,738)**	**€(134,910)**
Investing activities		
Purchase of property, plant and equipment	(40,664)	(28,621)
Proceeds from sale of property, plant and equipment	8	568
Purchase of intangibles assets	(5,247)	(32,937)
Acquisition of subsidiaries and businesses, net of cash acquired	891	(6,056)
Net cash flows used in investing activities	**€(45,012)**	**€(67,046)**
Financing activities		
Proceeds from issuance of share capital, net of costs	680,122	247,871
Proceeds from loans and borrowings	102,397	8,067
Repayment of loans and borrowings	(904)	-
Payments related to lease liabilities	(3,188)	(2,215)
Net cash flows from financing activities	**€778,427**	**€253,723**
Increase in cash and cash equivalents	470,677	51,767
Change in cash resulting from exchange rate differences	635	46
Cash and cash equivalents at January 1	519,149	411,495
Cash and cash equivalents at September 30	**€990,461**	**€463,308**

The accompanying notes form an integral part of these interim condensed consolidated financial statements.

Selected Explanatory Notes to the Interim Condensed Consolidated Financial Statements

1 Corporate Information

BioNTech SE is a limited company incorporated and domiciled in Germany. American Depositary Shares ("ADS") representing BioNTech's shares have been publicly traded on the 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, or IFRS, unaudited interim condensed 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" and have been prepared on a going concern basis in accordance with the IFRS as issued by the International Accounting Standards Board, or IASB.

BioNTech combines decades of groundbreaking research in immunology, cutting-edge therapeutic platforms and a suite of patient profiling and bioinformatic tools to develop immunotherapies for cancer and other diseases. BioNTech leverages powerful new therapeutic mechanisms and exploits a diverse array of biological targets to harness the power of each patient's immune system to address the unique molecular signature of each patient's underlying disease. The breadth of BioNTech's immunotherapy technologies and expertise has enabled the Group to develop therapies to address a range of rare and infectious diseases, and BioNTech has recently rapidly mobilized these with the aim of addressing the COVID-19 pandemic.

During the nine months ended September 30, 2020, the following changes to the Group structure occurred:

- On May 6, 2020 BioNTech SE acquired Neon Therapeutics, Inc., Cambridge, Massachusetts, United States (formerly Nasdaq: NTGN), or Neon. Under the merger agreement by and among BioNTech, Neon and BioNTech's wholly-owned subsidiary, Endor Lights, Inc., New York, United States, Endor Lights, Inc. merged with and into Neon. The new subsidiary operates under the name BioNTech US Inc., a wholly-owned subsidiary of BioNTech SE, and serves as BioNTech's headquarters in the United States.
- On July 17, 2020, BioNTech IVAC GmbH was renamed to BioNTech Manufacturing GmbH and on August 7, 2020, BioNTech Small Molecules GmbH was renamed to BioNTech Europe GmbH.
- On September 17, 2020, following the shareholder resolution, the liquidation process for BioNTech Austria Beteiligungen GmbH was initialized.
- Two new real estate entities have been founded in Germany: BioNTech Real Estate An der Goldgrube GmbH & Co. KG and BioNTech Real Estate Adam-Opel-Straße GmbH & Co. KG, both Holzkirchen. Both are partnerships wholly-owned by its limited partner BioNTech Real Estate Holding GmbH, a wholly-owned subsidiary of BioNTech SE.

These unaudited interim condensed consolidated financial statements of the Group as of and for the three and nine months ended September 30, 2020 were authorized for issuance in accordance with a resolution of the audit committee on November 10, 2020.

2 Basis of Preparation, Significant Accounting Policies and further Accounting Topics

Basis of Preparation and Principles of Consolidation

The accompanying unaudited interim condensed consolidated financial statements as of and for the three and nine months ended September 30, 2020 have been prepared in accordance with IAS 34 Interim Financial Reporting.

The unaudited interim condensed consolidated financial statements do not include all the in-formation and disclosures required in the consolidated financial statements and should be read in conjunction with the Group's consolidated financial statements and accompanying notes included in the Group's Annual Report on Form 20-F as of and for the year ended December 31, 2019.

BioNTech prepares and presents its unaudited interim condensed consolidated financial statements in Euros. Numbers have been rounded, may not add up precisely to the totals provided and percentages may not precisely reflect the absolute figures.

The unaudited interim condensed consolidated financial statements as of and for the three and nine months ended September 30, 2020 include BioNTech SE and its subsidiaries. All intercompany transactions and balances have been eliminated in consolidation.

Use of Estimates

The preparation of the unaudited interim condensed consolidated financial statements requires management to make judgments, estimates and assumptions that affect the reported amounts. Management continually evaluates its judgments and estimates in relation to assets, liabilities, which also includes the fair value measurement of derivatives, contingent liabilities, revenue and expenses. Management bases its judgments and estimates on historical experience and on other various factors it believes to be reasonable under the circumstances, the result of which forms the basis of the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions and conditions and may materially affect the financial results or the financial position reported in future periods.

Significant Accounting Policies

The accounting policies adopted in the preparation of the unaudited interim condensed consolidated financial statements are consistent with those followed in the preparation of the Group's consolidated financial statements for the year ended December 31, 2019. Certain policies have been further specified as described below due to the activities related to and the progress made in the Covid-19 vaccine development.

Research and Development Expenses

Research and development expenses consist of costs incurred in performing research and development activities, including personnel-related expenses, contract services and costs for purchased materials, laboratory supplies and non-capital equipment used in the research and development process. Research and development expenses include BioNTech's share of expenses under the terms of collaboration agreements and 100% of the expenses for wholly-owned product candidates. Research and development expenses shared under collaboration agreements which are initially incurred by the collaboration partners and subsequently charged to BioNTech are recorded as purchased services classified within research and development. Cost reimbursements from partners for research and development expenses initially incurred by BioNTech and due to BioNTech under the agreements, are recorded as a reduction to purchased services classified within research and development expenses. The value of goods and services received from contract research organizations and contract manufacturing organizations in the reporting period are estimated based on the level of services performed and progress made in the respective period. Amounts are recorded as accrued expenses in cases where BioNTech has not received an invoice from the service provider. Advance payments for goods or services that will be used or rendered for future research and development activities are recognized as other current assets or other current financial assets respectively. The amounts are currently expensed as the related goods are delivered or the services performed. Management's estimates are based on the best information available at the time. However, additional information may become available in the future and management may adjust the estimate in such future periods. In this event, BioNTech may be required to record adjustments to research and development expenses in future periods when the actual level of activity becomes

more certain. BioNTech considers resulting increases or decreases in cost as changes in estimates and reflects such changes in research and development expenses in the period identified.

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.

Due to the inherent risk of failure in drug development and the uncertainty of approval, management has determined that these criteria are not met in the Biotech business sector until regulatory approval has been obtained. Therefore, as the Group has not yet obtained regulatory approval for any of its programs, or product candidates, no development expenditures have been capitalized. The related expenditure is reflected in the statements of operations in the period in which the expenditure is incurred.

Pre-launch products

Prior to initial regulatory approval, costs relating to production of products are expensed as research and development expenses in the period incurred. If pre-launch products are sold, the respective product gross margin may be higher compared to the expected recurring margin as the underlying costs will not be included in cost of sales. For the three and nine months ended September 30, 2020 and 2019, no revenues have been recorded related to pre-launch products.

Government grants

The Group has specified its accounting for government grant with respect to the presentation of grants related to assets. In September 2020, in connection with becoming eligible for funding from an initiative by the German Federal Ministry of Education (*Bundesministerium für Bildung und Forschung*, or the BMBF), the Group elected to present grants received related to assets as deferred income within the statements of financial position. Income is subsequently recognized in profit or loss over the useful live of the underlying asset subject to funding.

The standards applied for the first time as of January 1, 2020, as disclosed in the notes to the consolidated financial statements as of December 31, 2019, had no impact on the unaudited interim condensed consolidated financial statements of the Group as of September 30, 2020. In the course of 2020 an amendment to IFRS 16 Leases with an effective date June 1, 2020 was issued by the International Accounting Standards Board addressing COVID-19-related rent concessions which does not have an impact on the interim condensed consolidated financial statements of the Group.

Impact of COVID-19

On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 as a pandemic, which continues to spread around the world.

In response, BioNTech's BNT162 program is evaluating several vaccine candidates against COVID-19, including BNT162b2 as the lead candidate currently being developed in a global Phase 3 trial. As part of the program, BioNTech executed two strategic collaborations with large pharmaceutical companies to globally develop BioNTech's vaccine candidates and to support a global supply of a vaccine upon approval. The collaboration with Pfizer Inc. (NYSE: PFE), or Pfizer, aims to rapidly advance multiple COVID-19 vaccine candidates based on BioNTech's proprietary mRNA vaccine technology. As part of their strategic collaboration, BioNTech and Shanghai Fosun Pharmaceutical (Group) Co.,

Ltd (Stock Symbol: 600196.SH, 02196.HK), or Fosun Pharma, will jointly conduct clinical trials in China, leveraging BioNTech's proprietary mRNA vaccine technology and Fosun Pharma's clinical development and commercialization capabilities in China. Fosun Pharma will commercialize the vaccine in China upon regulatory approval.

As BioNTech advances its clinical programs, it is in close contact with its principal investigators and clinical sites, which are located in jurisdictions affected by the COVID-19 pandemic, and is assessing the impact of the COVID-19 pandemic on its clinical trials, expected timelines and costs on an ongoing basis. BioNTech has modified its business practices, in response to the spread of COVID-19, including restricting employee travel, developing social distancing plans for employees and cancelling physical participation in meetings, events and conferences. In addition, for certain programs, including BNT111, BNT113, BNT122, BNT141 and BNT142 (RiboMabs), BNT151 and BNT152/153 (RiboCytokines), BNT221, BNT161 (Influenza) and BNT171 (Rare Disease), the commencement of trials has been delayed, partially due to slowed patient enrollment or other delays as a result of the COVID-19 pandemic. This delay had an impact on revenue recognition related to non-COVID-19 collaborations. The partial disruption, even temporary, may severely impact BioNTech's operations and overall business by delaying the progress of its clinical trials and preclinical studies. BioNTech's 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. Such factors were evaluated and considered carefully when preparing these unaudited interim condensed consolidated financial statements. BioNTech will continue to evaluate potential effects of the COVID-19 pandemic.

3 Segment Information

For the three and nine months ended September 30, 2020 and 2019, respectively, the following tables present revenue and operating results for the Group's operating segments consistent with the presentation in the notes to the consolidated financial statements as of December 31, 2019. The tables below reconcile segment figures to Group figures for the periods indicated.

	Biotech Business Unit				External Services Business Unit			
(in thousands)	**Clinical**	**Technology Platform**	**Manufacturing**	**Business Service**	**Product Sales & External Services**	**Total**	**Adjustments**	**Group**
Three months ended September 30, 2020								
Revenues								
Collaboration Revenues	€41,777	€4,118	€13,754	-	-	€59,649	-	€59,649
Revenues from other sales transactions	216	66	32	-	7,495	7,809	-	7,809
Cost of sales	-	-	-	-	(6,463)	(6,463)	(377)	(6,840)
Gross Profit	**€41,993**	**€4,184**	**€13,786**	**-**	**€1,032**	**€60,995**	**€(377)**	**€60,618**
Income / Expenses								
Research and development expenses	(124,275)	(51,036)	(52,132)	(493)	(145)	(228,081)	375	(227,706)
Sales and marketing expenses	-	-	-	(3,772)	(496)	(4,268)	-	(4,268)
General and administrative expenses	-	-	(1,281)	(21,241)	(802)	(23,324)	-	(23,324)
Other result	4,129	1,882	2,223	34	33	8,301	(3)	8,298
Segment operating loss	**€(78,153)**	**€(44,970)**	**€(37,404)**	**€(25,472)**	**€(378)**	**€(186,377)**	**€(5)**	**€(186,382)**

	Biotech Business Unit				External Services Business Unit			
(in thousands)	**Clinical**	**Technology Platform**	**Manufacturing**	**Business Service**	**Product Sales & External Services**	**Total**	**Adjustments**	**Group**
Three months ended September 30, 2019								
Revenues								
Collaboration Revenues	€7,174	€1,972	€13,091	-	-	€22,237	-	€22,237
Revenues from other sales transactions	-	142	-	-	6,283	6,425	-	6,425
Cost of sales	-	-	-	-	(4,166)	(4,166)	(64)	(4,230)
Gross Profit	**€7,174**	**€2,114**	**€13,091**	**-**	**€2,117**	**€24,496**	**€(64)**	**€24,432**
Income / Expenses								
Research and development expenses	(21,948)	(14,289)	(12,668)	(1,397)	(158)	(50,460)	64	(50,396)
Sales and marketing expenses	-	-	-	(355)	(315)	(670)	-	(670)
General and administrative expenses	-	-	(883)	(8,702)	(859)	(10,444)	(138)	(10,582)
Other result	47	101	28	35	131	342	-	342
Segment operating loss	**€(14,727)**	**€(12,074)**	**€(432)**	**€(10,419)**	**€916**	**€(36,736)**	**€(138)**	**€(36,874)**

	Biotech Business Unit				External Services Business Unit			
(in thousands)	**Clinical**	**Technology Platform**	**Manufacturing**	**Business Service**	**Product Sales & External Services**	**Total**	**Adjustments**	**Group**
Nine months ended September 30, 2020								
Revenues								
Collaboration Revenues	€60,740	€11,543	€41,112	-	-	€113,395	-	€113,395
Revenues from other sales transactions	319	311	32	-	22,826	23,488	-	23,488
Cost of sales	-	-	-	-	(16,897)	(16,897)	(1,447)	(18,344)
Gross profit	**€61,059**	**€11,854**	**€41,144**	**-**	**€5,929**	**€119,986**	**€(1,447)**	**€118,539**
Income / Expenses								
Research and development expenses	(182,719)	(113,740)	(88,987)	(3,563)	(453)	(389,462)	1,445	(388,017)
Sales and marketing expenses	-	-	-	(6,395)	(1,413)	(7,808)	-	(7,808)
General and administrative expenses	-	(5)	(3,457)	(52,215)	(2,275)	(57,952)	-	(57,952)
Other result	4,114	1,950	2,265	264	47	8,640	(3)	8,637
Segment operating income / (loss)	**€(117,546)**	**€(99,941)**	**€(49,035)**	**€(61,909)**	**€1,835**	**€(326,596)**	**€(5)**	**€(326,601)**

	Biotech Business Unit				External Services Business Unit			
(in thousands)	**Clinical**	**Technology Platform**	**Manufacturing**	**Business Service**	**Product Sales & External Services**	**Total**	**Adjustments**	**Group**
Nine months ended September 30, 2019								
Revenues								
Collaboration Revenues	€25,605	€1,972	€36,683	-	-	€64,260	-	€64,260
Revenues from other sales transactions	-	605	2	8	15,726	16,341	-	16,341
Cost of sales	-	-	-	-	(12,770)	(12,770)	(155)	(12,925)
Gross profit	**€25,605**	**€2,577**	**€36,685**	**€8**	**€2,956**	**€67,831**	**€(155)**	**€67,676**
Income / Expenses								
Research and development expenses	(65,634)	(52,503)	(38,905)	(3,732)	(420)	(161,194)	155	(161,039)
Sales and marketing expenses	-	-	-	(924)	(984)	(1,908)	-	(1,908)
General and administrative expenses	-	-	(2,741)	(29,398)	(2,204)	(34,343)	(138)	(34,481)
Other result	307	389	42	61	378	1,177	-	1,177
Segment operating loss	**€(39,722)**	**€(49,537)**	**€(4,919)**	**€(33,985)**	**€(274)**	**€(128,437)**	**€(138)**	**€(128,575)**

The segments are managed based on external sales and operating profit/loss, which represents the operating profit/loss incurred within 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 deviations in classification between cost of sales and research and development cost. In order to reconcile the segment figures to the Group's unaudited interim condensed consolidated financial statements, some of the research and development expenses are reclassified to cost of sales. Whenever revenues are attributable to different segments, these revenues are split based on the cost incurred. 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 other results that are not directly attributable to one of the segments are allocated to Business Service.

Revenue at BioNTech is differentiated between revenues resulting from collaboration and license agreements and revenues from other sales transactions. The Company collaborates with pharmaceutical and healthcare companies and several global academic collaborators. During the three and nine months ended September 30, 2020, revenue generated from the Genentech, Inc., or Genentech, and Pfizer collaboration agreements each represented more than 10% of BioNTech's overall revenue from collaboration and license agreements. Revenues were partly recorded in the Clinical and the Manufacturing segment and, with respect to Pfizer, in the Technology Platform segment as well. During the three and nine months ended September 30, 2019, revenue generated from the Genentech and Pfizer collaboration agreements represented more than 10% of BioNTech's overall revenue from collaboration and license agreements. Revenues were recorded in the Clinical segment and, with respect to Genentech, also in the Manufacturing segment. Total amounts of revenues from these collaboration and license agreements in the periods presented are disclosed in Note 4.

Revenues from other sales transactions are 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 while manufacturing facilities and sales offices are located and managed in Germany. External sales originate in Germany.

4 Revenues from Contracts with Customers

Disaggregated revenue information

Set out below is the disaggregation of the Group's revenues from contracts with customers:

	Three months ended September 30,		Nine months ended September 30,	
(in thousands)	**2020**	**2019**	**2020**	**2019**
Revenues resulting from collaboration and license agreements	€59,649	€22,237	€113,395	€64,260
Pfizer Inc.	*45,643*	*3,587*	*69,843*	*10,761*
Genentech Inc.	*11,991*	*16,677*	*38,877*	*47,620*
Shanghai Fosun Pharmaceutical (Group) Co., Ltd	*1,697*	-	*2,598*	-
Sanofi S.A.	*318*	*152*	*2,077*	*4,058*
Eli Lilly and Company	-	*1,821*	-	*1,821*
Revenues from other sales transactions	7,809	6,425	23,488	16,341
Total	**€67,458**	**€28,662**	**€136,883**	**€80,601**

During the nine months ended September 30, 2020, revenues from BioNTech's two new collaboration agreements aimed at developing a COVID 19 vaccine were recognized for the first time.

On March 13, 2020, BioNTech entered into a collaboration and license agreement with Fosun Pharma. Fosun Pharma paid BioNTech a non-refundable upfront cash payment of k€901 (k$1,000) upon signing the agreement in addition to an equity investment of k€45,568 (k$50,000) (see Note 12 for the capital contribution). BioNTech is eligible to receive future milestone payments of up to k$84,000 for potential aggregate consideration of k$135,000.

The non-refundable upfront cash payment received from Fosun Pharma was subsequently fully recognized as revenue. In addition, during the three months ended September 30, 2020, revenue of k€1,697 was recognized by achieving a development milestone. In total, during the nine months ended September 30, 2020, k€2,598 revenue was recognized from the Fosun Pharma collaboration and license agreement.

On April 9, 2020, BioNTech entered into a collaboration and license agreement with Pfizer in which BioNTech and Pfizer equally share development costs. Pfizer agreed to pay BioNTech k€170,146 (k$185,000), including an equity investment of k€103,890 (k$113,000) (see Note 12 for the capital contribution) and a non-refundable upfront cash payment of k€66,256 (k$72,000) which were received in late April 2020 and May 2020, respectively. BioNTech is eligible to receive future milestone payments of up to k$563,000 for potential aggregate consideration of k$748,000.

The non-refundable upfront cash payment received from Pfizer that was initially classified as a contract liability was fully recognized as revenue during the nine months ended September 30, 2020 based on costs incurred. During the three and nine months ended September 30, 2020, revenues of k€45,643 and k€66,256 were recorded respectively.

As services are performed under a collaboration agreement, revenue recognition will be continued in future periods in accordance with BioNTech's accounting policy as described in "—Critical Accounting Policies and Use of Estimates" and Note 2.3.4 to BioNTech's consolidated financial statements included in its Annual Report on Form 20-F as of and for the year ended December 31, 2019.

Product sales included within revenue from other sales transactions are displayed below:

	Three months ended September 30,		Nine months ended September 30,	
(in thousands)	**2020**	**2019**	**2020**	**2019**
Product sales of JPT Peptide Technologies GmbH	€4,831	€3,057	€13,868	€8,892

5 Business Combinations

Lipocalyx GmbH

In December 2019, BioNTech Delivery Technologies GmbH (previously BioNTech Protein Therapeutics GmbH), or 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, or Lipocalyx, and its related parties in exchange for a total consideration of cash at an amount of k€6,516 and additional contingent consideration estimated at the closing date of January 6, 2020 at an amount of k€572. The employees of Lipocalyx were transferred automatically to BioNTech Delivery Technologies with effect as of the closing date.

The Group acquired the assets of Lipocalyx and its related parties to combine the acquired technologies and the related know-how with already existing product candidates of the Group to improve their functionality and performance.

The final fair values of the identifiable net assets of Lipocalyx as at the date of acquisition were:

	Fair value recognized on acquisition
(in thousands)	Lipocalyx GmbH
Assets	
Goodwill	€896
Other intangible assets	5,978
Property, plant and equipment	75
Inventories	139
Total identifiable net assets at fair value	**€7,088**
Consideration	
Cash paid	€6,516
Contingent consideration liability	572
Total consideration	**€7,088**

The interim condensed consolidated statements of operations include the result of Lipocalyx since the acquisition date. From the date of acquisition through September 30, 2020, Lipocalyx contributed k€1,082 to operating loss in the Technology Platform business segment of the Group. From the date of acquisition through September 30, 2020, Lipocalyx generated k€176 in revenues. Given the timing of closing, the contribution to operating loss and revenues, if the transaction had occurred at the beginning of the reporting period, would not differ materially. Goodwill recognized is primarily attributed to the expected synergies and other benefits from combining the assets and activities of Lipocalyx with those of the Group. The goodwill resulting from the Lipocalyx acquisition during the nine months ended September 30, 2020 was allocated to the Technology Platform segment.

Transaction costs of k€17 relating to the acquisition have been expensed and are included in the general and administrative expenses in the interim condensed consolidated statements of operations and are included in cash flows used in operating activities in the interim condensed consolidated statements of cash flows.

The purchase agreement with Lipocalyx includes the following contingent cash considerations to the previous owners:

- k€1,000 upon successful completion of a Phase 1 clinical trial designed to show and establish a sufficient safety margin justifying further development of the first pharmaceutical product relating to acquired technologies formulated in a manner covered by a valid granted claim in a major country of a patent within the assigned IP rights; and
- k€1,000 upon successful completion of the first Phase 2 clinical trial of the first pharmaceutical product relating to acquired technologies formulated in a manner covered by a valid granted claim in a major country of a patent within the assigned IP rights.

At the acquisition date, the fair value of the contingent consideration was k€572. The contingent consideration is presented in 'non-current financial liabilities' in the interim condensed consolidated statements of financial position (see Note 10).

BioNTech US Inc. (formerly Neon Therapeutics, Inc.)

On May 6, 2020, BioNTech acquired Neon, a biotechnology company developing novel neoantigen-based T-cell therapies ("the Merger"). Through the acquisition, BioNTech will be able to leverage Neon's expertise in the development of neoantigen therapies, with both vaccine and T cell capabilities.

Based on the acquisition date share price, the aggregate value of the merger consideration was k€89,890 (k$97,144) financed by issuing 1,935,488 American Depositary Shares representing BioNTech's ordinary shares as a stock transaction and including a de minimis cash consideration which was paid to settle Neon's outstanding stock options.

The fair values and values in accordance with IFRS 3 of the identifiable net assets of BioNTech US Inc. as at the date of acquisition were as follows:

(in thousands)	**Fair value recognized on acquisition** BioNTech US Inc.
Assets	
Intangible assets	€29,867
Property, plant and equipment	5,617
Right-of-use assets	6,896
Other assets non-current and current	2,704
Cash	7,749
Total assets	**€52,833**
Liabilities	
Trade payables	1,723
Other liabilities non-current and current	17,793
Total liabilities	**€19,516**
Total identifiable net assets at fair value	**€33,317**

(in thousands)	Fair value recognized on acquisition BioNTech US Inc.
Total identifiable net assets at fair value	**€33,317**
Goodwill from the acquisition	56,573
Consideration transferred	**€89,890**

Consideration	
Shares issued, at fair value	89,548
Cash paid	342
Total consideration	**€89,890**

As at the date of acquisition, k€8,043 of deferred tax liabilities had been provisionally recorded arising from the assets acquired in the business combination. Provisionally, tax benefits acquired as part of the business combination were assessed as not satisfying the criteria for separate recognition. During the three months ended September 30, 2020, BioNTech finalized its assessment of deferred taxes related to the acquisition of Neon and determined that loss carryforwards which existed as of the acquisition date, should be recognized to the extent of acquired deferred tax liabilities (k€8,043) and therefore recorded a deferred tax asset of k€8,043 against goodwill. Since the conditions to offset were fulfilled, the deferred tax assets and liabilities were offset. Additionally, the deferred tax asset on tax losses incurred since acquisition through June 30, 2020 (k€2,317) which had been offset against the acquired deferred tax liability as of June 30, 2020, was reversed through income tax expense during the three months ended September 30, 2020 as this deferred tax asset was no longer deemed recoverable as the entire acquired deferred tax liability was offset with the acquired deferred tax asset with the finalization of the purchase price allocation. The net impact on income tax expense in the nine months ended September 30, 2020 is nil.

The interim condensed consolidated statements of operations include the results of BioNTech US since the acquisition date. From the date of acquisition through September 30, 2020, BioNTech US contributed k€17,912 to the operating loss in all biotech business unit operating segments of the Group, primarily in the Technology Platform segment. If the transaction had occurred at the beginning of the reporting period, k€49,202 would have contributed to the operating loss. This amount includes expenses resulting from the Merger and should not necessarily be considered representative of the future consolidated results of operations or financial condition on a consolidated basis. From the date of acquisition, BioNTech US did not generate any revenue and no revenue would have been generated if the transaction had occurred at the beginning of the reporting period.

Goodwill recognized is primarily attributable to the expected synergies and other benefits from combining two organizations with a common culture of pioneering translational science and a shared vision for the future of cancer immunotherapy as described above. The goodwill resulting from the BioNTech US acquisition during the nine months ended September 30, 2020 was allocated to the Technology Platform segment.

Transaction costs of k€1,073 relating to the acquisition have been expensed and are included in the general and administrative expenses in the interim condensed consolidated statements of operations. In the interim condensed consolidated statements of cash flows they are included in cash flows used in operating activities. The attributable costs of the issuance of the shares of k€1,320 were recorded in equity as a deduction from the capital reserve and are included in cash flows from financing activities in the interim condensed consolidated statements of cash flows.

Reconciliation of goodwill

The reconciliation of the carrying amount of goodwill at the beginning and end of the reporting period is presented below

(in thousands)	**Goodwill**
Acquisition costs	
As of January 1, 2020	**€2,978**
Acquisition of subsidiaries and businesses	57,469
Currency differences	(4,355)
As of September 30, 2020	**€56,092**

Carrying amount	**Goodwill**
As of January 1, 2020	**€2,978**
As of September 30, 2020	**€56,092**

The amount of goodwill recognized from acquiring subsidiaries and businesses includes the measurement period adjustment of k€8,043 resulting from the subsequent recognition of deferred tax assets during the reporting period (see above and Note 7).

6 Research and Development Expenses

BioNTech's nature of business and primary focus of activities, including development of its platforms and manufacturing technologies, generate a significant amount of research and development expenses which are the largest component of total operating expenses.

The research and development expenses recognized during the three and nine months ended September 30, 2020 and September 30, 2019 are shown in the following table:

	Three months ended September 30,		**Nine months ended September 30,**	
(in thousands)	**2020**	**2019**	**2020**	**2019**
Purchased services	€143,104	€15,121	€201,142	€45,434
Wages, benefits and social security expense	29,177	16,422	88,694	60,869
Laboratory supplies	43,971	9,407	65,148	27,701
Depreciation and amortization	7,211	6,799	21,122	19,150
IT costs	1,064	580	3,493	1,449
Lease and lease related cost	1,167	605	2,832	1,868
Transport costs	397	356	1,216	876
Other	1,615	1,106	4,370	3,692
Total	**€227,706**	**€50,396**	**€388,017**	**€161,039**

During the three and nine months ended September 30, 2020, research and development expenses increased mainly due to an increase in development expenses from BioNTech's BNT162 program, the vaccine program against COVID-19. Research and development expenses include BioNTech's share of expenses derived from the collaboration with Pfizer under which shared development costs are shared equally between the partners.

7 Income Tax

The Group calculates the interim income tax expense using the tax rate that would be applicable to the expected total annual earnings. Deferred tax assets on tax losses of subsidiaries incorporated in Germany have not been capitalized as there is not sufficient probability that there will be future taxable profits against which the unused tax losses can be utilized. During the three months ended September 30, 2020, BioNTech finalized its assessment of deferred taxes related to the acquisition of Neon and determined that loss carryforwards which existed as of the acquisition date, should be recognized to the extent of acquired deferred tax liabilities (k€8,043) and therefore recorded a deferred tax asset of k€8,043 against goodwill. Since the conditions to offset were fulfilled, the deferred tax assets and liabilities were offset. Additionally, the deferred tax asset on tax losses incurred since acquisition through June 30, 2020 (k€2,317) which had been offset against the acquired deferred tax liability as of June 30, 2020, was reversed through income tax expense during the three months ended September 30, 2020 as this deferred tax asset was no longer deemed recoverable as the entire acquired deferred tax liability was offset with the acquired deferred tax asset with the finalization of the purchase price allocation. The net impact on income tax expense in the nine months ended September 30, 2020 is nil. Accumulated tax losses relate to Germany and the United States. There is no expiration date for any of the accumulated tax losses under German tax law. With respect to accumulated losses incurred at the level of BioNTech USA Holding LLC and BioNTech Research and Development Inc. since their incorporation and tax losses of BioNTech US incurred since 2018 have no expiration date under U.S. tax law. The carry forward of tax losses prior 2018 of BioNTech US is partially limited in time and amount. Deviating federal and state rules apply.

8 Intangible Assets

During the nine months ended September 30, 2020, the Group acquired intangible assets with a cost of k€5,248 (nine months ended September 30, 2019: k€13,721), excluding intangible assets acquired through business combinations (see Note 5). The acquisitions during the nine months ended September 30, 2020 mainly related to advance payments (k€2,626) as well as concessions, licenses, in-process R&D and similar rights (k€2,622). During the nine months ended September 30, 2019, the acquisitions mainly related to concessions, licenses, in-process R&D and similar rights (k€8,318) as well as advance payments (k€5,403).

9 Property, Plant and Equipment

During the nine months ended September 30, 2020, the Group acquired property, plant and equipment with a cost of k€40,664 (nine months ended September 30, 2019: k€28,621), excluding property, plant and equipment acquired through business combinations (see Note 5). The acquisitions during the nine months ended September 30, 2020 were related to construction in progress and advance payments (k€30,036), equipment, tools and installations (k€8,034) as well as land and buildings (k€2,594). During the nine months ended September 30, 2019, the acquisitions were related to construction in progress and advance payments (k€12,012), equipment, tools and installations (k€9,433) as well as land and buildings (k€7,176).

10 Financial Assets and Financial Liabilities

Set out below, is an overview of financial assets, other than cash and cash equivalents, held by the Group as of September 30, 2020 and December 31, 2019:

Financial assets at amortized cost

(in thousands)	**September 30, 2020**	**December 31, 2019**
Other financial assets	€17,843	€1,680
Trade receivables	7,170	11,913
Total	**€25,013**	**€13,593**
Total current	25,013	13,593
Total non-current	-	-

Set out below, is an overview of financial liabilities, other financial liabilities and trade payables held by the Group as of September 30, 2020 and December 31, 2019:

Interest-bearing loans and borrowings

(in thousands)	**Maturity**	**September 30, 2020**	**December 31, 2019**
Convertible note - host contract	08/28/2024	€86,695	-
2.15% € 10,000,000 secured bank loan	12/30/2027	9,407	9,000
2.08% € 9,450,000 secured bank loan	09/30/2028	9,213	7,600
Total		**€105,315**	**€16,600**
Total current		2,944	1,823
Total non-current		102,371	14,777

Other financial liabilities

(in thousands)	**September 30, 2020**	**December 31, 2019**
Derivatives not designated as hedging instrument		
Convertible note - embedded derivative	€19,910	-
Financial liabilities at fair value through profit or loss		
Contingent consideration	572	-
Total financial liabilities at fair value	**€20,482**	**-**
Other financial liabilities at amortized cost, other than interest-bearing loans and borrowings		
Trade payables	41,912	20,498
Lease liabilities	58,224	57,612
Other financial liabilities	126,778	10,351
Total other financial liabilities at amortized cost, other than interest-bearing loans and borrowings	**€226,914**	**€88,461**
Total other financial liabilities	**€247,396**	**€88,461**
Total current	174,146	34,334
Total non-current	73,250	54,127

Manufacturing Financing

BioNTech entered into an agreement with the European Investment Bank (EIB) for a €100 million credit facility to partially support the development of BNT162 and fund expansion of BioNTech's manufacturing capacity to provide worldwide supply of BNT162 in response to the COVID-19 pandemic. Under this arrangement, the EIB agreed to provide BioNTech with a credit in an amount up to €100 million to partially finance such development and expansion. The credit consists of (i) a term loan in the amount of €50 million that may be drawn in a single tranche upon the achievement of certain milestone events (Credit A), and (ii) a term loan in the amount of €50 million that may be drawn in a single tranche (Credit B). Credit B may only be drawn after Credit A has been drawn down and upon the additional 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. As of September 30, 2020, there has been no draw down.

June 2020 Private Placement – Convertible Note

A fund associated with Temasek Capital Management Pte. Ltd., or Temasek, and another accredited investor have contributed a private investment which BioNTech refers to as the "June 2020 Private Placement". The private placement includes an investment in ordinary shares (see Note 12) and a k€100,000 investment in a 4-year mandatory convertible note. The four-year mandatory convertible note has a coupon of 4.5% per annum and a conversion premium of 20% above its reference price. Subject to customary closing conditions, the investment closed as of August 28, 2020. As of that date, the convertible note has been classified as a financial liability according to IAS 32 because the conversion features of the note lead to a conversion into a variable number of shares and is measured at amortized costs since the fair value option was not applied. On initial recognition, the financial liability was measured at the present value of the contractually determined future cash flows discounted at the effective interest rate of 9.0%. The financial liability is subsequently measured at amortized cost by using the effective interest rate method until extinguished upon conversion. The conversion features provided for in the contract were identified as a combined embedded derivative since they share the same risk exposure and are interdependent. The embedded derivative was bifurcated from the convertible note, as host contract, and is recognized as a separate financial instrument. Based on the classification as derivative, the instrument is measured at fair value through profit and loss until it is extinguished upon conversion. The fair value of the embedded derivative is determined by modeling the stock price movement using the Cox-Rubinstein binomial tree model to derive the value of the conversion right. The primary inputs used in the model include stock price volatility, credit spreads, risk-free interest rate and foreign exchange forward rates. Stock price volatility is based on implied volatility for BioNTech, credit risk is model implied and adjusted for movement in credit spreads for B-rated corporates at each valuation date, the risk-free interest rate is based on currency specific time congruent IBOR and swap rates whereas the foreign exchange forward rates are based on observable market data.

Risk management activities

No changes have occurred regarding the Group's risk management activities as disclosed in the notes to the consolidated financial statements as of December 31, 2019.

Fair values

Fair values of cash and cash equivalents, trade receivables, trade payables, and other current financial assets and liabilities approximate their carrying amounts largely due to the short-term maturities of these instruments.

The financial liabilities measured at amortized cost include two fixed-interest rate loans as well as a recently issued convertible note. As of September 30, 2020 and December 31, 2019, the carrying value approximates their fair values as there have been no significant changes in relevant interest rates since the inception of the respective loans and note.

The fair values of financial instruments measured at fair value are reassessed on a quarterly basis. The valuation technique used for measuring the fair value of the embedded derivative is based on significant observable inputs (Level 2).

During the three and nine months ended September 30, 2020, the fair value adjustment derived from remeasuring the embedded derivative was recognized as finance expenses in profit or loss and amounted to k€6,296. The initial fair value of the contingent consideration determined at acquisition remains valid since no changes of the underlying performance criteria have occurred.

11 Other Assets

Set out below, is an overview of other assets as of September 30, 2020 and December 31, 2019:

(in thousands)	**September 30, 2020**	**December 31, 2019**
Prepayments on inventories	€31,645	€351
Sales tax receivable	12,130	7,536
Receivables from government grants	8,500	-
Deferred exclusivity fee	4,000	-
Other	3,048	1,182
Total	**€59,323**	**€9,069**
Total current	54,146	9,069
Total non-current	5,177	-

Government Grant

In September 2020, BioNTech became eligible to receive up to €375.0 million in funding from an initiative by the German Federal Ministry of Education (*Bundesministerium für Bildung und Forschung*, or the BMBF) to support the COVID-19 vaccine program BNT162. The milestone-based BMBF funding will be used to accelerate BioNTech's vaccine development, as well as for upscaling of manufacturing capabilities in Germany. As of September 30, 2020, k€8,500 were recorded as other current asset since they relate to amounts drawn down for which there is reasonable assurance that the government grant will be received, and all conditions, wholly in the control of the company, will be complied with. The funding drawn down represents a compensation for expenses already incurred in the period ended September 30, 2020. Therefore, k€8,500 were recognized as other operating income within the statements of operations during the three months ended September 30, 2020.

12 Issued Capital and Reserves

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 unaudited interim condensed consolidated financial statements and notes to the unaudited interim condensed consolidated financial statements give retroactive effect to the share split for all periods presented.

Capital transactions during the nine months ended September 30, 2020

During the nine months ended September 30, 2020, the issued share capital of BioNTech increased by k€14,006. Each share has a nominal value of €1.00. As a result of the financing transactions the capital reserve increased by k€785,150. Costs of k€30,233 related to these equity transactions were recorded in equity as deduction from the capital reserve. The financing transactions that occurred during the nine months ended September 30, 2020, were as follows:

Shanghai Fosun Pharmaceuticals (Group) Co., Ltd

As part of the BNT162 program, BioNTech entered a strategic alliance with Fosun Pharma to develop COVID-19 vaccine candidates in China. Fosun Pharma agreed to make an equity investment of k€45,568 (k$50,000) for 1,580,777 ordinary shares in BioNTech via Fosun Industrial Co., Limited, Hong Kong. The increase in share capital with a nominal amount of k€1,581 was subject to execution of share subscription documentation and approval from regulatory authorities in China and became effective with the registration with the commercial register (*Handelsregister*) on April 23, 2020. As a result of the transaction the capital reserve increased by k€43,987.

Pfizer Inc., New York, New York, United States

As part of the collaboration between BioNTech and Pfizer, for the co-development of BNT162, Pfizer agreed to make an equity investment of k€103,890 (k$113,000). The issuance of 2,377,446 ordinary shares with the nominal amount of k€ 2,377 was registered with the commercial register (*Handelsregister*) on May 5, 2020. As a result of the transaction the capital reserve increased by k€101,513.

Neon Therapeutics, Inc., Cambridge, Massachusetts, United States

BioNTech acquired Neon by issuing 1,935,488 American Depositary Shares representing BioNTech's ordinary shares with the nominal amount of k€ 1,935 to former stockholders of Neon in the Merger. The capital increase was registered with the commercial register (*Handelsregister*) on May 8, 2020. As a result of the transaction the capital reserve increased by k€87,613.

Global Offering

On July 27, 2020 BioNTech increased its share capital by k€5,500 (k$6,379) in conjunction with the underwritten offering of 5,500,000 ADS each representing one of BioNTech's ordinary shares at a public offering price of $93.00 per ADS ("Underwritten Offering"). On August 27, 2020, following the Underwritten Offering, BioNTech increased its share capital by additional k€16 (k$19) in conjunction with the rights offering of 16,124 ADS each representing one of BioNTech's ordinary shares at a public offering price of $93.00 per ADS ("Rights Offering"). The Underwritten Offering and the Rights Offering are part of a single, global offering which BioNTech refers to as the Global Offering. The gross proceeds of the Global Offering were k€436,295 (k$513,000) including k€5,516 increase in share capital and k€430,779 increase in capital reserve.

June 2020 Private Placement – Equity Investment

A fund associated with Temasek Capital Management Pte. Ltd., or Temasek, and another accredited investor have contributed a private investment which BioNTech refers to as the "June 2020 Private Placement". The private placement includes an investment in a 4-year mandatory convertible note (see Note 10) and an investment of k€123,855 in ordinary shares. The issuance of 2,595,996 ordinary shares with the nominal amount of k€ 2,596 was registered with the commercial register (*Handelsregister*) on September 8, 2020. As result of the transaction the capital reserve increased by k€121,259.

Capital transactions during the nine months ended September 30, 2019

During the comparative period of nine months ended September 30, 2019, the issued share capital of BioNTech increased by k€28,491. Each share has a nominal value of €1.00. As a result of the financing transactions the capital reserve increased by k€226,494. Costs of k€858 related to these equity transactions were recorded in equity as deduction from the capital reserve.

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).

As of March 14, 2019, BioNTech acquired the remaining 5.5% of non-controlling interests in BioNTech Cell & Gene Therapies GmbH previously held by Eli Lilly Nederland B.V. in exchange for issuing 2,374,794 new ordinary shares with an imputed nominal value 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 in 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.

Of the share capital issued in 2019, k€12,465 relates to a new financing round (referred to as the Series B round). As part of the Series B round, 12,465,288 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) were issued to certain new and existing shareholders. As a result of the Series B round, the capital reserve increased by k€186,083.

On August 30, 2019, BioNTech entered into agreements with the Bill & Melinda Gates Foundation ("BMGF") under which BioNTech is required to perform certain research and development activities. The issuance of 3,038,674 ordinary shares with the nominal amount of k€ 3,039 was registered with the commercial register (*Handelsregister*) on September 26, 2019. As result of the transaction the capital reserve increased by k€46,826.

13 Share-Based Payments

Management Board Grant (Cash-Settled)

Since the beginning of 2020, the first year following the completion of BioNTech's initial public offering ("IPO"), the current service agreements with BioNTech's Management Board have provided for a short-term incentive compensation of up to a maximum of fifty percent of the annual base salary for the years 2020, 2021 and 2022. The amount of such short-term incentive compensation will depend on the achievement of certain company goals in the particular fiscal year, which goals will be set uniformly for all members of the Management Board. Fifty percent of the incentive compensation will be paid promptly upon achievement of the applicable company goals (first installment), with the remaining amount payable one year later, subject to adjustment relative to the performance of the price of the American Depositary Shares representing BioNTech's ordinary shares during that year (second installment).

For each of the three yearly awards, the second installment of the short-term incentive compensation that is dependent on the price of the American Depositary Shares representing BioNTech's ordinary shares, represents a cash-settled share-based payment arrangement. The fair values of the liabilities are recognized over the award's vesting period beginning as of the service commencement date (January 1, 2020) until each separate determination date and are remeasured until settlement date.

During the three months ended September 30, 2020, the Group recognized share-based payment expenses of k€83 as research & development expenses and of k€124 as general & administrative expenses in the interim condensed consolidated statements of operations (three months ended September 30, 2019: Nil).

During the nine months ended September 30, 2020, the Group recognized share-based payment expenses of k€248 as research & development expenses and of k€373 as general & administrative expenses in the interim condensed consolidated statements of operations (nine months ended September 30, 2019: Nil).

Management Board Grant (Equity-Settled)

From the beginning of 2020, the first year following the completion of BioNTech's IPO, until the end of the term of the Management Board member's employment agreement, the service agreements with BioNTech's Management Board provide for a long-term incentive compensation in terms of a yearly grant of options to purchase BioNTech shares. The right to receive options in 2020, 2021 and 2022 represents an equity-settled share-based payment arrangement.

The options allocated each year will be subject to the terms, conditions, definitions and provisions of the Employee Stock Ownership Plan ("ESOP") and the applicable option agreement thereunder. The

number of options to be allocated 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. The value used to calculate the number of options for Ryan Richardson increases to €280,000 for the year 2022.

The allocation of the number of options to be received in 2020 took place on February 13, 2020 (allocation date). The allocations of the number of options to be received in 2021 and 2022 are estimated to take place on the first and second anniversary of the allocation date (estimated allocation dates).

The share options allocated and expected to be allocated to BioNTech's Management Board as of the dates indicated are presented in the tables below.

Allocation date February 13, 2020	**Share options outstanding**	**Weighted-average exercise price (€)**
Prof. Ugur Sahin, M.D.	97,420	28.32
Sean Marett	38,968	28.32
Dr. Sierk Poetting	38,968	28.32
Dr. Özlem Türeci	38,968	28.32
Ryan Richardson	33,772	28.32

Estimated allocation date February 13, 2021	**Share options expected to be allocated**	**Weighted-average exercise price (€)**
Prof. Ugur Sahin, M.D.	45,128	59.35*
Sean Marett	18,051	59.35*
Dr. Sierk Poetting	18,051	59.35*
Dr. Özlem Türeci	18,051	59.35*
Ryan Richardson	15,644	59.35*

* Valuation parameter derived from the Monte-Carlo simulation model

Estimated allocation date February 13, 2022	**Share options expected to be allocated**	**Weighted-average exercise price (€)**
Prof. Ugur Sahin, M.D.	44,736	59.87*
Sean Marett	17,894	59.87*
Dr. Sierk Poetting	17,894	59.87*
Dr. Özlem Türeci	17,894	59.87*
Ryan Richardson	16,701	59.87*

* Valuation parameter derived from the Monte-Carlo simulation model

For the awards with estimated allocation dates, the numbers of awards expected to be allocated have been calculated using the valuation parameter derived from the Monte-Carlo simulation model. The numbers will be adjusted until the actual allocation has occurred and the number of options granted has ultimately been determined. The options will vest annually in equal installments over four years commencing on the first anniversary of the allocation date and will be exercisable four years after the allocation date.

The options will be subject to the terms, conditions, definitions and provisions of the ESOP and the applicable option agreement thereunder. The vested options 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 ordinary shares outstanding immediately following the initial public offering (other than ordinary 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 options 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 values at the (estimated) allocation dates of the Management Board Grant. This model incorporates the impact of the performance criteria regarding share price and index development described above. The parameters used for measuring the fair values as of the respective (estimated) allocation dates were as follows:

	Allocation date February 13, 2020	**Estimated allocation date February 13, 2021**	**Estimated allocation date February 13, 2022**
Weighted average fair value*	€10.83	€16.43	€15.80
Weighted average share price	€28.20	€ 59.13*	€ 59.13*
Exercise price	€28.32	€ 59.35*	€ 59.87*
Expected volatility (%)	36.6%	27.8%	27.5%
Expected life (years)*	4.75	5.31	6.34
Risk-free interest rate (%)	1.61 %	0.64%	0.64%

* Valuation parameter derived from the Monte-Carlo simulation model

The exercise of the option rights in accordance with the terms of the ESOP gives the Management Board members the right to obtain shares against payment of the exercise price. The per share exercise price of the options is the Euro equivalent of the arithmetic mean of the closing prices of the ten last trading days prior to the allocation date. For the award allocated as of February 13, 2020 the exercise price has been determined to be $30.78 (€28.32). The exercise prices for the awards with estimated allocation dates as of February 13, 2021 and February 13, 2022 have been derived from the Monte-Carlo simulation model. Expected volatility was based on an evaluation of the historical volatilities of comparable companies over the historical period commensurate with the expected option term. The expected term was based on general optionholder behavior for employee options.

The share options allocated and expected to be allocated under the Management Board Grant were as follows:

	Share options (expected to be allocated)	**Weighted-average exercise price (€)**
As of January 1, 2020	-	-
Granted as of allocation date February 13, 2020	248,096	28.32
Expected to be allocated as of estimated allocation date February 13, 2021	114,925	59.35*
Expected to be allocated as of estimated allocation date February 13, 2022	115,119	59.87*
As of September 30, 2020	**478,140**	**43.37**

* Valuation parameter derived from the Monte-Carlo simulation model

As of September 30, 2020, the share options allocated and expected to be allocated had a remaining weighted-average expected life of 4.95 years.

The expenses recognized for employee services received during the three and nine months ended September 30, 2020 are shown in the following table:

	Three months ended September 30,	Nine months ended September 30,
(in thousands)	**2020**	**2020**
Research and development expenses	€224	€942
General and administrative expenses	183	774
Total	**€407**	**€1,716**

Chief Executive Officer Grant (Equity-Settled)

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. As disclosed in the notes to the consolidated financial statements as of December 31, 2019, the option will be subject to the terms, conditions, definitions and provisions of the ESOP and the applicable option agreement thereunder.

During the three and nine months ended September 30, 2020, no further options were granted or forfeited.

As of September 30, 2020, the share options outstanding had a remaining expected life of 4.37 years.

During the three months ended September 30, 2020 the Group has recognized k€3,208 of share-based payment expenses as research & development expenses in the interim condensed consolidated statements of operations (three months ended September 30, 2019: Nil).

During the nine months ended September 30, 2020 the Group has recognized k€9,624 of share-based payment expenses as research & development expenses in the interim condensed consolidated statements of operations (nine months ended September 30, 2019: Nil).

Employee Stock Ownership Plan (Equity-Settled)

On November 15, 2018, the Group established a share option program that grants selected employees options to receive shares in the company. The program is designed as an Employee Stock Ownership Plan (ESOP) as disclosed in the notes to the consolidated financial statements as of December 31, 2019. The amounts disclosed in this note have been retrospectively adjusted to reflect the share split as described in Note 12.

Set out below is an overview of changes to share options outstanding and number of ordinary shares underlying these options that occurred during the nine months ended September 30, 2020.

	Share options outstanding	Number of ordinary shares underlying options	Weighted-average exercise price (€)
As of January 1, 2019	658,109	11,845,962	10.14
Granted	14,511	261,198	15.17
Forfeited	(12,612)	(227,016)	10.14
As of September 30, 2019	**660,008**	**11,880,144**	**10.25**
As of January 1, 2020	655,383	11,796,894	10.23
Forfeited	(9,144)	(164,592)	10.81
As of September 30, 2020	**646,239**	**11,632,302**	**10.23**

During the nine months ended September 30, 2020 no further options were granted but 9,144 share options were forfeited. During the nine months ended September 30, 2019, 14,511 options were granted and 12,612 were forfeited.

As of September 30, 2020, the share options outstanding had a remaining weighted-average expected life of 3.98 years.

The expenses recognized for employee services received during the three and nine months ended September 30, 2020 and September 30, 2019 are shown in the following table:

	Three months ended September 30,		Nine months ended September 30,	
(in thousands)	**2020**	**2019**	**2020**	**2019**
Cost of sales	€213	€228	€639	€684
Research and development expenses	2,787	2,745	8,360	17,249
Sales and marketing expenses	28	26	83	80
General and administrative expenses	1,242	1,500	3,726	4,472
Total	**€4,270**	**€4,499**	**€12,808**	**€22,485**

14 Related Party Disclosures

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 consummated transactions with the Group during the period.

BioNTech has 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., BioNTech's co-founder and Chief Executive Officer, is a significant shareholder of TRON.

The aggregate value of transactions related to key management personnel were as follows for the periods indicated:

	Three months ended September 30,		Nine months ended September 30,	
(in thousands)	**2020**	**2019**	**2020**	**2019**
Consulting services / patent assignment	€15	€4	€21	€19
Purchases of various goods and services from TRON	2,604	2,096	6,439	6,259
Total	**€2,619**	**€2,100**	**€6,460**	**€6,278**

The outstanding balances of transactions related to key management personnel were as follows as of the dates indicated:

(in thousands)	**September 30, 2020**	**December 31, 2019**
Consulting service provider	€15	-
TRON	988	1,843
Total	**€1,003**	**€1,843**

Other Related Party Transactions

ATHOS KG, Holzkirchen, Germany owns 100% of shares in AT Impf GmbH, Munich, Germany and is the beneficial owner of BioNTech SE. AT Impf GmbH, Munich, Germany is the parent company of the Group. Entities controlled by ATHOS KG mainly provide rental and property management activities and sell property, plant and equipment to BioNTech. The total amount of transactions with ATHOS KG or entities controlled by them was as follows for the periods indicated:

	Three months ended September 30,		Nine months ended September 30,	
(in thousands)	**2020**	**2019**	**2020**	**2019**
Purchases of various goods and services from entities controlled by ATHOS KG	€331	€251	€1,781	€1,523
Purchases of property and other assets from entities controlled by ATHOS KG	-	-	2,349	-
Total	**€331**	**€251**	**€4,130**	**€1,523**

The outstanding balances of transactions with ATHOS KG or entities controlled by them were as follows as of the dates indicated:

(in thousands)	**September 30, 2020**	**December 31, 2019**
ATHOS KG	€646	€51
Total	**€646**	**€51**

None of the balances are secured and no bad debt expense has been recognized in respect of amounts owed by related parties.

15 Events after the Reporting Period

On October 20, 2020, BioNTech Pharmaceuticals Asia Pacific Pte. Ltd., Singapore, was incorporated as a wholly-owned subsidiary of BioNTech SE, and is intended to serve as to serve as BioNTech's headquarters for the region.

In September 2020, BioNTech signed a share purchase agreement with Novartis AG to acquire their manufacturing facility in Marburg, Germany which was closed at the end of October 2020. Based on a preliminary calculation, BioNTech will acquire the entire share capital of Novartis Manufacturing GmbH in exchange for a total cash consideration of k€78,194. The amount may change since it is subject to adjustments based on closing statements. Preliminary to any purchase price allocation, the book values of current and non-current assets of Novartis Manufacturing GmbH amounted to k€23,127 and k€111,066, respectively. Current and non-current liabilities had been recorded with an amount of k€16,292 and k€40,805, respectively. All amounts disclosed are derived from unaudited financial information prepared in accordance with IFRS by the acquiree. The Marburg production site is a state-of-the-art, multi-platform GMP certified manufacturing facility that currently employs approximately 300 employees. The well-established biotechnology drug substance and drug product manufacturing equipment, as well as an experienced team offers favorable conditions for a rapid transition to a mRNA manufacturing site and the third site in the BioNTech manufacturing network in Germany expected to produce BNT162 for global supply, pending regulatory authorization or approval. It is expected to be fully operational in the first half of 2021 with an annual production capacity of up to 750 million doses of potential COVID-19 vaccine.

On November 9, 2020, BioNTech filed a universal shelf registration statement on Form F-3 (File No. 333-249991) (the "Registration Statement") with the U.S. Securities and Exchange Commission

(the "SEC"). In addition, BioNTech entered into a sales agreement (the "Sales Agreement") with Jefferies LLC and SVB Leerink LLC (the "Agents") pursuant to which the Company may offer and sell American Depositary Shares representing ordinary shares for aggregate gross sale proceeds of up to $500,000,000 (the "ADSs") from time to time through the Agents (the "Offering"). We are not obligated to make any sales of ADSs under the Sales Agreement. BioNTech filed a prospectus supplement with the SEC in connection with the Offering, which is included in the Registration Statement. Upon delivery of an issuance notice and subject to the terms and conditions of the Sales Agreement, the Agents may sell the ADSs by any method permitted that is deemed an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended, including sales made directly on or through The Nasdaq Global Select Market ("Nasdaq"), the existing trading market for the ADSs. BioNTech or the Agents may suspend or terminate the offering of ADSs upon notice to the other party, subject to certain conditions. The Agents will act as sales agents on a commercially reasonable efforts basis consistent with their normal trading and sales practices and applicable state and federal law, rules and regulations and the rules of Nasdaq. BioNTech has agreed to pay the Agents commissions for their services of acting as agent of up to 3.0% of the gross proceeds from the sale of the ADSs pursuant to the Sales Agreement. BioNTech has also agreed to provide the Agents with customary indemnification and contribution rights. The offering of the ADSs pursuant to the Sales Agreement will terminate upon the earlier of (a) the sale of all of the ADSs subject to the Sales Agreement or (b) the termination of the Sales Agreement by Agents or us, as permitted therein.

Operating and Financial Review and Prospects

In this report, unless stated or the context otherwise requires, references to the "Company," "BioNTech," "we," "us" and "our" refer to BioNTech SE and its consolidated subsidiaries. The following "Operating and Financial Review and Prospects" should be read together with the unaudited interim condensed consolidated financial statements and related notes as presented above. 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 the "Risk Factors" section further below. Please also see "Forward-Looking Statements" included at the end of this quarterly report for the three and nine months ended September 30, 2020.

Operating Results

Overview

BioNTech was founded in 2008 on the understanding that every cancer patient's tumor is unique and that in order to effectively address this challenge, we must create individualized treatments for each patient. To realize this vision, we combine decades of groundbreaking research in immunology, cutting-edge therapeutic platforms and a suite of patient profiling and bioinformatic tools to develop immunotherapies for cancer and other diseases. We leverage powerful new therapeutic mechanisms and exploit a diverse array of biological targets to harness the power of each patient's immune system to address the unique molecular signature of each patient's underlying disease. The breadth of our immunotherapy technologies and expertise has also enabled us to develop therapies to address a range of rare and infectious diseases, and we have rapidly mobilized these with the aim of addressing the COVID-19 pandemic. We believe we are uniquely positioned to develop and commercialize the next generation of immunotherapies with the potential to significantly improve clinical outcomes and usher in a new era of immunotherapy.

We and our collaborators have advanced a development pipeline of over 20 product candidates, of which 12 have entered 13 ongoing clinical trials. Based on our deep understanding of the human immunsystem and in-house manufacturing capabilities, we and our collaborators are developing multiple mRNA-based vaccine candidates for a range of infectious diseases alongside our diverse oncology pipeline. As part of our BNT162 vaccine program against COVID-19, the lead candidate BNT162b2 was selected to be advanced into a currently ongoing Phase 3 study enrolling up to 44,000 participants. As part of our programs focusing on oncology, we have treated over 500 patients across 17 tumor types to date. Our immunotherapy drug classes consist of messenger ribonucleic acid, or mRNA, therapeutics, cell therapies, antibodies and small molecule immunomodulators. Our product candidates span across oncology, infectious diseases and rare diseases. As part of our vertically-integrated business model, we have built comprehensive, highly automated, on-demand in-house manufacturing capabilities aimed at complementing the development our immunotherapy pipeline.

We have assembled an exceptional team of over 1,800 employees, including approximately 300 employees from our acquisition of the production site in Marburg in October 2020. We have established relationships with eight pharmaceutical collaborators, including Bayer AG, or Bayer, Genentech, Inc., or Genentech, Genevant Sciences GmbH, or Genevant, Genmab A/S, or Genmab, Pfizer Inc., or Pfizer, Regeneron Pharmaceuticals, Inc., or Regeneron, Sanofi S.A., or Sanofi and Shanghai Fosun Pharmaceutical (Group) Co., Ltd., or Fosun Pharma.

Key Pipeline Updates

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

Oncology

BioNTech has continued to advance its broad oncology pipeline of 11 product candidates in 12 ongoing trials. Since the beginning of the third quarter, the Company has provided data updates for BNT111, BNT114, BNT131 and BNT311.

FixVac

Our FixVac product candidates contain selected combinations of pharmacologically optimized uridine mRNA encoding known cancer-specific shared antigens. These candidates 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. FixVac is currently being evaluating in five clinical trials including:

- BNT111 in a Phase 1 trial in advanced melanoma.
    - On July 29, data from an exploratory data analysis of a Phase 1 trial for BNT111, the Company's lead mRNA-based FixVac cancer vaccine program, was published in Nature. The publication highlighted the favorable safety profile of BNT111 in stage IIIB-C and stage IV melanoma patients who were pre-treated with several lines of systemic therapy including PD-1 inhibitors. The trial also demonstrated BNT111's ability to mediate durable objective responses as a single agent and in combination with anti-PD-1 antibodies.
    - In July, BioNTech and Regeneron announced a strategic collaboration to jointly conduct a randomized Phase 2 trial for the treatment of patients with melanoma progressing during or after prior therapy with a PD-1 inhibitor, utilizing a combination of BNT111 and Regeneron's Libtayo®. This trial is currently under review by the FDA. We are currently targeting commencement of the trial in the first half of 2021, subject to allowance of the IND by the FDA.
- BNT112 in an ongoing Phase 1/2 trial in prostate cancer.
- BNT113 in a Phase 1 trial in HPV16+ head and neck cancers. We are planning to initiate a Phase 2 trial with registrational potential for BNT113 in HPV+ head and neck cancers. This trial is currently under review by the FDA. We are currently targeting commencement of the trial in the second half of 2020 and dosing of first patient in the first half of 2021, subject to allowance of the IND by the FDA.
- BNT114 in a Phase 1 trial in triple negative breast cancer (TNBC).
    - On September 18, a data update was presented at the ESMO Virtual Congress 2020 for one treatment arm from the TNBC-MERIT trial, a first-in-human trial assessing the safety and immunogenicity of RNA immunotherapy in patients suffering from triple negative breast cancer (TNBC). This arm is investigating the individualized neoantigen vaccine encoding up to 20 cancer neoantigens determined by next generation sequencing. The preliminary analysis showed that the neoantigen vaccine is highly efficient in inducing strong poly-epitopic T-cell responses in the post-(neo) adjuvant setting. In all 14 patients vaccine-induced T-cell responses against up to 10 neoantigens could be detected of which the majority was de novo. In 12 out of 14 patients T-cell responses were of such high magnitude that they could be detected directly ex vivo.
- BNT115 in an ongoing Phase 1 trial in ovarian cancer.
- BNT116 is in preclinical development for non-small cell lung cancer.

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. RO7198457 (BNT122/ RG6180) is partnered with Genentech.

- Enrollment rate of Phase 2 trial (IMCODE-001) in first-line melanoma is slower than expected due to the impact of the COVID-19 pandemic.
- U.S. Investigational New Drug (IND) application for a randomized Phase 2 trial in circulating tumor DNA positive, surgically resected Stage 2 (high risk)/Stage 3 colon cancer granted in July 2020. An additional randomized Phase 2 study is planned to evaluate the efficacy and safety of BNT122 plus atezolizumab compared with atezolizumab alone in patients with early and adjuvant stage non-small-cell lung cancer (NSCLC).

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).

- Interim data was presented at the SITC 2020 conference from an ongoing first-in-human Phase 1 dose escalation and expansion trial evaluating the safety, pharmacokinetics and anti-tumor activity of BNT131 in patients with advanced solid tumors. The data demonstrated that BNT131 was generally well tolerated, with no patient experiencing a dose limiting toxicity or grade 3 or greater treatment-related adverse events to date. As a monotherapy, downstream effector cytokines signals and T cell infiltration suggest an immunomodulatory effect.

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.

- Initiation of a first-in-human Phase 1/2a open-label, multi-center dose escalation and dose expansion basket trial is expected for 2H 2020. The study targets patients with CLDN6-positive relapsed or refractory advanced solid tumors, including ovarian and testicular cancers. The study assesses CLDN6 CAR-T cell immunotherapy in combination with a CLDN6 RNA vaccine for improved expansion and persistence of CAR T cells (CARVac). The primary outcome measure of the trial will be safety, with secondary efficacy outcome measures to include objective response rate, disease control rate and duration of response.

Neo-antigen targeting T cells

Through our recent Neon acquisition, we obtained a neoantigen-targeting T cell platform that can be utilized to develop product candidates across several neoantigen-targeting non-engineered and engineered T cell therapies. Our lead product candidate under this platform is our individualized neoantigen-targeting T cell therapy, BNT221.

- Dosing of the first patient in a Phase 1 dose escalation trial for the treatment of metastatic melanoma in patients who are refractory or unresponsive to checkpoint inhibitors is expected in 1H 2021. BNT221 (NEO-PTC-01) is a personal neoantigen-targeted T cell therapy candidate derived from patients` blood cells and consisting of multiple T cell populations targeting selected neoantigens from each patient`s tumor. The primary objectives of the trial will be to

evaluate the safety and feasibility of administering BNT221, in addition to an evaluation of immunogenicity and clinical efficacy.

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.

- Interim data from a first-in-human Phase 1/2 trial of BNT311 in 61 heavily pretreated patients with advanced solid tumors was presented at the SITC 2020 conference. In the dose escalation phase, BNT311 demonstrated a manageable safety profile and encouraging early single-agent clinical activity. Most adverse events were mild to moderate, treatment-related Grade 3 transaminase elevations resolved with corticosteroids. No treatment-related bilirubin increases or Grade 4 transaminase elevations were observed. Clinical benefit was observed across tumor types and dose levels, including in patients resistant to prior immunotherapy and with tumor types less sensitive to immune checkpoint inhibitors. Disease control was achieved in 65.6% of patients in the dose escalation portion, including partial responses in one TNBC patient, one ovarian cancer patient and two immune checkpoint inhibitor pre-treated NSCLC patients. In the expansion cohort, which includes patients with PD-L1 relapsed/refractory NSCLC, two of 12 patients that could be objectively assessed achieved single-agent confirmed partial responses. One patient had an unconfirmed partial response and four patients demonstrated stable disease.
- We have initiated a Phase 1/2 trial of GEN1042 (BNT312) in solid tumors.

Targeted cancer antibodies

MVT-5873 (BNT321) is a fully human IgG1 monoclonal antibody targeting sialyl Lewis A (sLea), a novel epitope expressed specifically in pancreatic and other solid tumors. MVT-5873 (BNT321) is currently in Phase 1 clinical development in pancreatic cancer.

Small molecule immunomodulators

BNT411 is our novel small molecule TLR7 agonist product candidate. BNT411 is engineered for high potency and high selectivity for the TLR7 receptor to activate both the adaptive and innate immune system.

- On July 8, 2020, the first patient was dosed in a Phase 1/2a, first-in-human, open-label, dose-escalation trial with expansion cohorts to evaluate the safety, pharmacokinetics, pharmacodynamics and preliminary efficacy of BNT411 as a monotherapy in patients with solid tumors, and in combination with atezolizumab, carboplatin and etoposide in patients with chemotherapy-naïve extensive-stage small cell lung cancer (ES-SCLC).

In addition, we have several other cancer immunotherapy programs in pre-clinical 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 in the first half of 2021 and BNT142 in the second 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 an open-label, multicenter Phase 1/2a dose escalation, safety, pharmacokinetic (PK) and pharmacodynamic (PD) trial of BNT151 with expansion cohorts in multiple solid tumor indications in the first half of 2021. The monotherapy dose escalation will enroll patients with multiple solid tumors that are metastatic or unresectable with no available standard therapy likely to confer clinical benefit. In the combined treatment dose escalation, patients with different solid tumors will be enrolled and treated with BNT151 and the respective standard of care
- We expect to initiate a Phase 1 clinical trials for BNT152/BNT153 (combination) in the first half of 2021.

Infectious Disease Immunotherapies

COVID-19 Vaccine Program

In response to the coronavirus global pandemic, the company assembled a global consortium of partners including Pfizer (worldwide collaboration outside of China) and Fosun Pharma (China). BioNTech's vaccine program against COVID-19, BNT162, leverages our proprietary mRNA platform. Currently there are four vaccine candidates: two of the four vaccine candidates include a nucleoside modified mRNA (modRNA), one includes a uridine containing mRNA (uRNA), and the fourth vaccine candidate utilizes self-amplifying mRNA (saRNA). Each mRNA format is combined with a lipid nanoparticle (LNP) formulation. The larger spike sequence is included in two of the vaccine candidates, and the smaller optimized receptor binding domain (RBD) from the spike protein is included in the other two candidates.

Clinical

- BNT162b2 demonstrated evidence of efficacy against COVID-19 in participants without prior evidence of SARS-CoV-2 infection based on the first interim efficacy analysis from the Phase 3 clinical study conducted on November 8, 2020, by an external, independent Data Monitoring Committee (DMC). After discussion with the FDA, BioNTech and Pfizer recently elected to drop the 32-case interim analysis and conduct the first interim analysis at a minimum of 62 cases. Upon conclusion of those discussions, the evaluable case count reached 94 and the DMC performed its first analysis on all cases. The case split between vaccinated participants and those who received the placebo indicates a vaccine efficacy rate above 90%, at seven days after the second dose. This means that protection was demonstrated to have been achieved 28 days after the initiation of the vaccination, which consists of a 2-dose schedule. As the study continues, the final vaccine efficacy percentage may vary. The DMC has not reported any serious safety concerns and recommends that the study continues to collect additional safety and efficacy data as planned. Pfizer and BioNTech plan to submit data from the full Phase 3 trial for scientific peer-review publication. The Phase 3 trial, which is being conducted globally at 150 sites across 6 countries has enrolled 43,538 participants, 38,955 of whom have received a second dose as of November 8, 2020. Approximately 42% of global participants and 30% of U.S. participants have racially and ethnically diverse backgrounds. The trial is continuing to enroll and is expected to continue through the final analysis when a total of 164 confirmed COVID-19 cases have accrued. The study also will evaluate the potential for the vaccine candidate to provide protection against COVID-19 in those who have had prior exposure to SARS-CoV-2, as well as vaccine prevention against severe COVID-19 disease.
- In addition to the primary efficacy endpoints evaluating confirmed COVID-19 cases accruing from seven days after the second dose, the final analysis now will include, with the approval of the FDA, new secondary endpoints evaluating efficacy based on cases accruing 14 days after the second dose as well. The companies believe that the addition of these secondary endpoints will help align data across all COVID-19 vaccine studies and allow for cross-trial learnings and comparisons between these novel vaccine platforms.

- BioNTech and Pfizer initiated a Phase 1/2 clinical trial in Japan to evaluate safety, tolerability and immunogenicity of two doses separated by 21 days and a single dose of BNT162b2. The randomized, placebo-controlled, and observer-blind study is being conducted in healthy adults 20 to 85 years of age.
- BioNTech and Fosun initiated a Phase 1 study to evaluate safety and immunogenicity in Chinese participants. We expect to initiate a Phase 2 clinical trial in China with BNT162b2 upon regulatory IND approval from the Chinese regulatory authority, National Medical Products Administration (NMPA), by the end of 2020.

Commercial

- BioNTech and Pfizer previously announced commercial supply agreements for 2020 and 2021 - totaling more than 570 million doses, including options to purchase an additional 600 million doses - with multiple governments, including Canada, Japan, the UK, the U.S. and the EU. All agreements are subject to clinical success and regulatory approval.
- Based on supply projections, we expect to supply globally up to 50 million vaccine doses in 2020 and manufacture up to 1.3 billion doses in 2021.
- BioNTech closed the acquisition of a GMP manufacturing facility in Germany, with the intent to accelerate BNT162 manufacturing scale-up for commercial supply in 2021.

Regulatory

- BioNTech and Pfizer received Fast Track designation for BNT162b1 and BNT162b2 from the U.S. Food and Drug Administration (FDA).
- BioNTech and Pfizer initiated rolling submissions for BNT162b2 to the European Medicines Agency (EMA), the Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK and Health Canada.
- BioNTech and Pfizer continue to accumulate safety data from the Phase 3 trial and currently estimate that the median of two months of safety data following the second dose of the vaccine candidate, the amount of safety data specified by the FDA in its guidance for potential EUA, will be available for submission by the third week of November. A submission for EUA is planned for soon thereafter. Trial participants will continue to be monitored for long-term protection and safety for an additional two years after their second dose.

Flu vaccine

We have a collaboration with Pfizer to develop mRNA-based immunotherapies for the prevention of influenza, product candidate BNT161.

Infectious diseases

We have a research collaboration with the University of Pennsylvania, under which we have the exclusive option to develop and commercialize mRNA immunotherapies for the treatment of up to 10 infectious disease indications. We have also 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.

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. BioNTech has put the programs under review in order to focus on other areas.

Financial Operations Overview

The following table shows our consolidated statements of operations for each period presented:

	Three months ended September 30,		Nine months ended September 30,	
	2020	**2019**	**2020**	**2019**
(in thousands)	*(unaudited)*		*(unaudited)*	
Revenues from contracts with customers	€67,458	€28,662	136,883	€80,601
Cost of sales	(6,840)	(4,230)	(18,344)	(12,925)
Gross profit	**€60,618**	**€24,432**	**€118,539**	**€67,676**
Research and development expenses	(227,706)	(50,396)	(388,017)	(161,039)
Sales and marketing expenses	(4,268)	(670)	(7,808)	(1,908)
General and administrative expenses	(23,324)	(10,582)	(57,952)	(34,481)
Other operating income	8,764	347	9,962	1,340
Other operating expenses	(466)	(5)	(1,325)	(163)
Operating loss	**€(186,382)**	**€(36,874)**	**€(326,601)**	**€(128,575)**
Finance income*	474	7,294	1,067	9,170
Finance expenses*	(21,081)	(82)	(24,455)	(233)
Interest expense related to lease liability	(552)	(433)	(1,432)	(1,283)
Loss before tax	**€(207,541)**	**€(30,095)**	**€(351,421)**	**€(120,921)**
Income taxes	(2,491)	(8)	(293)	(28)
Loss for the period	**€(210,032)**	**€(30,103)**	**€(351,714)**	**€(120,949)**

* Foreign exchange differences on a cumulative basis are either shown as finance income or expenses and might switch between those two positions during the year-to-date reporting periods.

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:

	Three months ended September 30,		Nine months ended September 30,	
	2020	**2019**	**2020**	**2019**
(in thousands)	*(unaudited)*		*(unaudited)*	
Revenues from contracts with customers				
Revenues resulting from collaboration and license agreements	€59,649	€22,237	€113,395	€64,260
Revenues from other sales transactions	7,809	6,425	23,488	16,341
Total revenues from contracts with customers	**€67,458**	**€28,662**	**€136,883**	**€80,601**

The following table summarizes our collaboration revenue for the periods indicated:

	Three months ended September 30,		Nine months ended September 30,	
	2020	**2019**	**2020**	**2019**
(in thousands)	*(unaudited)*		*(unaudited)*	
Revenues resulting from collaboration and license agreements				
Pfizer Inc.	€45,643	€3,587	€69,843	€10,761
Genentech Inc.	11,991	16,677	38,877	47,620
Shanghai Fosun Pharmaceutical (Group) Co., Ltd	1,697	-	2,598	-
Sanofi S.A.	318	152	2,077	4,058
Eli Lilly and Company	-	1,821	-	1,821
Total revenues resulting from collaboration and license agreements	**€59,649**	**€22,237**	**€113,395**	**€64,260**

Our collaboration revenue consists of milestone payments, upfront licensing payments and reimbursement of development expenses. Certain of these payments are initially recorded as contract liabilities on our statements of financial position and are subsequently recognized as revenue in accordance with our accounting policy as described in "—Critical Accounting Policies and Use of Estimates" and Note 2.3.4 to our consolidated financial statements included in our Annual Report on Form 20-F as of and for the year ended December 31, 2019.

From the three months ended September 30, 2019 to the three months ended September 30, 2020, total revenues resulting from collaboration and license agreements increased from €22.2 million to €59.6 million. Total revenues resulting from collaboration and license agreement for the nine months ended September 30, 2020 increased from €64.3 million for the comparative prior year period to €113.4 million.

During the three and nine months ended September 30, 2020, revenues from our two new collaboration agreements were recognized for the first time. As part of the BNT162 program, our vaccine program against COVID-19, we collaborate with Pfizer and Fosun Pharma. The BNT162 program is evaluating multiple vaccine candidates, each of which represent a unique combination of messenger RNA format and target antigen. During the three months ended March 31, 2020, upon signing the agreement, a non-refundable upfront cash payment of €0.9 million was received from Fosun Pharma, which subsequently was fully recognized as revenue. In addition, during the three months ended September 30, 2020, revenue of €1.7 million was recognized by achieving a development milestone. In total, during the nine months ended September 30, 2020, €2.6 million revenue was recognized from the Fosun Pharma collaboration and license agreement. During the three months ended June 30, 2020, a non-refundable upfront cash payment of €66.3 million was received from Pfizer which has a restricted purpose by being dedicated to activities to be performed under the collaboration and license agreement. The non-refundable upfront cash payment was fully recorded as revenue during the nine months ended September 30, 2020 based on costs incurred. During the three and nine months ended September 30, 2020, €45.6 million and €66.3 million were recorded respectively. As services are performed under a collaboration agreement, revenue recognition will be continued in future periods in accordance with our accounting policy.

For certain programs, the commencement of trials has been delayed, partially due to slowed patient enrollment or other delays as a result of the COVID-19 pandemic. Accordingly, during the three and nine months ended September 30, 2020, revenues from our collaboration programs with Genentech, Sanofi and from the non-COVID-19 collaboration with Pfizer have mostly decreased compared to the

prior year periods. We will continue to evaluate potential effects of the COVID-19 pandemic. Our collaborations with Bayer, Genevant and Genmab did not generate any revenue in the three and nine months ended September 30, 2020 and 2019.

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. During the three and nine months ended September 30, 2020, those revenues increased due to increased orders.

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. With respect to our BNT162 program, our most advanced program, our ability to generate sales revenue is subject to regulatory authorization or approval. Timing of product manufacturing, delivery and receipt of regulatory approval will determine the period in which revenue may be recognized. Costs relating to production of pre-launch products are expensed as research and development expenses, in the period incurred. In case pre-launch products are sold, the respective product gross margin may be higher compared to the expected recurring margin as the underlying costs will not be included in cost of sales. For the three and nine months ended September 30, 2020 and 2019, no revenues have been recorded related to pre-launch products. If the vaccine candidate is approved, we and our collaboration partner Pfizer expect to supply globally up to 50 million vaccine doses in 2020 and manufacture up to 1.3 billion doses in 2021. 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.

Cost of Sales

The following table summarizes our cost of sales for the periods indicated:

	Three months ended September 30,		Nine months ended September 30,	
	2020	**2019**	**2020**	**2019**
(in thousands)	*(unaudited)*		*(unaudited)*	
Cost of sales				
Wages, benefits and social security expense	€2,362	€2,445	€8,385	€6,228
Laboratory supplies	2,476	393	4,445	2,417
Purchased services	676	534	1,946	1,543
Depreciation and amortization	444	372	1,217	1,066
Other	882	486	2,351	1,671
Total cost of sales	**€6,840**	**€4,230**	**€18,344**	**€12,925**

From the three months ended September 30, 2019 to the three months ended September 30, 2020, cost of sales increased from €4.2 million to €6.8 million. Cost of sales for the nine months ended September 30, 2020 increased from €12.9 million for the comparative prior year period to €18.3 million. The increase was mainly due to an increase in headcount leading to higher wages, benefits and social security expenses as well as an increase in expenses for purchasing laboratory supplies.

Research and Development Expenses

The nature of our business and primary focus of our activities, including development of our platforms and manufacturing technologies, generate a significant amount of research and development expenses which in this respect still account for the largest component of our total operating expenses. Research and development expenses include our share of expenses under the terms of collaboration agreements and 100% of the expenses for wholly-owned product candidates. Research and development expenses shared under our collaboration agreements which are initially incurred by the collaboration partners and subsequently charged to us are recorded as purchased services classified within research and development. Cost reimbursements from partners for research and development expenses initially incurred by

us and due to us under the agreements, are recorded as a reduction to purchased services classified within research and development expenses. Research costs are expensed as incurred. Development expenditures on an individual project are recognized as an intangible asset if, and only if, the capitalization criteria are met. Due to the inherent risk of failure in drug development and the uncertainty of approval, management has determined that these criteria are not met in the Biotech business sector until regulatory approval has been obtained. Therefore, as we have not yet obtained regulatory approval for any of our programs, or product candidates, no development expenditures have been capitalized. The related expenditure is reflected in the statements of operations in the period in which the expenditure is incurred.

Research and development expenses represent costs incurred for the following:

- cost to develop our platforms;
- discovery efforts leading to product candidates;
- clinical development expenses for our programs;
- costs related to pre-launch products;
- 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;
- shared development expenses incurred under collaboration agreements with our partners;
- 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:

	Three months ended September 30,		Nine months ended September 30,	
	2020	**2019**	**2020**	**2019**
(in thousands)	*(unaudited)*		*(unaudited)*	
Research and development expenses				
Purchased services	€143,104	€15,121	€201,142	€45,434
Wages, benefits and social security expense	29,177	16,422	88,694	60,869
Laboratory supplies	43,971	9,407	65,148	27,701
Depreciation and amortization	7,211	6,799	21,122	19,150
IT costs	1,064	580	3,493	1,449
Lease and lease related cost	1,167	605	2,832	1,868
Transport costs	397	356	1,216	876
Other	1,615	1,106	4,370	3,692
Total research and development expenses	**€227,706**	**€50,396**	**€388,017**	**€161,039**

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.

From the three months ended September 30, 2019 to the three months ended September 30, 2020, research and development expenses increased from €50.4 million to €227.7 million. Research and development expenses for the nine months ended September 30, 2020 increased from €161.0 million for the comparative prior year period to €388.0 million. The increase was mainly due to an increase in development expenses from our BNT162 program, our vaccine program against COVID-19. Research and development expenses include our share of expenses under the terms of the collaboration agreement. Shared development costs are equally shared between Pfizer and us. The amount of shared development expenses which were initially incurred by the collaboration partner Pfizer and subsequently charged to us were recorded as purchased services classified within research and development and the reimbursement from Pfizer for research and development expenses initially incurred by us were recorded as a reduction to research and development expenses. The increase was further driven by an increase in headcount leading to higher wages, benefits and social security expenses as well as an increase in expenses for purchased laboratory supplies. In addition, from May 6, 2020, the date of acquisition, our new U.S.-based subsidiary, BioNTech US Inc., contributed €13.4 million to the research and development expenses of the Group.

Sales and Marketing Expenses

Our sales and marketing expenses mainly consist of personnel-related costs and expenses for purchased services. 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.

From the three months ended September 30, 2019 to the three months ended September 30, 2020, sales and marketing expenses increased from €0.7 million to €4.3 million. Sales and marketing expenses for the nine months ended September 30, 2020 increased from €1.9 million for the comparative prior year period to €7.8 million. The increase was mainly due to increased marketing consulting expenses.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the periods indicated:

	Three months ended September 30,		Nine months ended September 30,	
	2020	**2019**	**2020**	**2019**
(in thousands)	*(unaudited)*		*(unaudited)*	
General and administrative expenses				
Wages, benefits and social security expense	€7,042	€4,407	€21,236	€13,957
Purchased services	7,574	1,477	15,862	4,593
IT and office equipment	2,104	1,127	4,814	3,219
Depreciation and amortization	1,164	1,311	3,887	3,841
Insurance premiums	1,882	171	3,496	246
Lease and lease related cost	741	480	1,651	1,290
Job advertisement expenses	806	130	1,623	449
Other	2,011	1,479	5,383	6,886
Total general and administrative expenses	**€23,324**	**€10,582**	**€57,952**	**€34,481**

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

From the three months ended September 30, 2019 to the three months ended September 30, 2020, general and administrative expenses increased from €10.6 million to €23.3 million. General and administrative expenses for the nine months ended September 30, 2020 increased from €34.5 million for the comparative prior year period to €58.0 million. The increase was mainly influenced by higher expenses for purchased management consulting and legal services as well as an increase in headcount leading to higher wages, benefits and social security expenses. In addition, from May 6, 2020, the date of acquisition, our new U.S.-based subsidiary, BioNTech US Inc. contributed €4.5 million to the general and administrative expenses of the Group.

Other Operating Income / Expenses

Other operating income for the three months ended September 30, 2020 amounted to €8.8 million compared to €0.3 million for the three months ended September 30, 2019. Other operating income for the nine months ended September 30, 2020 amounted to €10.0 million compared to €1.3 million for the comparative prior year period. The increase was mainly derived from drawing down €8.5 million government grants under the funding which we became eligible to from an initiative by the German Federal Ministry of Education (*Bundesministerium für Bildung und Forschung*, or the BMBF) to support our COVID-19 vaccine program BNT162 (as described below in "—Liquidity and Capital Resources"). The funding drawn down represents a compensation for expenses already incurred in the period ended September 30, 2020. Therefore, €8.5 million were recognized as other operating income within the statements of operations during the three months ended September 30, 2020.

Other operating expenses for the three months ended September 30, 2020 amounted to €0.5 million compared to €0.0 million for the three months ended September 30, 2019. Other operating expenses for the nine months ended September 30, 2020 amounted to €1.3 million compared to €0.2 million for the comparative prior year period. The amount mainly included losses from asset disposals.

Finance Income / Expenses

Our finance income and expenses consist of interest income and interest expenses on cash, fair value changes on certain financial liabilities as well as foreign exchange gains and losses. Foreign exchange differences on a cumulative basis, are either shown as finance income or expenses and might switch between those two positions during the year-to-date reporting periods.

Finance income for the nine months ended September 30, 2020 amounted to €1.1 million compared to €9.2 million for the nine months ended September 30, 2019. The latter included €8.1 million attributable to unrealized foreign exchange gains. Finance expenses for the nine months ended September 30, 2020 amounted to €24.5 million compared to €0.2 million for the nine months ended September 30, 2019. The former included €17.2 million attributable to unrealized foreign exchange losses as well as €6.3 million expenses arising from fair value measurement adjustments of the derivative embedded within the convertible note.

Tax Losses

We calculate the interim income tax expense using the tax rate that would be applicable to the expected total annual earnings. Deferred tax assets on tax losses of subsidiaries incorporated in Germany have not been capitalized as there is not sufficient probability that there will be future taxable profits against which the unused tax losses can be utilized. During the three months ended September 30, 2020, we finalized our assessment of deferred taxes related to the acquisition of Neon Therapeutics, Inc., Cambridge, Massachusetts, United States (formerly Nasdaq: NTGN), or Neon, and determined that loss carryforwards which existed as of the acquisition date, should be recognized to the extent of acquired deferred tax liabilities (€8.0 million) and therefore recorded a deferred tax asset of €8.0 million against goodwill. Since the conditions to offset were fulfilled, the deferred tax assets and liabilities were offset. Additionally, the deferred tax asset on tax losses incurred since acquisition through June 30, 2020 (€2.3 million) which had been offset against the acquired deferred tax liability as of June 30, 2020, was reversed through income tax expense during the three months ended September 30, 2020 as this deferred tax asset was no longer deemed recoverable as the entire acquired deferred tax liability was offset with the acquired deferred tax asset with the finalization of the purchase price allocation. The net impact on income tax expense in the nine months ended September 30, 2020 is nil. Accumulated tax losses relate to Germany and the United States. There is no expiration date for any of the accumulated tax losses under German tax law. With respect to accumulated losses incurred at the level of BioNTech USA Holding LLC and BioNTech Research and Development Inc. since their incorporation and tax losses of BioNTech US incurred since 2018 have no expiration date under U.S. tax law. The carry forward of tax losses prior 2018 of BioNTech US is partially limited in time and amount. Deviating federal and state rules apply.

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 us 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:

	Three months ended September 30,		Nine months ended September 30,	
	2020	**2019**	**2020**	**2019**
(in thousands)	*(unaudited)*		*(unaudited)*	
Revenues	€59,963	€22,379	€114,057	€64,875
Gross profit	**€59,963**	**€22,379**	**€114,057**	**€64,875**
Research and development expenses	(227,936)	(50,302)	(389,009)	(160,774)
Sales and marketing expenses	(3,772)	(355)	(6,395)	(924)
General and administrative expenses	(22,522)	(9,585)	(55,677)	(32,139)
Other result	8,268	211	8,593	799
Operating loss	**€(185,999)**	**€(37,652)**	**€(328,431)**	**€(128,163)**

Comparison of the three and nine months ended September 30, 2020 and 2019

Revenue

The following table summarizes the revenue of our biotech business unit by segment for each period presented:

	Three months ended September 30,		Change	
	2020	**2019**	**€**	**%**
(in thousands)	*(unaudited)*			
Revenues				
Clinical	€41,993	€7,174	€34,819	485
Technology Platform	4,184	2,114	2,070	98
Manufacturing	13,786	13,091	695	5
Business Service	-	-	-	-
Total unit revenues	**€59,963**	**€22,379**	**€37,584**	**168**

(in thousands)	Nine months ended September 30, 2020 (unaudited)	2019	Change €	Change %
Revenues				
Clinical	€61,059	€25,605	€35,454	138
Technology Platform	11,854	2,577	9,277	360
Manufacturing	41,144	36,685	4,459	12
Business Service	-	8	(8)	(100)
Total unit revenues	**€114,057**	**€64,875**	**€49,182**	**76**

Revenue of our biotech business unit increased by €37.6 million, or 168%, to €60.0 million in the three months ended September 30, 2020 from €22.4 million in the three months ended September 30, 2019 as well as by €49.2 million, or 76%, to €114.1 million in the nine months ended September 30, 2020 from €64.9 million in the nine months ended September 30, 2019. During the nine months ended September 30, 2020, revenues from our two new collaboration agreements were recognized for the first time primarily driving the overall increase in revenues across all segments. As part of our BNT162 program, we executed two strategic collaborations with Pfizer and Fosun Pharma. The program is evaluating several vaccine candidates against COVID-19, including BNT162b2 as the lead candidate currently being developed in a global Phase 3 trial. During the three and nine months ended September 30, 2020, €45.6 million and €66.3 million respectively were recognized from the collaboration agreement with Pfizer. The revenue was mainly recorded in the Clinical segment (€39.3 million and €49.2 million during the three and nine months ended September 30, 2020, respectively) but was accompanied by revenue recorded in the other two segments as well, based on the underlying costs incurred (€4.2 million and €10.2 million in the Manufacturing segment as well as €2.1 million and €6.9 million in the Technology Platform segment during the three and nine months ended September 30, 2020, respectively). During the three and nine months ended September 30, 2020, €1.7 million and €2.6 million respectively were recognized from the collaboration agreement with Fosun Pharma and recorded in the Technology Platform segment.

These effects were offset by decreased revenues from our collaboration programs with Genentech, Sanofi and from the collaboration with Pfizer to develop mRNA-based immunotherapies for the prevention of influenza. For certain programs, the commencement of trials has been delayed, partially due to slowed patient enrollment or other delays as a result of the COVID-19 pandemic.

As summarized above, the increase in revenue in our Clinical segment of €34.8 million from €7.2 million in the three months ended September 30, 2019 to €42.0 million in the three months ended September 30, 2020 as well as the increase of €35.5 million from €25.6 million in the nine months ended September 30, 2019 to €61.1 million in the nine months ended September 30, 2020 is mainly derived from the first time recognition of revenue from our Pfizer collaboration agreement to co-develop our potential first-in-class COVID-19 mRNA vaccine program. The effect offsets the decreased revenues from our collaboration agreements with Genentech and Sanofi which are also recorded in the Clinical segment.

Likewise, the increase in revenue in our Technology Platform segment of €2.1 million from €2.1 million in the three months ended September 30, 2019 to €4.2 million in the three months ended September 30, 2020 as well as the increase of €9.3 million from €2.6 million in the nine months ended September 30, 2019 to €11.9 million in the nine months ended September 30, 2020 is due to the first time recognition of revenues under our two new collaboration agreements aiming at preventing COVID-19 as well as revenue recorded from our Sanofi collaboration compensating the decrease in revenue from our collaboration with Eli Lilly.

The increase in revenue in our Manufacturing segment of €0.7 million from €13.1 million in the three months ended September 30, 2019 to €13.8 million in three months ended September 30, 2020 as well as the increase of €4.5 million from €36.7 million in the nine months ended September 30, 2019 to €41.1 million in nine months ended September 30, 2020 results from the first time recognition of revenue from our Pfizer collaboration agreement to co-develop our potential first-in-class COVID-19 mRNA vaccine program, offsetting the decreased revenue from our Genentech collaboration program due to the reasons mentioned above.

Research and Development Expenses

The following table summarizes the research and development expenses of our biotech business unit by segment for each period presented:

	Three months ended September 30,		Change	
	2020	**2019**	**€**	**%**
(in thousands)	*(unaudited)*			
Research and development expenses				
Clinical	€124,275	€21,948	€102,327	466
Technology Platform	51,036	14,289	36,747	257
Manufacturing	52,132	12,668	39,464	312
Business Service	493	1,397	(904)	(65)
Total unit research and development expenses	**€227,936**	**€50,302**	**€177,634**	**353**

	Nine months ended September 30,		Change	
	2020	**2019**	**€**	**%**
(in thousands)	*(unaudited)*			
Research and development expenses				
Clinical	€182,719	€65,634	€117,085	178
Technology Platform	113,740	52,503	61,237	117
Manufacturing	88,987	38,905	50,082	129
Business Service	3,563	3,732	(169)	(5)
Total unit research and development expenses	**€389,009**	**€160,774**	**€228,235**	**142**

Research and development expenses of our biotech business unit increased by €177.6 million, or 353%, to €227.9 million in the three months ended September 30, 2020 from €50.3 million in the three months ended September 30, 2019 as well as by €228.2 million, or 142%, to €389.0 million in the nine months ended September 30, 2020 from €160.8 million in the nine months ended September 30, 2019. The increase was mainly due to an increase in development expenses from our BNT162 program, our vaccine program against COVID-19. Research and development expenses include our share of expenses under the terms of the collaboration agreement. Shared development costs are equally shared between Pfizer and us. The amount of shared development expenses which were initially incurred by the collaboration partner Pfizer and subsequently charged to us were recorded as purchased services classified within research and development and the reimbursement from Pfizer for research and development expenses initially incurred by us were recorded as a reduction to research and development expenses. The increase was further driven by an increase in headcount leading to higher wages, benefits and social security expenses as well as an increase in expenses for purchased laboratory supplies. In addition, from May 6, 2020, the date of acquisition, our new U.S.-based subsidiary, BioNTech US Inc., contributed €13.4 million to the research and development expenses of the Group.

The following table summarizes our clinical research and development expenses, broken down by drug class and selected platforms, for each period presented:

	Three months ended September 30,		Change	
	2020	**2019**	**€**	**%**
(in thousands)	*(unaudited)*			
Clinical research and development expenses				
mRNA				
FixVac	€5,152	€3,470	€1,682	48
iNeST	4,817	7,097	(2,280)	(32)
Infectious Disease Vaccines*	96,139	1,040	95,099	9,144
Other mRNA	4,753	4,887	(134)	(3)
Total mRNA	110,861	16,495	94,366	572
Cell Therapies	2,154	559	1,595	285
Antibodies	10,944	2,866	8,078	282
Small Molecule Immunomodulators	99	1,091	(992)	(91)
Other	217	937	(720)	(77)
Total clinical research and development expenses	**€124,275**	**€21,948**	**€102,327**	**466**

*Infectious Disease Vaccines was previously included in other mRNA

	Nine months ended September 30,		Change	
	2020	**2019**	**€**	**%**
(in thousands)	*(unaudited)*			
Clinical research and development expenses				
mRNA				
FixVac	€11,488	€7,849	€3,639	46
iNeST	18,893	15,420	3,473	23
Infectious Disease Vaccines*	109,236	3,237	105,999	3,275
Other mRNA	13,179	15,188	(2,009)	(13)
Total mRNA	152,796	41,694	111,102	266
Cell Therapies	4,902	677	4,225	624
Antibodies	22,941	9,771	13,170	135
Small Molecule Immunomodulators	1,351	1,889	(538)	(28)
Other	729	11,602	(10,873)	(94)
Total clinical research and development expenses	**€182,719**	**€65,634**	**€117,085**	**178**

*Infectious Disease Vaccines was previously included in other mRNA

During the three months ended September 30, 2020, other mRNA expenses mainly included €2.0 million Intratumoral Immunotherapy costs, €1.1 million RiboMabs costs, €1.0 million RiboCytokines costs and €0.1 million Protein Replacement Therapy costs. Other mRNA expenses during the three months ended September 30, 2019 mainly included €2.0 million RiboCytokines costs, €1.1 million Intratumoral Immunotherapy costs, €0.6 million RiboMabs costs and €0.2 million Protein Replacement Therapy costs.

During the nine months ended September 30, 2020, other mRNA expenses mainly included €4.8 million Intratumoral Immunotherapy costs, €2.8 million RiboCytokines costs, €2.7 million RiboMabs costs and €1.3 million Protein Replacement Therapy costs. Other mRNA expenses during the nine months ended September 30, 2019 mainly included €6.2 million RiboCytokines costs, €3.7 million Intratumoral Immunotherapy costs, €2.6 million RiboMabs costs and €1.1 million Protein Replacement Therapy costs.

Sales and Marketing Expenses

Sales and marketing expenses of our biotech business unit increased by €3.4 million, or 963%, to €3.8 million in the three months ended September 30, 2020 from €0.4 million in the three months ended September 30, 2019 as well as by €5.5 million, or 592%, to €6.4 million in the nine months ended September 30, 2020 from €0.9 million in the nine months ended September 30, 2019. The increase was mainly due to increased marketing consulting expenses.

General and Administrative Expenses

General and administrative expenses of our biotech business unit increased by €12.9 million, or 135%, to €22.5 million in the three months ended September 30, 2020 from €9.6 million in the three months ended September 30, 2019 as well as by €23.6 million, or 73%, to €55.7 million in the nine months ended September 30, 2020 from €32.1 million in the nine months ended September 30, 2019. The increase was mainly influenced by higher expenses for purchased management consulting and legal services as well as an increase in headcount leading to higher wages, benefits and social security expenses. In addition, from May 6, 2020, the date of acquisition, our new U.S.-based subsidiary, BioNTech US Inc. contributed €4.5 million to the general and administrative expenses of the Group.

Other Result

The other result of our biotech business unit increased by €8.1 million, or 3818%, to €8.3 million in the three months ended September 30, 2020 from €0.2 million in the three months ended September 30, 2019. The other result of our biotech business unit increased by €7.8 million, or 975%, to €8.6 million in the nine months ended September 30, 2020 from €0.8 million in the nine months ended September 30, 2019. The increase was mainly derived from drawing down €8.5 million government grants under the BMBF funding. The funding drawn down represents a compensation for expenses already incurred in the period ended September 30, 2020. Therefore, €8.5 million were recognized as other operating income within the statements of operations during the three months ended September 30, 2020.

External Services Business Unit

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

	Three months ended September 30,		**Nine months ended September 30,**	
	2020	**2019**	**2020**	**2019**
(in thousands)	*(unaudited)*		*(unaudited)*	
Revenues	€7,495	€6,283	€22,826	€15,726
Cost of sales	(6,463)	(4,166)	(16,897)	(12,770)
Gross profit	**€1,032**	**€2,117**	**€5,929**	**€2,956**
Research and development expenses	(145)	(158)	(453)	(420)
Sales and marketing expenses	(496)	(315)	(1,413)	(984)
General and administrative expenses	(802)	(859)	(2,275)	(2,204)
Other result	33	131	47	378
Operating income (loss)	**€(378)**	**€916**	**€1,835**	**€(274)**

In the three months ended September 30, 2020, our external services business unit generated an operating loss of €0.4 million. The result decreased compared to the operating income of €0.9 million generated during the three months ended September 30, 2019 due to increased cost of sales during the

interim period. Overall, in the nine months ended September 30, 2020, our external services business unit generated an operating income of €1.9 million and was able to turn the operating loss of €0.3 million generated during the nine months ended September 30, 2019 around mainly by increasing revenues due to increased orders.

Related Party Transactions

Related party transactions that occurred during the three and nine months ended September 30, 2020 and 2019 are explained in Note 14 to the unaudited interim condensed consolidated financial statements.

Merger Agreement with BioNTech US Inc. (formerly Neon Therapeutics, Inc.)

On May 6, 2020, we acquired Neon Therapeutics, Inc. (formerly Nasdaq: NTGN), or Neon, a biotechnology company developing novel neoantigen-based T-cell therapies, through a stock transaction and including de minimis cash consideration, or the Merger. The Merger was first announced on January 16, 2020. Neon, now BioNTech US Inc., or BioNTech US, is operated as a wholly-owned subsidiary of BioNTech SE. The new subsidiary is based in Cambridge, Massachusetts and serves as our U.S. headquarters.

The transaction combines two organizations with a common culture of pioneering translational science and a shared vision for the future of cancer immunotherapy. Through the acquisition, we leverage Neon's deep expertise in the development of neoantigen therapies, with both vaccine and T-cell capabilities. Our most advanced program acquired in the Merger is BNT221 (NEO-PTC-01), a personalized neoantigen-targeted T-cell therapy candidate consisting of multiple T-cell populations targeting the most therapeutically relevant neoantigens from each patient's tumor. We also acquired a precision T-cell therapy program targeting shared neoantigens in genetically defined patient populations. The lead program from this approach, BNT222 (NEO-STC-01), is a T-cell therapy candidate targeting shared RAS neoantigens. In addition, Neon had assembled libraries of high-quality TCRs against various shared neoantigens across common HLAs. This pipeline is underpinned by Neon's platform technologies including RECON®, its machine-learning bioinformatics platform, and NEO-STIM™, its proprietary process to directly prime, activate and expand neoantigen-targeting T-cells *ex vivo*.

Based on the acquisition date share price, the implied aggregate value of the merger consideration was €89.9 million ($97.1 million) financed by issuing 1,935,488 ordinary shares as a stock transaction and including a de minimis cash consideration which was paid to settle Neon's outstanding stock options.

Impact of COVID-19

On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 as a pandemic, which continues to spread around the world.

As we advance our clinical programs, we are in close contact with our principal investigators and clinical sites, which are located in jurisdictions affected by the COVID-19 pandemic, and are assessing the impact of the COVID-19 pandemic on our clinical trials, expected timelines and costs on an ongoing basis. We have modified our business practices, in response to the spread of COVID-19, including restricting employee travel, developing social distancing plans for employees and cancelling physical participation in meetings, events and conferences. In addition, for certain programs, including BNT111, BNT113, BNT122, BNT141 and BNT142 (RiboMabs), BNT151 and BNT152/153 (RiboCytokines), BNT221, BNT161 (Influenza) and BNT171 (Rare Disease), the commencement of trials has been delayed, partially due to slowed patient enrollment or other delays as a result of the COVID-19 pandemic. This partial disruption, even temporary, may severely impact our operations and overall business by delaying the progress of our clinical trials and preclinical studies. 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. Such factors were evaluated and considered carefully when preparing this quarterly report for the three and nine months ended September 30, 2020. We will continue to evaluate potential effects of the COVID-19 pandemic.

COVID-19 Collaborations

Aiming at preventing COVID-19, our BNT162 program is evaluating multiple vaccine candidates, including BNT162b2 as the lead candidate currently being developed in a global Phase 3 trial. As part of the program, we executed two strategic collaborations with large pharmaceutical companies to globally develop our vaccine candidates and to support a global supply of a potential vaccine upon approval. The collaboration with Pfizer aims to rapidly advance multiple COVID-19 vaccine candidates based on our proprietary mRNA vaccine technology. As part of our strategic collaboration, we and Fosun Pharma will jointly conduct clinical trials in China, leveraging our proprietary mRNA vaccine technology and Fosun Pharma's clinical development and commercialization capabilities in China. Fosun Pharma will commercialize the vaccine in China upon regulatory approval.

The collaboration and license agreement entered into with Fosun Pharma includes a non-refundable upfront cash payment of €0.9 million ($1.0 million) as well as an equity investment of €45.6 million ($50.0 million), both received in April 2020. The issuance of 1,580,777 ordinary shares with the nominal amount of €1.6 million was registered within the commercial register (*Handelsregister*) as of April 23, 2020. BioNTech is eligible to receive future milestone payments of up to $84.0 million. One development milestone with an amount of €1.7 million was achieved and received by us in September.

Under the terms of the agreement, Pfizer agreed to pay us $185.0 million in upfront payments, including an equity investment of €103.9 million ($113.0 million) and a cash payment of €66.3 million ($72.0 million) which were received in two installments in late April 2020 and May 2020. The issuance of 2,377,446 ordinary shares with the nominal amount of € 2.4 million was registered with the commercial register (*Handelsregister*) on May 5, 2020. We are eligible to receive future milestone payments of up to $563.0 million for potential aggregate consideration of $748.0 million.

We and Pfizer are jointly conducting clinical trials for COVID-19 vaccine candidates across approximately 150 clinical trial sites globally. In late April 2020, we and Pfizer announced that the German regulatory authority, the Paul-Ehrlich-Institut, approved the Phase 1/2 clinical trial and the first patients in the first cohort of the Phase 1/2 clinical trial were dosed shortly thereafter. In early May 2020, Pfizer and we initiated a clinical trial for BNT162 in the U.S. and the first participants were dosed shortly thereafter.

During the clinical development stage, we and our partners are providing clinical supply of the vaccine from our and our partners' GMP-certified mRNA manufacturing facilities in Europe. We and Pfizer are working together to scale-up manufacturing capacity at risk to support a global supply upon approval in order to help address the pandemic. If the vaccine candidate is approved, we and Pfizer would work jointly to commercialize the vaccine worldwide (excluding China which is covered by the collaboration with Fosun Pharma).

We and Pfizer previously announced commercial supply agreements for 2020 and 2021 – totaling more than 570 million doses, including options to purchase an additional 600 million doses – with multiple governments, including Canada, Japan, the UK, the U.S. and the EU. All agreements are subject to clinical success and regulatory approval.

Based on preclinical and clinical data observed to date, we and Pfizer have progressed our BNT162 program into a Phase 2b/3 trial which commenced in late July 2020. For the initial Phase 2b/3 trial, we selected our nucleoside-modified mRNA (modRNA) vaccine candidate variant targeting the 2P-mutated full spike protein, BNT162b2. Both BNT162b2 and our BNT162b1 vaccine candidate, which uses modRNA and encodes the receptor binding domain antigen, received Fast Track status from the FDA. On the basis of data collected and analyzed for BNT162b1 and BNT162b2, including the overall observed safety, tolerability and immunogenicity profiles for each vaccine candidate at different dose levels, along with input from the FDA, we selected BNT162b2 as our lead candidate to take into a Phase 2b/3 trial.

In August, we and Fosun initiated a Phase 1 study to evaluate safety and immunogenicity in Chinese participants. We expect to initiate a Phase 2 clinical trial in China with BNT162b2 upon regulatory IND approval from the Chinese regulatory authority, National Medical Products Administration (NMPA), by the end of 2020.

On October 6, 2020, we announced the initiation of a rolling submission to the European Medicines Agency (EMA) for BNT162b2. The EMA's decision to start a rolling review follows the encouraging preliminary results from pre-clinical and early clinical studies in adults, which suggest that BNT162b2 triggers the production of neutralizing antibodies and TH-1 dominant CD4+ and CD8+ T cells that target SARS-CoV-2. A combination of an antibody and T cell response is believed to be important in eliciting protection against viral infection and disease. We and Pfizer plan to work with the EMA's Committee for Medicinal Products for Human Use (CHMP) to complete the rolling review process to facilitate the final Marketing Authorization Application (MAA).

On October 21, 2020 we and Pfizer announced initiation of a Phase 1/2 clinical trial in Japan to evaluate safety, tolerability and immunogenicity of two doses separated by 21 days and a single dose of BNT162b2. The randomized, placebo-controlled, and observer-blind study is being conducted in healthy adults ages 20 to 85.

BNT162b2 demonstrated evidence of efficacy against COVID-19 in participants without prior evidence of SARS-CoV-2 infection, based on the first interim efficacy analysis from the Phase 3 clinical study conducted on November 8, 2020, by an external, independent Data Monitoring Committee (DMC). After discussion with the FDA, we and Pfizer recently elected to drop the 32-case interim analysis and conduct the first interim analysis at a minimum of 62 cases. Upon conclusion of those discussions, the evaluable case count reached 94 and the DMC performed its first analysis on all cases. The case split between vaccinated individuals and those who received the placebo indicates a vaccine efficacy rate above 90%, at seven days after the second dose. This means that protection is achieved 28 days after the initiation of the vaccination, which consists of a 2-dose schedule. As the study continues, the final vaccine efficacy percentage may vary. The DMC has not reported any serious safety concerns and recommends that the study continues to collect additional safety and efficacy data as planned. We and Pfizer plan to submit data from the full Phase 3 trial for scientific peer-review publication.

The Phase 3 clinical trial of BNT162b2 began on July 27 and has enrolled 43,538 participants to date, 38,955 of whom have received a second dose of the vaccine candidate as of November 8, 2020. Approximately 42% of global participants and 30% of U.S. participants have racially and ethnically diverse backgrounds. The trial is continuing to enroll and is expected to continue through the final analysis when a total of 164 confirmed COVID-19 cases have accrued.

In addition to the primary efficacy endpoints evaluating confirmed COVID-19 cases accruing from seven days after the second dose, the final analysis now will include, with the approval of the FDA, new secondary endpoints evaluating efficacy based on cases accruing 14 days after the second dose as well. The companies believe that the addition of these secondary endpoints will help align data across all COVID-19 vaccine studies and allow for cross-trial learnings and comparisons between these novel vaccine platforms.

Critical Accounting Policies and Use of Estimates

Our unaudited interim condensed consolidated financial statements for the three and nine months ended September 30, 2020 have been prepared in accordance with IFRS, as issued by the IASB.

The preparation of the consolidated financial statements in accordance with IFRS requires 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 respective reporting period. 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, establishing the fair value of intangibles and derivatives, the formation of provisions, as well as income taxes. We base our assumptions and estimates on parameters available when the consolidated financial statements are 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.

Our critical accounting policies are those related to revenue recognition, research and development expenses, share-based compensation, fair value measurement of share-based awards as well as taxes. Our critical accounting policies are discussed further in Item 5 of our Annual Report on Form 20-F as of and for the year ended December 31, 2019 as well as Note 2.3 to our consolidated financial statements included in that Annual Report. Our accounting policies have been specified as described in Note 2 to the unaudited interim condensed consolidated financial statements. Actual results in the areas related to critical accounting estimates could differ from management's estimates.

Liquidity and Capital Resources

We have historically funded our operations primarily from private placements of our ordinary shares, from issuing ordinary shares in connection with our initial public offering, proceeds from collaborators and services and proceeds from secured bank loans. Recently we issued a convertible note as part of a private investment. As of September 30, 2020, we had cash and cash equivalents of €990.5 million. Cash and cash equivalents are invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation, and consist primarily of cash in banks and on hand and short-term deposits with an original maturity of three months or less, which are stated at fair value.

We maintain two secured loans with Deutsche Bank AG, or Deutsche Bank, to finance the buildouts of our JPT Peptide Technologies GmbH facility and Innovative Manufacturing Services GmbH 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. The loan is repayable in equal quarterly installments of k€322.6 commencing on June 30, 2020. As of September 30, 2020, the full amount under this facility is drawn down and the first two scheduled repayments have occurred. 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. The loan is repayable by quarterly installments of k€286.4 commencing on September 30, 2020. As of September 30, 2020, the full amount under this facility is drawn down and the first scheduled repayment has occurred. Each of these facilities is secured by liens over our property.

In December 2019, we 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 us 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.

In June 2020, we entered into an agreement with the EIB for a €100 million credit facility to partially support the development of BNT162 and fund expansion of our manufacturing capacity to provide worldwide supply of BNT162 in response to the COVID-19 pandemic. Under this arrangement, the EIB agreed to provide us with a credit in an amount up to €100 million to partially finance such development and expansion. The credit consists of (i) a term loan in the amount of €50 million that may be drawn in a single tranche upon the achievement of certain milestone events (Credit A), and (ii) a term loan in the amount of €50 million that may be drawn in a single tranche (Credit B). Credit B may only be drawn after Credit A has been drawn down and upon the achievement of certain milestone events. Each tranche under Credit A and Credit B must be repaid within six years from the date on which the tranche is disbursed. As of September 30, 2020, there has been no draw down.

On July 27, 2020, 5,500,000 ADS each representing one of our ordinary shares were offered on the Nasdaq Global Select Market at a public offering price of $93.00 per ADS ("Underwritten Offering"). On August 27, 2020, following the Underwritten Offering, 16,124 ADS each representing one of our ordinary shares were issued additionally at a public offering price of $93.00 per ADS ("Rights Offering"). The Underwritten Offering and the Rights Offering are part of a single, global offering which we refer to as the Global Offering. The gross proceeds of the Global Offering were €436.3 million ($513.0 million).

A fund associated with Temasek Capital Management Pte. Ltd., or Temasek, and another accredited investor have contributed a private investment which we refer to as the "June 2020 Private Placement". The private placement includes an investment in a 4-year mandatory convertible note and an investment in ordinary shares. The €100.0 million four-year mandatory convertible note has a coupon of 4.5% per annum and a conversion premium of 20% above the reference price. Subject to customary closing conditions, the investment closed as of August 28, 2020. The investment of €123.9 million for 2,595,996 of our ordinary shares is subject to a 180-day lock-up agreement and was registered with the commercial register (Handelsregister) on September 8, 2020.

In September 2020, we became eligible to receive up to €375.0 million in funding from an initiative by the German Federal Ministry of Education (*Bundesministerium für Bildung und Forschung*, or the BMBF) to support our COVID-19 vaccine program BNT162. The milestone-based BMBF funding will be used to accelerate our vaccine development, as well as for upscaling of manufacturing capabilities in Germany. As of September 30, 2020, €8.5 million were recorded as other current asset since they relate to amounts drawn down for which there is reasonable assurance that the government grant will be received, and all conditions, wholly in our control, will be complied with. The funding drawn down represents a compensation for expenses already incurred in the period ended September 30, 2020. Therefore, €8.5 million were recognized as other operating income within the statements of operations during the three months ended September 30, 2020.

Cash Flow

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

	Nine months ended September 30,	
	2020	**2019**
(in thousands)	*(unaudited)*	
Net cash flows from (used in):		
Operating activities	€(262,738)	€(134,910)
Investing activities	(45,012)	(67,046)
Financing activities	778,427	253,723
Total cash inflow	**€470,677**	**€51,767**

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 nine months ended September 30, 2020 was €262.7 million, comprising a loss before tax of €351.4 million, non-cash adjustments of €50.1 million, and a net positive change in assets and liabilities of €39.7 million. Non-cash items primarily included depreciation and amortization, share-based compensation expenses, non-cash effective finance expenses as well as an offsetting effect from government grant income not yet received in cash. The net change in assets and liabilities includes two offsetting effects: the amounts spent in advance for future services and products are overcompensated by the increase in liabilities outstanding on shared development expenses under our COVID-19 collaboration which were initially incurred by the collaboration partner Pfizer and subsequently charged to us.

Net cash used in operating activities for the nine months ended September 30, 2019 was €134.9 million, comprising a loss before tax of €120.9 million, non-cash adjustments of €46.8 million, and a net negative change in assets and liabilities of €60.4 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.

Overall, the increase in net cash used in operating activities from the nine months ended September 30, 2019 to the nine months ended September 30, 2020 was primarily due to an increase in spending on development expenses from our BNT162 program, our vaccine program against COVID-19.

Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2020 was €45.0 million, of which €40.7 million was attributable to the purchase of property, plant and equipment, mainly including the amounts spent with respect to the new buildings at our BioNTech IMFS facility in Idar-Oberstein and €5.2 million was attributable to the purchase of intangible assets. The net cash used attributable to the acquisition of assets, employees and proprietary know-how of Lipocalyx GmbH and its related parties based in Halle, Germany was offset by the net cash acquired attributable to the acquisition of Neon.

Net cash used in investing activities for the nine months ended September 30, 2019 was €67.0 million of which €32.9 million was attributable to the purchase of intangible assets, including the final installment payment for the license agreement for the CellScript patent and €28.6 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 €0.6 million. In addition, €6.1 million was attributable to the acquisition of MAB Discovery GmbH's operational antibody generation unit based near Munich, Germany.

Financing Activities

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

During the nine months ended September 30, 2020, we generated cash from financing activities of €778.4 million, primarily from proceeds from the issuance of shares in the amount of €680.1 million received from Fosun Pharma via Fosun Industrial Co., Limited, Hong Kong, Pfizer, the Global Offering as well as the June 2020 Private Placement, net of transaction costs related to all financing transactions. In addition, €102.4 million proceeds from loans and borrowings were generated mainly from issuing a 4-year mandatory convertible note.

During the nine months ended September 30, 2019, we generated cash from financing activities of €253.7 million, primarily from proceeds from the issuance of shares in the amount of €247.9 million, partially offset by the payment of finance lease liabilities in the amount of €2.2 million.

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 €776.5 million as of September 30, 2020 and €424.8 million as of December 31, 2019. We may incur losses for 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. Mainly influenced by the spending related to our BNT162 program, we expect the net cash used in operating activities and for investments into property, plant and equipment to be between €450 million and €600 million in the full year 2020, likely to hit the upper end of the range due to our acquisition of the manufacturing facility in Marburg. We anticipate that existing cash and cash equivalents, without considering any potential proceeds from the shelf registration statement filed and the Sales Agreement entered with Jefferies and Leerink for an at-the-market offering program, will enable us to fund our operating expenses and capital requirements through at least the next 24 months if we do not generate cash from commercialization of the BNT162 COVID-19 vaccine.

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;
- our ability to receive approval for a COVID-19 vaccine, and the amount and timing of revenues for any such vaccine if approved;
- 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, European Medicines Agency 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.

Risk Factors

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

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 and €351.7 million and €120.9 million for the nine months ended September 30, 2020 and September 30, 2019, respectively. As of September 30, 2020, we had accumulated losses of €776.5 million. We have devoted most of our financial resources to research and development, including our clinical and preclinical development activities and the development of our platforms. To date, we have financed our operations primarily through the sale of equity securities and proceeds from collaborations and, to a lesser extent, through revenue from manufacturing operations and grants from governmental and private organizations. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through equity or debt financings, sales of assets, collaborations or grants. We have not completed pivotal clinical trials for our programs and do not 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:

- our ability to receive approval for a COVID-19 vaccine, and the size and timing of orders for any such vaccine if approved;
- 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 product candidates;
- 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 may be 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 minimize and manage product recalls or inventory losses caused by unforeseen events, cold chain interruption or testing difficulties;
- 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;
- our and our collaborators' ability to defend against claims of infringement of the intellectual property rights of third parties;
- potential advantages that our competitors and potential competitors may have in securing funding, obtaining the rights to critical intellectual property or developing competing technologies or products;
- our ability to obtain additional capital that may be necessary to expand our business;
- our collaborators' ability to obtain additional capital that may be necessary to develop and commercialize products under our collaboration agreements;
- our ability to minimize and manage product liability claims arising from the use of our product candidates and our products, if approved;
- 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 may not generate 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, certain of our U.S. subsidiaries have, and may in the future have,

federal and state NOL carryforwards. U.S. federal NOL carryforwards generated in taxable years ending after December 31, 2017 are not subject to expiration. U.S. federal NOL carryforwards generated in taxable years ending December 31, 2017 and prior are partially limited in time and amount, subject to applicable state and federal rules. U.S. state NOL carryforward are partially limited in time and amount, subject to applicable state rules.

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 September 30, 2020, we had cash and cash equivalents of €990.5 million. We anticipate that existing cash and cash equivalents, without considering any potential proceeds from the shelf registration statement filed and the Sales Agreement entered with Jefferies and Leerink for an at-the-market offering program, will enable us to fund our operating expenses and capital requirements through at least the next 24 months if we do not generate cash from commercialization of the BNT162 COVID-19 vaccine. 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;
- our ability to receive approval for a COVID-19 vaccine, and the amount and timing of revenues for any such vaccine if approved;
- 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 four credit facilities with an aggregate drawing capacity of €170 million. As of September 30, 2020, two secured credit facilities with a total aggregate drawing of €20 million were fully drawn down and the first scheduled repayments have occurred. 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.

We have assembled an exceptional team of over 1,800 employees, including approximately 300 employees from our acquisition of the production site in Marburg in October 2020. 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 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 no later than December 31, 2020, 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 no later than December 31, 2020. 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 to date taken advantage of reduced reporting burdens. 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.

We face risks related to health epidemics, such as COVID-19, that could adversely affect our operations.

Our business could be adversely impacted by the effects of COVID-19 or other epidemics. The COVID-19 pandemic may negatively impact our revenue or operations in the future and could also affect our ability to enroll patients in clinical studies and complete clinical trials on the timelines we currently anticipate. For certain of our programs, including BNT111, BNT113, BNT122, BNT141 and BNT142 (RiboMabs), BNT151 and BNT152/153 (RiboCytokines), BNT221, BNT161 (Influenza) and BNT171 (Rare Disease), the commencement of trials has been delayed, partially due to slowed patient enrollment or other delays as a result of the COVID-19 pandemic. In addition, in response to the spread of COVID-19, we have modified our business practices, in response to the spread of COVID-19, including restricting employee travel, developing social distancing plans for employees and cancelling physical participation in meetings, events and conferences. This partial disruption, even temporary, may severely impact our operations and overall business by delaying the progress of our clinical trials and preclinical studies. 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.

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.

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 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.

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

Based on preclinical and clinical data observed to date, we and Pfizer have progressed our BNT162 program into a Phase 2b/3 trial which commenced in late July 2020. For the initial Phase 2b/3 trial, we selected our nucleoside-modified mRNA (modRNA) vaccine candidate variant targeting the 2P-mutated full spike protein, BNT162b2. Both BNT162b2 and our BNT162b1 vaccine candidate, which uses modRNA and encodes the receptor binding domain antigen, received Fast Track status from the FDA. On the basis of data collected and analyzed for BNT162b1 and BNT162b2, including the overall observed safety, tolerability and immunogenicity profiles for each vaccine candidate at different dose levels, along with input from the FDA, we selected BNT162b2 as our lead candidate to take into a Phase 2b/3 trial.

We cannot guarantee that the candidate variant that we selected will ultimately prove to be the optimal variant. We and Pfizer chose the variant to advance based on our scientific judgment in light of the preclinical and clinical data available to us at the time as to which variant has the best chance for success. It is possible that subsequent data regarding the variant we chose could prove to be less favorable or subsequent data from a variant that is not advanced could prove to be more favorable.

Regardless of the variant we selected for Phase 2b/3, we cannot guarantee that the results from subsequent data analyses and announcements will be in line with the data that we have previously published. The total number of patients evaluated in Phase 1 is small relative to the number we intend to evaluate in Phase 2b/3 and may not be indicative of the safety or immunogenicity of BNT162 in a larger and more diverse patient population in the clinical setting or upon commercialization. Similarly, the samples of convalescent sera, or blood samples from people who have recovered from COVID-19, used to benchmark the level of antibodies produced by subjects receiving BNT162 in Phase 1 clinical studies, have been taken from a small number of people and may not be representative of the antibody levels in a broader population of people who have recovered from COVID-19. Future results in clinical trials of BNT162 may not be as positive when compared to the antibody levels in other samples of convalescent sera.

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

In addition, by definition our Phase 1/2 clinical trials are designed to evaluate only safety and not efficacy. Positive results from these Phase 1/2 trials do not guarantee we will be able to demonstrate in our Phase 2b/3 trial that BNT162 is efficacious. On November 9, 2020 we and Pfizer announced that BNT162b2 demonstrated evidence of efficacy against COVID-19 in participants without prior evidence of SARS-CoV-2 infection, based on the first interim efficacy analysis conducted on November 8, 2020 by an external, independent Data Monitoring Committee (DMC) from the Phase 3 clinical study. However, the final analysis from that clinical study is not complete and could differ from the interim analysis as additional safety and additional efficacy data are collected. Failure to adequately demonstrate safety or to eventually demonstrate sufficient efficacy of BNT162 could delay or prevent us from receiving regulatory approval of BNT162 and there can be no assurance that BNT162 will be approved in a timely manner, if at all.

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

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

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

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

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

As a result of the emergency situations in many countries, there is a heightened risk that a COVID-19 vaccine may be subject to adverse governmental actions in certain countries, including intellectual property expropriation, compulsory licenses, strict price controls or other actions. Additionally, we may need to, or we may be required by governmental or non-governmental authorities to, set aside specific quantities of doses of BNT162 for designated purposes or geographic areas. We are likely to face challenges related to the allocation of supply of BNT162, particularly with respect to geographic distribution. Thus, even if BNT162 is approved, such governmental actions may limit our ability to recoup our current and future expenses.

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

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

To date, BNT162 has moved rapidly through the regulatory review process of the FDA and foreign regulatory authorities. The speed at which all parties are acting to create and test many therapeutics and vaccines for COVID-19 is unusual, and evolving or changing plans or priorities within the FDA and foreign regulatory authorities, including changes based on new knowledge of COVID-19 and how the disease affects the human body, may significantly affect the regulatory timeline for BNT162. Results

from clinical testing may raise new questions and require us to redesign proposed clinical trials, including revising proposed endpoints or adding new clinical trial sites or cohorts of subjects.

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

Additionally, the FDA has the authority to grant an Emergency Use Authorization, or EUA, to allow unapproved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when there are no adequate, approved, and available alternatives. On October 6, 2020, the FDA issued its Guidance for Industry on Emergency Use Authorization for Vaccines to prevent COVID-19, outlining the FDA's expectations for any EUA request for a vaccine candidate. Many of FDA's expectations, such as for chemistry, manufacturing and controls information, non-clinical and clinical study information, and a benefit-risk profile, are identical to the requirements for a biologics license application. In addition, FDA gave detailed guidance on some of the specific data it expects a vaccine manufacturer to submit with its EUA request, including safety data from phase 3 trials including "a median follow-up duration of at least two months after completion of the full vaccination regimen" and additional safety data, including local and systemic adverse events in a sufficient number of study subjects to characterize the reactogenicity in each age cohort, all safety data up to database lock, including data for >3,000 vaccine recipients "followed for serious adverse events and adverse events of special interest for at least one month after completion of the full vaccination regimen", data on at least five cases of severe COVID-19 among study subjects to support a risk analysis for vaccine-induced enhanced respiratory disease, safety and outcomes data for subjects who were previously infected with COVID-19 who may have been asymptomatic, and a safety follow-up plan to collect data from individuals who receive the vaccine under an EUA.

If we are granted an Emergency Use Authorization for BNT162, we would be able to commercialize BNT162 prior to FDA approval. However, the FDA may revoke an Emergency Use Authorization where it is determined that the underlying health emergency no longer exists or warrants such authorization, and we cannot predict how long, if ever, an Emergency Use Authorization would remain in place. Such revocation could adversely impact our business in a variety of ways, including if BNT162 is not yet approved by the FDA and if we and our manufacturing partners have invested in the supply chain to provide BNT162 under an Emergency Use Authorization.

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

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

We also may be restricted or prohibited from marketing or manufacturing a BNT162 vaccine, even after obtaining product approval, if previously unknown problems with the product or its manufacture are

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

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

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

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

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;
- with respect to infectious disease vaccine trials in particular, we have to wait for particular level of infection in the placebo arm in order to assess protection provided by vaccine, and we cannot control the rate of exposure or infection which can make timing uncertain;
- 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 are seeking approval for our COVID-19 vaccine candidate (and expect to also do so for future vaccine product candidates) via a placebo-controlled trial, which means that approval cannot be obtained until a certain level of infection occurs in the population of trial participants who receive placebo rather than our test vaccine. Furthermore, if another vaccine is approved before ours, and agencies may require proof of superiority relative to the already-approved vaccine in order to grant approval; our vaccine may not achieve such superiority and therefore may not be approved.

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. The COVID-19 global pandemic has introduced additional challenges in enrolling patients into many of our clinical trials. 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;
- impacts of the COVID-19 global pandemic; 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. As discussed above, each of the foregoing risks is 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, Czech, 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. On November 9, 2020 we and Pfizer announced that BNT162b2 demonstrated evidence of efficacy against COVID-19 in participants without prior evidence of SARS-CoV-2 infection, based on the first interim efficacy analysis conducted on November 8, 2020 by an external, independent Data Monitoring Committee (DMC) from the Phase 3 clinical study. However, the final analysis from that clinical study is not complete and could differ from the interim analysis as additional safety and additional efficacy data are collected. 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. For example, our BNT162 vaccine must be shipped and stored at very cold temperatures. 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. If we, our partners and customers are unable to adequately manage these issues, the market opportunity for our products may be reduced.

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 have only recently begun building our 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 only recently begun to develop our 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, such as mRNA vaccines and therapies, and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- 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 oth

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

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

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

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

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

There are many issued and pending patent filings that claim aspects of technologies that we may need for our mRNA product candidates or other product candidates, including patent filings that relate to relevant delivery technologies. There are also many issued patents that claim targeting genes or portions of genes that may be relevant for immunotherapies we wish to develop. In addition, there may be issued and pending patent applications that may be asserted against us in a court proceeding or otherwise based upon the asserting party’s belief that we may need such patents for the development, manufacturing and commercialization of our product candidates. Thus, it is possible that one or more organizations, ranging from our competitors to non-practicing entities or patent assertion entities, has or will hold patent rights to which we may need a license, or hold patent rights which could be asserted against us. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If

those organizations refuse to grant us a license to such patent rights on reasonable terms or a court rules that we need such patent rights that have been asserted against us and we are not able to obtain a license on reasonable terms or at all, we may be unable to perform research and development or other activities or market products covered by such patents, and we may need to cease the development, manufacture and commercialization of one or more of the product candidates we may develop. Any of the foregoing could result in a material adverse effect on our business, financial condition, results of operations or prospects.

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. For example, we are targeting potential commercialization of BNT162 as early as the end of 2020, at which point any protection provided by the 271(e)(1) safe harbor will no longer be available for that product. 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. For example, if we are successful in completing clinical trials for our COVID-19 vaccine candidate, BNT162, we may become exposed to one or more lawsuits from third parties who consider our product to infringe their patents at the time that we submit an application for marketing approval.

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; also, multiple oppositions have been filed against our EP patent number 2714071, which relates to our iNeST product candidates, and whose claims recite steps relating to neoantigen selection. 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 in

volved 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 and the ADSs

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

Biopharmaceutical companies that are developing potential therapeutics and vaccines to combat COVID-19, including BioNTech SE, have experienced significant volatility in the price of their securities upon publication of preclinical and clinical data as well as news about their development programs. For example, following the announcement of our collaborations with Pfizer and Fosun Pharma relating to the development of BNT162, our vaccine candidate program for the prevention of COVID-19, the last reported sales price of the ADSs representing our ordinary shares on the Nasdaq Global Select Market increased from $30.93 on March 13, 2020, the day before the announcement, to $92.00 on March 18, 2020, before decreasing to $46.50 on March 20, 2020. In addition to the preclinical and clinical data we and Pfizer have already disclosed in connection with our BNT162 development program, we and Pfizer intend over the coming months to make public several additional COVID-19 vaccine data readouts and clinical updates. We have also announced that we and Pfizer have entered into supply agreements with a number of governments, including the United Kingdom, the United States, Japan and Canada for BNT162, if approved, and are in late-stage discussions with other govern

ments and governmental bodies related to the establishment of supply agreements for BNT162, if approved. We cannot predict public reaction or the impact on the market price of the ADSs representing our ordinary shares once the terms of any of these supply arrangements are announced. We also cannot guarantee that the ultimate supply agreements we enter into, if any, will be for the number of doses we currently estimate, that any options contained in the agreements will be exercised or that aggregate consideration to be received under any such supply agreements will ultimately be what we currently expect. Given the attention being paid to the COVID-19 pandemic and the public scrutiny of COVID-19 development announcements and data releases to date, and given that we are among the current leaders in the development of a vaccine, we expect that the public announcements we and Pfizer intend to make in the coming months regarding the ongoing development of BNT162 will attract significant attention and scrutiny and that, as a result, the price of the ADSs representing our ordinary shares may be particularly volatile during this time.

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.

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

Our articles of association provide that the United States District Court for the Southern District of New York shall be the competent court of jurisdiction for the resolution of any litigation on the grounds of or in connection with U.S. federal or state capital market laws. In the absence of these provisions, under the Securities Act of 1933, as amended, or the Securities Act, U.S. federal and state courts have been found to have concurrent jurisdiction over suits brought to enforce duties or liabilities created by the Securities Act. This choice of forum provision will not apply to suits brought to enforce duties or liabilities created by the Securities Exchange Act of 1934, as amended, which already provides that such federal district courts have exclusive jurisdictions over such suits.

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

were to find the choice of forum provision contained in our articles of association to be inapplicable or unenforceable, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition and operating results. The choice of forum provision may also impose additional litigation costs on shareholders who assert that the provision is not enforceable or invalid. The United States District Court for the Southern District of New York may also reach different judgments or results than would other courts, including courts where a shareholder considering a U.S.-based action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our shareholders.

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

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

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

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

Our executive officers, directors, five percent shareholders, and their affiliates beneficially own a majority of our ordinary shares (including ordinary shares represented by ADSs) as of September 30, 2020, and will have the ability to influence us through their ownership positions. For example, these shareholders, acting together, may be able to exert significant influence over matters such as elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our ordinary shares that you may believe are in your best interest as one of our shareholders.

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.

A significant portion of our total outstanding ordinary shares were restricted from immediate resale following our initial public offering and other registered public offerings but may be sold in the near future. 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.

We intend to file one or more registration statements on Form S-8 under 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, upon which shares registered under such registration statements will be available for sale in the open market.

Sales of ADSs or our ordinary shares as restrictions end or pursuant to registration rights may make it more difficult for us to finance our operations through the sale of equity securities in the future at a time

and at a price that we deem appropriate. These sales also could cause the trading price of the ADSs to fall and make it more difficult to sell the ADSs.

Disclaimer

Forward-Looking Statements

This quarterly report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, but not limited to, statements concerning: our expected cash usage for 2020 and beyond; our anticipated cash runway; the planned next steps in BioNTech's pipeline programs and specifically including, but not limited to, statements regarding plans to initiate clinical trials of BioNTech's product candidates; expectations for data announcements with respect to BioNTech's clinical trials; the timing for any potential emergency use authorizations or approvals for BNT162; and our ability to scale-up manufacturing capacity for BNT162 and supply the quantities of BNT162 to support clinical development and, if approved, market demand, including our production estimates for 2020 and 2021. In some cases, forward-looking statements can be identified by terminology such as "will," "may," "should," "expects," "intends," "plans," "aims," "anticipates," "believes," "estimates," "predicts," "potential," "continue," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. The forward-looking statements in this press release are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond BioNTech's control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements. You should review the risks and uncertainties described under the heading "Risk Factors" in this quarterly report and in subsequent filings made by BioNTech with the SEC, which are available on the SEC's website at https://www.sec.gov/. Except as required by law, BioNTech disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise. These forward-looking statements are based on BioNTech's current expectations and speak only as of the date hereof.

About BioNTech

Biopharmaceutical New Technologies is a next generation immunotherapy company pioneering novel therapies for cancer and other serious diseases. The Company exploits a wide array of computational discovery and therapeutic drug platforms for the rapid development of novel biopharmaceuticals. Its broad portfolio of oncology product candidates includes individualized and off-the-shelf mRNA-based therapies, innovative chimeric antigen receptor T cells, bi-specific checkpoint immuno-modulators, targeted cancer antibodies and small molecules. Based on its deep expertise in mRNA vaccine development and in-house manufacturing capabilities, BioNTech and its collaborators are developing multiple mRNA vaccine candidates for a range of infectious diseases alongside its diverse oncology pipeline. BioNTech has established a broad set of relationships with multiple global pharmaceutical collaborators, including Genmab, Sanofi, Bayer Animal Health, Genentech, a member of the Roche Group, Regeneron, Genevant, Fosun Pharma, and Pfizer.

For more information, please visit www.BioNTech.de

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Unaudited Pro Forma Condensed Combined Financial Information

On May 6, 2020 BioNTech SE ("BioNTech") acquired Neon Therapeutics, Inc., Cambridge, Massachusetts, United States ("Neon"; formerly Nasdaq: NTGN), a biotechnology company developing novel neoantigen-based T-cell therapies ("the Merger"). Through the acquisition, BioNTech will be able to leverage Neon's expertise in the development of neoantigen therapies, with both vaccine and T cell capabilities. Under the merger agreement by and among BioNTech, Neon and BioNTech's wholly owned subsidiary, Endor Lights, Inc., New York, United States, Endor Lights, Inc. merged with and into Neon. The new subsidiary operates under the name BioNTech US Inc., a wholly owned subsidiary of BioNTech SE, and serves as BioNTech's headquarters in the United States. Based on the acquisition date share price, the aggregate value of the merger consideration was k€89,890 (k$97,144) financed by issuing 1,935,488 American Depositary Shares representing BioNTech's ordinary shares as a stock transaction and including a de minimis cash consideration which was paid to settle Neon's outstanding stock options.

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

The unaudited pro forma condensed combined statements of operations for the year ended December 31, 2019 and the nine months ended September 30, 2020 give effect to this transaction as if it had occurred on January 1, 2019. Neon's pre-acquisition interim operating results cover the stub period through May 5, 2020. From the date of acquisition on, Neon's financial information is prepared under IFRS and included in the unaudited interim condensed consolidated financial statements of BioNTech SE and its subsidiaries. Accordingly, the transaction is already reflected in the interim condensed consolidated statement of financial position as of September 30, 2020.

The unaudited pro forma condensed combined financial information is based on the fair values and values in accordance with IFRS 3 of the identifiable net assets of Neon as at the date of acquisition as they were presented within BioNTech's unaudited interim condensed consolidated financial statements and related notes as of and for the three and nine months ended September 30, 2020.

As indicated in Note 5 to the unaudited pro forma condensed combined financial information, BioNTech has adjusted the historical financial information of BioNTech and Neon to eliminate nonrecurring charges that are directly attributable to the transaction.

Additionally, as indicated in Note 2 to the unaudited pro forma condensed combined financial information, estimated effects related to the application of IFRS for the year ended 2019 and the stub period ended May 5, 2020 have been based on approximate assessments and as indicated in Note 3 to the unaudited pro forma condensed consolidated financial information, the reporting currency has been applied based on a simplified method. Actual results of a combined entity might differ materially from this unaudited pro forma condensed combined financial information.

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

with the pro forma condensed combined financial information. The unaudited pro forma condensed combined financial information should be read together with:

- BioNTech's audited consolidated financial statements and related notes as of and for the year ended December 31, 2019 included in its Annual Report on Form 20-F for the fiscal year ended December 31, 2019, filed with the Securities and Exchange Commission (the "SEC") on March 31, 2020;
- BioNTech's unaudited interim condensed consolidated financial statements and related notes as of and for the three months ended March 31, 2020 included in its Form 6-K filed with the SEC on May 12, 2020;
- BioNTech's unaudited interim condensed consolidated financial statements and related notes as of and for the three and six months ended June 30, 2020 included in its Form 6-K filed with the SEC on August 11, 2020;
- BioNTech's unaudited interim condensed consolidated financial statements and related notes as of and for the three and nine months ended September 30, 2020 included in its Form 6-K filed with the SEC on November 10, 2020;
- Neon's audited consolidated financial statements and related notes as of and for the year ended December 31, 2019 included in its Form 10-K filed with the SEC on March 2, 2020; and
- Neon's unaudited interim condensed consolidated financial statements and related notes as of and for the three months ended March 31, 2020 included in its Form 10-Q filed with the SEC on May 1, 2020.

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

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

Unaudited Pro Forma Condensed Combined Statement of Operations

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

	BioNTech SE Historical IFRS EUR	NEON THERAPEUTICS Inc. Historical USGAAP USD	NEON THERAPEUTICS Inc. Historical USGAAP EUR[1]	NEON THERAPEUTICS Inc. IFRS Adjustments EUR[1]	Pro Forma Adjustments EUR[1]	Notes	Pro Forma Combined EUR[1]
Revenue	108,589	-	-	-	-		108,589
Cost of sales	(17,361)	-	-	-	-		(17,361)
Research and development expenses	(226,466)	(59,718)	(53,768)	(226)	(1,132)	2 a), 2 b), 5 a)	(281,592)
Sales and marketing expenses	(2,718)	-	-	-	-		(2,718)
General and administrative expense	(45,547)	(21,420)	(19,286)	(715)	-	2 a), 2 b)	(65,548)
Other operating income	2,724	-	-	-	-		2,724
Other operating expenses	(739)	-	-	-	-		(739)
Operating loss	(181,518)	(81,138)	(73,054)	(941)	(1,132)		(256,645)
Finance income, net	2,078	1,401	1,261	(660)	-	2 a)	2,679
Other expenses	-	(39)	(35)	-	-		(35)
Loss before tax	(179,440)	(79,776)	(71,828)	(1,601)	(1,132)		(254,001)
Income taxes	268	-	-	-	-		268
Loss for the period	(179,172)	(79,776)	(71,828)	(1,601)	(1,132)		(253,733)
Loss for the period attributable to non-controlling interests	(116)	-	-	-	-		(116)
Net loss attributable to common stockholders	(179,056)	(79,776)	(71,828)	(1,601)	(1,132)		(253,617)
Basic and diluted loss per share	(0.85)						(1.19)
Weighted-average shares	211,499				1,935		213,434

[1] Please see Note 3 to the unaudited pro forma condensed combined financial information.

Unaudited Pro Forma Condensed Combined Statement of Operations

For the nine months ended September 30, 2020 (in thousands, except for per share information)

	BioNTech SE Historical IFRS EUR	NEON THERAPEUTICS Inc. Stub Period Historical U.S. GAAP USD	NEON THERAPEUTICS Inc. Stub Period Historical U.S. GAAP EUR[1]	NEON THERAPEUTICS Inc. IFRS Adjustments for Stub Period EUR[1]	Pro Forma Adjustments EUR[1]	Notes	Pro Forma Combined EUR[1]
Revenue	136,883	-	-	-	-		136,883
Cost of sales	(18,344)	-	-	-	-		(18,344)
Research and development expenses	(388,017)	(15,439)	(14,063)	533	3,443	2 a), 2 b), 5a), 5 b), 5 c)	(398,104)
Sales and marketing expenses	(7,808)	-	-	-	-		(7,808)
General and administrative expense	(57,952)	(18,983)	(17,290)	710	13,472	2 a), 2 b), 5 b), 5 c)	(61,060)
Other operating income	9,962	-	-	-	-		9,962
Other operating expenses	(1,325)	-	-	-	-		(1,325)
Operating loss	(326,601)	(34,422)	(31,353)	1,243	16,915		(339,796)
Finance income, net	(24,820)	69	63	(225)	-	2 a)	(24,982)
Other expenses	-	-	-	-	-		-
Loss before tax	(351,421)	(34,353)	(31,290)	1,018	16,915		(364,778)
Income taxes	(293)	-	-	-	-		(293)
Net loss attributable to common stockholders	(351,714)	(34,353)	(31,290)	1,018	16,915		(365,071)
Basic and diluted loss per share	(1.53)						(1.57)
Weighted-average shares	230,419				1,935		232,354

[1] Please see Note 3 to the unaudited pro forma condensed combined financial information.

Notes to the Unaudited Pro Forma Condensed Combined Financial Information

1 Basis of Preparation

The historical consolidated financial statements of BioNTech and Neon have been adjusted in the unaudited pro forma condensed combined financial information to give effect to pro forma events that are (1) directly attributable to the business combination, (2) factually supportable and (3) expected to have a continuing impact on the combined results following the business combination. The business combination was accounted for under the acquisition method of accounting in accordance with IFRS 3, Business Combinations. As the acquirer for accounting purposes, within its unaudited interim condensed consolidated financial statements and related notes as of and for the three and nine months ended September 30, 2020, BioNTech has identified fair values and values in accordance with IFRS 3 of the identifiable net assets of Neon as at the date of acquisition. In addition, BioNTech has performed an approximate conversion to conform the U.S. GAAP accounting policies of Neon to its own accounting policies under IFRS.

2 Accounting Policy Conformity Changes

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

a) Neon adopted ASC 842 as of January 1, 2019 for lease accounting. For the year ended December 31, 2019 and the nine months ended September 30, 2020, BioNTech applied IFRS 16 for lease accounting. The following adjustments reflect as if Neon had adopted IFRS 16 as of January 1, 2019 through May 5, 2020:

- Decrease in research and development expenses of k€349 and decrease of general and administrative expenses of k€78 and increase of finance expense of k€660 for the year ended December 31, 2019, respectively, due to increased depreciation and reclassification of operating lease interest expense into finance expense.

- Decrease in research and development expenses of k€119 and decrease of general and administrative expenses of k€26 and increase of finance expense of k€225 for the stub period from January 1, 2020 through May 5, 2020, respectively, due to increased depreciation and reclassification of operating lease interest expense into finance expense.

b) The following adjustments reflect the change from straight-line method to the accelerated method of recognizing stock compensation expense per IFRS 2 and the reversal of mark-to-market expense for stock options granted to non-employees:

- Increase in research and development expenses of k€575 and increase in general and administrative expenses of k€793 for the year ended December 31, 2019.

- Decrease in research and development expenses of k€414 and decrease in general and administrative expenses of k€684 for the stub period from January 1, 2020 through May 5, 2020.

3 Foreign Currency Adjustments

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

	$ / €
Average exchange rate for the year ended December 31, 2019	1.11
Average exchange rate for the stub period from January 1, 2020 through May 5, 2020	1.10
Exchange rate as of closing	1.08

4 Financing Transaction

Financing Transaction

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

Purchase Price Allocation

Fair values and values in accordance with IFRS 3 of the identifiable net assets of BioNTech US Inc. as at the date of acquisition are presented within BioNTech's unaudited interim condensed consolidated financial statements and related notes as of and for the three and nine months ended September 30, 2020.

These results have been used to prepare pro forma adjustments in the unaudited pro forma condensed combined statements of operations. During the measurement period, further considerations were made especially with respect to the recoverability of tax losses carried forward.

As at the date of acquisition, k€8,043 of deferred tax liabilities had been provisionally recorded arising from the assets acquired in the business combination. Provisionally, tax benefits acquired as part of the business combination were assessed as not satisfying the criteria for separate recognition. During the three months ended September 30, 2020, BioNTech finalized its assessment of deferred taxes related to the acquisition of Neon and determined that loss carryforwards which existed as of the acquisition date, should be recognized to the extent of acquired deferred tax liabilities (k€8,043) and therefore recorded a deferred tax asset of k€8,043 against goodwill. Since the conditions to offset were fulfilled, the deferred tax assets and liabilities were offset. Additionally, the deferred tax asset on tax losses incurred since acquisition through June 30, 2020 (k€2,317) which had been offset against the acquired deferred tax liability as of June 30, 2020, was reversed through income tax expense in the three months ended September 30, 2020 as this deferred tax asset was no longer deemed recoverable as the entire acquired deferred tax liability was offset with the acquired deferred tax asset with the finalization of the purchase price allocation. The net impact on income tax expense in the nine months ended September 30, 2020 is nil. This measurement period adjustment, increasing net assets and decreasing goodwill, did not have any impact on the pro forma adjustments to the unaudited pro forma condensed combined statements of operations for the year ended December 31, 2019 and the nine months ended September 30, 2020.

5 Pro Forma Adjustments

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

a) As part of the valuation analysis, BioNTech identified intangible assets in form of in-process research and development projects. The fair value of identifiable intangible assets is determined primarily using the income method approach. BioNTech used certain assumptions based on publicly available data for the industry. Amortization for the in-process research and development in the amounts of k€1,132 for the year ended December 31, 2019 and k€377 for the stub period from January 1, 2020 through May 5, 2020 has been reflected in the unaudited pro forma condensed combined statements of operations.

b) Transaction costs and payments derived from retention, severance and bonus arrangements that have been executed in connection with the acquisition have been expensed but are non-recurring in nature and would not reflect expenses of the combined entity on an ongoing basis. Consequently, these directly attributable expenses consist of research and development expenses in an amount of k€1,493 as well as general and administrative expenses in an amount of k€9,628 which are eliminated in the unaudited pro forma condensed combined statement of operations.

c) Stock compensation acceleration expenses in connection with the acquisition have been expensed but are non-recurring in nature and would not reflect expenses on an ongoing basis. Directly attributable research and development expenses of k€2,327 as well as general and administrative expenses of k€3,844 are eliminated in the unaudited pro forma condensed combined statement of operations.