

**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 2022**

**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 May 9, 2022, BioNTech SE (the “Company”) issued a press release announcing its first quarter 2022 financial results and corporate update and details of a conference call to be held at 8:00 am EST on May 9, 2022 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 s the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**BioNTech SE**

By: /s/ Jens Holstein

Name: Jens Holstein

Title: Chief Financial Officer

Date: May 9, 2022

## EXHIBIT INDEX

<u>Exhibit</u>	<u>Description of Exhibit</u>
99.1	<a href="#">BioNTech Announces First Quarter 2022 Financial Results and Corporate Update</a>
99.2	<a href="#">First Quarter 2022: Corporate Update and Financial Results</a>

## BioNTech Announces First Quarter Financial Results and Corporate Update

- First quarter revenues of €6.4 billion<sup>1</sup>, net income of €3.7 billion and fully diluted earnings per share of €14.24 (\$15.97<sup>2</sup>)
- Reiterates BioNTech COVID-19 2022 vaccine revenue guidance of €13 billion to €17 billion
- First-in-class CAR-T program targeting CLDN-6 (BNT211) in solid tumors showed manageable safety profile and signs of clinical activity; preliminary Phase 1/2 data presented at AACR Annual Meeting 2022
- Continued pipeline expansion to 16 clinical stage oncology programs in 20 ongoing clinical trials

Conference call and webcast scheduled for May 9, 2022, at 8:00 am ET (2:00 pm CET)

**MAINZ, Germany, May 9, 2022 (GLOBE NEWSWIRE)** -- BioNTech SE (Nasdaq: BNTX, "BioNTech" or the "Company") today reported financial results for the three months ended March 31, 2022 and provided an update on its corporate progress.

"During the first quarter, we demonstrated continued execution across our growth pillars in addressing infectious diseases and oncology," said Ugur Sahin, M.D., CEO and Co-Founder of BioNTech. "We have enhanced our COVID-19 vaccine leadership and reported encouraging data for our first-in-human CAR-T therapy in solid tumors. Driven by our execution in innovation, we believe we are well positioned to achieve multiple product launches in the coming years, which would facilitate significant long-term growth."

### Key First Quarter Financial Results

in millions, except per share data	First Quarter 2022	First Quarter 2021
Total Revenues <sup>1</sup>	€6,374.6	€2,048.4
Net Profit	€3,698.8	€1,128.1
Diluted Earnings per Share	€14.24	€4.39

"We believe the global deployment of our vaccine has likely saved millions of lives and had a significant impact on humanity. As a result of an increased order volume initially placed in late 2021 following the then emerging Omicron variant, we began the year 2022 with strong revenues and earnings, leaving us well-positioned to achieve the 2022 financial guidance we issued a few months ago," said Jens Holstein, CFO of BioNTech. "This notable financial performance also helps us to invest heavily in research and development in the years to come fueling the potential to drive future waves of innovation and growth."

#### Outlook for the 2022 Financial Year Reiterated

The Company reiterates its prior 2022 financial year outlook, which includes the following components:

##### *BioNTech COVID-19 Vaccine Revenues for the 2022 Financial Year:*

Estimated BioNTech COVID-19 vaccine revenues for the full 2022 financial year	€13 billion - €17 billion
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This revenue estimate reflects expected revenues related to BioNTech's share of gross profit from COVID-19 vaccine sales in the collaboration partners' territories, from direct COVID-19 vaccine sales to customers in BioNTech's territory and expected revenues generated from products manufactured by BioNTech and sold to collaboration partners.

##### *Planned 2022 Financial Year Expenses and Capex:*

R&D expenses	€1,400 million - €1,500 million
SG&A expenses	€450 million - €550 million
Capital expenditures	€450 million - €550 million

The ranges reflect current base case projections and do not include potential effects caused by or driven from additional collaborations or potential mergers and acquisitions transactions.

##### *Estimated 2022 Financial Year Tax Assumptions:*

BioNTech Group estimated annual effective income tax rate	~28%
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#### Capital Allocation Framework

Given BioNTech's strong financial, scientific and operational accomplishments, BioNTech believes that it has the resources to diligently allocate its current capital to drive a multi-platform strategy and continue to strengthen BioNTech as a fully integrated global

biotechnology company, allowing it to invest in research and development activities and its global development organization, mergers and acquisitions and business development opportunities, and enhance its global footprint, including commercial and manufacturing infrastructure.

In addition, BioNTech has undertaken the following steps to return capital to shareholders, as announced in March 2022.

- The Company has authorized a share repurchase program of American Depositary Shares (ADSs), pursuant to which the Company may repurchase issued and outstanding ADSs in the amount of up to \$1.5 billion over the next two years. The first tranche of the share repurchase program, with a value of up to \$1.0 billion, commenced on May 2, 2022.
- The Management Board and Supervisory Board have proposed a special cash dividend of €2.00 per ordinary share (including those held in the form of ADSs), which corresponds to an aggregate of approximately €486.0 million, based on the number of ordinary shares and ADSs outstanding as of April 30, 2022, pending approval at the Annual General Meeting to be held in June 2022, which the Company expects to serve as the record date for the dividend.

#### **Detailed First Quarter Financial Results**

- *Revenues:* Total revenues reported were €6,374.6 million<sup>1</sup> for the three months ended March 31, 2022, compared to €2,048.4 million<sup>1</sup> for the comparative prior year period. The increase was mainly due to increased commercial revenues from the supply and sales of the Company's COVID-19 vaccine worldwide.

Under the collaboration agreements, territories have been allocated between BioNTech, Pfizer and Fosun Pharma based on marketing and distribution rights. During the three months ended March 31, 2022, BioNTech's commercial revenues included €4,586.9 million<sup>1</sup> gross profit share (€1,504.7 million<sup>1</sup> gross profit share and €247.2 million<sup>1</sup> sales milestones during the comparative prior year period). BioNTech's share of the collaboration partners' gross profit is based on COVID-19 vaccine sales in Pfizer's and Fosun Pharma's territories and represents a net figure.

In addition, during the three months ended March 31, 2022, BioNTech recognized €1,163.1 million of direct COVID-19 vaccine sales to customers in BioNTech's territory, Germany and Turkey, as well as €603.2 million sales of products manufactured by BioNTech for its collaboration partners (€199.8 million and €63.9 million, respectively during the comparative prior year period).

- *Cost of Sales:* Cost of sales was €1,294.1 million for the three months ended March 31, 2022, compared to €233.1 million for the comparative prior year period.

The increase in cost of sales resulted mainly from the recognition of costs related to BioNTech's COVID-19 vaccine revenues which included the share of gross profit owed to its collaboration partner Pfizer. This increase in cost of sales is additionally attributed to expenses arising from inventory write-offs and for production capacities derived from contracts with Contract Manufacturing Organizations.

- *Research and Development Expenses:* Research and development expenses were €285.8 million for the three months ended March 31, 2022, compared to €216.2 million for the comparative prior year period. The increase was mainly due to recognizing costs related to the production of pre-launch Omicron vaccine products as research and development expenses in the period incurred and an increase in headcount. The increase was partly offset by lower research and development expenses related to the Company's COVID-19 vaccine program as compared to the prior year period.
- *General and Administrative Expenses:* General and administrative expenses were €90.8 million for the three months ended March 31, 2022, compared to €38.9 million for the comparative prior year period. The increase was mainly due to increased expenses for purchased management consulting and legal services as well as an increase in headcount.
- *Income Taxes:* Income taxes were accrued in an amount to €1,319.3 million of tax expenses for the three months ended March 31, 2022, compared to €514.2 million of tax income for the comparative prior year period. The derived effective income tax rate for the three months ended March 31, 2022 was 26.3%.
- *Net Profit:* Net profit was €3,698.8 million for the three months ended March 31, 2022, compared to €1,128.1 million for the comparative prior year period.
- *Cash, Cash Deposits and Trade Receivables:* As of March 31, 2022, cash and cash equivalents were €6,164.1 million. In addition, trade receivables remained outstanding as of March 31, 2022, mainly due to the contractual settlement of the gross profit share under the COVID-19 collaboration with Pfizer, which has a temporal offset of more than one calendar quarter. As Pfizer's fiscal quarter for subsidiaries outside the United States differs from BioNTech's financial reporting cycle, it creates an additional time lag between the recognition of revenues and the payment receipt. Trade receivables for example include the gross profit share for the fourth quarter of 2021 (as defined by the contract) for which the settlement payment was received subsequent to the end of the reporting period in April 2022. Of the total trade receivables of €12,695.8 million which were outstanding as of March 31, 2022, €5,243.8 million were received in cash by mid-April 2022.
- *Shares Outstanding:* Shares outstanding as of March 31, 2022, were 243,019,216.

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

<sup>1</sup>BioNTech's profit share is estimated based on preliminary data shared between Pfizer and BioNTech as further described in BioNTech's Annual Report on Form 20-F for the year ended December 31, 2021 as well as its Quarterly Report as of and for the three months ended March 31, 2022, filed as an exhibit to BioNTech's Current Report on Form 6-K filed on May 9, 2022. Any changes in the estimated share of the collaboration partner's gross profit will be recognized prospectively.

<sup>2</sup>Calculated applying the average foreign exchange rate for the three months ended March 31, 2022 as published by the German Central Bank (*Deutsche Bundesbank*).

### **First Quarter 2022 and Subsequent Program Updates**

On March 30, 2022, BioNTech announced its Full Year 2021 Financial Results and Corporate Update as a part of the Annual Report filed on Form 20-F, also highlighting developments between January 1 and March 30, 2022 ([link to press release](#)). A summary of these developments as well as details of subsequent developments that occurred after March 30, 2022 is provided in the sections below.

#### **COVID-19 Vaccine Program – BNT162**

BNT162b2, the first ever approved mRNA-based product, has paved the way for a new class of medicines. BioNTech and Pfizer continue to execute on plans for global COVID-19 vaccine leadership with multiple new product launches, including label expansions, pediatric dosage forms, and development of follow-on and next generation vaccine candidates.

#### *Commercial updates*

In the first quarter of 2022, BioNTech and Pfizer have invoiced approximately 750 million COVID-19 vaccine doses. As of end-April 2022, the Companies have signed orders for approximately 2.4 billion doses in 2022. As part of BioNTech's pledge to equitable access to medicines, the Companies are on track to deliver a total of more than two billion doses of COVID-19 vaccine to low- and middle-income countries by the end of 2022.

#### *Manufacturing updates*

BioNTech and Pfizer's global COVID-19 vaccine supply chain and manufacturing network includes 20 manufacturing facilities spanning four continents.

- In February 2022, BioNTech announced its turnkey manufacturing solution, named "BioNTainer," which is designed to enable scalable mRNA vaccine production in bulk. The novel approach utilizes a modular manufacturing unit made up of state-of-the-art manufacturing containers. BioNTainers are designed and equipped to manufacture a

range of mRNA-based vaccines, for example COVID-19 vaccine doses. With their scalable and modular approach, BioNTainers are intended to enable the production of high-quality mRNA vaccine manufacturing worldwide. The establishment of the first modular mRNA manufacturing facility in the African Union is expected to start in the second half of 2022.

#### *Clinical development and regulatory updates*

BioNTech and Pfizer's COVID-19 vaccine has received multiple regulatory approvals including expansions of authorizations for booster and pediatric vaccinations, and updated storage conditions.

Label expansions achieved in the first quarter of 2022 include approvals in multiple geographies of a booster dose in individuals 12 years and older, which were supported by real-world vaccine efficacy data.

The U.S. Food and Drug Administration (FDA) also expanded the Emergency Use Authorization (EUA) in the first quarter of 2022 to include a second booster (fourth dose) for both individuals aged 50 years and older and individuals aged 12 years and older with certain kinds of immunocompromised conditions, who have previously received a booster of any authorized or approved COVID-19 vaccine.

The Companies are continuing a robust booster development program to address waning efficacy and partial escape variants and to provide continued protection by the vaccine.

Additionally, BioNTech and Pfizer continue to monitor protection offered by BNT162b2 against emerging SARS-CoV-2 variants. BNT162b2 offers a high level of protection against variants of concern, including Alpha, Beta, and Delta, and laboratory results published in *Science* demonstrated three doses of BNT162b2 neutralize the SARS-CoV-2 Omicron variant.

Real-world data from Israel suggest a fourth dose of BNT162b2 increases immunogenicity and lowers rates of confirmed infections and severe illness in the elderly population. A real-world study conducted by the Israeli Ministry of Health showed that in individuals over 60 years of age, confirmed infection and severe disease after a fourth dose was lower compared to individuals who did not receive a fourth dose (Bar-On YM, et al MedRxiv. Protection by 4th dose of BNT162b2 against Omicron in Israel; February 1, 2022).

BioNTech and Pfizer are evaluating follow-on COVID-19 vaccines, including an Omicron-adapted candidate and bivalent vaccines directed against the Omicron and other strains of SARS-CoV-2, as well as novel next generation vaccine concepts. The studies are part of the ongoing effort to develop next generation COVID-19 vaccines designed to provide a broad protection against emerging variants of concern.

In a recent preprint publication (bioRxiv. Omicron breakthrough infection drives cross-variant neutralization and memory B cell formation; April 1, 2022) BioNTech showed that Omicron breakthrough infection in BNT162b2 vaccinated individuals results in strong neutralizing activity against both Omicron and previous SARS-CoV-2 variants of concern. *In vitro* analyses of blood sera samples from individuals double- and triple-vaccinated with BNT162b2 demonstrated that Omicron breakthrough infection mediated a broad B cell recall response, primarily through expanded preformed memory B cells that recognize antigens shared broadly by different variants, rather than inducing new B cells against strictly Omicron-specific antigens. These observations suggest that a vaccine adapted to the Omicron strain spike could similarly reshape the B-cell memory repertoire and be more beneficial than an extended series of boosters with the existing vaccines directed against the ancestral strain.

- In January 2022, BioNTech and Pfizer announced the initiation of clinical trials to evaluate the safety, tolerability, and immunogenicity of an Omicron-adapted vaccine in healthy adults 18 to less than 56 years of age and adults greater than 55 years of age. The study is evaluating approximately 2,150 participants across multiple cohorts examining different regimens of the current COVID-19 vaccine or an Omicron-adapted vaccine in both vaccine experienced and naive subjects. The study also includes cohorts evaluating a bivalent Omicron-adapted vaccine. A data update is now expected in the coming weeks and will be shared with regulatory agencies.
- In February 2022, following a request from the U.S. FDA, BioNTech and Pfizer initiated a rolling submission seeking to amend the EUA to include children six months to less than five years of age in response to the urgent public health need in this population. The Phase 1/2/3 trial for this patient population was designed to evaluate safety, tolerability, and immunogenicity. Following study amendments, BioNTech and Pfizer are evaluating a three-dose regimen of 3 µg per dose in children six months to less than five years of age. The data are now expected in the coming weeks.
- In April 2022, multiple regulatory agencies, including the EMA and U.S. FDA authorized the extension of the shelf-life of the vaccine from nine months to twelve months when stored at -90°C to -60°C.
- In April 2022, BioNTech and Pfizer announced data from a Phase 2/3 clinical trial demonstrating high immune response following a booster (third) dose of BNT162b2 in 140 healthy children five through 11 years of age. Data demonstrated that a booster dose given approximately six months after the second dose of the 10 µg primary series increased neutralizing antibodies by six-fold against the SARS-CoV-2 wild-type strain compared to levels seen after two doses. Also, data from a

subanalysis of 30 sera showed a 36-fold increase in SARS-CoV-2 Omicron neutralizing titers following a booster dose. The vaccine was well tolerated with no new safety signals observed. The Companies submitted these data to U.S. FDA at the end of April 2022. Additional submissions to other regulatory agencies worldwide are ongoing.

- In May 2022, the European Commission approved the reduction of the interval between the primary course and booster vaccination from six months to three months in individuals 12 years of age and older.

#### ***Additional Infectious Disease Programs***

Prevention and treatment of infectious diseases is a long-term growth pillar for BioNTech, and the Company's objective is to be a leader in mRNA vaccines for infectious diseases. With investments in multiple programs to address diseases with major impact on global population health and on people in lower income countries, the Company is advancing its pipeline of mRNA vaccines and therapeutics to address multiple high-need indications.

BioNTech is on track to initiate four first-in-human clinical trials in the second half of 2022 that include mRNA-based product candidates designed to address shingles (in collaboration with Pfizer), malaria, tuberculosis and herpes simplex virus type 2 (HSV 2).

#### ***Influenza Vaccine Program***

BioNTech is collaborating with Pfizer to develop an influenza vaccine based on the Company's suite of mRNA platforms.

A Phase 1 trial to evaluate BNT161, an mRNA vaccine candidate, is ongoing and a dose-finding study for a self-amplifying RNA (saRNA) vaccine candidate is planned. A data update is expected in 2022.

#### ***Oncology***

BioNTech's immuno-oncology strategy is based on pioneering approaches that harness the immune response to treat cancer. BioNTech has multiple clinical stage assets across different therapeutic classes which may have the potential to tackle tumors using complementary strategies, either by targeting tumor cells directly, or by modulating the immune response against the tumor. The Company's oncology pillars include mRNA therapeutic vaccines, CAR-T immunotherapies, cell therapies, individualized neoantigen specific immunotherapies, RiboMabs, next-generation checkpoint immunomodulators, anti-tumor antibodies and small molecules. Many product candidates have the potential to be combined with other pipeline assets or already approved therapies.

This diverse toolkit of different technologies and modes of action has the potential to address a broad range of solid tumors in different disease stages, using both off-the-shelf and individualized approaches. For its antigen-specific immune therapies, BioNTech has assembled libraries of more than 300 proprietary or known shared antigens and has developed predictive algorithms capable of efficiently identifying multiple neoantigens on an individualized basis for any patient.

BioNTech's clinical stage oncology pipeline includes a total of 16 product candidates in 20 ongoing clinical trials including five now in randomized Phase 2 clinical trials: two FixVac programs (BNT111 and BNT113), two indications for the iNeST product candidate autogene cevumeran (BNT122/RO7198457), and the bispecific antibody checkpoint immunomodulator BNT311 (GEN1046). BioNTech's first-in-human trial of the Company's novel CAR-T cell therapy candidate, BNT211, is continuing to show encouraging clinical data, an important proof-point of the Company's scientific innovation engine.

BioNTech expects continued pipeline advancement and expansion, as well as further data readouts from the ongoing trials, in 2022.

### ***mRNA programs***

#### ***FixVac***

BioNTech's off-the-shelf cancer immunotherapy approach, FixVac, leverages the Company's proprietary uridine mRNA (uRNA) backbone that encodes cancer-specific shared antigens for intravenous administration using the proprietary RNA-LPX formulation and is optimized for induction of strong antigen-specific immune responses. FixVac product candidates may be of clinical utility in combination with anti-PD1 in patients with a lower mutational burden tumors, including those who have already experienced checkpoint inhibitor (CPI) therapy.

Two FixVac programs are in ongoing Phase 2 trials: BNT111 in PD1 inhibitor refractory/relapsed melanoma (in collaboration with Regeneron) and BNT113 in HPV16+ PDL1+ head and neck cancer.

- BNT116 – The first-in-human clinical trial to evaluate the safety, tolerability and preliminary efficacy of BNT116 is expected to be initiated in the second half of 2022.

In March 2022, BioNTech announced the expansion of its strategic collaboration with Regeneron. Under the agreement, the combination of BNT116 and Libtayo is expected to be advanced into clinical development for the treatment of advanced non-small-cell lung cancer (NSCLC).

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

BioNTech's individualized cancer immunotherapy approach (iNeST) is also based on pharmacologically optimized uridine mRNA (uRNA) backbone delivered in the Company's proprietary RNA-LPX formulation.

BioNTech's lead iNeST product candidate, autogene cevumeran (BNT122), is being developed together with Genentech as part of a co-development and co-commercialization collaboration.

Individual mRNA cancer vaccines encode the patient's own tumor mutations, against which neoantigen specific CD4 and CD8 T cell responses are generated *in vivo*. BioNTech believes this modality is well-suited for use in early-stage cancers and the adjuvant setting.

- A randomized Phase 2 trial of autogene cevumeran in the adjuvant treatment of circulating tumor DNA (ctDNA) positive, surgically resected Stage II (high-risk)/Stage III colorectal cancer is ongoing. The trial is expected to enroll about 200 patients to evaluate the efficacy of autogene cevumeran compared to watchful waiting after surgery and chemotherapy, the current standard of care for these high-risk patients.
- A data update from the ongoing randomized Phase 2 trial of autogene cevumeran combined with pembrolizumab in patients with 1L metastatic melanoma is expected in the second half of 2022.

#### *RiboMabs*

BioNTech's RiboMab product candidates, BNT141 and BNT142, are designed to encode cancer cell targeting antibodies. These product candidates leverage the Company's proprietary optimized mRNA technology combining nucleoside modifications to minimize immunogenicity with modifications in the mRNA backbone to maximize protein expression. RiboMabs may address the limitations of recombinant antibodies, including avoidance of protein manufacturing challenges and short plasma half-life.

- BNT141 encodes an antibody targeting Claudin-18.2, expressed in high unmet medical need tumors, including multiple epithelial solid tumors, such as gastric and pancreatic cancers. In January 2022, the first participant was dosed in an open-label, multi-site Phase 1/2 dose escalation, safety, and pharmacokinetic trial of BNT141 followed by expansion cohorts in patients with Claudin (CLDN)-18.2-positive tumors.
- BNT142 encodes a bispecific T cell engaging antibody that targets CD3, a T cell receptor component, and Claudin-6 (CLDN6), an oncofetal cell surface antigen found in solid tumors. BioNTech plans to start a Phase 1 clinical trial for BNT142 in the first half of 2022.

## Cell therapies

### *CAR-T cell immunotherapy*

BNT211, BioNTech's first chimeric antigen receptor, or CAR-T cell product candidate, targets CLDN6-positive solid tumors in combination with a CAR-T cell-amplifying RNA-vaccine, or CARVac, encoding CLDN6. CARVac is also based on pharmacologically optimized uridine mRNA (uRNA) backbone delivered in the Company's proprietary RNA-LPX formulation. CLDN-6 CAR-T cells are equipped with a second-generation CAR of high sensitivity and specificity for the tumor-specific carcino-embryonic antigen CLDN6. CARVac drives *in vivo* expansion of transferred CAR-T cells, increasing their persistence and efficacy. BNT211 is designed to overcome CAR-T cell therapy limitations in patients with solid tumors.

- BNT211 – A Phase 1/2 open-label dose escalation and dose expansion trial evaluating BNT211 in patients with CLDN6-positive solid tumors is ongoing.

Data from the ongoing trial were presented at the American Association for Cancer Research (AACR) Conference 2022. The presentation included data from 16 patients who received CLDN6 CAR-T cells at two dose levels alone or combined with CARVac. Tumor indications included testicular cancer (eight patients), ovarian cancer (four patients), endometrial cancer, fallopian tube cancer, sarcoma, and gastric cancer (one patient each).

The preliminary efficacy data showed encouraging signs of clinical activity with a disease control rate of 86% and an overall response rate of 43%. All 16 patients showed robust CAR-T cell engraftment with peak expansion 10 to 17 days after infusion reaching cell frequencies of  $10^9$  total cell counts or above at the higher dose level. At the first efficacy assessment six weeks post infusion, six of 14 evaluable patients showed a partial response, or PR, and five patients had stable disease, or SD, with shrinkage of target lesions. Responses were seen in four testicular and two ovarian cancer patients. At 12 weeks, four of the six patients with a PR showed deepening and durability of responses with one patient reaching a complete response 18 weeks after infusion. All four testicular cancer patients in the higher dose level had disease control and three of these patients showed objective responses. In addition, one testicular cancer patient showed partial response after infusion of the lowest CAR-T dose level in combination with CARVac. Antitumor activity tended to be higher at the higher CAR-T dose and when combined with the vaccine, with four of five patients in the CARVac combination group showing a partial response.

The results also demonstrated an encouraging safety profile as adverse events and dose limiting toxicities were manageable.

Another data update from the ongoing Phase 1/2 trial is expected in the second half of 2022.

## Corporate Updates

A key component of BioNTech's corporate strategy is strengthening the Company's technology platforms, digital capabilities and infrastructure through select strategic partnerships and acquisitions. In the first quarter of 2022, BioNTech entered into several new collaborations and research agreements. These included a collaboration with InstaDeep Ltd. to develop an early warning system for new SARS-CoV-2 variants, a multi-target discovery collaboration with Crescendo Biologics Ltd., and an asset purchase and option agreement with MediGene AG to develop novel T cell receptor-based immunotherapies against cancer.

- In April 2022, BioNTech was granted a pandemic preparedness contract by the Federal Republic of Germany. The framework agreement is aimed at pandemic preparedness including manufacturing and supply of mRNA vaccines in emergency situations in Germany. Under the preparedness agreement, which has an initial term of five years, BioNTech will reserve and maintain manufacturing capabilities to produce at least 80 million mRNA-based vaccine doses per year.
- In April 2022, BioNTech entered into an exclusive research collaboration with Matinas Biopharma to evaluate the combination of mRNA formats and Matinas' proprietary Lipid Nanocrystal, or LNC, platform technology, including a potential formulation for oral vaccines.

## Environmental, Social, and Governance (ESG)

BioNTech's commitment to social responsibility, responsible governance, environmental and climate protection, respecting human rights, and providing equitable access to medicines is intrinsic to the vision of the Company. This commitment is best demonstrated through the Company's efforts to democratize access to innovative medicines. In addition to the COVID-19 vaccine pledge to low and middle income countries, the Company is also addressing high medical need diseases such as malaria and tuberculosis that are prevalent on the African continent.

At the beginning of April 2022, BioNTech published its second ESG report (Sustainability Report 2021), which can be found in the Investor Relations section of BioNTech's website.

## Upcoming Investor and Analyst Events

- The Annual General Meeting will take place on June 1, 2022.
- BioNTech plans to host a Virtual Capital Markets Day, for analysts and investors on June 29, 2022.

## Conference Call and Webcast Information

BioNTech invites investors and the general public to join a conference call and webcast with investment analysts on the same day at 8.00 a.m. EDT (2.00 p.m. CEST) to report its financial results and provide a corporate update for the first quarter of 2022.

The slide presentation and audio of the webcast will be available via this [link](#).

To participate in the conference call, please dial the following numbers ten minutes prior to the start and provide the Conference ID:

United States international:	+1 646 741 3167
United States domestic (toll-free):	+1 877 870 9135
Germany:	+49 (0) 692 2222 625
Conference ID:	3698083

Participants may also access the slides and the webcast of the conference call via the "Events & Presentations" page of the Investor Relations section of the Company's website at <https://biontech.de/>. A replay of the webcast will be available shortly after the conclusion of the call and archived on the Company's website for 30 days following the call.

#### **About BioNTech**

Biopharmaceutical New Technologies (BioNTech) 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, 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: BioNTech's expected revenues and net profit related to sales of BioNTech's COVID-19 vaccine, referred to as COMIRNATY® where approved for use under full or conditional marketing authorization, in territories controlled by BioNTech's collaboration partners, particularly for those figures that are derived from preliminary estimates provided by BioNTech's partners; BioNTech's pricing and coverage negotiations with governmental authorities, private health insurers and other third-party payors after BioNTech's initial sales to national governments; the future commercial demand and medical need for initial or booster doses of a COVID-19 vaccine; 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 rate and degree of market acceptance of BioNTech's COVID-19 vaccine and, if approved, BioNTech's investigational medicines; 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 collaboration between BioNTech and Pfizer to develop and market a COVID-19 vaccine (including a potential booster dose of BNT162b2 and/or a potential booster dose of a variation of BNT162b2 having a modified mRNA sequence); the ability of BNT162b2 to prevent COVID-19 caused by emerging virus variants; BioNTech's ability to identify research opportunities and discover and develop investigational medicines; 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's COVID-19 vaccine and other products and product candidates developed or manufactured by us; BioNTech's ability to progress BioNTech's Malaria, Tuberculosis and HIV programs, including timing for selecting clinical candidates for these programs and the commencement of a clinical trial, as well as any data readouts; the development of sustainable vaccine production and supply solutions on the African continent and the nature and feasibility of these solutions; BioNTech's estimates of vaccine revenues, and projections of estimated research and development expenses, selling, general and administrative expenses, capital expenditures, and income

taxes; BioNTech's ability and that of BioNTech's collaborators to commercialize and market BioNTech's product candidates, if approved, including BioNTech's COVID-19 vaccine; BioNTech's ability to manage BioNTech's development and expansion; regulatory developments in the United States and foreign countries; BioNTech's ability to effectively scale BioNTech's production capabilities and manufacture BioNTech's products, including BioNTech's target COVID-19 vaccine production levels, and BioNTech's product candidates; and other factors not known to BioNTech 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 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 quarterly report on Form 6-K for the quarter ended March 31, 2022 and in subsequent filings made by BioNTech with the SEC, which are available on the SEC's website at <https://www.sec.gov/>. Except as required by law, BioNTech disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise. These forward-looking statements are based on BioNTech's current expectations and speak only as of the date hereof.

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## Interim Consolidated Statements of Profit or Loss

<i>(in millions, except per share data)</i>	Three months ended March 31,	
	2022 <i>(unaudited)</i>	2021 <i>(unaudited)</i>
Revenues		
Research & development revenues	12.4	20.9
Commercial revenues	6,362.2	2,027.5
<b>Total revenues</b>	<b>€6,374.6</b>	<b>€2,048.4</b>
Cost of sales	(1,294.1)	(233.1)
Research and development expenses	(285.8)	(216.2)
Sales and marketing expenses	(14.3)	(8.7)
General and administrative expenses	(90.8)	(38.9)
Other operating expenses	(71.6)	(0.6)
Other operating income	134.7	111.3
<b>Operating income</b>	<b>€4,752.7</b>	<b>€1,662.2</b>
Finance income	272.1	24.8
Finance expenses	(6.7)	(44.7)
<b>Profit before tax</b>	<b>€5,018.1</b>	<b>€1,642.3</b>
Income taxes	(1,319.3)	(514.2)
<b>Profit for the period</b>	<b>€3,698.8</b>	<b>€1,128.1</b>
<b>Earnings per share</b>		
Basic profit for the period per share	€15.13	€4.64
Diluted profit for the period per share	€14.24	€4.39

## Interim Consolidated Statements of Financial Position

<i>(in millions)</i>	March 31, 2022 <i>(unaudited)</i>	December 31, 2021
<b>Assets</b>		
<b>Non-current assets</b>		
Intangible assets	€216.0	€202.4
Property, plant and equipment	358.3	322.5
Right-of-use assets	198.6	197.9
Other financial assets	48.4	21.3
Other assets	0.8	0.8
Deferred expenses	11.4	13.6
<b>Total non-current assets</b>	<b>€833.5</b>	<b>€758.5</b>
<b>Current assets</b>		
Inventories	459.3	502.5
Trade and other receivables	12,695.8	12,381.7
Other financial assets	0.9	381.6
Other assets	64.9	64.9
Income tax assets	0.4	0.4
Deferred expenses	80.7	48.5
Cash and cash equivalents	6,164.1	1,692.7
<b>Total current assets</b>	<b>€19,466.1</b>	<b>€15,072.3</b>
<b>Total assets</b>	<b>€20,299.6</b>	<b>€15,830.8</b>
<b>Equity and liabilities</b>		
<b>Equity</b>		
Share capital	246.8	246.3
Capital reserve	1,976.3	1,674.4
Treasury shares	(3.8)	(3.8)
Retained earnings	13,581.7	9,882.9
Other reserves	109.7	93.9
<b>Total equity</b>	<b>€15,910.7</b>	<b>€11,893.7</b>
<b>Non-current liabilities</b>		
Loans and borrowings	155.4	171.6
Other financial liabilities	6.1	6.1
Income tax liabilities	4.4	4.4
Provisions	240.0	184.9
Contract liabilities	66.4	9.0
Other liabilities	11.2	12.8
Deferred tax liabilities	50.9	66.7
<b>Total non-current liabilities</b>	<b>€534.4</b>	<b>€455.5</b>
<b>Current liabilities</b>		
Loans and borrowings	30.6	129.9
Trade payables	123.7	160.0
Other financial liabilities	1,381.9	1,190.4
Government grants	3.0	3.0
Refund liabilities	90.0	90.0
Income tax liabilities	1,614.0	1,568.9
Provisions	339.2	110.2
Contract liabilities	192.0	186.1
Other liabilities	80.1	43.1
<b>Total current liabilities</b>	<b>€3,854.5</b>	<b>€3,481.6</b>
<b>Total liabilities</b>	<b>€4,388.9</b>	<b>€3,937.1</b>
<b>Total equity and liabilities</b>	<b>€20,299.6</b>	<b>€15,830.8</b>

## Interim Consolidated Statements of Cash Flows

<i>(in millions)</i>	Three months ended March 31,	
	2022	2021
<b>Operating activities</b>		
Profit for the period	€3,698.8	€1,128.1
Income taxes	1,319.3	514.2
<b>Profit before tax</b>	<b>€5,018.1</b>	<b>€1,642.3</b>
Adjustments to reconcile profit before tax to net cash flows:		
Depreciation and amortization of property, plant, equipment, intangible assets and right-of-use assets	27.6	13.0
Share-based payment expense	9.4	17.3
Net foreign exchange differences	6.1	(31.2)
Gain on disposal of property, plant and equipment	—	0.2
Finance income	(217.3)	(0.3)
Finance expense	6.7	44.7
Movements in government grants	—	(67.9)
Net loss on derivative instruments at fair value through profit or loss	(1.9)	—
Working capital adjustments:		
Increase in trade and other receivables, contract assets and other assets	(403.5)	(2,100.5)
Decrease / (increase) in inventories	43.2	(82.8)
Increase in trade payables, other financial liabilities, other liabilities, contract liabilities, refund liabilities and provisions	857.5	255.5
Interest received	0.7	0.3
Interest paid	(6.4)	(1.8)
Income tax paid	(1,290.0)	(0.1)
<b>Net cash flows from / (used in) operating activities</b>	<b>€4,050.2</b>	<b>€(311.3)</b>
<b>Investing activities</b>		
Purchase of property, plant and equipment	(44.1)	(21.7)
Proceeds from sale of property, plant and equipment	—	0.9
Purchase of intangible assets and right-of-use assets	(16.7)	(7.5)
Investment into equity instruments designated at fair value through OCI	(27.0)	—
Proceeds from maturity of other financial assets	375.2	—
<b>Net cash flows from / (used in) investing activities</b>	<b>€287.4</b>	<b>€(28.3)</b>
<b>Financing activities</b>		
Proceeds from issuance of share capital and treasury shares, net of costs	110.5	—
Repayment of loans and borrowings	(18.8)	(0.7)
Payments related to lease liabilities	(11.4)	(3.8)
<b>Net cash flows from / (used in) financing activities</b>	<b>€80.3</b>	<b>€(4.5)</b>
Net increase / (decrease) in cash and cash equivalents	4,417.9	(344.1)
Change in cash and cash equivalents resulting from exchange rate differences	53.5	25.4
Cash and cash equivalents at the beginning of the period	1,692.7	1,210.2
<b>Cash and cash equivalents at March 31</b>	<b>€6,164.1</b>	<b>€891.5</b>

BIONTECH

1<sup>st</sup> Quarter 2022  
Financial Results  
& Corporate Update

May 9, 2022

Exhibit 99.2



## 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, but not limited to, statements concerning: our expected revenues and net profit related to sales of our COVID-19 vaccine, referred to as COMIRNATY<sup>®</sup> where approved for use under full or conditional marketing authorization, in territories controlled by our collaboration partners, particularly for those figures that are derived from preliminary estimates provided by our partners; our pricing and coverage negotiations with governmental authorities, private health insurers and other third-party payors after our initial sales to national governments; the future commercial demand and medical need for initial or booster doses of a COVID-19 vaccine; 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, if approved, our investigational medicines; 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 collaboration with Pfizer to develop and market a COVID-19 vaccine (including a potential booster dose of BNT162b2 and/or a potential booster dose of a variation of BNT162b2 having a modified mRNA sequence); the ability of BNT162b2 to prevent COVID-19 caused by emerging virus variants; 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 ability to progress our Malaria, Tuberculosis and HIV programs, including timing for selecting clinical candidates for these programs and the commencement of a clinical trial, as well as any data readouts; the nature and duration of support from the World Health Organization, the European Commission and other organizations with establishing infrastructure; the development of sustainable vaccine production and supply solutions on the African continent and the nature and feasibility of these solutions; our estimates of research and development revenues, commercial revenues, cost of sales, research and development expenses, sales and marketing expenses, general and administrative expenses, capital expenditures, income taxes, shares outstanding; our ability and that of our collaborators to commercialize and market our product candidates, if approved, including our COVID-19 vaccine; 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; 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 presentation 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 presentation for the three months ended March 31, 2022 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 presentation 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

COMIRNATY® ▼ (the Pfizer-BioNTech COVID-19 vaccine) has been granted conditional marketing authorization (CMA) by the European Commission to prevent coronavirus disease 2019 (COVID-19) in people from 5 years of age. The vaccine is administered as a primary course of 2 doses, 3 weeks apart. In addition, the CMA has been expanded to include a booster dose (third dose) at least 6 months after the second dose in individuals 12 years of age and older. For immunocompromised individuals, a third primary course dose may be given at least 28 days after the second dose. The European Medicines Agency's (EMA's) human medicines committee (CHMP) has completed its rigorous evaluation of COMIRNATY®, concluding by consensus that sufficiently robust data on the quality, safety and efficacy of the vaccine are now available.

### IMPORTANT SAFETY INFORMATION:

- Events of anaphylaxis have been reported. Appropriate medical treatment and supervision should always be readily available in case of an anaphylactic reaction following the administration of the vaccine.
- There is an increased risk of myocarditis and pericarditis following vaccination with Comirnaty. These conditions can develop within just a few days after vaccination, and have primarily occurred within 14 days. They have been observed more often after the second vaccination, and more often in younger males. Available data suggest that the course of myocarditis and pericarditis following vaccination is not different from myocarditis or pericarditis in general.
- Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions (e.g. dizziness, palpitations, increases in heart rate, alterations in blood pressure, paraesthesia, hypoesthesia and sweating) may occur in association with the vaccination process itself. Stress-related reactions are temporary and resolve on their own. Individuals should be advised to bring symptoms to the attention of the vaccination provider for evaluation. It is important that precautions are in place to avoid injury from fainting.
- Vaccination should be postponed in individuals suffering from acute severe febrile illness or acute infection. The presence of a minor infection and/or low-grade fever should not delay vaccination.
- As with other intramuscular injections, the vaccine should be given with caution in individuals receiving anticoagulant therapy or those with thrombocytopenia or any coagulation disorder (such as haemophilia) because bleeding or bruising may occur following an intramuscular administration in these individuals.
- The efficacy and safety of the vaccine has not been assessed in immunocompromised individuals, including those receiving immunosuppressant therapy. The efficacy of Comirnaty may be lower in immunocompromised individuals. As with any vaccine, vaccination with COMIRNATY® may not protect all vaccine recipients. Individuals may not be fully protected until 7 days after their second dose of vaccine.
- In clinical studies, adverse reactions in participants 16 years of age and older were injection site pain (> 80%), fatigue (> 60%), headache (> 50%), myalgia and chills (> 30%), arthralgia (> 20%), pyrexia and injection site swelling (> 10%) and were usually mild or moderate in intensity and resolved within a few days after vaccination. A slightly lower frequency of reactogenicity events was associated with greater age.
- The overall safety profile of COMIRNATY® in participants 5 to 15 years of age was similar to that seen in participants 16 years of age and older.
- The most frequent adverse reactions in children 5 to 11 years of age were injection site pain (>80%), fatigue (>50%), headache (>30%), injection site redness and swelling (>20%), myalgia and chills (>10%).
- The most frequent adverse reactions in clinical trial participants 12 to 15 years of age were injection site pain (> 80%), fatigue and headache (> 70%), myalgia and chills (> 40%), arthralgia and pyrexia (> 20%).
- A large amount of observational data from pregnant women vaccinated with Comirnaty during the second and third trimester have not shown an increase in adverse pregnancy outcomes. While data on pregnancy outcomes following vaccination during the first trimester are presently limited, no increased risk for miscarriage has been seen. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/fetal development, parturition or post-natal development. Comirnaty can be used during pregnancy.
- No effects on the breast fed newborn/infant are anticipated since the systemic exposure of breast feeding woman to Comirnaty is negligible. Observational data from women who were breast feeding after vaccination have not shown a risk for adverse effects in breast fed newborns/infants. Comirnaty can be used during breast feeding. Interactions with other medicinal products or concomitant administration of COMIRNATY® with other vaccines has not been studied.
- For complete information on the safety of COMIRNATY® always make reference to the approved Summary of Product Characteristics and Package Leaflet available in all the languages of the European Union on the EMA website.

The black equilateral triangle ▼ denotes that additional monitoring is required to capture any adverse reactions. This will allow quick identification of new safety information. Individuals can help by reporting any side effects they may get. Side effects can be reported to [EudraVigilance](#) or directly to BioNTech using email [medinfo@biontech.de](mailto:medinfo@biontech.de), telephone +49 6131 9084 0, or via the website [www.biontech.de](http://www.biontech.de)

# Safety Information

## AUTHORIZED USE IN THE U.S.

COMIRNATY<sup>®</sup> (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine 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. It is also authorized under EUA to provide a 2-dose primary series to individuals 5 years of age and older, a third primary series dose to individuals 5 years of age and older who have been determined to have certain kinds of immunocompromise, a single booster dose to individuals 12 years of age and older who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY<sup>®</sup>, a single booster dose to individuals 18 years of age and older who have completed primary vaccination with a different authorized COVID-19 vaccine, a second booster dose to individuals 50 years of age and older who have received a first booster dose of any authorized COVID-19 vaccine, and a second booster dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise and who have received a first booster dose of any authorized COVID-19 vaccine. The booster schedule is based on the labeling information of the vaccine used for the primary series.

## IMPORTANT SAFETY INFORMATION

Individuals should not get the vaccine if they:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine

Individuals should tell the vaccination provider about all of their medical conditions, including if they:

- have any allergies
- have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects the immune system
- are pregnant, plan to become pregnant, or are breastfeeding
- have received another COVID-19 vaccine
- have ever fainted in association with an injection

The vaccine may not protect everyone. Side effects reported with the vaccine include:

- There is a remote chance that the vaccine could cause a severe allergic reaction.
  - A severe allergic reaction would usually occur within a few minutes to 1 hour after getting a dose of the vaccine. For this reason, vaccination providers may ask individuals to stay at the place where they received the vaccine for monitoring after vaccination
  - Signs of a severe allergic reaction can include difficulty breathing, swelling of the face and throat, a fast heartbeat, a bad rash all over the body, dizziness, and weakness
  - If an individual experiences a severe allergic reaction, they should call 9-1-1 or go to the nearest hospital
- Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the vaccine, more commonly in males under 40 years of age than among females and older males. In most of these people, symptoms began within a few days following receipt of the second dose of the vaccine. The chance of having this occur is very low. Individuals should seek medical attention right away if they have any of the following symptoms after receiving the vaccine:
  - chest pain
  - shortness of breath
  - feelings of having a fast-beating, fluttering, or pounding heart
- Additional side effects that have been reported with the vaccine include:
  - severe allergic reactions, non-severe allergic reactions such as injection site pain, tiredness; headache; muscle pain; chills; joint pain; fever; injection site swelling; injection site redness; nausea; feeling unwell; swollen lymph nodes (lymphadenopathy); decreased appetite; diarrhea; vomiting; arm pain; and fainting in association with injection of the vaccine
- These may not be all the possible side effects of the vaccine. Serious and unexpected side effects may occur. The possible side effects of the vaccine are still being studied in clinical trials. Call the vaccination provider or healthcare provider about bothersome side effects or side effects that do not go away

Data on administration of this vaccine at the same time as other vaccines have not yet been submitted to FDA. Individuals considering receiving this vaccine with other vaccines should discuss their options with their healthcare provider. Patients should always ask their healthcare providers for medical advice about adverse events. Individuals are encouraged to report negative side effects of vaccines to the US Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). Visit <https://www.vaers.hhs.gov> or call 1-800- 822-7967. In addition, side effects can be reported to Pfizer Inc. at [www.pfizersafetyreporting.com](http://www.pfizersafetyreporting.com) or by calling 1-800-438-1985.

# Agenda

**01** First Quarter 2022 Highlights  
Ugur Sahin, CEO

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**02** Pipeline Update  
Özlem Türeci, CMO

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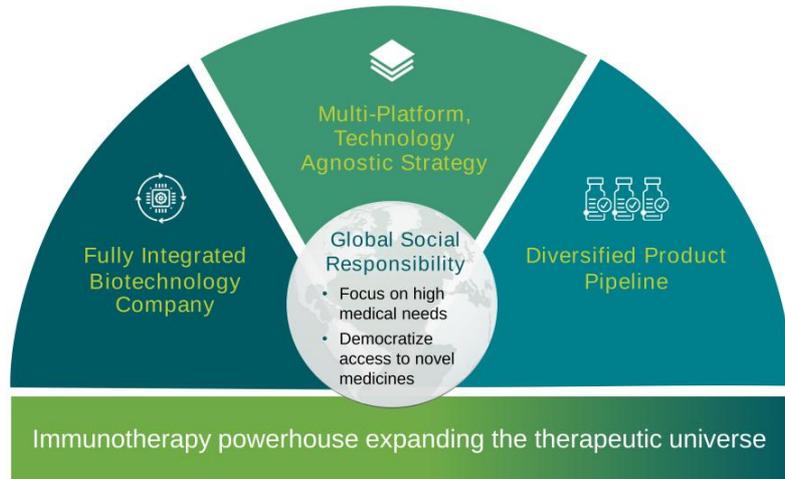
**03** Financial Results  
Jens Holstein, CFO

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**04** Corporate Outlook  
Ryan Richardson, Chief Strategy Officer

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## Our Vision: Harnessing The Power Of The Immune System To Fight Human Diseases



## Highlights in Q1 2022



<sup>1</sup> BioNTech's profit share is estimated based on preliminary data shared between Pfizer and BioNTech as further described in the Annual Report on Form 20-F for the year ended December 31, 2021 as well as the Quarterly Report as of and for the three months ended March 31, 2022, filed as an exhibit to BioNTech's Current Report on Form 6-K. Any changes in the estimated share of the collaboration partner's gross profit will be recognized prospectively.  
NSCLC = non-small cell lung cancer

## Proactive Approach to Managing COVID-19 at a Global Scale

### Strong global position to tackle COVID-19 pandemic



- Delivered nearly 3.4 bn<sup>1</sup> doses cumulatively to >175 countries and regions
- On track to achieve pledge to deliver a total of 2 bn doses to low- and middle-income countries by end of 2022

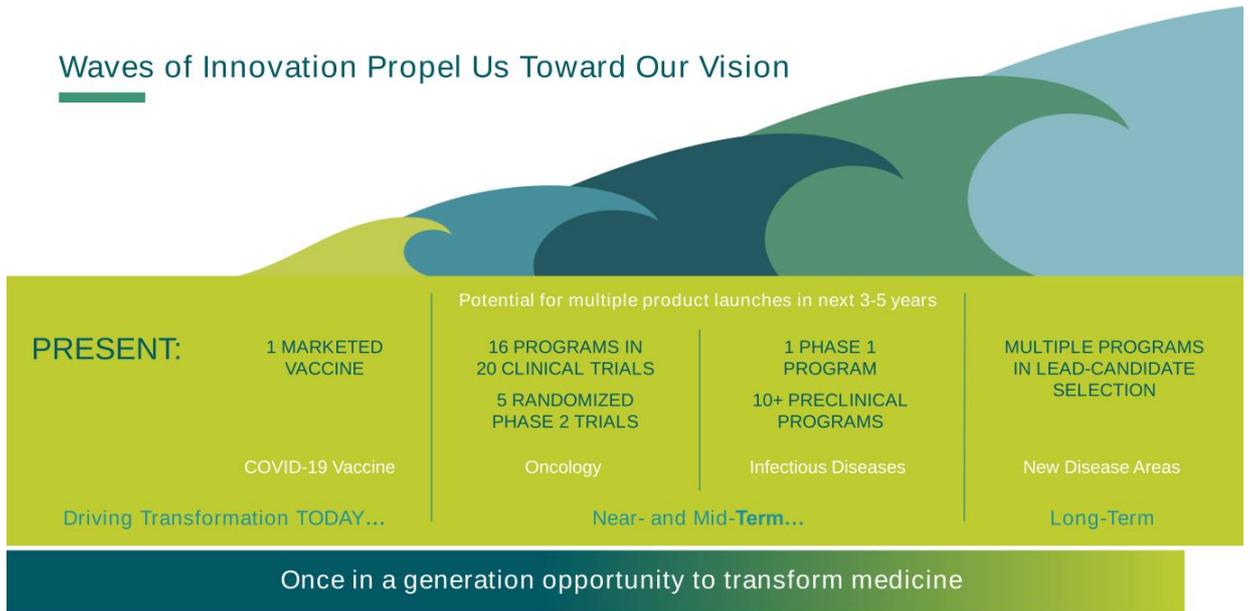
<sup>1</sup> As of end-April 2022

### Innovation to stay ahead of COVID-19

- ✓ Optimized formulation
- ✓ Pediatric label expansion
  - Submission for boosters in children 5 to <12 yrs
  - Evaluating 3-dose primary regimen in children 6 months to <5 yrs; data expected in coming weeks
- ✓ Future pandemic preparedness
  - Monitoring of emerging variants
  - Rapid data-guided vaccine adaptation
- ✓ Pre-emptive approach to variants
  - Comprehensive variant-adapted and next-gen vaccine development program
  - Broad research program to study anti-SARS-CoV-2 immune profile after vaccinations, boosters, breakthrough infections to inform strategy

BIONTECH

## Waves of Innovation Propel Us Toward Our Vision



# Agenda

**01** First Quarter 2022 Highlights  
Ugur Sahin, CEO

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**02** Pipeline Update  
Özlem Türeci, CMO

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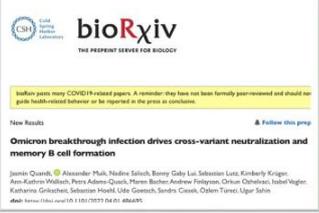
**03** Financial Results  
Jens Holstein, CFO

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**04** Corporate Outlook  
Ryan Richardson, Chief Strategy Officer

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# COVID-19 Vaccine R&D Strategy to Drive Pandemic Preparedness

	Purpose	Latest Developments
Landscape Research	Inform Understanding of Dynamic SARS-CoV-2 Immunity	 <p><b>Omicron Infection After Vaccination Drives Cross-Variant Neutralization and B Cell Immunity<sup>1</sup></b></p> <ul style="list-style-type: none"> <li>Exposure to Omicron spike boosts strong and broad neutralizing activity against SARS-CoV-2 VOCs</li> <li>Robust recall and expansion of preformed memory B cells that recognize epitopes shared across variants</li> </ul> <p>Data suggest Omicron-adapted vaccination after COMIRNATY could provide similar cross-strain immunity</p>
Product Research	Explore Various Follow-On and Next-Gen Vaccine Approaches	 <p>Omicron-Adapted    Mono-/ Multi-valent    T Cell Enhancing    Pan-Coronavirus covering</p>
Product Development	Assess Safety, Tolerability and Immunogenicity of Variant-Adapted Vaccines	Emerging data from ongoing clinical trials evaluating mono- or bivalent variant adapted vaccines will be reviewed and discussed with regulators

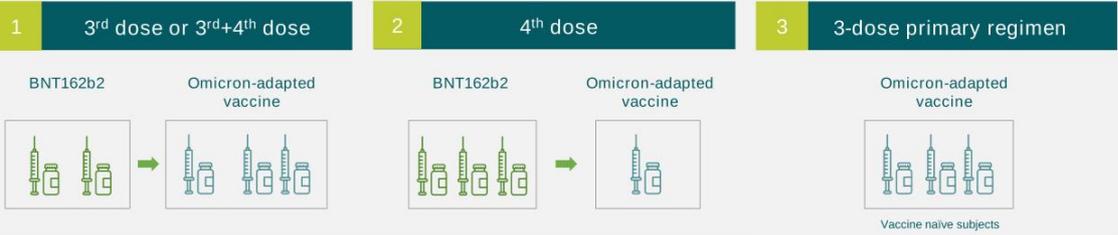
<sup>11</sup> 1 bioRxiv. Omicron breakthrough infection drives cross-variant neutralization and memory B cell formation; April 1, 2022. Available at: <https://www.biorxiv.org/content/10.1101/2022.04.01.486695v1.full.pdf>  
VOC, variants of concern

# Comprehensive Clinical Response Strategy to Omicron Variant

## Assessing Safety, Tolerability and Immunogenicity of an Omicron-Adapted Vaccine

### Evaluating different Omicron-adapted monovalent vaccine regimens

- N~1500, 18-55 years
- Vaccine experienced and naïve subjects



### Evaluating bivalent Wild-Type/Omicron-adapted and Omicron-adapted vaccines

- N~650, >55 years
- Two dosages: 30 µg and 60 µg

<sup>12</sup> BioNTech. Available at: <https://investors.biontech.de/news-releases/news-release-details/pfizer-and-biontech-initiate-study-evaluate-omicron-based-covid>. Accessed January 2022; ClinicalTrials.gov. Available at: <https://www.clinicaltrials.gov/ct2/show/NCT04955626>. Accessed March 2022.

## Oncology: Advancement Across Multiple Modalities and Indications

Drug class	Platform	Product candidate	Indication (targets)	Pre-clinical	Phase 1	Phase 2	Phase 3
mRNA	FixVac (fixed combination of shared cancer antigens)	BNT111	Advanced melanoma				
		BNT112	Prostate cancer				
		BNT113	HPV16+ head and neck cancer				
		BNT115 <sup>1</sup>	Ovarian cancer <sup>1</sup>				
		BNT116	NSCLC				
	iNeST (patient specific cancer antigen immune therapy)	Autogene cevumeran (BNT122) <sup>2</sup>	1L melanoma				
			Adjuvant colorectal cancer				
	Intratumoral Immunotherapy	SAR441000 (BNT131) <sup>3</sup>	Solid tumors				
			Solid tumors (IL-12sc, IL15-sushi, GM-CSF, IFN $\alpha$ )				
			Multiple solid tumors (CLDN18.2)				
			Multiple solid tumors (CD3+CLDN6)				
			Multiple solid tumors (optimized IL-2)				
	RiboMabs (mRNA-encoded antibodies)	BNT141	Multiple solid tumors (IL-7, IL-2)				
Multiple solid tumors (CD3+CLDN6)							
Multiple solid tumors (IL-7, IL-2)							
RiboCytokines (mRNA-encoded cytokines)	BNT152, BNT153	Multiple solid tumors (CLDN6)					
		Pancreatic, other cancers (CLDN18.2)					
Cell Therapies	CAR-T Cells + Carvac	BNT211	Multiple solid tumors (CLDN6)				
		BNT212	Pancreatic, other cancers (CLDN18.2)				
		BNT221 (NEO-PTC-01)	Multiple solid tumors				
Cell Therapies	Neoantigen-based T cells	TCR engineered T cells	To be selected				
			All tumors				
Antibodies	Next-Gen CP Immunomodulators	GEN1046 (BNT311) <sup>4</sup>	Metastatic NSCLC (PD-L1x4-1BB)				
			Multiple solid tumors (PD-L1x4-1BB)				
			Multiple solid tumors (CD40x4-1BB)				
Antibodies	Targeted Cancer Antibodies	BNT321 (MVT-5873)	Pancreatic cancer (sLea)				
			Pancreatic cancer (sLea)				
SMIM	Toll-Like Receptor Binding	BNT411	Solid tumors (TLR7)				

13 <sup>1</sup>BNT115 is currently being studied in an investigator-initiated Phase 1 trial. <sup>2</sup>Collaboration with Genentech <sup>3</sup>Collaboration with Sanofi. <sup>4</sup>Collaboration with Genmab. SMIM, Small Molecule Immunomodulators

## Focused Execution in 2022 Across 5 Phase 2 Programs in Various Solid Tumor Types

Platform	FixVac Off-the-shelf mRNA vaccine		iNeST Individualized mRNA immunotherapy		Bispecific Next-generation immunotherapy
Program	<b>BNT111</b> R/R Melanoma	<b>BNT113</b> HPV16+ HNSCC	Autogene cevumeran <b>BNT122<sup>1</sup></b> 1L Melanoma	Autogene cevumeran <b>BNT122<sup>1</sup></b> Adjuvant colorectal cancer	<b>BNT311<sup>2</sup></b> R/R NSCLC
How	<ul style="list-style-type: none"> <li>Encodes 4 tumor-associated antigens covering &gt;90% of cutaneous melanoma patients</li> <li>U.S. Fast Track Designation and Orphan Drug Designation</li> </ul>	<ul style="list-style-type: none"> <li>Encodes HPV16 oncoproteins E6 &amp; E7</li> </ul>	<ul style="list-style-type: none"> <li>Targets 20 neo-antigens unique to each patient</li> <li>Data update expected 2H 2022</li> </ul>	<ul style="list-style-type: none"> <li>Targets 20 neo-antigens unique to each patient</li> </ul>	<ul style="list-style-type: none"> <li>Conditional 4-1BB co-stimulation while blocking PD(L)1 axis</li> </ul>
Why	<ul style="list-style-type: none"> <li>Potential to improve outcomes in combo with anti-PD1</li> </ul>	<ul style="list-style-type: none"> <li>Potential for synergistic anti-tumor effect in combination with anti-PD1</li> </ul>	<ul style="list-style-type: none"> <li>Trial success may unlock 1L use of iNeST as combination therapy with anti-PD(L)1 in anti-PD1-naive advanced cancers</li> </ul>	<ul style="list-style-type: none"> <li>Potential to address residual cancer cells that remain – focus on recurrence free survival</li> </ul>	<ul style="list-style-type: none"> <li>Enhances T cell and NK cell function and targets them to tumor lesions</li> </ul>

14 R/R, refractory/relapsed; HPV16+, human papilloma virus type 16 positive; HNSCC, head and neck squamous cell carcinoma; NK cell, Natural killer cell; CPI, checkpoint inhibitor  
<sup>1</sup> Collaboration with Genentech, <sup>2</sup> Collaboration with Genmab.

# BNT211: CAR-T Cell Program with Potential Targeting Multiple High-Need Solid Tumors

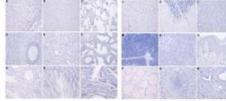
## 2nd generation CAR

- Directed against CLDN6
- Cancer specific carcino-embryonic antigen
- Expressed in multiple solid cancers with high medical need

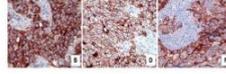
## CARVac

- drives in vivo expansion, persistence and efficacy of CAR-T cells

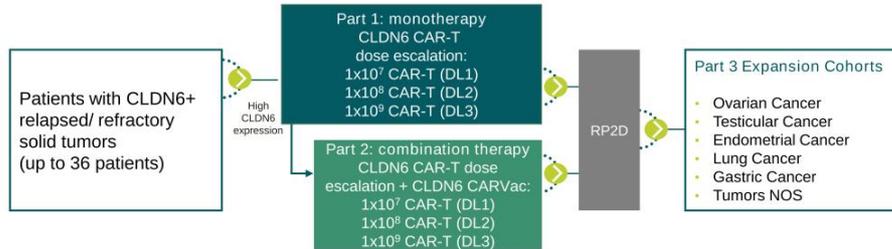
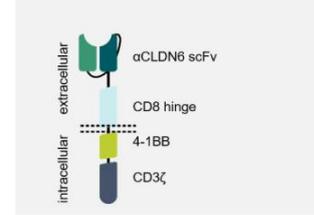
CLDN6 not present in healthy tissues



CLDN6 expressed in multiple cancers



BNT211 CAR Structure



15 CLDN6, Claudin-6; CAR-T cells, chimeric antigen receptor engineered T cells; scFv, single chain variable fragment; RP2D, recommended Phase 2 dose; NOS, not otherwise specified; Reinhard K, et al. Science 2020; 367:446-453

# BNT211: CAR-T in Solid Tumors Encouraging Efficacy and Safety Profiles Presented at AACR



## Safety

CLDN6 CAR-T cells as monotherapy or combined with CARVac well tolerated at dose levels evaluated to date ( $1 \times 10^7$  and  $1 \times 10^8$  CAR-T)

- Grade 1-2 CRS seen in 70% of patients at  $1 \times 10^8$  CAR-T dose, manageable by administration of tocilizumab
- 2 DLTs observed, both patients fully recovered and showed clinical benefit
- MTD not reached yet



## Efficacy

- Robust CAR-T engraftment achieved in all patients translating into clinical activity: ORR 43%, DCR of 86% in evaluable patients (n=14;  $1 \times 10^7$  and  $1 \times 10^8$  CAR-T)
  - 6 PR, 5 SD+, 1 SD (Testicular, ovarian and other tumors, 6 weeks post-infusion)
  - 5 testicular cancer patients show promising responses at  $1 \times 10^8$  CAR-T: ORR 80%, DCR 100%; 1 CR, 3 PR, 1 SD
- CARVac supports CAR-T engraftment and mediates physiologic expansion plus upregulation of survival pathways
- Some patients show continuing CAR-T persistence (>150 days post infusion)
- Patients with initial PR showed further deepening of responses

Data cut-off: MAR 10, 2022

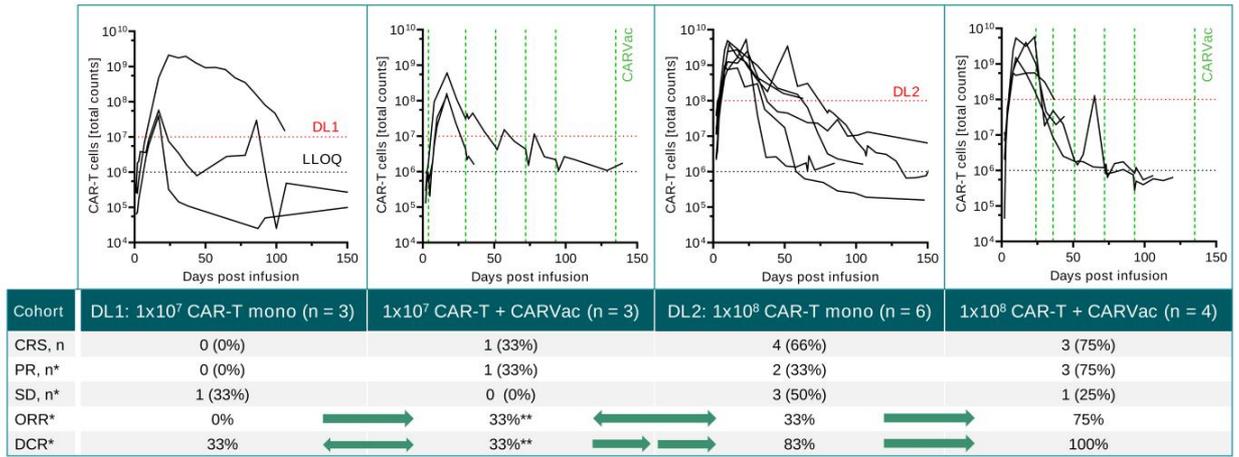
DL1:  $1 \times 10^7$  CAR-T; DL2:  $1 \times 10^8$  CAR-T

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CLDN6, Claudin-6; DLT, dose-limiting toxicity; MTD, maximum tolerated dose; CRS, cytokine release syndrome; CR, complete response; DCR, disease control rate; DL, dose level; ORR, overall response rate; PR, partial response; SD, stable disease

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## Robust CAR-T Engraftment Seen in all Patients and Persisting CAR-T in Responding Patients



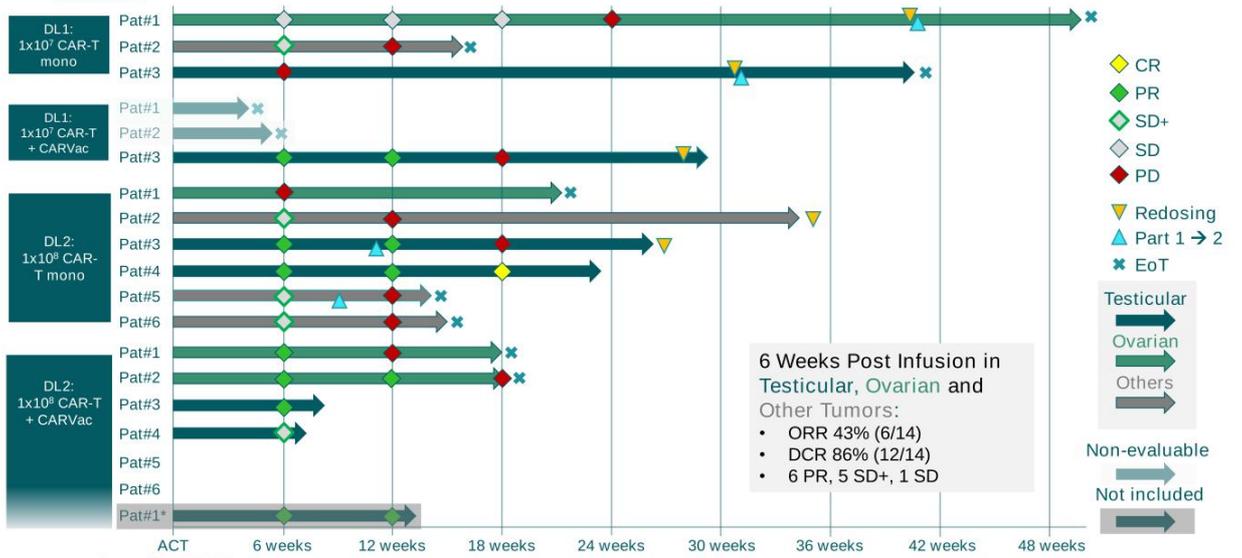
Data cut-off: MAR 10, 2022.

DL1: 1x10<sup>7</sup> CAR-T; DL2: 1x10<sup>8</sup> CAR-T

CRS, cytokine release syndrome; DCR, disease control rate; DL, dose level; DLT, dose-limiting toxicity; ORR, overall response rate; PR, partial response; SD, stable disease; \*At first tumor assessment (6 weeks post infusion); \*\*2 patients died due to disease progression before first tumor assessment.

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# Efficacy Observed at 6 Weeks Post Infusion



Data cut-off: MAR 10, 2022.

DL1: 1x10<sup>7</sup> CAR-T; DL2: 1x10<sup>8</sup> CAR-T

DL, dose level; CR, complete response; DCR, disease control rate; EoT, end of trial (due to PD); ORR, overall response rate; PD, progressive disease; PR, partial response; SD, stable disease, SD+, SD with shrinkage of target lesions; \*50% lymphodepletion



## Responses in Two Testicular Cancer Patients with Relapse After Prior Treatment

	Baseline	6 weeks post infusion	12 weeks post infusion	Post 12-week scan
<b>Patient 1</b> 61-year-old male patient diagnosed 2008 (DL2: $1 \times 10^8$ )				<ul style="list-style-type: none"> <li>• No new lesions detected</li> <li>• Tumor marker (AFP) at normal level</li> <li>• Patient has ongoing CR</li> </ul>
<b>Patient 2</b> 56-year-old male patient diagnosed 2020 (DL1: $1 \times 10^7$ + CARVac)				<ul style="list-style-type: none"> <li>• After initial response New lesions were detected</li> <li>• On-treatment biopsy showed positivity for CLDN6</li> <li>• Patient was re-dosed on d197</li> </ul>

# Agenda

**01** First Quarter 2022 Highlights  
Ugur Sahin, CEO

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**02** Pipeline Update  
Özlem Türeci, CMO

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**03** Financial Results  
Jens Holstein, CFO

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**04** Corporate Outlook  
Ryan Richardson, Chief Strategy Officer

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## Key Highlights For Q1 2022

Total Revenues <sup>1</sup>	Operating Result
 <b>€6.4 bn</b>	 <b>€4.8 bn</b>
Diluted EPS	Cash and Trade Receivables
 <b>€14.24</b>	 <b>€6.2 bn + €12.7 bn</b>

<sup>22</sup> 1. BioNTech's profit share is estimated based on preliminary data shared between Pfizer and BioNTech as further described in the Annual Report on Form 20-F for the year ended December 31, 2021, as well as the Quarterly Report as of and for the three months ended March 31, 2022, filed as an exhibit to BioNTech's Current Report on Form 6-K. Any changes in the estimated share of the collaboration partner's gross profit will be recognized prospectively.

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## First Quarter 2022 COVID-19 Vaccine Commercial Revenues



Strong Q1 2022 - BioNTech reiterates 2022 financial year guidance

23 1. BioNTech's profit share is estimated based on preliminary data shared between Pfizer and BioNTech as further described in the Annual Report on Form 20-F for the year ended December 31, 2021 as well as the Quarterly Report as of and for the three months ended March 31, 2022, filed as an exhibit to BioNTech's Current Report on Form 6-K. Any changes in the estimated share of the collaboration partner's gross profit will be recognized prospectively.

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## Q1 2022 Financial Results – Profit or Loss

(in millions, except per share data) <sup>1</sup>	Q1 2022	Q1 2021
Research & development revenues	€12.4	€20.9
Commercial revenues <sup>2</sup>	6,362.2	2,027.5
<b>Total revenues</b>	<b>€6,374.6</b>	<b>€2,048.4</b>
Cost of sales	(1,294.1)	(233.1)
Research and development expenses	(285.8)	(216.2)
Sales and marketing expenses	(14.3)	(8.7)
General and administrative expenses	(90.8)	(38.9)
Other operating income less expenses	63.1	110.7
<b>Operating income</b>	<b>€4,752.7</b>	<b>€1,662.2</b>
Finance income less expenses	265.4	(19.9)
Income taxes	(1,319.3)	(514.2)
<b>Profit for the period</b>	<b>€3,698.8</b>	<b>€1,128.1</b>
<b>Earnings per share</b>		
Basic profit for the period per share	€15.13	€4.64
Diluted profit for the period per share	€14.24	€4.39

<sup>1</sup> 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 consolidated statements of profit or loss has been condensed.

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<sup>2</sup> BioNTech's profit share is estimated based on preliminary data shared between Pfizer and BioNTech as further described in the Annual Report on Form 20-F for the year ended December 31, 2021 as well as the Quarterly Report as of and for the three months ended March 31, 2022, filed as an exhibit to BioNTech's Current Report on Form 6-K. Any changes in the estimated share of the collaboration partner's gross profit will be recognized prospectively.

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## 2022 Financial Year Guidance Reiterated

COVID-19 Vaccine Revenues for FY 2022 <sup>1</sup>	
Estimated BioNTech COVID-19 vaccine revenues	€ 13 – 17 bn

Planned FY 2022 Expenses and Capex <sup>1</sup>	
R&D expenses	€ 1,400 - 1,500 m
SG&A expenses	€ 450 - 550 m
Capital expenditure	€ 450 - 550 m

Estimated FY 2022 Tax Assumptions	
BioNTech Group estimated annual effective income tax rate	~28% <sup>2</sup>

25 <sup>1</sup> Ranges reflect current base case projections and do not include potential effects caused by or driven from additional collaborations or potential M&A transactions.  
<sup>2</sup> BioNTech Group estimated annual effective income tax rate decreased from 31.6% (FY 2021) to ~28% (FY 2022) mainly due to decreasing average trade tax rates.

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**01** First Quarter 2022 Highlights  
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## Significant Pipeline Expansion and Maturation Expected in 2022

Continue COVID-19 Vaccine Leadership	Execute in Oncology	Expand in Infectious Disease	Advance into New Therapeutic Areas
 <ul style="list-style-type: none"><li>• Label &amp; geographic expansion</li><li>• Next-generation vaccines</li><li>• Innovations for pandemic preparedness</li></ul>	 <ul style="list-style-type: none"><li>• First randomized Phase 2 readout</li><li>• Prepare for registrational trials</li><li>• POC data for CAR-T cell therapy</li></ul>	 <ul style="list-style-type: none"><li>• Initiate 4 FIH vaccine trials</li><li>• 10+ additional mRNA vaccine programs</li><li>• Precision antibacterials</li></ul>	 <ul style="list-style-type: none"><li>• Autoimmune disease</li><li>• Regenerative medicine</li><li>• Cardiovascular disease</li></ul>
<p data-bbox="470 593 1241 622">Invest in Foundation to Enable Accelerated Innovation and Expansion</p> <p data-bbox="347 633 1364 663">Digital &amp; AI Capabilities   Technologies   Development Team   Manufacturing   Global Footprint</p>			

## COVID-19 Vaccine Outlook 2022



Order Book for 2022<sup>1</sup>:  
~2.4 bn doses



Pipeline of variant-adapted and next generation  
COVID-19 vaccines in multiple active clinical trials

### Upcoming Data

BNT162b2	Timing
<ul style="list-style-type: none"><li>Data for 4<sup>th</sup> dose in adults, aged 16 to 65 years<sup>2</sup></li><li>Data for 3-dose regimen in children, aged 6 months to &lt;5 years</li></ul>	ongoing coming weeks
Follow-on and next generation vaccines	
<ul style="list-style-type: none"><li>Omicron-adapted vaccine: monovalent, bivalent - 3rd and/or 4th dose</li><li>Multiple updates: Follow on and next-gen vaccines</li></ul>	coming weeks 2H

2B 1 As of mid-April 2022; In combination with contracts entered into by Pfizer

## Further Expected Pipeline Milestones in 2022

4 Infectious Disease First-in-Human Trial Starts	
• Shingles vaccine <sup>1</sup>	2H
• Tuberculosis vaccine <sup>2</sup>	2H
• HSV 2 vaccine	2H
• Malaria vaccine	2H
3 Oncology First-in-Human Trial Starts	
• BNT141 – RiboMab, solid tumors	✓ FPD in January
• BNT142 – RiboMab, solid tumors	1H
• BNT116 – FixVac in combination w/Libtayo, NSCLC	2H
3 Data Updates	
• BNT161 – Influenza mRNA vaccine <sup>1</sup>	2022
• BNT122 <sup>3</sup> Phase 2 – iNeST in combination w/Pembrolizumab, 1L Melanoma	2H
• BNT211 Phase 1/2 – CAR-T/CLDN6+, multiple solid tumors	2H

<sup>29</sup> HSV 2, Herpes simplex virus type 2; FPD, first patient dosed; CLDN, Claudin; NSCLC, non-small cell lung cancer  
<sup>1</sup> Partnered with Pfizer, <sup>2</sup> Collaboration with BMGF, <sup>3</sup> Partnered with Genentech

# SAVE THE DATE

BIONTECH

Annual General Meeting  
June 1, 2022

Virtual Capital Markets Day  
June 29, 2022

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**THANK  
YOU**

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