

**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 MAY 2021  
COMMISSION FILE NUMBER 001-39081**

**BioNTech SE**

(Translation of registrant's name into English)

**An der Goldgrube 12 D-  
55131 Mainz Germany  
+49 6131-9084-0**

(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):

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**DOCUMENTS INCLUDED AS PART OF THIS FORM 6-K**

On May 10, 2021, BioNTech SE (the “Company”) issued a press release announcing its first quarter 2021 financial results and corporate update and details of a conference call to be held at 8:00 am EST on May 10, 2021 to discuss the results. The press release and the conference call presentation are attached as Exhibits 99.1 and 99.2, respectively, and incorporated by reference herein.

The information contained in Exhibits 99.1 and 99.2 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, unless expressly set forth by specific reference in such a filing.

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**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, 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: May 10, 2021

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## EXHIBIT INDEX

<u>Exhibit</u>	<u>Description of Exhibit</u>
99.1	<a href="#">BioNTech Announces First Quarter 2021 Financial Results and Corporate Update</a>
99.2	<a href="#">First Quarter 2021: Corporate Update and Financial Results</a>

## BioNTech Announces First Quarter 2021 Financial Results and Corporate Update

- *More than 450 million doses of BNT162b2 supplied to 91 countries or territories worldwide as of May 6, 2021.*
- *Signed agreements for over 1.8 billion doses of BNT162b2 in 2021 and first contracts signed for periods 2022 and beyond.*
- *Announced planned expansion of global footprint to Asia with establishment of first regional headquarters for southeast Asia in Singapore, including a fully-integrated and state-of-the art mRNA manufacturing facility.*
- *In oncology, a first-in-human Phase 1 trial started for the neoantigen-targeting T cell therapy, BNT221. The development of BioNTech's oncology pipeline has continued to accelerate with 14 product candidates now in 15 ongoing trials.*

Conference call and webcast scheduled for May 10, 2021, at 8:00 a.m. ET (2:00 p.m. CET)

**MAINZ, Germany, May 10, 2021 (GLOBE NEWSWIRE)** -- BioNTech SE (Nasdaq: BNTX, "BioNTech" or "the Company"), a next generation immunotherapy company pioneering novel therapies for cancer and infectious diseases, today provided an update on its corporate progress and reported financial results for the quarter ended March 31, 2021.

"BioNTech has continued to execute the delivery of our COVID-19 vaccine globally to more than 90 countries and territories. Through our continued innovation, we are expanding access to new populations and geographies, and addressing emerging variants," said **Ugur Sahin, BioNTech's Co-founder and CEO**. "We are moving into later stage testing for three of our oncology programs in the near future and plan to launch multiple new products over the next five years. Looking ahead, we will further optimize our technologies and expand our pipeline into additional therapeutic indications, as we meet our ambition to become a global, fully-integrated immunotherapy company."

### First quarter 2021 and subsequent updates

#### *Infectious disease*

#### **COVID-19 vaccine program – BNT162b2**

In March 2021, BioNTech announced its Full Year 2020 Financial Results and Corporate Update as a part of the Annual Report filed on Form 20-F, highlighting developments relating to its COVID-19 vaccine program between January 1 and March 30, 2021 ([Link to press release](#)). A summary of these developments as well as full details of subsequent developments that occurred after March 30, 2021 is provided below.

As of May 6, 2021 BioNTech and Pfizer have shipped approximately 450 million doses of BNT162b2 to 91 countries and territories around the world.

To date, the companies have signed orders of approximately 1.8 billion doses for delivery in 2021, and they have also signed the first contracts for 2022 and beyond. Further discussions for additional dose commitments are ongoing for 2021 and beyond. BioNTech expects BNT162b2 annual manufacturing capacity to reach 3 billion doses by the end of 2021, and expects to have capacity to manufacture more than 3 billion doses in 2022.

Multiple clinical trials are ongoing to expand the authorization of BNT162b2 to additional population groups, such as children from 6 months to 11 years of age, and to collect further data in healthy pregnant women.

To date, there is no evidence that an adaptation of BioNTech's current COVID-19 vaccine against key identified emerging variants is necessary. Despite this, BioNTech has developed a comprehensive strategy to address these variants should the need arise in the future. As part of BioNTech's strategy to contend with the variant challenge, BioNTech submitted to the U.S. Food and Drug Administration (FDA), and the FDA has approved an additional amendment to the study protocol of the global Phase 1/2/3 trial which includes: (1) an assessment of the impact of a third dose of BNT162b2 in prolonging immunity against COVID-19 and in protecting against COVID-19 caused by potential newly emerging SARS-CoV-2 variants, and (2) an assessment of a modified, variant-specific version of BNT162b2. The aim of this study is to explore the regulatory pathway that BioNTech and Pfizer would pursue if SARS-CoV-2 were to change enough to require an updated vaccine. This trial started in March 2021.

In the first quarter of 2021, BioNTech also advanced its work to broaden access through improvements to its cold chain distribution systems and processes. Both the FDA and the European Medicines Agency (EMA) have approved the transportation and storage of undiluted frozen vials of BNT162b2 at temperatures (-20°C) commonly found in pharmaceutical freezers for a period of up to two weeks. Further stability data have been assessed and formulation optimization activities are ongoing, including a study to evaluate a lyophilized (or freeze-dried) and a ready-to-use formulation of BNT162b2.

#### *BNT162b2 clinical development updates*

- On March 31, 2021, BioNTech and Pfizer announced that BNT162b2 demonstrated 100% efficacy and robust antibody responses in a Phase 3 trial in adolescents aged 12 to 15 with or without prior evidence of SARS-CoV-2 infection. The trial enrolled 2,260 adolescents in the United States. In the trial, 18 cases of COVID-19 were observed in the placebo group (n=1,129) versus none in the vaccinated group (n=1,131). Vaccination with BNT162b2 elicited high SARS-CoV-2 neutralizing antibody titers, demonstrating strong immunogenicity in a subset of adolescents one month after the second dose. BNT162b2 administration was generally well tolerated.
- On March 31, 2021, BioNTech and Pfizer began evaluating the administration of a single booster dose five to seven months after receiving the second dose of BNT162b2. To demonstrate duration of protection, and protection against the emerging variants of concern, an additional dose of BNT162b2 or of BNT162b2SA (encoding for the spike protein of the variant B.1.351) is being given to about 600 Phase 3 participants. About 30 participants that received BNT162b2SA will be given another dose of BNT162b2SA.

A new cohort of approximately 300 participants will be enrolled who are COVID-19 vaccine-naïve (i.e., including BNT162b2-naïve) and have not been infected with COVID-19. They will receive BNT162b2SA given as a two-dose series, separated by 21 days. The objective of this Phase 1/2/3 protocol amendment is to describe the safety and tolerability profile of BNT162b2SA, to evaluate its non-inferiority compared to BNT162b2, and to analyze the immune response generated by BNT162b2SA. By evaluating BNT162b2SA as a prototype vaccine, the companies aim to inform the development of an efficient regulatory pathway for testing future modified mRNA vaccines, using the current pathways for flu vaccines as models (blueprint study).

- On April 1, 2021, BioNTech and Pfizer announced updated topline results confirming high efficacy and no serious safety concerns through up to six months following the second dose. Topline efficacy was based on an analysis of 927 confirmed symptomatic cases of COVID-19 observed in the pivotal Phase 3 study through March 13, 2021. BNT162b2 was 91.3% effective against COVID-19, measured seven days through up to six months after the second dose. The vaccine was also 100% effective against severe disease, as that term is defined by the U.S. Centers for Disease Control and Prevention, and 95.3% effective against severe COVID-19 as that term is defined by the FDA. Safety data collected from more than 12,000 vaccinated participants who had a follow-up time of at least six months after the second dose demonstrated a favorable safety and tolerability profile.  
In an additional exploratory analysis of 800 trial participants enrolled in South Africa, where the B.1.351 lineage is prevalent, nine cases of COVID-19 were observed, all in the placebo group, indicating vaccine efficacy of 100%. Of these cases, eight were of the B.1.351 lineage, confirming efficacy against B.1.351 virus. These data support previous results from immunogenicity studies demonstrating that BNT162b2 induced a robust neutralizing antibody response to the B.1.351 variant and, although lower than to the wild-type strain, it does not appear to affect the observed high efficacy against COVID-19 caused by this variant, as published in the *New England Journal of Medicine*.<sup>2</sup>
- On April 1, 2021, BioNTech and Pfizer started a Phase 3, randomized, observer-blind study to evaluate the safety, tolerability, and immunogenicity of multiple formulations of BNT162b2, administered on a two-dose (separated by 21 days) schedule in adults aged 18 to 55. Part 1 of the study is comparing the safety and tolerability of lyophilized (or freeze-dried) BNT162b2 to the current frozen-liquid formulation of BNT162b2 and is evaluating non-inferiority of the immune response. Part 2 of the study will evaluate the safety and immunogenicity of a ready-to-use formulation of BNT162b2, and will be initiated in May 2021. The study, which is being conducted in the United States, will enroll approximately 610 participants. BioNTech and Pfizer expect to obtain results from both study parts in the third quarter of 2021.

#### *Regulatory updates*

- On April 9, 2021, BioNTech and Pfizer requested amendments to the U.S. Emergency Use Authorization to expand the use of BNT162b2 to adolescents aged 12 to 15.

- On April 30, 2021, BioNTech and Pfizer submitted to EMA a variation to the European Conditional Marketing Authorization (CMA) for COMIRNATY® to request an extension of the indication for use in adolescents 12 to 15 years of age. If EMA approves the variation, the amended CMA will be valid in all 27 member states of the European Union.
- On April 30 and May 4, 2021, BioNTech and Pfizer submitted new stability data of BNT162b2 to the FDA and EMA in order to update the product's label to extend the storage at standard refrigerator temperatures of 2°C to 8°C to four weeks.
- On May 5, 2021, BioNTech and Pfizer Canada announced that Health Canada has expanded the Interim Order authorization for BNT162b2 to include individuals 12 to 15 years of age. This is the first COVID-19 vaccine authorized in Canada for use in this age group.
- On May 7, 2021, BioNTech and Pfizer announced the initiation of a Biologics License Application (BLA) with the FDA for approval of BNT162b2 to prevent COVID-19 in individuals 16 years of age and older. Data to support the BLA will be submitted by the companies to the FDA on a rolling basis over the coming weeks, with a request for Priority Review. BioNTech is the Marketing Authorization Holder in the European Union, and the holder of emergency use authorizations or equivalent in the United States (together with Pfizer), United Kingdom, Canada and other countries in advance of a planned application for full marketing authorizations in these countries.

#### *Commercial updates*

- On April 19, 2021, BioNTech and Pfizer announced an agreement with the European Commission (EC) to supply an additional 100 million doses of its COVID-19 vaccine, as a result of the EC's decision to exercise its option. The total number of doses to be delivered to the European Union by the end of 2021 is now 600 million.
- In April 2021, Pfizer and BioNTech entered into an agreement with Israel to supply several million doses in 2022, with an option to purchase additional doses. The companies also entered into an agreement with Canada to supply up to 125 million doses in 2022 and 2023, with options to purchase up to 60 million additional doses in 2024. Discussions for additional dose commitments with governments and territories worldwide are also ongoing for 2021 and beyond.
- On May 6, 2021, BioNTech and Pfizer announced that they have signed a Memorandum of Understanding with the International Olympic Committee to donate doses of COVID-19 Vaccine to help vaccinate athletes, and their delegations, participating in the Olympic and Paralympic Games Tokyo 2020, which are scheduled to take place in July 2021.
- On May 7, 2021, the European Commission (EC) announced that BioNTech and Pfizer plan to supply the EC with 900 million doses of COMIRNATY®, the Companies' COVID-19 vaccine, to the 27 European Union (EU) member states beginning December 2021 through 2023, with an option for the EC to request up to an additional 900 million doses. This contract is expected to close upon final confirmation by the EC.

### *Manufacturing updates*

- BioNTech expects capacity to reach up to 3 billion doses by end of 2021, and expects to have capacity to manufacture more than 3 billion doses in 2022.
- In March 2021, EMA approved the manufacturing of BioNTech's COVID-19 vaccine drug product at its facility in Marburg, Germany. This manufacturing facility is one of the largest mRNA vaccine manufacturing sites worldwide with an annual production capacity of up to one billion doses of COVID-19 vaccine, once fully operational. The first batches of vaccines manufactured at the Marburg facility were delivered in mid-April.
- BioNTech plans to deliver up to 250 million doses of BNT162b2 in the first half of 2021.

### **Oncology**

BioNTech is accelerating the development of a broad oncology pipeline, which has now advanced 14 product candidates in 15 ongoing trials. In April 2021 the Company started a first-in-human Phase 1 trial for the T cell therapy, targeting personalized neoantigens, named BNT221. Additional important milestones in the advancement of BioNTech's immuno-oncology pipeline in the first quarter of 2021 included the initiation of first-in-human trials for CARVac (BNT211) and RiboCytokines (BNT151). BioNTech also expects to further advance its oncology pipeline in 2021 with up to three additional programs expected to move into randomized Phase 2 trials. Additionally, three preclinical programs are expected to move into Phase 1 trials in the second half of 2021.

During the remainder of 2021, BioNTech expects at least four data updates from its ongoing clinical trials.

### **mRNA programs**

#### *FixVac*

- BNT111 – In collaboration with Regeneron, a randomized Phase 2 trial for the treatment of patients with advanced melanoma progressing during or after prior therapy with a PD-1 inhibitor, utilizing a combination of BNT111 and Regeneron and Sanofi's Libtayo® (cemiplimab) is planned to start in the first half of 2021.
- BNT113 – A Phase 2 trial evaluating BNT113 in combination with pembrolizumab versus pembrolizumab monotherapy as a first-line treatment in patients with unresectable recurrent or metastatic HPV16+ head and neck squamous cell carcinoma (HNSCC) expressing PD-L1, is planned to start in the first half of 2021 in the United States and the European Union. BNT113 has not been combined with anti-PD1 before and the Phase 2 trial will start with a run in portion designed to demonstrate the safety of the combination of BNT113 and pembrolizumab. These data are required to address the partial clinical hold on the subsequent randomized part of the Phase 2 trial.

#### *Individualized neoantigen specific immunotherapy (iNeST)*

- BNT122 (Autogene Cevumeran) – BioNTech's iNeST product candidate is partnered with Genentech.

For the adjuvant treatment of colorectal cancer, first patient dosing in a randomized Phase 2 trial in circulating tumor DNA positive, surgically resected Stage 2 (high risk)/Stage 3 colorectal cancer is now planned in the second half of 2021.

#### *RiboCytokines*

- BNT151 – A Phase 1/2a dose escalation trial evaluating BNT151 with expansion cohorts in multiple solid tumor indications is ongoing.
- BNT152+153 – BioNTech plans to start a Phase 1 trial for BNT152 (encoding IL-7) plus BNT153 (encoding IL-2) in multiple solid tumors in the first half of 2021.

#### *RiboMabs*

- BNT141 – In February 2021, the FDA approved the IND for a Phase 1 first-in-human clinical trial for BNT141. BioNTech plans to start the trial in the second half of 2021.
- BNT142 – BioNTech plans to start a Phase 1 clinical trial for BNT142 in the second half of 2021.

#### **Antibodies**

##### *Next-generation checkpoint immunomodulators*

BNT311 and BNT312 are partnered with Genmab.

- BNT311/GEN1046 – A Phase 1/2a dose escalation trial with multiple expansion cohorts in patients with malignant solid tumors is ongoing. A data update for the trial is planned in the second half of 2021.
- BNT312/GEN1042 – A Phase 1/2a dose escalation trial with expansion cohorts in patients with solid tumors is ongoing. The first data disclosure for the trial is planned in the second half of 2021.

#### **Cell therapies**

##### *CAR-T cell immunotherapy*

- BNT211 – A first-in-human Phase 1/2a open-label, multi-center dose escalation and dose expansion basket trial of BNT211 with Claudin-6 CAR-T cells as monotherapy, or in combination of Claudin-6 CAR-T cells with Claudin-6 CARVac, is ongoing. The trial is enrolling patients with CLDN6-positive relapsed or refractory advanced solid tumors including ovarian, testicular, lung, gastric and endometrial cancers. The combination of CLDN6 CAR-T cell immunotherapy and CARVac is expected to improve expansion and persistence of CLDN6 CAR-T.  
BioNTech plans to present early data from the ongoing BNT211 Phase 1/2a trial on three patients treated with a starting dose of CLDN6 CAR-T cells at the upcoming 18th Association for Cancer Immunotherapy (CIMT) Annual Meeting 2021. In these heavily pretreated patients with solid tumors, neither acute nor dose-limiting toxicities were observed and all adverse events were transient and mild to moderate. Robust CAR-T cell engraftment could be detected in all three patients, as well as early signs of clinical activity. Following completion of the first dose level with CAR-T cell monotherapy, the trial is now progressing to the next dose level and a combination treatment involving CAR-T cells with an RNA vaccine, which BioNTech refers to as CARVac. A data update is planned in the second half of 2021.

#### *Neoantigen-targeting T cell therapy*

- BNT221 – In April 2021, the first patient was dosed in a first-in-human Phase 1 dose escalation trial for the treatment of metastatic melanoma in patients who are refractory or unresponsive to checkpoint inhibitors. Part 1 consists of the monotherapy dose escalation of BNT221. In part 2, BNT221 will be added to anti-PD1 after first-line therapy. The primary objectives of the trial are to evaluate the safety and feasibility of administering BNT221, in addition to an evaluation of immunogenicity and clinical efficacy. BNT221 (NEO-PTC-01) is a personal neoantigen-targeted T cell therapy candidate derived from patients' peripheral blood cells. The product candidate consists of multiple CD8+ and CD4+ T cell populations targeting multiple selected neoantigens unique to each patient's tumor. The proprietary stimulation process allows for the induction of T cells from the naïve, as well as expansion of T cells from the memory compartment.

#### **Small molecule immunomodulators**

##### *Toll-like receptor binding agonist*

- BNT411 – A Phase 1/2a dose-escalation trial 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) is ongoing. A data update from this trial is planned in the second half of 2021.

#### **Corporate development**

- On May 9, 2021, BioNTech agreed the heads of terms with Fosun Pharma to establish a 50/50 Joint Venture (JV) to manufacture the COVID-19 vaccine in Mainland China. The establishment of a JV will be conditional on BioNTech receiving approval for its COVID-19 vaccine in Mainland China and agreement with Fosun Pharma on a definitive JV agreement, in addition to other conditions. As part of its global supply strategy, BioNTech believes that establishing local manufacturing capacity for the COVID-19 vaccine could substantially increase the Company's ability to supply vaccines to China upon approval.
- On May 10, 2021, BioNTech announced plans to expand its global footprint to Asia with the establishment of its first regional headquarters for southeast Asia in Singapore. In addition to selecting Singapore as its future regional headquarters, BioNTech plans to establish a fully integrated mRNA manufacturing facility in Singapore with support from the Singaporean Economic Development Board (EDB). The new facility will leverage cutting-edge manufacturing and digital infrastructure and will be equipped to produce a range of novel mRNA vaccines and therapeutics. The envisioned site will bring highly automated and end-to-end mRNA production capabilities. The facility, with an estimated annual capacity of several hundred million doses, will provide regional and global supply capacity, as well as a rapid response capability for southeast Asia to address potential pandemic threats. BioNTech plans to open its Singapore office and initiate construction of the manufacturing facility in 2021, subject to planning approval, and anticipates the site could be operational as early as 2023.

#### **First quarter 2021 financial results (unaudited)**

*Revenues:* Total revenues were estimated to be €2,048.4 million<sup>1</sup> for the three months ended March 31, 2021, compared to €27.7 million for the three months ended March 31, 2020. The

increase was mainly due to rapidly increasing the supply of COVID-19 vaccine worldwide. Under the collaboration agreements, territories have been allocated between BioNTech, Pfizer and Fosun Pharma based on marketing and distribution rights. BioNTech's commercial revenues include an estimated amount of €1,751.9 million<sup>1</sup> comprising BioNTech's share of gross profit from COVID-19 vaccine sales in Pfizer's territories, which represents a net figure, as well as sales milestones. In addition, €63.9 million sales to BioNTech's collaboration partners of products manufactured by BioNTech and €199.8 million direct COVID-19 vaccine sales to customers in BioNTech's territory have been recognized.

**Cost of Sales:** Cost of sales were estimated to be €233.1 million<sup>1</sup> for the three months ended March 31, 2021, compared to €5.9 million for the three months ended March 31, 2020. Estimated cost of sales of €223.2 million<sup>1</sup> were recognized with respect to BioNTech's COVID-19 vaccine sales and include Pfizer's share of gross profits earned by BioNTech.

**Research and Development Expenses:** Research and development expenses were €216.2 million for the three months ended March 31, 2021, compared to €65.1 million for the three months ended March 31, 2020. The increase was mainly due to an increase in research and development expenses for BioNTech's BNT162 program, recorded as purchased services with respect to those expenses, which were initially incurred by Pfizer and subsequently charged to BioNTech under the collaboration agreement. The increase was further driven by an increase in wages, benefits and social security expenses from increasing headcounts and recognizing expenses incurred under the new share-based-payment arrangements.

**General and Administrative Expenses:** General and administrative expenses were €38.9 million for the three months ended March 31, 2021, compared to €15.8 million for the three months ended March 31, 2020. The increase was mainly due to higher expenses for professional services, an increase in wages, benefits and social security expenses from increasing headcounts and recognizing expenses incurred under the new share-based-payment arrangements as well as higher insurance premiums.

**Income Taxes:** Interim income taxes were €514.2 million for the first quarter of 2021 and were recognized using the estimated annual effective income tax rate of approximately 31%.

**Net Profit / (Loss):** Net profit was €1,128.1 million for the three months ended March 31, 2021, compared to €53.4 million net loss for the three months ended March 31, 2020.

**Cash Position:** Cash and cash equivalents as of March 31, 2021 were €891.5 million.

**Shares Outstanding:** Shares outstanding as of March 31, 2021 were 241,521,065.

**Update on current signed COVID-19 vaccine order book:**

Estimated COVID-19 vaccine revenues to BioNTech upon delivery of currently signed supply contracts (~1.8 billion doses) is ~€12.4 billion.

The revenue estimate reflects:

- Expected revenues from direct COVID-19 vaccine sales to customers in BioNTech's territory
- Expected revenues from sales to collaboration partners of products manufactured by BioNTech
- Expected sales milestone payments from collaboration partners
- Expected revenues related to share of gross profit from COVID-19 vaccine sales in the collaboration partners' territories

Additional revenues related to further supply contracts for deliveries in 2021 expected with first contracts in place for 2022 and beyond.

Full year 2021 manufacturing capacity now targeting 3 billion doses and more than 3 billion doses for the year 2022.

**On Track with Previously Stated 2021 Financial Outlook:**

<b>Planned Full Year 2021 Expenses and Capex</b>	
R&D expenses	€750 million – €850 million Ramp-up of R&D investment in the second half of 2021 and beyond plan to accelerate pipeline development.
SG&A expenses	Up to €200 million
Capital expenditures	€175 million – €225 million
<b>Estimated Full Year 2021 Tax Assumptions</b>	
German tax group corporate tax rate	~31%

The full interim unaudited condensed consolidated financial statements can be found in BioNTech's Quarterly Report on Form 6-K, filed today with the SEC and available at <https://www.sec.gov/>.

<sup>1</sup> Estimated figures based on preliminary data shared between the collaboration partner and BioNTech as fully described in the Annual Report on Form 20-F as well as the Quarterly Report as of and for the Three Months Ended March 31, 2021, which is filed as an exhibit to BioNTech's Current Report on Form 6-K. Changes in the share of the collaboration partners' gross profit will be recognized prospectively.

<sup>2</sup> New England Journal of Medicine. Neutralizing Activity of BNT162b2-Elicited Serum; March 8, 2021. Available at <https://www.nejm.org/doi/full/10.1056/NEJMc2102017>

<sup>3</sup> Figures reflect current base case projections.

**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, bispecific 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](http://www.BioNTech.de)

### **Forward-Looking Statements**

This press release 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 revenues and net profit related to sales of our COVID-19 vaccine, referred to as COMIRNATY® in the European Union as authorized for use under conditional marketing approval, in territories controlled by our collaboration partners which are subject to numerous assumptions, particularly for those figures that are derived from preliminary estimates provided by our partners which are subject to numerous assumptions; our pricing and coverage negotiations with governmental authorities, private health insurers and other third-party payors after our initial sales to national governments; the extent to which a COVID-19 vaccine continues to be necessary in the future; competition from other COVID-19 vaccines or related to our other product candidates, including those with different mechanisms of action and different manufacturing and distribution constraints, on the basis of, among other things, efficacy, cost, convenience of storage and distribution, breadth of approved use, side-effect profile and durability of immune response; the rate and degree of market acceptance of our COVID-19 vaccine and our investigational medicines, if approved; the initiation, timing, progress, results, and cost of our research and development programs and our current and future preclinical studies and clinical trials, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available and our research and development programs; the timing of and our ability to obtain and maintain regulatory approval for our product candidates; our ability to identify research opportunities and discover and develop investigational medicines; the ability and willingness of our third-party collaborators to continue research and development activities relating to our development candidates and investigational medicines; the impact of the COVID-19 pandemic on our development programs, supply chain, collaborators and financial performance; unforeseen safety issues and claims for personal injury or death arising from the use of our COVID-19 vaccine and other products and product candidates developed or manufactured by us; our estimates of our expenses, ongoing losses, future revenue and capital requirements and our needs for or ability to obtain additional financing; our ability to identify, recruit and retain key personnel; our and our collaborators' ability to protect and enforce our intellectual property protection for our proprietary and collaborative product candidates, and the scope of such protection; the development of and projections relating to our competitors or our industry; our ability and that of our collaborators to commercialize and market our product candidates, if approved,

including our COVID-19 vaccine; our expected tax rate and the amount of and our ability to use net operating losses and research and development credits to offset future taxable income; our ability to manage our development and expansion; regulatory developments in the United States and foreign countries; our ability to effectively scale our production capabilities and manufacture our products, including our target COVID-19 vaccine production levels, and our product candidates; our ability to implement, maintain and improve effective internal controls; our plans for expansion in southeast Asia and China, including our planned regional headquarters and manufacturing facility in Singapore as well as the JV with Fosun Pharma; and other factors not known to us at this time.. 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 quarterly report 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 quarterly report 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.

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**Interim Condensed Consolidated Statements of Financial Position**

<i>(in millions)</i>	<b>March 31, 2021</b>	<b>December 31, 2020</b>
<b>Assets</b>	<i>(unaudited)</i>	
<b>Non-current assets</b>		
Intangible assets	€165.2	€163.5
Property, plant and equipment	242.4	227.0
Right-of-use assets	118.4	99.0
Other assets	1.0	1.0
Deferred tax assets	141.7	161.2
<b>Total non-current assets</b>	<b>€668.7</b>	<b>€651.7</b>
<b>Current assets</b>		
Inventories	146.9	64.1
Trade and other receivables	2,395.1	165.5
Other financial assets	0.5	137.2
Other assets	69.6	61.0
Income tax assets	0.9	0.9
Deferred expenses	31.5	28.0
Cash and cash equivalents	891.5	1,210.2
<b>Total current assets</b>	<b>€3,536.0</b>	<b>€1,666.9</b>
<b>Total assets</b>	<b>€4,204.7</b>	<b>€2,318.6</b>
<b>Equity and liabilities</b>		
<b>Equity</b>		
Share capital	246.3	246.3
Capital reserve	1,514.5	1,514.5
Treasury shares	(4.8)	(4.8)
Retained earnings / (Accumulated losses)	718.5	(409.6)
Other reserves	45.1	25.4
<b>Total equity</b>	<b>€2,519.6</b>	<b>€1,371.8</b>
<b>Non-current liabilities</b>		
Interest-bearing loans and borrowings	236.6	231.0
Other financial liabilities	73.0	31.5
Provisions	5.6	5.5
Contract liabilities	57.8	71.9
Other liabilities	1.0	0.6
Deferred tax liabilities	-	0.3
<b>Total non-current liabilities</b>	<b>€374.0</b>	<b>€340.8</b>
<b>Current liabilities</b>		
Interest-bearing loans and borrowings	18.0	9.1
Trade payables	106.2	102.3
Other financial liabilities	329.2	74.1
Government grants	3.2	92.0
Tax provisions	494.9	-
Other provisions	0.9	0.9
Contract liabilities	295.2	299.6
Other liabilities	63.5	28.0
<b>Total current liabilities</b>	<b>€1,311.1</b>	<b>€606.0</b>
<b>Total liabilities</b>	<b>€1,685.1</b>	<b>€946.8</b>
<b>Total equity and liabilities</b>	<b>€4,204.7</b>	<b>€2,318.6</b>

**Interim Condensed Consolidated Statements of Profit or Loss**

<i>(in millions, except per share data)</i>	<b>Three months ended March 31,</b>	
	<b>2021</b> <i>(unaudited)</i>	<b>2020</b> <i>(unaudited)</i>
Revenues		
Research & development revenues	€20.9	€21.2
Commercial revenues	2,027.5	6.5
<b>Total revenues</b>	<b>2,048.4</b>	<b>27.7</b>
Cost of sales	(233.1)	(5.9)
Research and development expenses	(216.2)	(65.1)
Sales and marketing expenses	(8.7)	(0.5)
General and administrative expenses	(38.9)	(15.8)
Other operating expenses*	(0.6)	(0.1)
Other operating income*	111.3	0.4
<b>Operating income / (loss)</b>	<b>€1,662.2</b>	<b>€(59.3)</b>
Finance income**	24.8	6.4
Finance expenses**	(44.0)	(0.1)
Interest expenses related to lease liabilities	(0.7)	(0.4)
<b>Profit / (loss) before tax</b>	<b>€1,642.3</b>	<b>€(53.4)</b>
Income taxes	(514.2)	-
<b>Profit / (Loss) for the period</b>	<b>€1,128.1</b>	<b>€(53.4)</b>
<b>Earnings per share</b>		
Basic profit / (loss) for the period per share	€4.64	€(0.24)
Diluted profit / (loss) for the period per share	€4.39	€(0.24)

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

\*\* Foreign exchange differences not related to operating activities 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.

**Interim Condensed Consolidated Statements of Cash Flows**

<i>(in millions)</i>	<b>Three months ended</b>	
	<b>March 31,</b>	
	<b>2021</b>	<b>2020</b>
	<i>(unaudited)</i>	<i>(unaudited)</i>
<b>Operating activities</b>		
Profit / (Loss) for the period	€1,128.1	€(53.4)
Income taxes	514.2	-
<b>Profit / (loss) before tax</b>	<b>€1,642.3</b>	<b>€(53.4)</b>
Adjustments to reconcile profit / (loss) before tax to net cash flows:		
Depreciation and amortization of property, plant, equipment and intangible assets	13.0	8.6
Share-based payment expense	17.3	8.4
Net foreign exchange differences	(31.2)	(0.3)
Gain on disposal of property, plant and equipment	0.2	0.1
Finance income	(0.3)	(0.4)
Interest on lease liability	0.7	0.4
Finance expense	44.0	0.1
Movements in government grants	(67.9)	-
Working capital adjustments:		
Increase in trade and other receivables, contract assets and other assets	(2,100.5)	(2.1)
Decrease / (Increase) in inventories	(82.8)	2.2
(Decrease) / Increase in trade payables, other financial liabilities, other liabilities, contract liabilities and provisions	255.5	(17.9)
Interest received	0.3	0.3
Interest paid	(1.8)	(0.5)
Income tax paid	(0.1)	(0.2)
<b>Net cash flows used in operating activities</b>	<b>€(311.3)</b>	<b>€(54.7)</b>
<b>Investing activities</b>		
Purchase of property, plant and equipment	(21.7)	(6.3)
Proceeds from sale of property, plant and equipment	0.9	-
Purchase of intangibles assets and right-of-use assets	(7.5)	(2.1)
Acquisition of subsidiaries and businesses, net of cash acquired	-	(6.5)
<b>Net cash flows used in investing activities</b>	<b>€(28.3)</b>	<b>€(14.9)</b>
<b>Financing activities</b>		
Proceeds from loans and borrowings	-	2.9
Repayment of loans and borrowings	(0.7)	-
Payments related to lease liabilities	(3.8)	(0.9)
<b>Net cash flows from/(used in) financing activities</b>	<b>€(4.5)</b>	<b>€2.0</b>
Net decrease in cash and cash equivalents	(344.1)	(67.6)
Change in cash and cash equivalents resulting from exchange rate differences	25.4	0.1
Cash and cash equivalents at January 1	1,210.2	519.1
<b>Cash and cash equivalents at March 31</b>	<b>€891.5</b>	<b>€451.6</b>



# First Quarter 2021

Corporate update and  
financial results

*May 10, 2021*



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## This slide presentation includes forward-looking statements

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended including BioNTech's efforts to combat COVID-19; the collaboration between BioNTech and Pfizer regarding a COVID-19 vaccine; our expectations regarding the potential characteristics of BNT162b2 in our continuing trials and/or in commercial use based on data observations to date, including real-world data gathered; the ability of BNT162b2 to prevent COVID-19 caused by emerging virus variants; the expected time point for additional readouts on trial data of BNT162b2 in our ongoing trials; the timing for submission of data for, or receipt of, any marketing approval or Emergency Use Authorization; our contemplated shipping and storage plan, including our estimated product shelf life at various temperatures; the ability of BioNTech to supply the quantities of BNT162 to support clinical development and market demand, including our production estimates and targets for 2021 and 2022; BioNTech's projected revenues for the COVID-19 vaccine in 2021; BioNTech's projected expenses, capital expenditures and tax rate for 2021; BioNTech's target vaccine production for 2021; BioNTech's COVID-19 vaccine revenues and net sales, which are subject to numerous estimates as more fully described in our Annual Report on Form 20-F and our Quarterly Report for the Three Months ended March 31, 2021; 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; BioNTech's plans for expansion in southeast Asia, including its planned regional headquarters and manufacturing facility in Singapore; and expectations for data announcements with respect to BioNTech's clinical trials. 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 quarterly report 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 quarterly report 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.

# Safety Information

## **AUTHORIZED USE IN THE U.S.:**

The Pfizer-BioNTech COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

## **IMPORTANT SAFETY INFORMATION FROM U.S. FDA EMERGENCY USE AUTHORIZATION PRESCRIBING INFORMATION:**

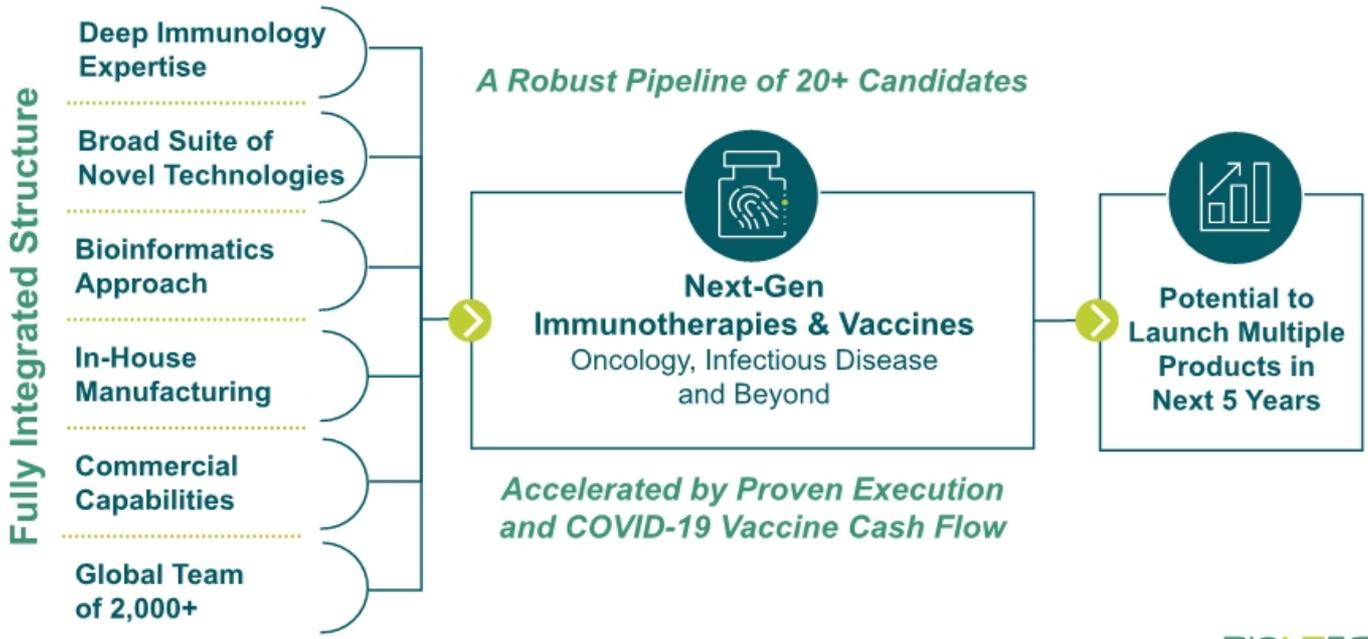
- Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine.
- Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine.
- Monitor Pfizer-BioNTech COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (<https://www.cdc.gov/vaccines/covid-19/>).
- Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer-BioNTech COVID-19 Vaccine.
- The Pfizer-BioNTech COVID-19 Vaccine may not protect all vaccine recipients.
- In clinical studies, adverse reactions in participants 16 years of age and older included pain at the injection site (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%), injection site swelling (10.5%), injection site redness (9.5%), nausea (1.1%), malaise (0.5%), and lymphadenopathy (0.3%).
- Severe allergic reactions, including anaphylaxis, have been reported following the Pfizer-BioNTech COVID-19 Vaccine during mass vaccination outside of clinical trials.
- Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Pfizer-BioNTech COVID-19 Vaccine.
- Available data on Pfizer-BioNTech COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.
- Data are not available to assess the effects of Pfizer-BioNTech COVID-19 Vaccine on the breastfed infant or on milk production/excretion.
- There are no data available on the interchangeability of the Pfizer-BioNTech COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Pfizer-BioNTech COVID-19 Vaccine should receive a second dose of Pfizer-BioNTech COVID-19 Vaccine to complete the vaccination series.
- Vaccination providers must report Adverse Events in accordance with the Fact Sheet to VAERS at <https://vaers.hhs.gov/reportevent.html> or by calling 1-800-822-7967. The reports should include the words "Pfizer-BioNTech COVID-19 Vaccine EUA" in the description section of the report.
- Vaccination providers should review the Fact Sheet for Information to Provide to Vaccine Recipients/Caregivers and Mandatory Requirements for Pfizer-BioNTech COVID-19 Vaccine Administration Under Emergency Use Authorization.

Please see Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) including Full EUA Prescribing Information available at [www.cvdvaccine-us.com](http://www.cvdvaccine-us.com).

## Agenda

First Quarter 2021 Highlights	COVID-19 Vaccine Update	Oncology Pipeline Update	Financial Results	Corporate Update & Outlook
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# Transformed into a Fully Integrated, Global Immunotherapy Company



# Building a 21st Century Global Immunotherapy Powerhouse



## Increase global footprint

- New regional headquarters planned in Singapore
- Commercial subsidiaries established in Germany and Turkey
- Offices established in the United States



## Expand integrated infrastructure

- Continue investment in innovation to support future product launches
- Invest in clinical, commercial and manufacturing, and digital capabilities
- Attract and retain top talent



## Rapidly advance pipeline

- 14 product candidates in 15 ongoing clinical trials
- 3 potentially registrational phase 2 trials initiating this year
- Advance innovations into first-in-human studies
- Strategic in-licensing to complement internal R&D

# Highlights From First Quarter 2021 and Beyond

## First Patients Dosed in Multiple First-in-Human Studies

- Next generation CAR-T in combination with CARVac (BNT211)
- NEO-STIM Neoantigen-targeting T cell therapy (BNT221)
- Ribocytokine (BNT151)

## Executorial Excellence in Infectious Disease with COVID-19 Vaccine

- >450M doses shipped to 91 countries and territories worldwide\*
- ~1.8 billion doses contracted to date for 2021, and with first contracts in place for 2022 and beyond
- €2.0 billion COVID-19 vaccine revenues in Q1
- Topline results confirming high efficacy and no serious safety concerns through up to six months following second dose
- 100% efficacy and robust antibody responses in Phase 3 trial of adolescents aged 12-15

\*as of May 6

7 In March 2021, BioNTech announced its Full Year 2020 Financial Results and Corporate Update as a part of the Annual Report filed in Form 20-F, highlighting developments relating to its COVID-19 vaccine program between January 1 and March 30, 2021. This slide focuses on developments that occurred after March 30, 2021.

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# Focused on Six Key Levers to Expand COVID-19 Vaccine Reach

## Increased Manufacturing Capacity

- Up to 3 billion doses by end of 2021; more than 3 billion doses in 2022
- First shipments from Marburg facility delivered mid April
- New regional headquarters in Singapore to house mRNA manufacturing facility

## Additional Populations

- Expect FDA feedback on EUA label expansion in adolescents 12 to 15 years in May
- Variation submitted to EMA to expand label in adolescents 12 to 15 years
- Ongoing study in children 6 months to 11 years of age; first data expected in Q3

## Additional Geographies

- Authorized or approved for emergency authorization in more than 70 countries worldwide
- Shipped to 91 countries and territories
- Regulatory submission for BLA in China underway

## Broadened & Decentralized Vaccine Access

- U.S. rolling BLA submission initiated
- Initiated Phase 3 trial to evaluate lyophilized and a ready-to use formulation; data expected in Q3
- Data submitted to FDA and EMA to broaden label to 4-week storage at 2°C to 8°C

## Addressing SARS-CoV-2 Variants

- Ongoing trial to evaluate variant-specific version BNT162b2<sub>SA</sub> in naïve and vaccinated individuals as well as third dose of BNT162b2 at 6 – 12 months post dose 2
  - Effect on waning immune response against original strain
  - Effect on immune response against variant strains

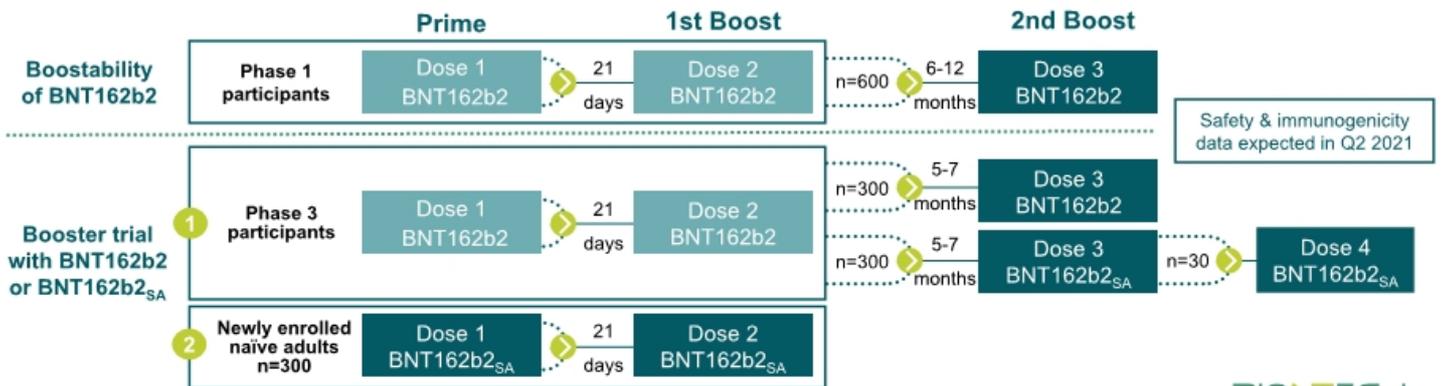
## Addressing Waning Immune Responses

8 In March 2021, BioNTech announced its Full Year 2020 Financial Results and Corporate Update as a part of the Annual Report filed in Form 20-F, highlighting developments relating to its COVID-19 vaccine program between January 1 and March 30, 2021. This slide focuses on developments that occurred after March 30, 2021.

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# Preemptive strategy to be prepared for addressing SARS-CoV-2 Variants

- **No evidence that adaptation of BNT162b2 is needed to date**
  - Sera of BNT162b2 vaccinated individuals neutralize B.1.1.7 (UK), B.1.351 (SA), and P.1 (Brazilian) lineage\* in *in vitro* studies
- **Expansion of global Phase 1/2/3 trials:**
  - 3<sup>rd</sup> dose to evaluate safety, magnitude and duration of immunity and variant protection
  - Variant specific booster to evaluate safety and immunogenicity of B.1.351 Spike version of BNT162b2 (BNT162b2<sub>SA</sub>)
  - “Blueprint” approach informs regulatory path and manufacturing



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9 \*B.117 (UK variant), B.1.351 (South African variant), and P.1 lineage (Brazilian variant)  
Liu et al., NEJM, Mar. 8, 2021

# Strong Order Book Growth in Q1

~1.8 billion doses contracted for 2021

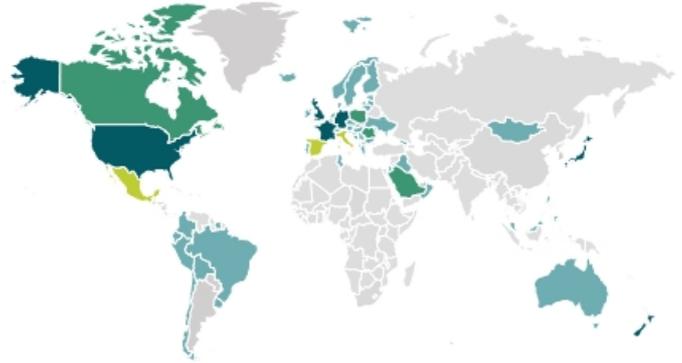
Selected Regions	Current Orders 2021
EU	600 million
US	300 million
Japan	144 million
UK	90 million
Other	~680 million

**First orders contracted for 2022 and beyond**

125 million doses for Canada in 2022/2023  
with option for 60 million in 2024

Millions of doses to be supplied to Israel in 2022

**Ongoing discussions in other regions for  
additional doses in 2021 and beyond**



**Expanding vaccine access to new  
populations & geographies with  
first supply contracts for post-2021**

## Manufacturing Capacity Increased to Address Worldwide Vaccine Need

- BioNTech now targeting 3 billion doses in 2021\*
  - Manufacturing capacity in 2022 to exceed 3 billion doses
- 
- BioNTech contributing more than 50% of drug substance
  - **Marburg site launch brings BioNTech manufacturing capacity to 1 billion doses annually**
  - BioNTech expects to deliver ~250 million doses in 1H 2021
  - Marburg site first batch delivered in April
  - Established mRNA manufacturing in Marburg facility in less than six months
  - To become one of the largest mRNA manufacturing sites worldwide



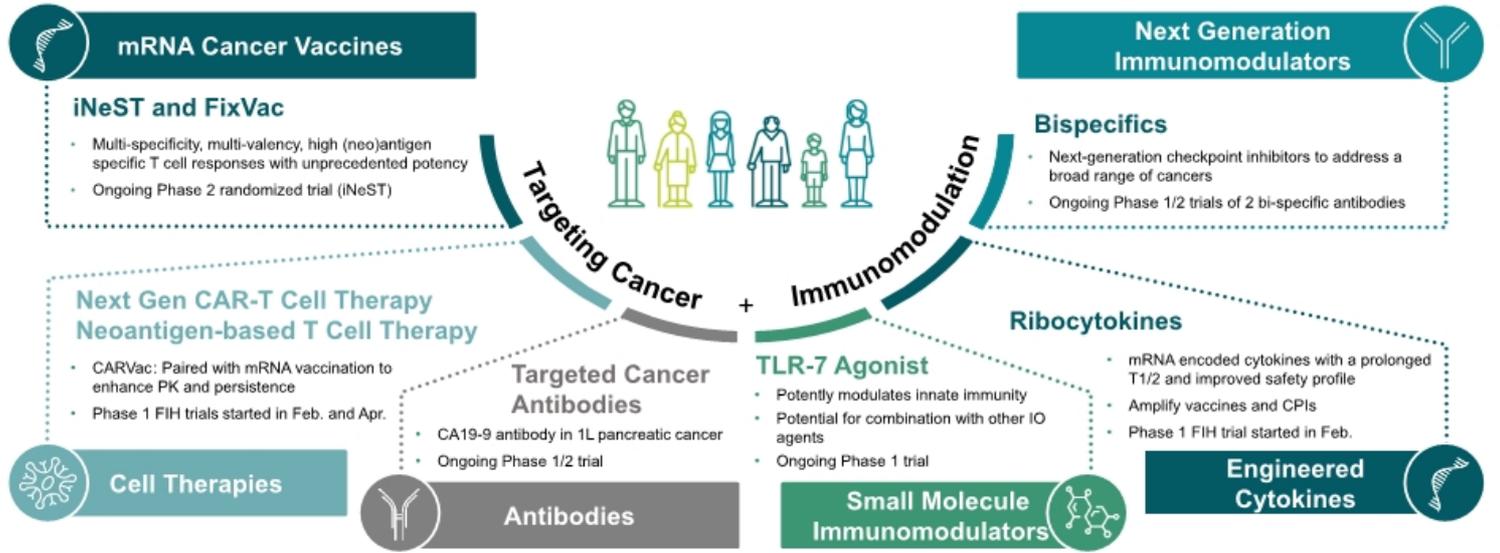
11 \*This assumes continuous process improvements and expansion at our current facilities and contingent upon adding more suppliers and contract manufacturers.

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## Agenda

First Quarter 2021 Highlights	COVID-19 Vaccine Update	<b>Oncology Pipeline Update</b>	Financial Results	Corporate Update & Outlook
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# Tackling Multiple Diseases with Different Therapeutic Modalities



Multiple blockbuster opportunities with synergistic combinations

13 PK, Pharmacokinetics; CA 19-9: Cancer antigen 19-9; IO, Immuno-oncology; CPI, Check-point Inhibitor

# Multiple Oncology Trials with Registrational Potential Starting in 2021

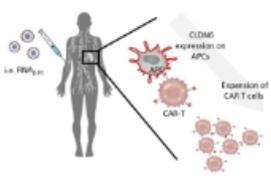
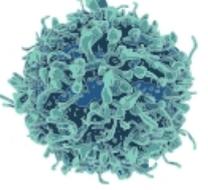
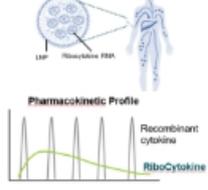
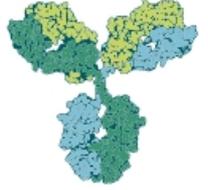
Plan to start randomized Phase 2 trials for 3 programs

..... Advanced Oncology Pipeline Programs ..... Near-Term Milestones .....

Drug Class	Platform	Product Candidate	Indication (Targets)	Preclinical	Phase 1	Phase 2	
mRNA	FixVac (fixed combination of shared cancer antigens)	BNT111	advanced melanoma				BNT111: Phase 2 to start in 1H 2021
		BNT113	HPV16+ head and neck cancer				BNT113: Phase 2 to start in 1H 2021
	iNeST (patient specific cancer antigen therapy)	autogene cevumeran (BNT122)	1L melanoma				BNT122: Phase 2 to start in 2H 2021 (adjuvant CRC)
			adjuvant colorectal cancer				
Antibodies	Next-Gen Checkpoint Immunomodulators	GEN1046 (BNT311)	solid tumors (PD-L1×4-1BB)				BNT311: Data update in 2H 2021
		GEN1042 (BNT312)	solid tumors (CD40×4-1BB)				BNT312: Data update in 2H 2021

14 Planned randomized trial start in 2021  
1L, first-line; CRC, Colorectal Cancer;

# Next Wave Oncology Advancing Innovation Beyond Current Boundaries

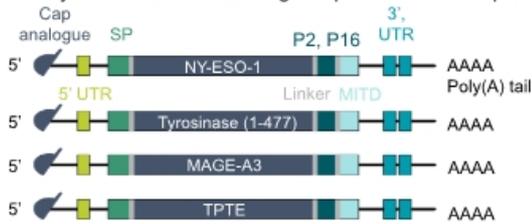
<b>CARVac</b> CAR-T cell amplifying mRNA therapy for solid tumors <sup>1</sup>	<b>NEOSTIM T cell therapy</b> Individualized Neoantigen specific T cell therapy	<b>RiboCytokines</b> mRNA encoded Cytokines	<b>RiboMabs<sup>2</sup></b> mRNA encoded Antibodies
 <ul style="list-style-type: none"> <li>• <b>BNT211 (CLDN 6 CAR)</b> Next generation CAR-T targeting CLDN6 with CARVac</li> </ul>	 <ul style="list-style-type: none"> <li>• <b>BNT221</b> PBMC derived ex vivo T cell therapy</li> </ul>	 <ul style="list-style-type: none"> <li>• <b>BNT151</b> (modified IL-2)</li> <li>• <b>BNT152 + BNT153</b> (IL-2/IL-7)</li> </ul>	 <ul style="list-style-type: none"> <li>• <b>BNT141</b> (undisclosed)</li> <li>• <b>BNT142</b> (CD3xCLDN6)</li> </ul>
Wholly owned: 			
FIH start: <b>FPD Feb. 2021</b>	<b>FPD Apr. 2021</b>	<b>BNT151: FPD Feb. 2021</b>	<b>2H 2021</b>

15 FPD, First patient dosed; CLDN6, Claudin-6, CAR-T cells, Chimeric antigen receptor T cells; IL-2, interleukin 2; IL-7, Interleukin 7; PBMC, peripheral blood mononuclear cells  
<sup>1</sup> Reinhard K, et al. Cancer Immunotherapy 2020; 367:446-453; 2 Stadler et al, Oncoimmunology 2018

# BNT111: FixVac Melanoma Compelling Preliminary Data

## Off-the-shelf mRNA Immunotherapy

- Fixed combination of non-nucleoside modified mRNA
- Encodes 4 tumor-associated antigens (TAA) covering ~95% of melanoma patients
- Intravenous formulation targets antigen presenting cells bodywide to stimulate antigen-specific T cell responses

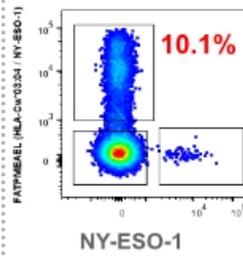


**nature**

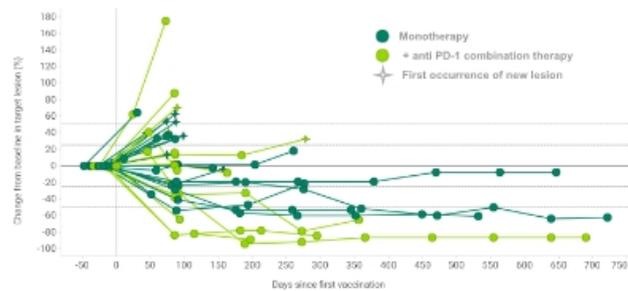
**An RNA vaccine drives immunity in checkpoint-inhibitor-treated melanoma**

Ugur Sahin, Petra Oehm, [...] Özlem Türeci

## Phase 1 trial in Advanced Melanoma published in Nature

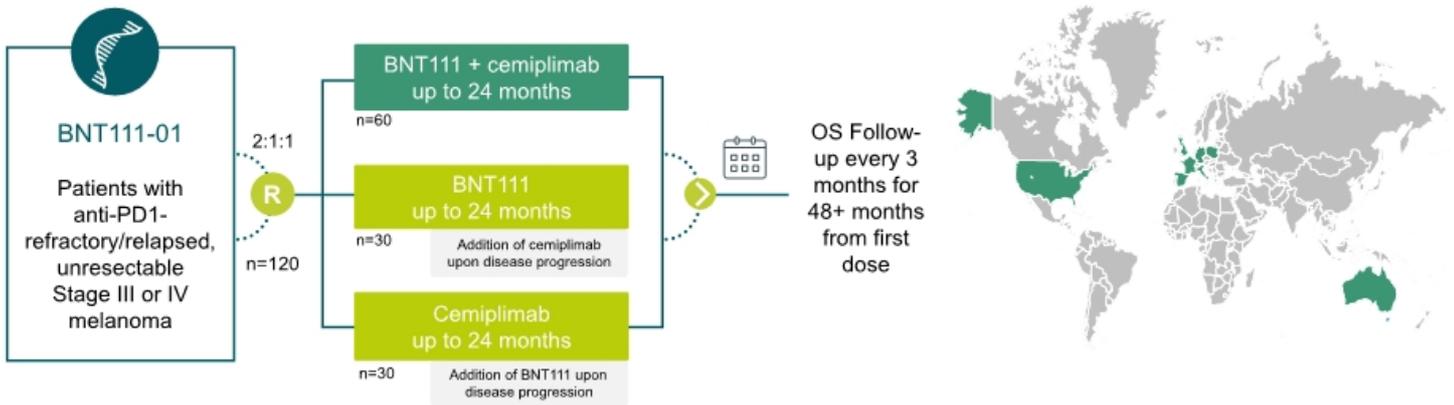


- Tolerable safety as monotherapy and in combination with CPI
- Durable Objective Responses in CPI-experienced patients with evaluable disease at baseline
  - ORR 35% for combination therapy (BNT111 + anti-PD1): 6/17 patients
- High-magnitude and persistent CD4+ and CD8+ T cell responses



16 TPTE, trans-membrane phosphatase with tensin homology; UTR, Untranslated Region; PD1, programmed death-ligand 1; CPI, Checkpoint inhibitor; ORR, overall response rate  
<https://www.nature.com/articles/s41586-020-2537-9>

# BNT111: FixVac Phase 2 Clinical Trial in anti-PD1 R/R Melanoma Patients



## Open-label, randomized Phase 2 trial with BNT111 and cemiplimab in combination or as single agents

- Collaboration with Regeneron

### Primary EP

- Arm 1: ORR by RECIST 1.1

### Secondary EP

- ORR (key secondary endpoint arms 2, 3)
- DOR, DCR, TTR, PFS, by RECIST 1.1
- OS, safety, tolerability, PRO

● main treatment arm

● calibrator arm

17 EP, endpoint; ORR, overall response rate; DOR, duration of response; DCR, disease control rate; TTR, time to response; PFS, progression free survival; OS, overall survival; PR, patient reported outcomes; R/R, refractory, relapsed  
<https://clinicaltrials.gov/ct2/show/record/NCT04526899>

# BNT211: Next Generation CAR-T Targeting CLDN6 with CARVac

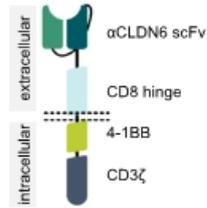
**CANCER IMMUNOTHERAPY**

## An RNA vaccine drives expansion and efficacy of claudin-CAR-T cells against solid tumors

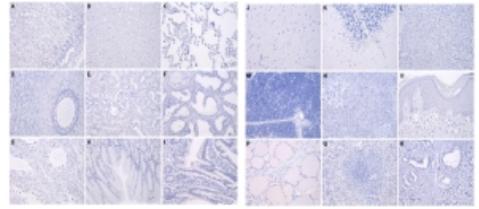
Katharina Reinhard<sup>1</sup>, Benjamin Rengstl<sup>1</sup>, Petra Oehm<sup>1</sup>, Kristina Michel<sup>1</sup>, Arne Billmeier<sup>1</sup>, Nina Hayduk<sup>1</sup>, Oliver Klein<sup>1</sup>, Kathrin Kunz<sup>1</sup>, Yasmina Ouchan<sup>1</sup>, Stefan Wolf<sup>1</sup>, Elmar Christ<sup>1</sup>, David Weber<sup>2</sup>, Martin Suchan<sup>2</sup>, Thomas Bukur<sup>2</sup>, Matthias Birtel<sup>1</sup>, Veronika Jahndel<sup>1</sup>, Karolina Mraz<sup>1</sup>, Kathleen Hobohm<sup>1</sup>, Lena Kranz<sup>1</sup>, Mustafa Diken<sup>2</sup>, Klaus Kühnke<sup>1</sup>, Özlem Türeci<sup>1,3,4,5,6,7,8,9,10,11</sup>



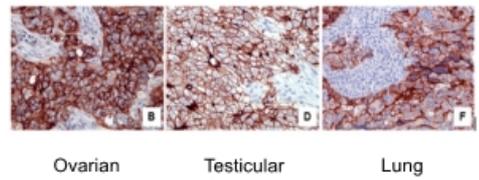
## BNT211 CAR Structure



### CLDN6 not present in healthy tissues



### CLDN6 expressed in multiple cancers

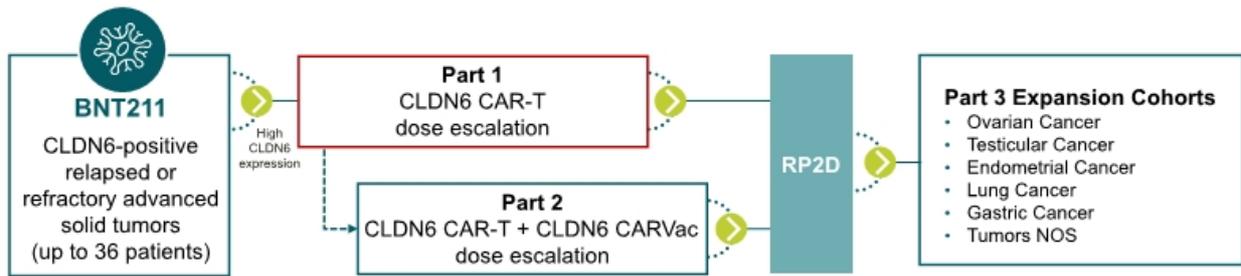


## CAR-T cell therapy + RNA Vaccine to amplify CAR-T cell *in vivo*

- New 2<sup>nd</sup> generation CAR directed against CLDN6, a new highly cancer cell specific carcino-embryonic antigen
- CLDN6 is expressed in multiple solid cancers with high medical need tumor types
- CARVac drives *in vivo* expansion, persistence and efficacy of CAR-T

18 CLDN6, Claudin-6; CAR-T cells, chimeric antigen receptor engineered T cells; scFv, single chain variable fragment  
Reinhard K, et al. Science 2020; 367:446-453

# BNT211: Next Generation CAR-T Therapy in Solid Tumors



## An open-label Phase 1/2a study of BNT211 in patients with advanced solid tumors

- Evaluation of safety and tolerability
- Ongoing Phase 1/2a study
- Monotherapy dose level 1 completed (3 patients)

19 CLDN6, Claudin-6; CAR-T cells, Chimeric Antigen Receptor engineered T cells; RP2D, recommended Phase 2 dose; NOS, not otherwise specified  
NCT04503278, <https://clinicaltrials.gov/ct2/show/NCT04503278>

# BNT211: CAR-T Engraftment and Stable Disease in First 2 Patients

Patient #	1	2	3
Age, gender	68 y, female	25 y, male	33 y, male
Tumor entity	Ovarian CA	Sarcoma	Testicular CA
CLDN6 II/III+	60%	80%	60%
Stage	FIGO IIIc	unknown	IIIc
Prior treatment lines	5	3	4
CAR-T infusion	FEB2021	MAR2021	MAR2021
DLTs	0	0	0
AEs ≥ grade 3*	0	0	0
CAR-T engraftment	9x (days 3-17)	>700x (days 3-24)	90x (days 3-10)

## First dose level was well tolerated

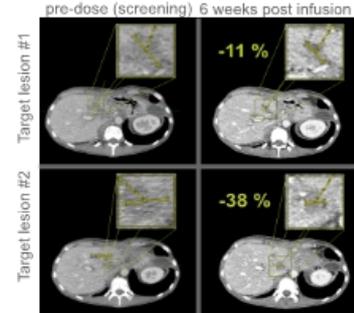
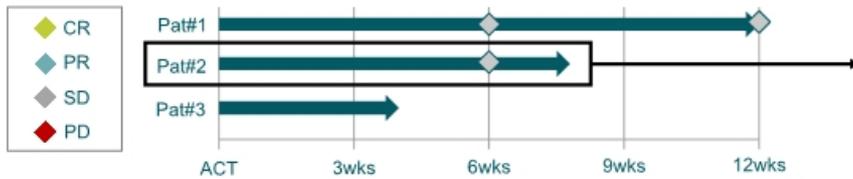
- AEs Mild to Moderate & Transient
  - No AEs ≥ grade 3 and no DLTs

## CAR-T detectable across different tumor types

- Robust engraftment in all patients,
  - Follow-up days 3-24 for patient #1 and #2, and days 3-10 for patient #3 post CAR-T cell transfer

## Tumor Reduction in Patient #2:

- 19.7% shrinkage of tumor (RECIST 1.1)



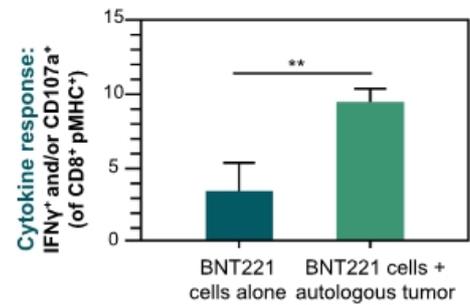
20 DLT, dose limiting toxicity; Pat, patient; CR, complete response; PR, partial response; SD, stable disease; PD, progressive disease; LD, lymphodepletion; FIGO, International Federation of Gynecology and Obstetrics; CLDN6, Claudin-6; AE, adverse event; CAR-T, Chimeric Antigen Receptor engineered T cells  
\* Suspected to be related to drug product

# BNT221: NEO-STIM<sup>®</sup> Personalized Neoantigen-Targeted Adoptive Cell Therapy

## Addresses limitations of TIL cell therapy approaches

- T cells induced from peripheral blood (NEO-STIM)
  - No gene engineering or viral vectors
- Targets each patient's personal tumor neoantigens
- Multiple specific CD8<sup>+</sup> and CD4<sup>+</sup> T cell populations that are functional and have a favorable phenotype
- First patient dosed in Phase 1 trial in anti-PD-1 experienced unresectable stage III or IV melanoma

BNT221 cells specifically recognize autologous tumor



21 TIL, tumor-infiltrating lymphocyte  
Lenkala D, et al. J Immunother Cancer 2020; 8(Suppl 3) A153

## Agenda

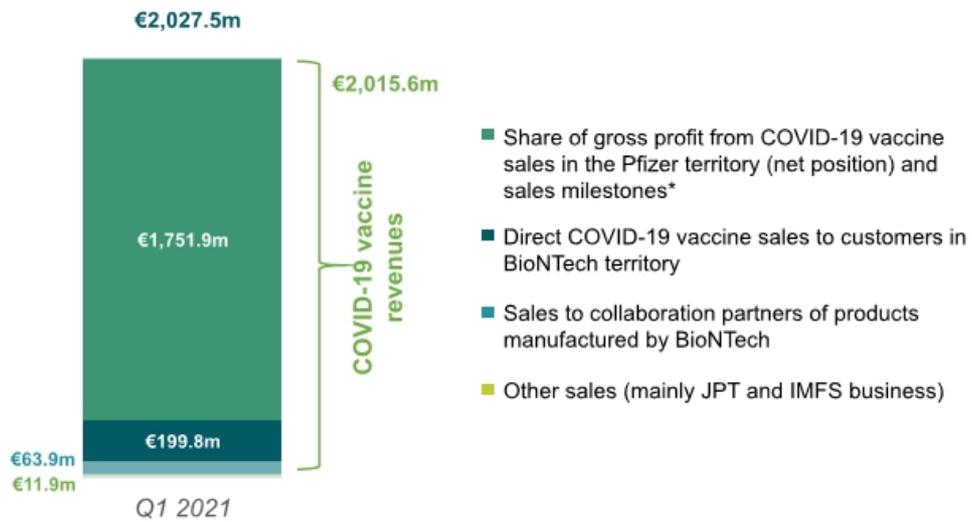
First Quarter 2021 Highlights	COVID-19 Vaccine Update	Oncology Pipeline Update	<b>Financial Results</b>	Corporate Update & Outlook
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## First Quarter 2021 Financial Results (unaudited) – Profit or Loss

<i>(in millions, except per share data)*</i>	Three months ended March 31	
	2021	2020
• Research & development revenues	€20.9	€21.2
• Commercial revenues	2,027.5	6.5
<b>Total revenues</b>	<b>€2,048.4</b>	<b>€27.7</b>
• Cost of sales	(233.1)	(5.9)
• Research and development expenses	(216.2)	(65.1)
• Sales and marketing expenses	(8.7)	(0.5)
• General and administrative expenses	(38.9)	(15.8)
• Other operating income less expenses	110.7	0.3
<b>Operating profit / (loss)</b>	<b>€1,662.2</b>	<b>€(59.3)</b>
• Finance income less expenses	(19.9)	5.9
• Income taxes	(514.2)	-
<b>Profit / (loss) for the period</b>	<b>€1,128.1</b>	<b>€(53.4)</b>
<b>Earnings per share</b>		
• Basic profit / (loss) for the period per share	€4.64	€(0.24)
• Diluted profit / (loss) for the period per share	€4.39	€(0.24)

# First Quarter 2021 COVID-19 Vaccine Deliveries Drove Revenue Growth

## Commercial revenues – identified revenue streams



\*Represents an estimated figure based on preliminary data shared between Pfizer and BioNTech. Changes in share of the collaboration partner's gross profit will be recognized prospectively.

## On Track with Previously Stated Financial Outlook

### Update on Current Signed COVID-19 Vaccine Order Book

- Estimated COVID-19 vaccine revenues to BioNTech upon delivery of signed supply contracts as of May 4, 2021 (~1.8 billion doses): ~€12.4 billion

### Planned Full Year 2021 Expenses and Capex

- R&D expenses: **€750 million – €850 million**
- SG&A expenses: **Up to €200 million**
- Capital expenditures: **€175 million – €225 million**
- *Ranges reflect current base case projections*
- *Ramp-up of R&D investment in 2H 2021 and beyond planned to broaden and accelerate pipeline development*

### Estimated Full Year 2021 Tax Assumptions

- German corporate tax rate: **~31%**

## Agenda

First Quarter 2021 Highlights	COVID-19 Vaccine Update	Oncology Pipeline Update	Financial Results	Corporate Update & Outlook
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## Increasing Our Global Footprint

- First location in Asia: regional headquarters in Singapore to house mRNA manufacturing facility with support from Singapore Economic Development Board
- Growing international workforce with teams in United States, an affiliate in Turkey and commercial organization, including salesforce in Germany



## Significant Pipeline Milestones expected in 2021

### 5+ Trial Updates



- **BNT162b2:** Multiple updates
- **BNT311:** Bi-specific CPI: PD-L1 x 4-1bb in solid tumors
- **BNT312:** Bi-specific checkpoint immunomodulator CD40 x 4-1bb in solid tumors
- **BNT211:** CLDN-6 CAR-T + CARVac in solid tumors
- **BNT411:** TLR-7 agonist +/- CPI in solid tumors

### 3 Randomized Phase 2 Trial Starts



- **BNT111:** FixVac + CPI in refractory melanoma
- **BNT113:** FixVac HPV16+ + CPI in 1L HNSCC
- **BNT122:** iNeST (autogene cevumeran) + CPI in adjuvant mCRC

### 7 First-in-human Phase 1 Trial Starts



- ✓ **BNT211:** CLDN-6 CAR-T + CARVac in solid tumors
- ✓ **BNT151:** Ribocytokine (modified IL-2)
- ✓ **BNT221:** NEOSTIM individualized neoantigen-T cell therapy in melanoma
- **BNT152+153:** RiboCytokine IL-2 / IL-7 combo in solid tumors
- **BNT141:** RiboMab (undisclosed)
- **BNT142:** RiboMab bi-specific CPI in solid tumors (CD3xCLDN6)
- **BNT161:** Influenza vaccine

28 CLDN6, Claudin-6; CAR-T cells, Chimeric antigen receptor T cells; IL-2, interleukin 2; IL-7, Interleukin 7; CPI, check-point inhibitor; HNSCC, head and neck squamous cell carcinoma; mCRC, metastatic colorectal cancer

# Strong Financial Position, Fully-Integrated Structure Enable Execution on Strategic Priorities for 2021

Vaccine revenue provides significant working capital to build long-term value for patients, shareholders and society



- **Continue to execute while driving iterative innovation against COVID-19**
  - Deliver COVID-19 vaccine to >1 billion people globally



- **Broaden and diversify early- and late-stage pipeline of next generation immunotherapies**
  - Accelerate pipeline in core therapeutic areas
    - Immuno-oncology: Usher in new era of individualized cancer medicine and *in vivo* cell therapy
    - Infectious disease: Advance mRNA vaccines and therapeutics to address infectious diseases beyond COVID-19
  - Further optimize platforms and initiate early product development in emerging areas
- **Increase global footprint and expand integrated infrastructure**

The logo for BIONTECH, with 'BIONTECH' in a light green, sans-serif font. The background of the entire page is a dark teal color with a pattern of faint, overlapping white circles and arcs.

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