# 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 MARCH 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):

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

On March 30, 2021, BioNTech SE (the "Company") issued a press release announcing its full year 2020 financial results and corporate update and details of a conference call to be held at 8:00 am EST on March 30, 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.

#### 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: <u>/s/ Dr. Sierk Poetting</u> Name: Dr. Sierk Poetting Title: Chief Financial Officer

Date: March 30, 2021

#### EXHIBIT INDEX

<u>Exhibit</u>	Description of Exhibit
99.1	BioNTech Announces Full Year 2020 Financial Results and Corporate Update
99.2	Fourth Quarter and Full Year 2020: Corporate Update and Financial Results



#### **BioNTech Announces Full Year 2020 Financial Results and Corporate Update**

- BNT162b2 vaccine approved or authorized for emergency or temporary use in over 65 countries and regions after successful global Phase 3 trial demonstrated safety and efficacy in preventing COVID-19.
- More than 200 million doses of BNT162b2 supplied as of March 23, 2021, with signed orders for 1.4 billion doses to date for delivery in 2021. BioNTech and Pfizer expect to expand manufacturing capacity to up to 2.5 billion doses by end of 2021.
- Evaluation of safety and immunogenicity of a third BNT162b2 dose initiated to understand the effect of a booster to prolong immunity and protection against COVID-19 caused by the circulating and potential newly emerging SARS-CoV-2 variants, with additional studies planned.
- In oncology, first patient dosed in first-in-human trials for CARVac (BNT211) and RiboCytokines (BNT151). Development of oncology
  pipeline is accelerating with 13 product candidates in 14 ongoing trials; at least four data updates, up to three programs expected to
  move into randomized Phase 2 trials, and six preclinical programs moving into Phase 1 trials.
- Recognized first commercial COVID-19 vaccine revenues. Total COVID-19 vaccine revenues of €270.5 million<sup>1</sup> for the Full Year 2020.
- Ended Full Year 2020 with strengthened financial position; cash and cash equivalents of €1.2 billion mainly as a result of financing transactions completed during the year.

Conference call and webcast scheduled for March 30, 2021, at 08:00 a.m. ET (2:00 p.m. CET)

**MAINZ, Germany, March 30, 2021 (GLOBE NEWSWIRE)** -- <u>BioNTech SE</u> (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 and full year ended December 31, 2020.

"2020 was a transformational year for BioNTech with the development and approval of the first mRNA drug in history. As of March 2021, we had delivered more than 200 million doses of our vaccine to more than 65 countries and regions together with our partners, and we are already seeing the first signs of vaccine associated reduction of COVID-19 cases and mortality in multiple countries" said **Ugur Sahin, Co-founder and CEO of BioNTech**. "We will continue to focus on innovating in the COVID-19 field by advancing new formulations and addressing vaccine variants, as well as initiating new trials in additional sub-populations. At the same time, we are accelerating the development of our cancer immunotherapies. We see a tremendous opportunity to reinvest the proceeds from our COVID-19 vaccine into extending and accelerating the research and development of new vaccines and therapeutics to improve the health of people worldwide by harnessing the full potential of the immune system."

#### Fourth Quarter 2020 and Subsequent Updates

#### Infectious disease

#### COVID-19 vaccine program – BNT162b2

In December 2020, BNT162b2 became the first mRNA vaccine to be approved or authorized for emergency or conditional use. BNT162b2 now has authorization or approval for emergency use or temporary use in more than 65 countries worldwide, including the United States, United Kingdom and European Union.

- On November 18, 2020, BioNTech and Pfizer announced that BNT162b2 met the Phase 3 study's primary efficacy endpoints in the final efficacy analysis. Analysis of the data indicated a vaccine efficacy rate of 95% for the prevention of a COVID-19 disease, measured seven days after the second dose. No serious safety concerns related to the vaccine were observed in the trial, with most solicited adverse events resolving shortly after vaccination. On December 10, 2020, results from the trial were published in the *New England Journal of Medicine*.
- On March 11, 2021, BioNTech and Pfizer announced additional real-world evidence data from the Israel Ministry of Health (MoH) that demonstrated dramatically lower incidence rates of COVID-19 disease in individuals fully vaccinated with our COVID-19 vaccine. The latest data from the MoH show that two weeks after the second vaccine dose, protection is even stronger with a vaccine effectiveness of at about 97% in preventing symptomatic disease, severe/critical disease and death. The analysis also showed a vaccine effectiveness of 94% against asymptomatic SARS-CoV-2 infections. Since this observational analysis was conducted when the variant B.1.1.7 (UK variant) was the dominant strain in Israel, it also provides real-world evidence of the effectiveness of BNT162b2 for prevention of COVID-19 infections, hospitalizations and deaths due to variant B.1.1.7. The data from this observational analysis were published on March 24, 2021, on *Lancet*'s preprint server.

#### Clinical development updates

- On October 21, 2020, BioNTech and Pfizer announced the start of a Phase 1/2 clinical trial in Japan to evaluate safety, tolerability and immunogenicity of BNT162b2 in healthy adults 20 to 85 years of age.
- On November 25, 2020, BioNTech and Fosun Pharma announced the start of a Phase 2 clinical trial of BNT162b2 in China to evaluate the safety and immunogenicity of BNT162b2 in healthy adults.
- On February 18, 2021, BioNTech and Pfizer announced that the first participants were dosed in a global Phase 2/3 trial to evaluate the safety, tolerability and immunogenicity of BNT162b2 in preventing COVID-19 in approximately 4,000 healthy pregnant women 18 years of age and older. The study will also assess safety in infants of vaccinated pregnant women and the transfer of potentially protective antibodies to their infants.

- On February 18, 2021, BioNTech and Pfizer announced that safety and efficacy data from the global Phase 3 study with subjects 12 to 15 years of age are expected to be submitted to the regulatory authorities in the second quarter of 2021.
- On February 25, 2021, BioNTech and Pfizer announced a trial to evaluate the safety and immunogenicity of a third dose of our COVID-19 vaccine on prolonging immunity against COVID-19 and to address potential newly emerging SARS-CoV-2 variants.
- In March, 2021, the U.S Food and Drug Administration (FDA) approved an additional amendment to the study protocol of the global Phase 1/2/3 trial for an additional dose of BNT162b2 or its modified version carrying the spike protein sequence of the South African variant (BNT162b2SA) in order to further describe duration of protection, and protection against the emerging variants of concern. An additional dose of either BNT162b2 or BNT162b2SA will be given to approximately 600 Phase 3 participants about five to seven months after their second dose of BNT162b2. A further dose of BNT162b2SA will be given to approximately 30 of those participants who receive BNT162b2SA. Approximately 300 BNT162b2-naïve participants will be enrolled and receive two doses of BNT162b2SA to describe protection against the emerging variants of concern and reference strains. The part of the trial with BNT162b2SA is expected to start in the second quarter of 2021.
- In March 2021, first participants were dosed in a Phase 1/2/3 study in healthy children 6 months to under 12 years of age. The Phase 1 dose-finding portion will evaluate the safety, tolerability and immunogenicity of two doses of BNT162b2 separated by 21 days in up to three age groups. Once the preferred dose level of BNT162b2 is identified for each age group, a Phase 2/3 trial to evaluate the safety, tolerability and immunogenicity on each age group will start. In addition, efficacy against confirmed COVID-19 and against asymptomatic infection will be assessed. Approximately 450 participants (300 in the BNT162b2 group and 150 in the placebo group) in each age group are expected to contribute to the immunobridging and persistence of immune response at 6 months after second dose analyses. Participants will be unblinded at the 6-month follow-up visit and participants that received placebo will be offered the opportunity to receive BNT162b2. All of the expected 4,500 participants will contribute to the vaccine effectiveness (VE) analysis for conditional VE and asymptomatic infection.
- BioNTech and Pfizer are also planning studies to further evaluate the vaccine in people with compromised immune systems.
- BioNTech and Pfizer will start a Phase 3 trial to evaluate the safety, tolerability and immunogenicity of lyophilized BNT162b2 presented in single-dose vials and of frozen liquid BNT162b2 in multidose vials. This trial will also assess the non-inferiority of the lyophilized formulation. The trial will be conducted in healthy adults 18 through 55 years of age and will start in the United States in April. We expect data from this trial in the third quarter of 2021.

#### Data on SARS-CoV-2 variants

• On March 8, 2021, BioNTech and Pfizer published data in the *New England Journal of Medicine* from an *in vitro* study of the neutralizing activity of BNT162b2-elicited serum

against the variants first detected in the United Kingdom (B.1.1.7 lineage), Brazil (P.1 lineage) and South Africa (B.1.351 lineage). The findings provide strong support that BNT162b2 will continue to protect against the B.1.1.7 lineage and the P.1 lineage. Sera neutralized all the viruses tested and showed no significant reduction in activity against both B.1.1.7-spike and P.1-spike viruses. While neutralization of the B.1.351-spike virus was lower, it was still robust.

#### Regulatory updates

- On December 2, 2020, BioNTech and Pfizer announced that the Medicines & Healthcare Products Regulatory Agency (MHRA) in the United Kingdom granted a temporary authorization for emergency use for BNT162b2 against COVID-19.
- On December 11, 2020, BioNTech and Pfizer announced that the U.S. FDA authorized the emergency use of BNT162b2 in individuals 16 years of age or older. BNT162b2 is authorized in the United States under an Emergency Use Authorization (EUA) while BioNTech and Pfizer gather additional data and prepare to file a planned Biologics License Application (BLA) with the U.S. FDA for full regulatory approval in 2021.
- On December 21, 2020, BioNTech and Pfizer announced the European Commission (EC) granted a conditional marketing authorization (CMA) for BNT162b2 in individuals 16 years of age and older. The CMA is valid in all 27 member states of the European Union.
- On February 14, 2021, Japan's Health Ministry approved BNT162b under the exceptional approval scheme in Japan.
- On February 25, 2021, the U.S. FDA and on March 26, 2021, the EMA, approved that undiluted frozen vials of BNT162b2 may be transported and stored at conventional temperatures commonly found in pharmaceutical freezers (-25°C to -15°C or -13°F to 5°F) for a period of up to two weeks. Further formulation optimization activities are ongoing.

#### **Commercial Updates**

We and our collaboration partners have supplied more than 200 million doses of our COVID-19 vaccine worldwide, as of March 23, 2021.

BioNTech and Pfizer have signed orders of 1.4 billion doses for delivery in 2021. Discussions for additional dose commitments are ongoing.

- On February 12, 2021, BioNTech and Pfizer announced that the U.S. government exercised its option for an additional 100 million doses of our COVID-19 vaccine. This agreement brings the total number of doses to be delivered to the United States to 300 million. Consistent with the agreements for the prior 200 million doses, the U.S. government will pay \$1.95 billion for the additional 100 million doses.
- On February 17, 2021, BioNTech and Pfizer announced an agreement with the EC to supply an additional 200 million doses of our COVID-19 vaccine. The EC has an option for an additional 100 million doses. The total number of doses to be delivered to the European Union by the end of 2021 is now 500 million, with an option for an additional 100 million doses.

#### Manufacturing

BioNTech and Pfizer expect to increase BNT162b2 manufacturing capacity to up to 2.5 billion doses by the end of 2021. The increase is driven by the optimization of production processes, the recent initiation of production at BioNTech's Marburg, Germany facility, regulatory approval for six dose vials, and the expansion of our manufacturing and supplier network. Additional measures and discussions with potential partners to further expand the manufacturing capacity and network are ongoing.

- In October 2020, BioNTech acquired a GMP manufacturing facility in Marburg, Germany, to accelerate BNT162b2 manufacturing scaleup for commercial supply in 2021.
- On March 26, 2021, BioNTech announced that the European Medicines Agency (EMA) approved the manufacturing of our COVID-19 vaccine drug product at the facility in Marburg. The approvals make BioNTech's Marburg manufacturing site one of the largest mRNA vaccine manufacturing sites worldwide with an annual production capacity of up to one billion doses of our COVID-19 vaccine, once fully operational. Due to optimized operational efficiencies which were initiated last year, BioNTech was able to increase the expected annual manufacturing capacity by 250 million doses. The first batches of vaccines manufactured at the Marburg site are expected to be delivered in the second half of April. BioNTech plans to produce up to 250 million doses of BNT162b2 in the first half of 2021.

#### Oncology

BioNTech is accelerating the development of its broad oncology pipeline with 13 product candidates in 14 ongoing trials. In 2021, we expect at least four data updates from our oncology pipeline with up to three programs expected to move into randomized Phase 2 trials and six preclinical programs moving into Phase 1 trials. This includes the first-in-human trials started for the lead candidates for both the CARVac (BNT211) and RiboCytokines (BNT151) product candidates.

#### mRNA programs

FixVac

- BNT111 We expect to start 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<sup>®</sup> (Cemiplimab) in the first half of 2021 in the United States and the European Union. Our IND for this trial in the United States is active as is a CTA approval in the European Union.
- BNT113 We expect to start 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 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)

Our iNeST product candidate BNT122 is partnered with Genentech.

- BNT122 has been given the international non-proprietary name (INN) "autogene cevumeran".
- An open-label Phase 1a/1b trial evaluating the safety, tolerability, immune response and pharmacokinetics of autogene cevumeran as a single agent and in combination with atezolizumab in patients with locally advanced or metastatic solid tumors (basket trial) is ongoing.
- A Phase 2 open-label trial evaluating the efficacy and safety of autogene cevumeran in combination with pembrolizumab versus
  pembrolizumab alone in patients with previously untreated advanced melanoma is ongoing.
- Given challenging accrual timelines in the context of the SARS-CoV-2 pandemic and the evolving landscape of treatment options in non-small cell lung cancer (NSCLC), BioNTech and Genentech decided to discontinue the previously planned Phase 2 trial in patients with high-risk resected early stage NSCLC. Genentech and BioNTech are evaluating further options for treating early disease cancer patients with autogene cevumeran.
- One of these early disease development options is 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 expected in the first half of 2021.

#### RiboCytokines

- BNT151 is a nucleoside-modified mRNA encoding for an IL-2 variant, a key cytokine in T cell immunity supporting the differentiation, proliferation, survival and effector functions of T cells. BNT151 is designed to stimulate anti-tumoral T cells without extensively triggering immunosuppressive regulatory T cells. In February 2021, the first patient was dosed in a first-in-human, open-label, multicenter Phase 1/2a trial. The trial evaluates dose escalation, safety, pharmacokinetics and pharmacodynamics of BNT151 with expansion cohorts in multiple solid tumor indications, including HNSCC, hepatocellular carcinoma (HCC), renal cell cancer (RCC), NSCLC, and triple-negative breast cancer (TNBC). The monotherapy dose escalation will enroll patients with 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.
- BNT152+153 In February, the U.S. FDA approved the IND for a Phase 1 trial for BNT152+153. We plan 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, the U.S. FDA approved the IND for a Phase 1 first-in-human clinical trial for BNT141. We expect to start the trial in the second half of 2021.
- BNT142 We expect 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 Data from a first-in-human Phase 1/2a trial of BNT311 (PD-L1x4-1BB) in 61 heavily pretreated patients with advanced solid tumors was presented at the SITC conference in November 2020. We expect a data update from this trial in the second half of 2021.
- BNT312/GEN1042 We expect first data disclosure from the Phase 1/2a trial of BNT312 in solid tumors in the second half of 2021.

#### **Cell therapies**

#### CAR-T cell immunotherapy

BNT211, BioNTech's most advanced CAR-T product candidate, targets the tumor-specific antigen CLDN6 and was developed in combination with a <u>C</u>AR-T cell <u>Amplifying RNA Vac</u>cine (CARVac) that encodes the CAR target for *in vivo* expansion upon CAR-T administration. CARVac is based on RNA-LPX technology known from FixVac and selectively delivers the RNA-encoded CAR target to antigen presenting cells, leading to CAR target expression on the cell surface.

 BNT211 – In February 2021, the first patient was dosed in a first-in-human Phase 1/2a open-label, multi-center dose escalation and dose expansion basket trial of BNT211 with or without a CLDN6 CARVac in patients with CLDN6-positive relapsed or refractory advanced solid tumors including but not limited to ovarian and testicular cancers. The combination with CLDN6 CARVac is expected to improve expansion and persistence of CLDN6 CAR-T. 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. We expect a data update for this trial in the second half of 2021.

#### Neoantigen-targeting T cell therapy

BNT221 (NEO-PTC-01) – 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 the first half of 2021. 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.

#### 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) remains ongoing. We expect a data update from this trial in the second half of 2021.

#### Full Year 2020 Financial Results

*Revenues*: Total revenues were estimated to be €345.4 million for the three months ended December 31, 2020, compared to €28.0 million for the three months ended December 31, 2019. For the year ended December 31, 2020, total revenues were estimated to be €482.3 million, compared to €108.6 million for the comparative prior year period. Total revenues increased due to recognizing revenues for the first time under our two new collaboration agreements to develop a COVID-19 vaccine and ultimately led to the recognition of COVID-19 vaccine commercial revenues. Under the Pfizer collaboration, territories have been allocated to BioNTech and Pfizer based on marketing and distribution rights. Our commercial revenues comprise an estimated amount of €188.5 million<sup>1</sup> share of gross profit from COVID-19 vaccine sales in the collaboration partner's territory, which represents a net figure. In addition, €61.4 million sales to our collaboration partner of products manufactured by us and €20.6 million direct COVID-19 vaccine sales to customers in our territory Germany have been recognized.

*Cost of Sales:* Cost of sales were estimated to be  $\notin$ 41.0 million for the three months ended December 31, 2020, compared to  $\notin$ 4.4 million for the three months ended December 31, 2019. For the year ended December 31, 2020, cost of sales were estimated to be  $\notin$ 59.3 million, compared to  $\notin$ 17.4 million for the comparative prior year period.  $\notin$ 35.6 million estimated cost of sales were recognized for the first time with respect to our COVID-19 vaccine sales and include Pfizer's share of gross profits earned by BioNTech. Cost of sales do not include costs relating to production of pre-launch products since those are expensed as research and development expenses in the period incurred.

Research and Development Expenses: Research and development expenses were €257.0 million for the three months ended December 31, 2020, compared to €65.4 million for the three months ended December 31, 2019. For the year ended December 31, 2020, research and development expenses were €645.0 million, compared to €226.5 million for the comparative prior year period. The increase was mainly due to an increase in research and development expenses for our BNT162 program. Research and development expenses include our share of expenses under the terms of the Pfizer collaboration agreement. Development costs are shared equally between Pfizer and us. The increase was further driven by an increase in expenses for purchased laboratory supplies 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 of our new U.S.-based subsidiary, BioNTech US Inc., contributed to our research and development expenses.

General and Administrative Expenses: General and administrative expenses were  $\in$  36.1 million for the three months ended December 31, 2020, compared to  $\in$  11.1 million for the three months ended December 31, 2019. For the year ended December 31, 2020, general

and administrative expenses were €94.0 million, compared to €45.5 million for the comparative prior year period. The increase was mainly due to higher expenses for professional services, an increase in headcount leading to higher wages, benefits and social security expenses and higher insurance premiums. In addition, from May 6, 2020, the date of acquisition of our new U.S.-based subsidiary, BioNTech US Inc., contributed to our general and administrative expenses.

*Income Taxes*: Following the authorization and approval of our COVID-19 vaccine for emergency or temporary use or having been granted conditional marketing authorization, the recognition of deferred tax assets was reevaluated. As of December 31, 2020, net deferred tax assets with respect to the accumulated tax losses and temporary differences of the German tax group were recognized with €161.0 million income tax effect.

*Net Profit / Loss*: Net profit was €366.9 million for the three months ended December 31, 2020, compared to €58.2 million net loss for the three months ended December 31, 2019. For the year ended December 31, 2020, net profit was €15.2 million, compared to €179.2 million net loss for the comparative prior year period.

Cash Position: Cash and cash equivalents as of December 31, 2020 were €1.2 billion.

Shares Outstanding: Shares outstanding as of December 31, 2020 were 241,521,065.

#### COVID-19 vaccine order book update:

Estimated COVID-19 vaccine revenues to BioNTech upon delivery of currently signed supply contracts (~1.4 billion doses): ~€9.8 billion.

Estimate reflects:

•Expected revenues from direct COVID-19 vaccine sales to customers in our territories

•Expected revenues from sales to our collaboration partners

•Expected sales milestone payments from our collaboration partners

•Expected revenues related to our 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.

Full year 2021 manufacturing capacity target raised from 2.0 to 2.5 billion doses to be able to address increased demand.

2021 financial outlook: BioNTech is providing the following outlook for the full year 2021 of selected financial metrics based on the current base case projections:

Planned Full Year 2021 Expenses and Capex<sup>2</sup>

R&D expenses	€750 million – €850 million
	Ramp-up of R&D investment in 2H 2021 and beyond planned to broaden and a development.
SG&A expenses	Up to €200 million
Capital expenditures	€175 million – €225 million
Estimated Full Year 2021 Tax Assumptions	

German tax group corporate tax rate	~31%
German tax group accumulated tax loss carryforwards as of December 31, 2020	~€450million <sup>3</sup>

Full financial statements can be found in the 20F filing as published on the SEC website under https://www.sec.gov/.

- 1 Estimated figures based on preliminary data shared between Pfizer and BioNTech as fully described in our Annual Report on Form 20-F. Changes in our share of the collaboration partner's gross profit will be recognized prospectively.
- 2 Ranges reflect current base case projections.
- 3 €457.9 million corporate income tax losses and €450.9 million trade tax losses related to the German tax group.

#### 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

#### **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 BioNTech's expected

revenues and net profit related to sales of BioNTech and Pfizer's COVID-19 vaccine, referred to as COMIRNATY® in the European Union as authorized for use under conditional marketing approval, in territories controlled by BioNTech's collaboration partners, particularly those such figures that are derived from preliminary estimates provided by BioNTech's partners; the extent to which a COVID-19 vaccine continues to be necessary in the future; competition from other COVID-19 vaccines or related to BioNTech's 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 pricing and reimbursement of BioNTech and Pfizer's COVID-19 vaccine and BioNTech's investigational medicines, if approved; the rate and degree of market acceptance of BioNTech and Pfizer's COVID-19 vaccine and BioNTech's investigational medicines, if approved; the initiation, timing, progress, results, and cost of BioNTech's research and development programs and BioNTech's 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 BioNTech's research and development programs; the timing of and BioNTech's ability to obtain and maintain regulatory approval for BioNTech's product candidates; the ability and willingness of BioNTech's third-party collaborators to continue research and development activities relating to BioNTech's development candidates and investigational medicines; the impact of the COVID-19 pandemic on BioNTech's development programs, supply chain, collaborators and financial performance; unforeseen safety issues and claims for personal injury or death arising from the use of BioNTech and Pfizer's COVID-19 vaccine, and other products and product candidates developed or manufactured by BioNTech; BioNTech's estimates of its expenses, ongoing losses, future revenue and capital requirements and BioNTech's needs for or ability to obtain additional financing; the development of and projections relating to BioNTech's competitors or its industry; BioNTech's ability to effectively scale its production capabilities and manufacture its products, including BioNTech and Pfizer's COVID-19 vaccine, and BioNTech's product candidates; BioNTech's projected net sales for the COVID-19 vaccine in 2021; BioNTech's projected gross margins, expenses and expenditures and tax rate for 2021; BioNTech's target vaccine production for 2021; and 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. In some cases, forward-looking statements can be identified by terminology such as "will," "may," "should," "expects," "intends," "plans," "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 BioNTech's Annual Report on Form 20-F filed with the US Securities and Exchange Commission (SEC) on March 31, 2020 and in subsequent filings made by BioNTech with the SEC, including the third quarter report, which are available on the SEC's website at 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.

#### **Investor Relations**

Sylke Maas, Ph.D. VP Investor Relations & Strategy Tel: +49 (0)6131 9084 1074 E-mail: Investors@biontech.de

#### **Media Relations**

Jasmina Alatovic Director Global External Communications Tel: +49 (0)6131 9084 1513 or +49 (0)151 1978 1385 E-mail: <u>Media@biontech.de</u>

#### **Consolidated Statements of Financial Position**

	December 31,	Decer
(in thousands)	2020	
Assets		
Non-current assets		
Intangible assets	€ 163,490	:
Property, plant and equipment	226,968	
Right-of-use assets	98,988	
Other assets	1,045	
Deferred tax assets	161,233	
Total non-current assets	€ 651,724	€
Current assets		
Inventories	64,120	
Trade receivables	165,468	
Other financial assets	137,234	
Other assets	60.966	
Income tax assets	898	
Deferred expenses	28,001	
Cash and cash equivalents	1,210,209	
Total current assets	€ 1,666,896	€
Total assets	€ 2,318,620	€
	0 2,010,020	<u>v</u>
Equity and liabilities		
Equity		
Share capital	246.310	
Capital reserve	1,514,451	
Treasury shares		
	(4,789)	,
Accumulated losses	(409,629)	(•
Other reserves	25,503	
Total equity	€ 1,371,846	€
Non-current liabilities		
Interest-bearing loans and borrowings	231,047	
Other financial liabilities	31,476	
Provisions	5,498	
Contract liabilities	71,892	
Other liabilities	566	
Deferred tax liabilities	281	
Total non-current liabilities	€ 340,760	€
Current liabilities		
Interest-bearing loans and borrowings	9,142	
Trade payables	102,288	
Other financial liabilities	74,075	
Government grants	91,951	
Tax provisions	11	
Other provisions	903	
Contract liabilities	299,583	
Other liabilities	28,061	
Total current liabilities	€ 606,014	€
Total liabilities	€ 946,774	€
Total equity and liabilities	€ 2,318,620	€
and the Alexandra and	,,	•

#### **Consolidated Statements of Operations**

		Years ended December 31,	
	2020	2019	
(in thousands, except per share data)			
Revenues			
Research & development revenues	€ 178.849	€ 84,428	€
Commercial revenues	303.476	, -	C
Total revenues	482,325	,	
Cost of sales	(59,333)	(17,361)	1
Research and development expenses	(645,029)	(226,466)	(1
Sales and marketing expenses	(14,512)	(2,718)	
General and administrative expenses	(94,049)	(45,547)	1
Other operating expenses	(2,358)	(739)	
Other operating income	250,539	2,724	
Operating loss	€ (82,417)	€ (181,518)	€
Finance income*	1,564		
Finance expenses*	(62,946)	(326)	
Interest expenses related to lease liabilities	(2,003)	(1,718)	
Share of loss of equity method investees	-	-	•
Loss before tax	€ (145,802)	€ (179,440)	€
Income taxes	161,000	268	
Profit / (Loss) for the period	€ 15,198		€
	0 13,130	C (173,172)	
Attributable to:			
Equity holders of the parent	15,198	(179,056)	1
Non-controlling interests		(116)	,
Profit / (Loss) for the period	€ 15,198		€
Earnings per share			
Basic and diluted, profit / (loss) for the period attributable to ordinary equity holders of the parent**	€ 0.06	€ (0.85)	

\* 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 years ended December 31, 2019 and December 31, 2018 have been adjusted to reflect capital increase due to 1:18 share split which occurred on September 18, 2019.

#### **Consolidated Statements of Cash Flows**

		Years ended December 31,
(in thousands)	2020	2019
Operating activities		
Profit / (Loss) for the period	€ 15,198	€ (179,172)
Income taxes	(161,000)	(268)
Loss before tax Adjustments to reconcile loss before tax to net cash flows:	€ (145,802)	€ (179,440)
Depreciation and amortization of property, plant, equipment and intangible assets	38,744	33,896
Share-based payment expense	32,142	30,236
Net foreign exchange differences	41,275	70
(Gain) / Loss on disposal of property, plant and equipment	595	542
Finance income	(1,564)	(1,782)
Interest on lease liability	2,003	1,717
Finance expense	20,336	326
Movements in government grants	91,951	-
Share of loss of an associate and a joint venture Other non-cash income	- 1.749	-
Working capital adjustments:	1,749	-
Decrease / (Increase) in trade receivable and contract assets	(247,886)	2.939
Decrease / (Increase) in inventories	(49,794)	(5,798)
(Decrease) / Increase in trade payables, other liabilities, contract liabilities and	204,583	(80,577)
provisions	204,383	(80,577)
Interest received	1,444	1,256
Interest paid	(3,628)	(2,044)
Income tax received (paid), net	378	122
Net cash flows used in operating activities	€ (13,474)	€ (198,537)
Investing activities		
Purchase of property, plant and equipment	(66,033)	(38,592)
Proceeds from sale of property, plant and equipment	1,241	21
Purchase of intangibles assets and right of use assets	(19,413)	(32,488)
Acquisition of subsidiaries and businesses, net of cash acquired Net cash flows used in investing activities	(60,643) € (144.848)	(6,056) € (77,115)
Net cash hows used in investing activities	£ (144,040)	£ (77,113)
Financing activities		
Proceeds from issuance of share capital, net of costs	753,007	375,351
Proceeds from loans and borrowings	156,027	11,000
Repayment of loans and borrowings	(1,566)	-
Payments related to lease liabilities Net cash flows from financing activities	(12,743) € <b>894,725</b>	(3,061) € 383,290
	€ 894,725	í
Net increase in cash and cash equivalents	736,403	107,638
Change in cash and cash equivalents resulting from exchange rate differences	(45,343)	16
Cash and cash equivalents at January 1	519,149	411,495
Cash and cash equivalents at December 31	€ 1,210,209	€ 519,149

Harnessing the full potential of the immune system to solve global health problems

# Fourth Quarter and Full Year 2020

Corporate update and financial results

March 30, 2021



# BIONTECH

## This slide presentation includes 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 BioNTech's expected revenues and net profit related to sales of BioNTech and Pfizer's COVID-19 vaccine, referred to as COMIRNATY® in the European Union as authorized for use under conditional marketing approval, in territories controlled by BioNTech's collaboration partners, particularly those such figures that are derived from preliminary estimates provided by BioNTech's partners; the extent to which a COVID-19 vaccine continues to be necessary in the future; competition from other COVID-19 vaccines or related to BioNTech's 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 pricing and reimbursement of BioNTech and Pfizer's COVID-19 vaccine and BioNTech's investigational medicines, if approved; the rate and degree of market acceptance of BioNTech and Pfizer's COVID-19 vaccine and BioNTech's investigational medicines, if approved; the initiation, timing, progress, results, and cost of BioNTech's research and development programs and BioNTech's 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 BioNTech's research and development programs; the timing of and BioNTech's ability to obtain and maintain regulatory approval for BioNTech's product candidates; the ability and willingness of BioNTech's third-party collaborators to continue research and development activities relating to BioNTech's development candidates and investigational medicines; the impact of the COVID-19 pandemic on BioNTech's development programs, supply chain, collaborators and financial performance; unforeseen safety issues and claims for personal injury or death arising from the use of BioNTech and Pfizer's COVID-19 vaccine, and other products and product candidates developed or manufactured by BioNTech's BioNTech's estimates of its expenses, ongoing losses, future revenue and capital requirements and BioNTech's needs for or ability to obtain additional financing; the development of and projections relating to BioNTech's competitors or its industry; BioNTech's ability to effectively scale its production capabilities and manufacture its products, including BioNTech and Pfizer's COVID-19 vaccine, and BioNTech's product candidates; BioNTech's projected net sales for the COVID-19 vaccine in 2021; BioNTech's projected gross margins, expenses and expenditures and tax rate for 2021; BioNTech's target vaccine production for 2021; and 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. In some cases, forward-looking statements can be identified by terminology such as "will," "may," "should," "expects," "intends," "plans," "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 BioNTech's Annual Report on Form 20-F filed with the US Securities and Exchange Commission (SEC) on March 31, 2020 and in subsequent filings made by BioNTech with the SEC, including the third quarter report, which are available on the SEC's website at 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.



# Safety Information

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

3

The Pfizer-BioNTech COVID19 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.
- In places parameter parameter parameter and the protect all vaccine receiptions. The Pfizzer BioNTech COVID-19 Vaccine receiption protect all vaccine receiptions. 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 to complete the vaccination series. Vaccination providers must report Adverse Events in accordance with the Fact Sheet to VAERS at <a href="https://vaers.hhs.gov/reportevent.htm">https://vaers.hhs.gov/reportevent.htm</a>) 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.cvdvaccineus.com



# Agenda

#### Full Year 2020 Highlights

COVID-19 Vaccine Update

Oncology Pipeline Update

Financial Results

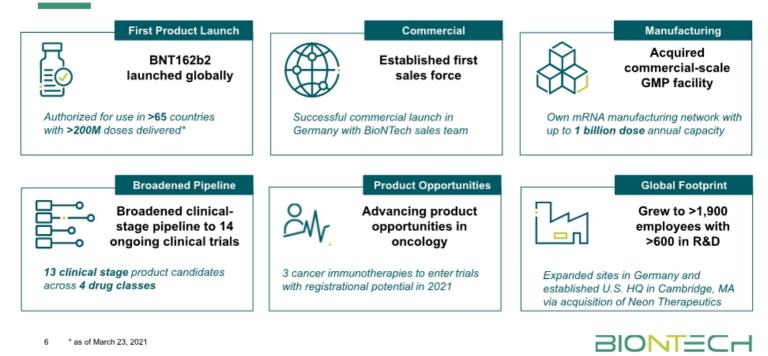
Strategic Outlook

4





# **BioNTech's capabilities were transformed in 2020**



# What 2020 has demonstrated to us

# Our mRNA technology has the potential to address major global health challenges:

The success of "first-generation" mRNA vaccines against COVID-19 highlights their future promise – we expect rapid iterations to further improve this new class of products. We have established a broad toolbox of mRNA technologies that underpin a diverse range of mRNA platforms.

#### Drug development can be faster:

7

While COVID-19 was an extraordinary case, we intend to apply the capabilities we have developed during "Project Lightspeed" to rapidly advance other innovative medicines to the market.

# BioNTech is well-placed to lead at the intersection of mRNA and immunology:

We own a vast IP portfolio and have more than a decade of accumulated know-how in the field. We plan to increase investment in our technology platforms to accelerate our platform and pipeline and stay at the forefront of the field.

#### Our model is powerful:

Our deep focus on innovation, coupled with powerful blue chip collaborators, gives us the ability to establish marketleading positions while building our own capabilities alongside our partners over the long-term.



# The Opportunity Ahead

1

8

Accelerate and expand our innovative pipeline

Launch multiple new products in the next 5 years

2

Build a 21st century global immunotherapy powerhouse



# We aim to fully exploit and industrialize the potential of our mRNA technology

Today	Tomorrow	The Future
mRNA vaccines established as a <b>New Drug Class</b>	mRNA technology to Displace Traditional Modalities	mRNA to open up new opportunities Beyond the Horizon
BNT162b2 Diversification and maturation of our mRNA technology enabled the accelerated development of our COVID-19 vaccine	<ul> <li>mRNA infectious disease vaccines</li> <li>mRNA cancer vaccines</li> <li>CAR-T cell amplifying mRNA vaccine</li> <li>Systemic mRNA encoded immuno-therapies</li> </ul>	<ul> <li>Autoimmune diseases</li> <li>Allergy</li> <li>Inflammation</li> <li>Regenerative medicine</li> <li>Other therapeutic areas</li> </ul>
	road IP portfolio covering technolo pertise and know-how built over th	

# Agenda

Full Year 2020 Highlights

COVID-19 Vaccine Update

Oncology Pipeline Update

Financial Results

Strategic Outlook



# BIONTECH

# Strong clinical results



- 95% effective against symptomatic COVID-19 infections<sup>1</sup>
- 94% efficacy in participants >65 years
- Well tolerated safety profile
- High titers of neutralizing antibodies
- Robust and poly-epitopic CD8+ and Th1 CD4+ T-cell responses<sup>2</sup>



11 Polack FP, et al. NEJM 2020, 383:2603-2615 <sup>2</sup>Sahin U, et al. preprint 2020 (https://www.medrxiv.org/content/10.1101/2020.12.09.20245175v1 )



# Compelling real-world evidence



Real-world data from observational study conducted by Israel Ministry of Health

Two weeks post-dose 2

- About 97% effective in preventing
  - symptomatic COVID-19
  - severe/critical COVID 19
  - Hospitalizations
  - Deaths
- 94% effective against asymptomatic infection
- Protective against B.1.1.7 variant



 
 Real-World-Data announced by The Israel Ministry of Health (MoH) on March 11, 2021:

 12
 https://www.businesswire.com/news/home/20210311005482/en/ Haas EJ, et al. preprint 2021; <a href="https://papers.srn.com/sol3/papers.cfm?abstract\_id=3811387">https://papers.srn.com/sol3/papers.cfm?abstract\_id=3811387</a>



# COVID-19 will likely become endemic. Re-vaccination may also be required.

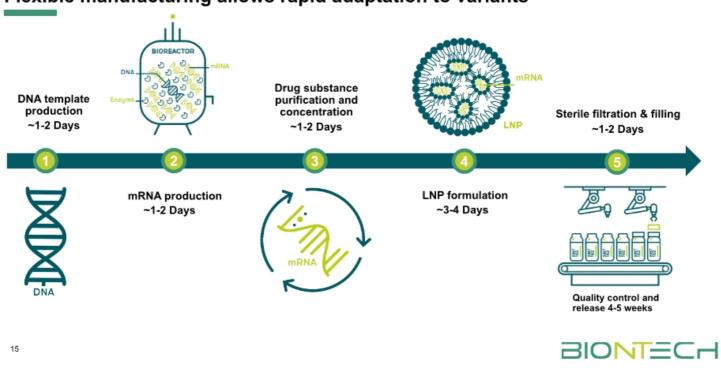
Observation	Implication	
1 Waning immune responses	Re-boostings may be required	
2 Variants are driving new infections	Variant-specific vaccines may be needed	
3 New mRNA vaccines can be rapidly designed and produced at scale	mRNA vaccines are well suited for long-term challenge	

#### 13

# BIONTECH

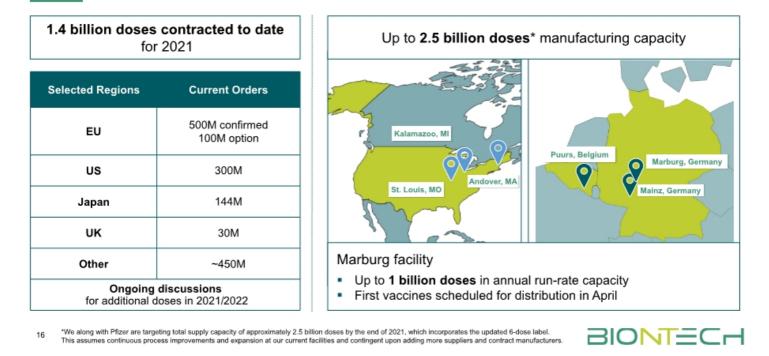
# Focused on six key levers to expand COVID-19 vaccine reach

Increased manufacturing capacity	<ul> <li>Up to 2.5 billion doses by end of 2021</li> <li>Continuous process improvements, expansion of supplier and CMO network</li> </ul>
Additional populations	<ul> <li>Global Phase 2/3 trial in healthy pregnant women ≥ 18 years of age ongoing</li> <li>Data in children 12-15 years of age to regulatory authorities in Q2</li> <li>Study in children 6 months to 11 years of age started</li> </ul>
	<ul> <li>Approved in more than 65 countries</li> </ul>
Additional geographies	<ul> <li>Japan's Health Ministry approved BNT162b2</li> <li>Submission to regulatory authorities in Mainland China in process</li> </ul>
Broadened & decentralized vaccine access	<ul> <li>U.S. FDA and EMA updated label with 2-week storage and transport at -25°C to -15°C</li> <li>Stability optimized, ready-to-use and lyophilized formulations expected in 2021</li> <li>BLA submission expected in United States in Q2</li> </ul>
Addressing SARS-CoV-2 variants	<ul> <li>Initiated variant-specific registration-enabling trial</li> <li>Additional variant-specific trials expected to be initiated in Q2</li> </ul>
Addressing waning immune responses	<ul> <li>Initiated trial to evaluate effect of third dose of BNT162b2 at 6 to 12 months post-dose 2</li> </ul>



# Flexible manufacturing allows rapid adaptation to variants

## Scaling up manufacturing capacity to address pandemic demand



# Agenda

Full Year 2020 Highlights

COVID-19 Vaccine Update

Oncology Pipeline Update

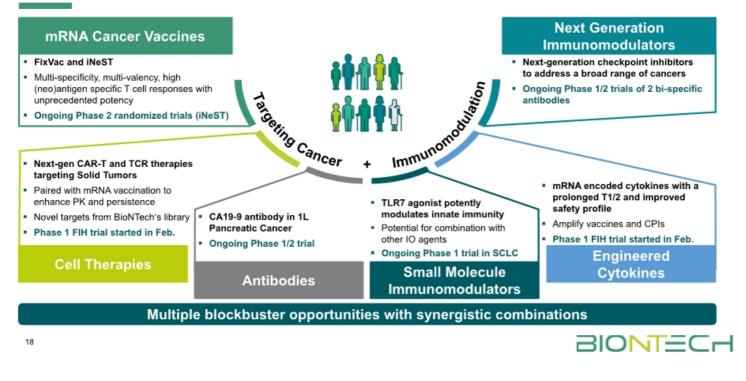
Financial Results

Strategic Outlook



# BIONTECH

### Rationally designed multi-platform immuno-oncology strategy



# Multiple oncology trials with registrational potential starting in 2021

#### Plan to initiate randomized Phase 2 trials for 3 programs

Most 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 1H 2021	
			adjuvant colorectal cancer				(adjuvant CRC)	
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	

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



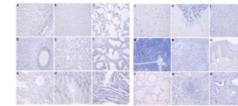
# Next wave oncology advancing innovation beyond current boundaries

CARVac CAR-T cell amplifying mRNA therapy for solid tumors <sup>1</sup>	NEOSTIM T cell therapy Individualized Neoantigen specific T cell therapy	RiboCytokines mRNA encoded Cytokines	RiboMabs <sup>2</sup> mRNA encoded Antibodies		
CLONE CONE Correstion of CAR T CAR T		Pharmacokinetic Profile Pharmacokinetic Profile Recombinant cytokine RiboCytokine			
<ul> <li>BNT211 (CLDN 6 CAR) Next generation CAR-T targeting CLDN6 with CARVac "primer"</li> </ul>	<ul> <li>BNT221 (PBMC derived ex vivo T cell therapy)</li> </ul>	<ul> <li>BNT151 (modified IL-2)</li> <li>BNT152 + BNT153 (IL-2/IL-7)</li> </ul>	<ul> <li>BNT141 (undisclosed)</li> <li>BNT142 (CD3xCLDN6)</li> </ul>		
Wholly owned: 🗸	~	~	~		
FIH start: FPD Feb. 2021	1H 2021	FPD Feb. 2021	2H 2021		
	CAR-T cells, Chimeric antigen receptor T cells; IL-2, intr 020; 367:446-453; <sup>2</sup> Stadler et al, Oncoimmunology 201		BIONTEC		

# BNT211: CLDN6-CAR demonstrates potent and robust target recognition

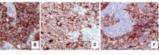
CANCER IMMUNOTHERAPY An RNA vaccine drives expansion and efficacy of claudin-CAR-T cells against solid tumors

Katharina Reinhard<sup>a</sup>", Benjamin Rengstl<sup>a</sup>", Petra Oehm<sup>2</sup>, Kristina Michel<sup>3</sup>, Arne Billmeier<sup>2</sup>, Nina Hayduk<sup>1</sup>, Oliver Klein<sup>1</sup>, Kathrin Kuna<sup>1</sup>, Yasmina Ouchan<sup>3</sup>, Stefan Walf, Elmar Clarist<sup>1</sup>, David Weber<sup>2</sup>, Martin Suchan<sup>2</sup>, Thomas Bukur<sup>2</sup>, Mathias Birtel<sup>1</sup>, Veronika Jahndel<sup>1</sup>, Karolina Mrce<sup>1</sup>, Kathleen Hoohohm<sup>1</sup>, Lens Krau<sup>2</sup>, Mustafa Diker<sup>3</sup>, Kause Kildheka<sup>2</sup>, Özlem Türec<sup>11</sup>, Ugur Sahlin<sup>23</sup> (;



CLDN6 not present in healthy tissues

CLDN6 expressed in multiple cancers



Ovarian Testicular

Lung

### Science

- Directed against new carcino-embryonic antigen CLDN6
- 2<sup>nd</sup> generation CAR functionalized with antibody-derived CLDN6-binding domain (aCLDN6-scFv)
- Binding domain mediates exclusive specificity and high sensitivity for CLDN6
- · Costimulatory domain (4-1BB) mediates prolonged survival and repetitive killing ability
- CLDN6-CAR showed strong recognition and lysis of CLDN6-positive target cells in preclinical studies
- 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 21

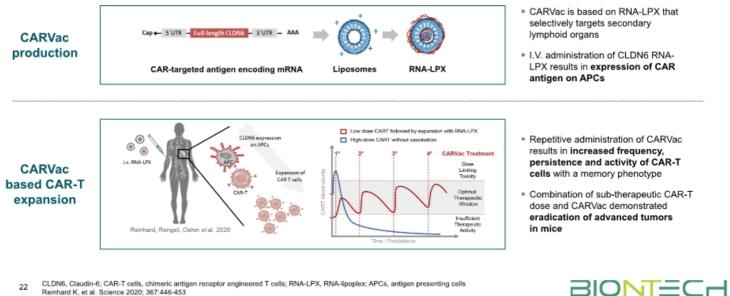
#### **BNT211 CAR Structure**





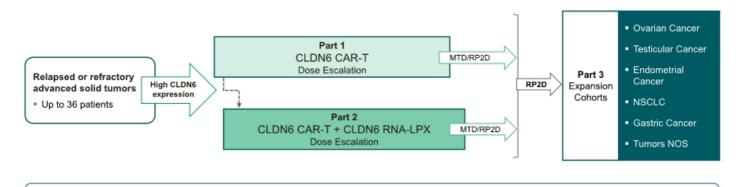
### BNT211: Repeated CARVac dosing enables tunable expansion of CAR-T cells

#### CAR-T cell Amplifying RNA Vaccine (CARVac) drives in vivo expansion and efficacy of CAR-T against solid tumors



CLDN6, Claudin-6; CAR-T cells, chimeric antigen receptor engineered T cells; RNA-LPX, RNA-lipoplex; APCs, antigen presenting cells Reinhard K, et al. Science 2020; 367:446-453 22

### BNT211: First-in-human CARVac trial with first data expected this year



 Phase 1/2a: Evaluation of safety and tolerability of CLDN6 CAR-T +/- CLDN6 RNA-LPX in patients with CLDN6-positive relapsed or refractory advanced solid tumors

3+3 dose escalation with bifurcated trial design

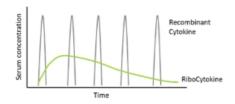
NSCLC, Non-Small Cell Lung Cancer; CLDN6, Claudin-6; CAR-T cells, Chimeric Antigen Receptor engineered T cells; RNA-LPX, RNA-lipoplex; 23 MTD, maximum tolerated dose; RP2D, recommended Phase 2 dose; NOS, not otherwise specified (e.g. rare tumors) https://clinicaltrials.gov/ct2/show/NCT04503278?term=nct04503278&draw=2&rank=1



# BNT151: Designed to overcome limitations of recombinant cytokine therapy

#### RiboCytokines: A novel therapeutic concept

- Cytokines encoded by mRNA and produced in patient
- Major improvements over recombinant cytokine therapies
  - Prolonged serum half-life
  - High bioavailability
  - Lower and less frequent dosing
  - Lower Toxicity
  - Sequence modifications easy to introduce



24 IL-2, interleukin-2 Vormehr, M. et al. SITC Poster Sess. (2019); Vormehr, M. et al. CICON Poster Sess. (2019)

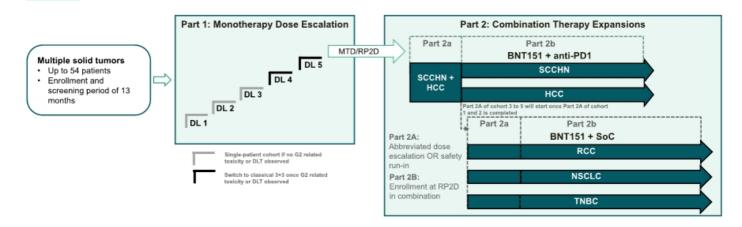
#### BNT151: Optimized mRNA-encoded IL-2



- BNT151 is nucleoside-modified mRNA encoding human IL-2 variant fused to human albumin
- IL-2 is a key cytokine in T cell immunity, supporting differentiation, proliferation, survival and effector functions of T cells
- BNT151 stimulates anti-tumoral T cells without extensively triggering immunosuppressive T<sub>regs</sub>
- · First patient dosed in first-in-human Phase 1/2a Trial



### BNT151-01 Open-label, multicenter Phase 1/2a, first-in-human trial



# Evaluation of dose escalation, safety, pharmacokinetics and pharmacodynamics of BNT151 with expansion cohorts in multiple solid tumor indications

NSCLC, Non-small Cell Lung Cancer; DL, dose level; MTD, maximum tolerated dose; RP2D, recommended Phase 2 dose; G2, grade 2; DLT, dose limiting toxicity; SoC, Standard of Care; SCCHN, Squamous cell carcinoma of the head and neck; HCC, Hepatocellular carcinoma; RCC, Renal cell carcinoma; TNBC, Triple-negative breast cancer; CPI; checkpoint inhibitor



# Agenda

Full Year 2020 Highlights

COVID-19 Vaccine Update

Oncology Pipeline Update

Financial Results

Strategic Outlook



# BIONTECH

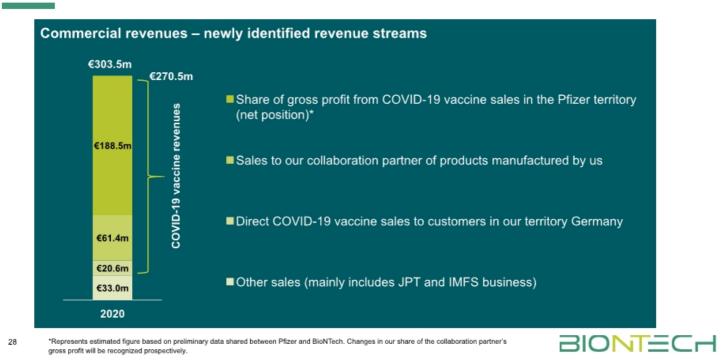
# 2020 Full Year Financial Results – Statement of Operations

(in millions)*	Three month Decembe		Years ended December 31,		
	2020	2019	2020	2019	
Research & development revenues	€ 65.4	€ 20.2	€ 178.8	€ 84.4	
Commercial revenues	€ 280.0	€ 7.8	€ 303.5	€ 24.2	
Total revenues	€ 345.4	€ 28.0	€ 482.3	€ 108.6	
Cost of sales	(41.0)	(4.4)	(59.3)	(17.4)	
Research and development expenses	(257.0)	(65.4)	(645.0)	(226.5)	
Sales and marketing expenses	(6.7)	(0.8)	(14.5)	(2.7)	
General and administrative expenses	(36.1)	(11.1)	(94.0)	(45.5)	
Other operating income less expenses	239.6	0.8	248.1	2.0	
Operating profit / (loss)	€ 244.2	€ (52.9)	€ (82.4)	€ (181.5)	
Finance income less expenses	(38.6)	(5.6)	(63.4)	2.0	
Income taxes	161.3	0.3	161.0	0.3	
Profit / (loss) for the period	€ 366.9	€ (58.2)	€ 15.2	€ (179.2)	

27 \*Numbers have been rounded, numbers presented may not add up precisely to the totals and may have been adjusted in the table context. Presentation of the statement of operations is condensed.



### 2020 COVID-19 vaccine deliveries drove revenue growth



# 2021 Financial Outlook

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

- Estimated COVID-19 vaccine revenues to BioNTech upon delivery of currently signed orders (~1.4 billion doses):
   ~€9.8 billion
  - Estimate reflects:
    - Expected revenues from direct COVID-19 vaccine sales to customers in our territories
    - Expected revenues from sales to our collaboration partners
    - Expected sales milestone payments from our collaboration partners
    - Expected revenues related to our 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
- Full year 2021 manufacturing capacity target raised from 2.0 to 2.5 billion doses to be able to address increased demand

29

# BIONTECH

# 2021 Financial Outlook

#### Planned Full Year 2021 Expenses and Capex

- R&D expenses:
- SG&A expenses:
- Capital expenditures:

€750 million – €850 million Up to €200 million €175 million – €225 million

~31%

- 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:
- Accumulated tax loss carryforwards as of December 31, 2020: ~€450 million\*

30 \*€457.9 million corporate income tax losses and €450.9 million trade tax losses related to the German tax group



# Agenda

#### Full Year 2020 Highlights

COVID-19 Vaccine Update

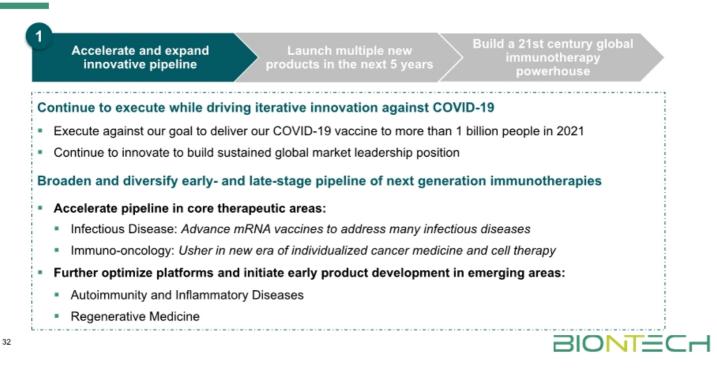
Oncology Pipeline Update

Financial Results

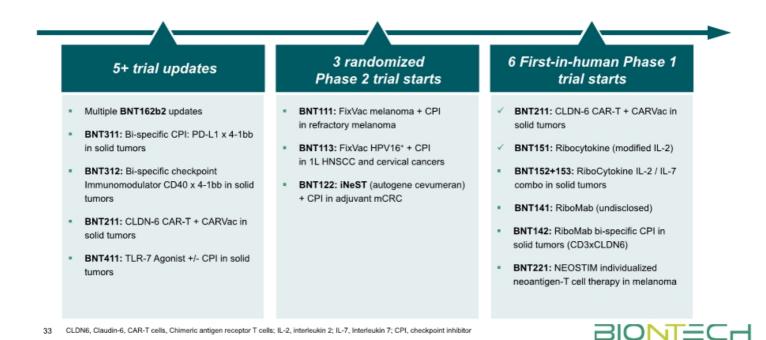
Strategic Outlook

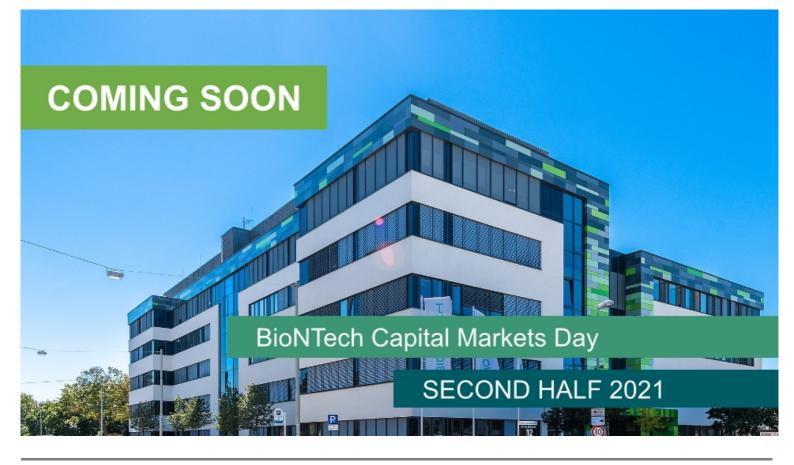


# Our strategic priorities for 2021

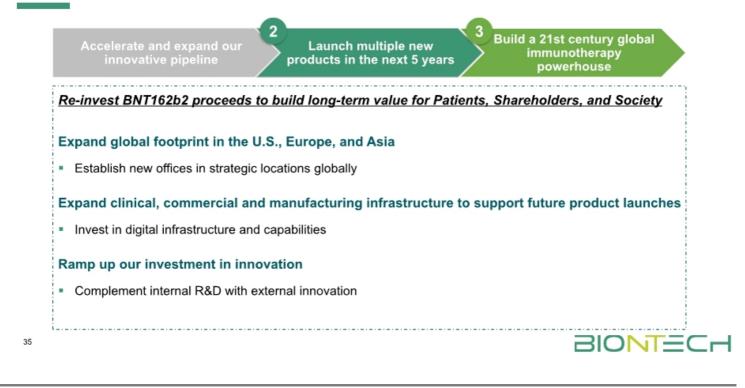


### Expected pipeline milestones in 2021





### Better positioned than ever to bring innovation to patients





An der Goldgrube 12 55131 Mainz Germany

M: investors@biontech.de

Copyright BioNTech SE 2021. All Rights Reserved