

**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 2023**

**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 8, 2023, BioNTech SE (the “Company”) issued a press release announcing its first quarter 2023 financial results and corporate update and details of a conference call to be held at 8:00 am EDT on May 8, 2023 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 Exchange Act, 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 8, 2023

## EXHIBIT INDEX

<u>Exhibit</u>	<u>Description of Exhibit</u>
99.1	<a href="#">BioNTech Announces First Quarter 2023 Financial Results and Corporate Update</a>
99.2	<a href="#">First Quarter 2023: Corporate Update and Financial Results</a>

### BioNTech Announces First Quarter 2023 Financial Results and Corporate Update

- COVID-19 vaccine franchise focused on vaccine adaptation readiness ahead of the fall season and advancing next generation vaccine candidates and combinations
- BioNTech and partner OncoC4 plan to start a Phase 3 clinical trial evaluating anti-CTLA-4 antibody BNT316 (ONC-392) as monotherapy in NSCLC patients who progress after PD-1/PD-L1 treatment
- Added new class of precision therapeutics to clinical-stage oncology portfolio, with next-generation Antibody-Drug Conjugate (ADC) candidates
- Presenting clinical data on antibody candidate BNT316 (ONC-392), ADC candidate BNT323 (DB-1303) and CAR-T candidate BNT211 at the 2023 American Society of Clinical Oncology Annual Meeting
- Broadened clinical-stage infectious disease vaccine pipeline with the start of a First-in-Human clinical trial for the first mRNA-based Tuberculosis vaccine candidates
- Reiterates BioNTech COVID-19 vaccine revenue guidance of approximately €5 billion in 2023
- First quarter<sup>1</sup> revenues of €1.3 billion<sup>2</sup>, net profit of €0.5 billion and fully diluted earnings per share of €2.05 (\$2.20<sup>3</sup>)

Conference call and webcast scheduled for May 8, 2023, at 8:00 am EDT (2:00 pm CEST)

MAINZ, Germany, May 8, 2023 (GLOBE NEWSWIRE) -- BioNTech SE (Nasdaq: BNTX, "BioNTech" or the "Company") today reported financial results for the three months ended March 31, 2023, and provided an update on its corporate progress.

"In the first quarter of 2023, we expanded our toolkit of cutting-edge technologies to new modalities and added a novel immune checkpoint inhibitor candidate targeting CTLA-4 and two investigational antibody-drug conjugates to our arsenal against cancer. These programs are strategically aligned with our vision to provide meaningful therapeutic benefits for patients with solid tumors along the entire treatment journey," said Prof. Ugur Sahin, M.D., CEO and Co-Founder of BioNTech. "We are taking significant steps in this direction as we prepare to initiate our first Phase 3 clinical trial in oncology for the novel anti-CTLA-4 antibody in NSCLC patients who have progressed after PD-1/PD-L1 treatment, a patient population with high medical need. We are also making progress in advancing our next generation COVID-19 vaccine candidate while we stand prepared for variant adaptation in case of public health need. For the remainder of 2023, we are focused on advancing our disruptive platforms against solid tumors and accelerating clinical programs in infectious diseases of high global need."

#### Financial Review for the First Quarter 2023

in millions €, except per share data	First Quarter 2023	First Quarter 2022
Total Revenues <sup>2</sup>	1,277.0	6,374.6
Net Profit	502.2	3,698.8
Diluted Earnings per Share	2.05	14.24

**Total revenues** reported were €1,277.0 million<sup>2</sup> for the three months ended March 31, 2023, compared to €6,374.6 million<sup>2</sup> for the comparative prior year period. The change was mainly due to lower commercial revenues from the supply and sales of the Company's COVID-19 vaccines worldwide.

**Cost of sales** were €96.0 million for the three months ended March 31, 2023, compared to €1,294.1 million for the comparative prior year period. The change was mainly due to decreasing sales from BioNTech's COVID-19 vaccine revenues.

**Research and development** expenses were €334.0 million for the three months ended March 31, 2023, compared to €285.8 million for the comparative prior year period. The change was mainly due to higher expenses incurred from progressing the clinical studies for pipeline candidates. The increase was further driven by an increased headcount.

**General and administrative** expenses were €119.4 million for the three months ended March 31, 2023, compared to €90.8 million for the comparative prior year period. The change was mainly due to increased expenses for IT, purchased external services, as well as an increase in headcount.

**Income taxes** were accrued in an amount of €205.5 million of tax expenses for the three months ended March 31, 2023, compared to €1,319.3 million of tax expenses for the comparative prior year period. The derived annual effective income tax rate for the three months ended March 31, 2023, was 29.0% which is expected to decrease over the 2023 financial year to be in line with BioNTech's guidance.

**Net profit** was €502.2 million for the three months ended March 31, 2023, compared to €3,698.8 million for the comparative prior year period.

**Cash and cash equivalents as well as security investments** were €12,143.9 million and €671.9 million, respectively, as of March 31, 2023. Subsequent to the end of the reporting period, the payment settling BioNTech's gross profit share for the fourth quarter of 2022 (as defined by the contract with Pfizer, Inc. ("Pfizer")) in the amount of €3,961.3 million was received from our collaboration partner as of April 14, 2023. The contractual settlement of the gross profit share under the COVID-19 vaccine program collaboration with Pfizer 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.

**Shares outstanding** as of March 31, 2023 were 240,990,499.

**Cash outflows and share consideration** in connection with the planned acquisition of InstaDeep Ltd. ("InstaDeep") and the upfront payments of the collaboration and license agreements with OncoC4, Inc. ("OncoC4") and Duality Biologics (Suzhou) Co. Ltd. ("DualityBio") of approximately €0.8 billion are expected (subject to change and excluding future potential earn-out and milestone payments).

"In the first quarter of 2023, our financial performance has been fully in line with our expectations and we executed according to our capital allocation priorities by growing and advancing our clinical-stage pipeline, announcing multiple significant business development transactions and continuing to pursue our share repurchase program," **said Jens Holstein, CFO of BioNTech.** "For the remainder of 2023, we remain focused on fulfilling our goals and continuing to provide value to our patients and shareholders."

#### Outlook for the 2023 Financial Year

The Company reiterates its prior financial year outlook:

##### *BioNTech COVID-19 Vaccine Revenues for the 2023 Financial Year:*

Estimated BioNTech COVID-19 vaccine revenues for the full 2023 financial year	~ €5 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, which may be influenced by costs such as inventory write-offs once materialized and shared with the collaboration partner Pfizer.

Revenue guidance is based on various assumptions, including, but not limited to, the expected transition from an advanced purchase agreement environment to commercial market ordering starting in some geographies and an expected regulatory recommendation to adapt the COVID-19 vaccines to address newly circulating variants or sublineages of SARS-CoV-2. The estimated BioNTech COVID-19 vaccine revenues reflect expected deliveries under existing or committed supply contracts and anticipated sales through traditional commercial orders. A re-negotiation of the existing supply contract with the European Commission is ongoing, with the potential for a rehasing of deliveries of doses across multiple years and/or a volume reduction. While a vaccine adaptation is expected to lead to increased demand, fewer primary vaccinations and lowered population-wide levels of boosting are anticipated. Seasonal demand is assumed, moving expected revenue generation significantly to the second half of the year 2023.

*Planned 2023 Financial Year Expenses and Capex<sup>4</sup>:*

R&D expenses <sup>5</sup>	€2,400 million - €2,600 million
SG&A expenses	€650 million - €750 million
Capital expenditures for operating activities <sup>6</sup>	€500 million - €600 million

*Estimated 2023 Financial Year Tax Assumptions:*

BioNTech Group estimated annual cash effective income tax rate	~ 27%
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**Operational Review and Pipeline Update for the First Quarter 2023 and Key Post Period-End Events**

*Oncology Pipeline*

**BNT316 (ONC-392)** is an anti-CTLA-4 monoclonal antibody candidate being developed in collaboration with OncoC4. BNT316 (ONC-392) offers a potentially differentiated safety profile that may allow for higher dosing and longer duration of treatment both as a monotherapy and in combination with other therapies.

- BioNTech and OncoC4 plan to start a Phase 3 clinical trial to evaluate BNT316 (ONC-392) as monotherapy in non-small cell lung cancer (NSCLC) patients who progress on anti-PD-1/PD-L1 antibody-based therapy in 2023.
- BioNTech and OncoC4 plan to present data from an expansion cohort evaluating BNT316 (ONC-392) as monotherapy in NSCLC patients as part of the ongoing Phase 1/2 clinical trial at the American Society of Clinical Oncology (ASCO) Annual Meeting held in Chicago, USA, from June 2-6, 2023.

**BNT323 (DB-1303)** is a HER2-targeted antibody-drug conjugate (ADC) candidate, being developed in collaboration with DualityBio.

- BNT323 (DB-1303) is currently being evaluated in a Phase 1/2 clinical trial in patients with advanced/unresectable, recurrent, or metastatic HER2-expressing solid tumors. BioNTech and DualityBio expect a data update from the ongoing trial at the 2023 ASCO Annual Meeting.
- In January, BNT323 (DB-1303) received Fast Track designation from the U.S. Food and Drug Administration for the treatment of patients with HER2-overexpressing advanced, recurrent, or metastatic endometrial carcinoma who have progressed on or after standard systemic treatment.

**Autogene cevumeran (BNT122)** is an mRNA cancer vaccine candidate based on an individualized neoantigen-specific immunotherapy (iNeST) approach being developed in collaboration with Genentech, a member of the Roche Group.

- A Phase 2 clinical trial of BNT122 in the adjuvant setting in patients with pancreatic ductal adenocarcinoma (PDAC) is planned to open in 2023.

**BNT211** is an autologous CLDN6-targeting chimeric antigen receptor (CAR) T cell therapy that is being tested alone and in combination with a CAR-T cell Amplifying RNA Vaccine, or CARVac, encoding CLDN6.

- BioNTech expects a data update from the ongoing Phase 1/2 dose escalation and expansion clinical trial, in patients with CLDN6-positive relapsed or refractory advanced solid tumors at the 2023 ASCO Annual Meeting.

*Infectious Diseases Pipeline*

**Next-generation COVID-19 Vaccine Program BNT162b2 + BNT162b4**

- In April, BioNTech reported preclinical data on BNT162b4, the vaccine component encoding conserved non-spike antigen derived T cell epitopes, alone and in combination with BNT162b2, encoding the full spike protein. In the preclinical study, the candidate protected from severe COVID-19 disease and enhanced viral clearance. The findings are in press in the peer-reviewed journal *Cell* (Arieta C. *et al.* *The T-cell-directed vaccine BNT162b4 encoding*

*conserved non-spike antigens protects animals from severe SARS-CoV-2 infection. Cell (2023). doi: <https://doi.org/10.1016/j.cell.2023.04.007>).*

- A Phase 1 clinical trial to evaluate the safety, tolerability, and immunogenicity of BNT162b4 in combination with BNT162b2 is ongoing.

#### **Tuberculosis Vaccine Program – BNT164**

- In April, BioNTech initiated a randomized, controlled, dose-finding Phase 1 clinical trial of BNT164 in partnership with the Bill and Melinda Gates Foundation. The clinical trial will evaluate the safety, reactogenicity, and immunogenicity of mRNA vaccine candidates against Tuberculosis.

#### **Shingles Vaccine Program – BNT167**

- In February, BioNTech and Pfizer initiated a multicenter, randomized, controlled, dose-selection Phase 1/2 clinical trial of BNT167, the companies' mRNA vaccine candidate against shingles (also known as herpes zoster). The clinical trial will evaluate the safety, tolerability, and immunogenicity of mRNA vaccine candidates against shingles.

#### **Corporate Update for the First Quarter 2023 and Key Post Period-End Events**

- In January, BioNTech entered into an agreement to acquire its long-standing strategic collaboration partner InstaDeep, enabling the creation of a fully integrated, enterprise-wide capability that leverages artificial intelligence and machine learning technologies across BioNTech's therapeutic platforms and operations. The transaction is subject to customary closing conditions and regulatory approvals.
- In January, BioNTech signed a Memorandum of Understanding with the Government of the United Kingdom to establish a multi-year collaboration focused on three strategic pillars: cancer immunotherapies based on mRNA or other drug classes, infectious disease vaccines, and investments into expanding BioNTech's footprint in the UK as one of the Company's key markets. The goal of the collaboration is to provide personalized cancer therapies for up to 10,000 patients by the end of 2030, either in clinical trials or as authorized treatments.
- In February, BioNTech completed construction of the Company's first proprietary plasmid DNA manufacturing facility. The plasmid DNA produced at this state-of-the-art facility in Marburg, Germany is planned to be used globally and serve as the basis for the manufacturing of mRNA- and cell-based products on a clinical or commercial scale.
- In March, BioNTech announced the establishment of an interdisciplinary mRNA Excellence Center to conduct research jointly with scientists from Weizmann Institute of Science in Israel. The Company's mRNA Excellence Center is expected to provide space for approximately 60 researchers to facilitate collaboration across various fields, including life science, computer science, mathematics, physics, and chemistry.
- In March, BioNTech provided an update on its plans to establish scalable mRNA vaccine production in Africa. The Company announced that six ISO-sized shipping containers for the first BioNTainer, a turnkey manufacturing solution designed to enable scalable mRNA vaccine production in bulk, arrived in Kigali, Rwanda.
- In March, BioNTech entered into an exclusive worldwide licensing and collaboration agreement with OncoC4 to co-develop and commercialize BNT316 (ONC-392), an anti-CTLA-4 monoclonal antibody candidate as monotherapy or combination therapy in various cancer indications.
- In March, BioNTech entered into a new share repurchase program pursuant to which the Company may purchase American Depositary Shares, each representing one ordinary share of the Company, in the amount of up to \$0.5 billion during the remainder of 2023.
- In April, BioNTech entered into exclusive license and collaboration agreements with DualityBio to develop, manufacture and commercialize two investigational topoisomerase-1 inhibitor-based ADC assets, BNT323 (DB-1303) and BNT324 (DB-1311).

#### **Environmental, Social, and Governance (ESG)**

BioNTech recognizes its responsibility as a corporate citizen and is committed to supporting its local communities and beyond through donations, sponsorships and volunteer activities. In response to the



earthquakes that hit Türkiye and Syria in February, BioNTech contributed to the humanitarian aid in both countries by donating €500,000 to the nonprofit organization 'Aktionsbündnis Katastrophenhilfe' (Action Alliance for Disaster Relief). For humanitarian aid in Ukraine, the Company donated €500,000 to the refugee relief 'UNO-Flüchtlingshilfe' – the partner of UN Refugee Agency (UNHCR) in Germany.

On March 27, 2023, BioNTech published its third ESG report (Sustainability Report 2022). The report is available in the Investor Relations section of [BioNTech's website](#).

#### Upcoming Investor and Analyst Events

- The Annual General Meeting is scheduled for May 25, 2023.
- BioNTech plans to host an Innovation Series Day on November 7, 2023.

#### Endnotes

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> Financial information is prepared and presented in Euros and numbers are rounded to millions and billions of Euros in accordance with standard commercial practice.

<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. Any changes in the estimated share of the collaboration partner's gross profit will be recognized prospectively.

<sup>3</sup> Calculated applying the average foreign exchange rate for the three months ended March 31, 2023, as published by the German Central Bank (*Deutsche Bundesbank*).

<sup>4</sup> Numbers reflect current base case projections and are calculated based on constant currency rates.

<sup>5</sup> Numbers include effects identified from additional collaborations or potential M&A transactions to the extent disclosed and will be updated as needed.

<sup>6</sup> Numbers exclude potential effects caused by or driven from collaborations or M&A transactions.

#### Conference Call and Webcast Information

BioNTech invites investors and the general public to join a conference call and webcast with investment analysts today, May 8, 2023 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 2023.

To access the live conference call via telephone, please register [via this link](#). Once registered, dial-in numbers and a pin number will be provided.

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

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.com/>. 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 immune checkpoint 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.com](http://www.BioNTech.com)

#### 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; the rate and degree of market acceptance of BioNTech's COVID-19 vaccine and, if approved, BioNTech's investigational medicines; expectations regarding anticipated changes in COVID-19 vaccine demand, including changes to the ordering environment and expected regulatory recommendations to adapt vaccines to address new variants or sublineages; the initiation, timing, progress, results, and cost of BioNTech's research and development programs, including those relating to additional formulations of BioNTech's COVID-19 vaccine, 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 and the availability of results; the status and potential outcome of re-negotiations of the existing supply contract with the European Commission; the timing and expected impact of the Company's planned acquisition of InstaDeep Ltd. and collaboration and licensing agreements with OncoC4, Inc., Duality Biologics (Suzhou) Co. Ltd. and others; the development of sustainable vaccine production and supply solutions, including BioNTainers, and the nature and feasibility of these solutions; and BioNTech's estimates of commercial and other revenues, cost of sales, research and development expenses, sales and marketing expenses, general and administrative expenses, capital expenditures, income taxes, net profit, cash, cash equivalents and security investments, shares outstanding and cash outflows and share consideration. 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. These risks and uncertainties include, but are not limited to: 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 timing of and BioNTech's ability to obtain and maintain regulatory approval for BioNTech's product candidates; the ability of BioNTech's COVID-19 vaccines to prevent COVID-19 caused by emerging virus variants; BioNTech's and its counterparties' ability to manage and source necessary energy resources; 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 potential claims that are alleged to arise from the use of BioNTech's COVID-19 vaccine and other products and product candidates developed or manufactured by BioNTech; BioNTech's and its collaborators' ability to commercialize and market BioNTech's COVID-19 vaccine and, if approved, its product candidates; BioNTech's ability to manage its development and expansion; regulatory developments in the United States and other 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; risks relating to the global financial system and markets; and other factors not known to BioNTech at this time. You should review the risks and uncertainties described under the heading "Risk Factors" in BioNTech's Report on Form 6-K for the period ended March 31, 2023 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.

## Contacts

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### Interim Consolidated Statements of Profit or Loss

Three months ended  
March 31,

<i>(in millions €, except per share data)</i>	2023 <i>(unaudited)</i>	2022 <i>(unaudited)</i>
Revenues		
Commercial revenues	1,276.5	6,362.2
Research & development revenues	0.5	12.4
<b>Total revenues</b>	<b>1,277.0</b>	<b>6,374.6</b>
Cost of sales	(96.0)	(1,294.1)
Research and development expenses	(334.0)	(285.8)
Sales and marketing expenses	(12.2)	(14.3)
General and administrative expenses	(119.4)	(90.8)
Other operating expenses	(118.1)	(71.6)
Other operating income	57.1	134.7
<b>Operating income</b>	<b>654.4</b>	<b>4,752.7</b>
Finance income	82.3	272.1
Finance expenses	(29.0)	(6.7)
<b>Profit before tax</b>	<b>707.7</b>	<b>5,018.1</b>
Income taxes	(205.5)	(1,319.3)
<b>Profit for the period</b>	<b>502.2</b>	<b>3,698.8</b>
<b>Earnings per share</b>		
Basic profit for the period per share	2.07	15.13
Diluted profit for the period per share	2.05	14.24

### Interim Consolidated Statements of Financial Position

<i>(in millions €)</i>	<b>March 31, 2023</b> <i>(unaudited)</i>	<b>December 31, 2022</b>
<b>Assets</b>		
<b>Non-current assets</b>		
Intangible assets	378.6	219.7
Property, plant and equipment	639.2	609.2
Right-of-use assets	208.4	211.9
Other financial assets	516.8	80.2
Other non-financial assets	4.4	6.5
Deferred tax assets	245.5	229.6
<b>Total non-current assets</b>	<b>1,992.9</b>	<b>1,357.1</b>
<b>Current assets</b>		
Inventories	424.1	439.6
Trade and other receivables	6,450.5	7,145.6
Contract assets	5.7	—
Other financial assets	358.0	189.4
Other non-financial assets	171.3	271.9
Income tax assets	532.6	0.4
Cash and cash equivalents	12,143.9	13,875.1
<b>Total current assets</b>	<b>20,086.1</b>	<b>21,922.0</b>
<b>Total assets</b>	<b>22,079.0</b>	<b>23,279.1</b>
<b>Equity and liabilities</b>		
<b>Equity</b>		
Share capital	248.6	248.6
Capital reserve	1,547.9	1,828.2
Treasury shares	(7.6)	(5.3)
Retained earnings	19,335.2	18,833.0
Other reserves	(858.8)	(848.9)
<b>Total equity</b>	<b>20,265.3</b>	<b>20,055.6</b>
<b>Non-current liabilities</b>		
Lease liabilities, loans and borrowings	172.4	176.2
Other financial liabilities	6.1	6.1
Income tax liabilities	10.8	10.4
Provisions	8.6	8.6
Contract liabilities	45.6	48.4
Other non-financial liabilities	14.0	17.0
Deferred tax liabilities	5.3	6.2
<b>Total non-current liabilities</b>	<b>262.8</b>	<b>272.9</b>
<b>Current liabilities</b>		
Lease liabilities, loans and borrowings	37.4	36.0
Trade payables	29.9	204.1
Other financial liabilities	435.9	785.1
Refund liabilities	80.2	24.4
Income tax liabilities	526.3	595.9
Provisions	320.4	367.2
Contract liabilities	22.0	77.1
Other non-financial liabilities	98.8	860.8
<b>Total current liabilities</b>	<b>1,550.9</b>	<b>2,950.6</b>
<b>Total liabilities</b>	<b>1,813.7</b>	<b>3,223.5</b>
<b>Total equity and liabilities</b>	<b>22,079.0</b>	<b>23,279.1</b>

## Interim Consolidated Statements of Cash Flows

Three months ended  
March 31,

<i>(in millions €)</i>	2023 <i>(unaudited)</i>	2022 <i>(unaudited)</i>
<b>Operating activities</b>		
Profit for the period	502.2	3,698.8
Income taxes	205.5	1,319.3
<b>Profit before tax</b>	<b>707.7</b>	<b>5,018.1</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	31.4	27.6
Share-based payment expenses	8.6	11.2
Net foreign exchange differences	53.1	6.1
Loss on disposal of property, plant and equipment	0.2	—
Finance income excluding foreign exchange differences	(82.3)	(217.3)
Finance expense excluding foreign exchange differences	1.2	6.7
Movements in government grants	(3.0)	—
Unrealized net (gain) / loss on derivative instruments at fair value through profit or loss	76.2	(1.9)
Working capital adjustments:		
Decrease / (increase) in trade and other receivables, contract assets and other assets	893.8	(403.5)
Decrease in inventories	15.5	43.2
(Decrease) / increase in trade payables, other financial liabilities, other liabilities, contract liabilities, refund liabilities and provisions	(861.6)	857.5
Interest received	53.6	0.7
Interest paid	(1.2)	(6.4)
Income tax paid	(844.9)	(1,290.0)
Share-based payments	(725.7)	(1.8)
<b>Net cash flows from / (used in) operating activities</b>	<b>(677.4)</b>	<b>4,050.2</b>
<b>Investing activities</b>		
Purchase of property, plant and equipment	(45.2)	(44.1)
Purchase of intangible assets and right-of-use assets	(9.6)	(16.7)
Investment in other financial assets	(680.6)	(27.0)
Proceeds from maturity of other financial assets	—	375.2
<b>Net cash flows from / (used in) investing activities</b>	<b>(735.4)</b>	<b>287.4</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)
Payments related to lease liabilities	(9.3)	(11.4)
Share repurchase program	(282.0)	—
<b>Net cash flows from / (used in) financing activities</b>	<b>(291.3)</b>	<b>80.3</b>
Net increase / (decrease) in cash and cash equivalents	(1,704.1)	4,417.9
Change in cash and cash equivalents resulting from exchange rate differences	(27.1)	53.5
Cash and cash equivalents at the beginning of the period	13,875.1	1,692.7
<b>Cash and cash equivalents as of March 31</b>	<b>12,143.9</b>	<b>6,164.1</b>

A microscopic image of a cell cluster, likely a spheroid, rendered in a teal color. The cluster is composed of many individual cells, each with visible nuclei and cytoplasm, arranged in a roughly spherical shape. The background is a solid teal color.

# Financial Results & Corporate Update

1<sup>st</sup> Quarter 2023

May 8, 2023

BIONTECH

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## — This Slide Presentation Includes Forward-Looking Statements

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, 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 COMIRNATYX 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; the rate and degree of market acceptance of BioNTech's COVID-19 vaccine and, if approved, BioNTech's investigational medicines; expectations regarding anticipated changes in COVID-19 vaccine demand, including changes to the ordering environment and expected regulatory recommendations to adapt vaccines to address new variants or sublineages; the initiation, timing, progress, results, and cost of BioNTech's research and development programs, including those relating to additional formulations of BioNTech's COVID-19 vaccine, 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 and the availability of results; the expected impact of the Company's planned acquisition of InstaDeep Ltd. and collaboration and licensing agreements with OncoC4, Inc., Duality Biologics (Suzhou) Co. Ltd and others; the development of sustainable vaccine production and supply solutions and the nature and feasibility of these solutions; and BioNTech's estimates of commercial and other revenues, cost of sales, research and development expenses, sales and marketing expenses, general and administrative expenses, capital expenditures, income taxes, net profit, cash, cash equivalents and security investments, shares outstanding and cash outflows and share consideration. 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. These risks and uncertainties include, but are not limited to: 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 timing of and BioNTech's ability to obtain and maintain regulatory approval for BioNTech's product candidates; the ability of BioNTech's COVID-19 vaccines to prevent COVID-19 caused by emerging virus variants; BioNTech's and its counterparties' ability to manage and source necessary energy resources; 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 potential personal injury or death arising from the use of BioNTech's COVID-19 vaccine and other products and product candidates developed or manufactured by BioNTech; BioNTech's and its collaborators' ability to commercialize and market BioNTech's COVID-19 vaccine and, if approved, its product candidates; BioNTech's ability to manage its 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; risks relating to the global financial system and markets; and other factors not known to BioNTech at this time. You should review the risks and uncertainties described under the heading "Risk Factors" in BioNTech's Report on Form 6-K for the period ended March 31, 2023 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.

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## Safety Information

**COMIRNATY (the Pfizer-BioNTech COVID-19 vaccine)** has been granted standard marketing authorization (MA) by the European Commission to prevent coronavirus disease 2019 (COVID-19) in the population aged 6 months and older. It is people from 5 years of age and older the vaccine is administered as a 2-dose series, 3 weeks apart. Adults and adolescents from the age of 12 to 17 years are given 30 micrograms per dose, children aged 5 to 11 years are given 10 micrograms per dose. There is a paediatric formulation containing 3 micrograms per dose available for infants and children 6 months to 4 years of age. In this age group, COMIRNATY can be given as a primary vaccination consisting of three doses (10 micrograms each), the first two doses are given 3 weeks apart, followed by a third dose given at least 6 weeks after the second dose. In addition, the MA has been expanded to include a booster dose (third dose) of 20 micrograms at least 3 months after the second dose in individuals 12 years of age and older. A booster dose of COMIRNATY 10 micrograms may be given to children from 5 to 11 years of age at least 6 months after the primary vaccination course. A third primary course dose may be administered at least 28 days after the second dose in people aged 5 years and older with a lowered immunological response. The European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) has concluded that the benefits of COMIRNATY outweigh the risks. The MA is accompanied by extensive monitoring of COMIRNATY, including by processes that sufficiently protect data on the vaccine, safety and efficacy of the vaccine are well monitored. COMIRNATY (the Pfizer-BioNTech COVID-19 vaccine), branded: COMIRNATY Original/OncoSim BA.1, COMIRNATY Original/OncoSim BA.4, COMIRNATY Original/OncoSim BA.5, which contains mRNA encoding for the spike protein of the wild-type and of the OncoSim BA.4-BA.5 Subunit of SARS-CoV-2. COMIRNATY Original/OncoSim BA.1, which contains mRNA encoding for the spike protein of the wild-type and of the OncoSim BA.1 Subunit of SARS-CoV-2. COMIRNATY Original/OncoSim BA.4, 10 micrograms per dose may be given to people aged from 5 years to 11 years after primary vaccination or a booster dose with a COVID-19 vaccine. There should be an interval of at least 3 months between administration of COMIRNATY Original/OncoSim BA.1 or COMIRNATY Original/OncoSim BA.4-5 and the last prior dose of a COVID-19 vaccine.

### IMPORTANT SAFETY INFORMATION:

- Cases 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, but very rare risk (1/10,000 cases) 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. From post-marketing experience, very rare adverse reactions of myocarditis and pericarditis, irrespective of acute posterior focal pericarditis, uncommon incidence of normo-, hypertensive and high-severity, dizziness common incidence of vomiting, very common dizziness and unknown incidence (can not be identified from available data) anaphylaxis, of parosmia, hypoaesthesia and orthonasal mucormycosis, extensive swelling of vaccinated limb, local swelling in vaccine recipients with a history of injection (contaminated injection) and heavy exertional headaches (not associated with the injection) and heavy exertional headaches (not associated with the injection) process (all). 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 practitioners are in place to avoid injury from falling.
- Vaccination should be postponed in individuals suffering from acute severe febrile illness or acute infection. The presence of a fever infection and/or high-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, safety and immunogenicity of the vaccine has not been assessed in immunocompromised individuals, including those receiving immunosuppressive therapy. The efficacy of COMIRNATY Original/OncoSim BA.1 or COMIRNATY Original/OncoSim BA.4-5 may be lower in immunocompromised individuals.
- As with any vaccine, vaccination with COMIRNATY Original/OncoSim BA.1 or COMIRNATY Original/OncoSim BA.4-5 may not protect all vaccine recipients. Individuals may not be fully protected until 7 days after their second dose of the vaccine.
- Adverse reactions observed during clinical studies and identified after post authorization experience are listed below according to the following frequency categories: Very common ( $\geq 1/10$ ), Common ( $\geq 1/100$  to  $< 1/10$ ), Uncommon ( $\geq 1/1,000$  to  $< 1/100$ ), Rare ( $\geq 1/10,000$  to  $< 1/1,000$ ), Very rare ( $< 1/10,000$ ).
- Common side effects: injection site redness, muscle aching, headache, muscle pain, chills, joint pain, dizziness, fever, chills, fatigue.
- Uncommon side effects: enlarged lymph nodes (more frequently observed after the booster dose), feeling unwell, arm pain, insomnia, dizziness, injection site itching, allergic reactions such as rash, itching, urticaria or angioedema, feeling weak or lack of energy/bleth, decreased appetite, excessive sweating, night sweats.
- Rare side effects: temporary one-sided facial drooping.
- Very rare side effects: inflammation of the heart muscle (myocarditis) or inflammation of the lining outside the heart (pericarditis), which can result in breathlessness, palpitations or chest pain.
- Not known incidence (cannot be estimated from the available data): anaphylaxis, extensive swelling of vaccinated limb, local swelling, joint pain and numbness, reduced sense of touch or sensation, a skin reaction that causes red spots or patches on the skin, heavy menstrual bleeding.
- A large amount of observational data from pregnant women vaccinated with the initially approved COMIRNATY vaccine 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. COMIRNATY can be used during pregnancy. No effects on breast-feeding were observed in the infants exposed to breast-feeding women to the initially approved COMIRNATY vaccine. Observational data from women who were breast-feeding while their vaccination have not shown a risk for adverse effects in breast-feeding infants. COMIRNATY Original/OncoSim BA.1 or COMIRNATY Original/OncoSim BA.4-5 can be used during pregnancy.
- Where detailed reactions that have been clinically meaningful, COMIRNATY Original/OncoSim BA.1 or COMIRNATY Original/OncoSim BA.4-5 can be used during pregnancy.
- No data are available yet regarding the use of COMIRNATY Original/OncoSim BA.1 or COMIRNATY Original/OncoSim BA.4-5 during breast-feeding. Observational data from women who were breast-feeding after vaccination with the initially approved COMIRNATY vaccine have not shown a risk for adverse effects in breast-feeding infants. COMIRNATY Original/OncoSim BA.1 or COMIRNATY Original/OncoSim BA.4-5 can be used during breast-feeding.
- Interactions with other medicinal products or concomitant administration of COMIRNATY Original/OncoSim BA.1 or COMIRNATY Original/OncoSim BA.4-5 with other vaccines has not been studied.
- Animal studies with COMIRNATY Original do not indicate direct or indirect harmful effects with respect to reproduction toxicity.
- In an analysis of Study 3 (Phase 2/3), 1,778 infants (1,778 Community 3 mcg and 508 placebo) were 6 to 23 months of age. The most frequent adverse reactions in infants 6 to 23 months of age that received any primary course dose included injection site ( $\geq 60\%$ ), drowsiness ( $\geq 40\%$ ), decreased appetite ( $\geq 30\%$ ), tenderness at the injection site ( $\geq 20\%$ ), injection site redness and fever ( $\geq 10\%$ ).
- The most frequent adverse reactions in children 2 to 4 years of age that received any primary course dose included pain at injection site and fatigue ( $\geq 40\%$ ), injection site redness and fever ( $\geq 10\%$ ).
- The overall safety profile for COMIRNATY in participants 5 to 11 years of age was similar to that seen in participants 12 years of age and older. The most frequent adverse reactions in children 5 to 11 years of age that received 2 doses were injection site pain ( $\geq 70\%$ ), fatigue ( $\geq 50\%$ ), headache ( $\geq 30\%$ ), injection site redness and swelling ( $\geq 20\%$ ), myalgia, chills, and diarrhoea ( $\geq 10\%$ ).
- The overall safety profile for COMIRNATY in adolescents 12 to 17 years of age was similar to that seen in participants 18 years of age and older. The most frequent adverse reactions in adolescents 12 to 17 years of age that received 2 doses were injection site pain ( $\geq 70\%$ ), fatigue and headache ( $\geq 70\%$ ), myalgia and chills ( $\geq 40\%$ ), arthralgia and pruritus ( $\geq 20\%$ ).
- The most frequent adverse reactions in participants 18 years of age and older that received 2 doses were injection site pain ( $\geq 80\%$ ), fatigue ( $\geq 60\%$ ), headache ( $\geq 50\%$ ), myalgia ( $\geq 40\%$ ), chills ( $\geq 30\%$ ), arthralgia ( $\geq 20\%$ ), pruritus and injection site redness ( $\geq 10\%$ ) and adverse safety events in moderate to severe and resolved within a few days after vaccination. A slightly lower frequency of reactogenicity events was associated with greater age.
- The safety of COMIRNATY Original/OncoSim BA.1 booster dose in individuals from 18 to 55 years of age is extrapolated from safety data from a subset of 315 adults 18 to 55 years of age who received a booster (fourth dose) of OncoSim BA.1 (monovalent) after completing 3 doses of COMIRNATY. The most frequent adverse reactions in these participants 18 to 55 years of age were injection site pain ( $\geq 70\%$ ), fatigue ( $\geq 60\%$ ), headache ( $\geq 40\%$ ), myalgia ( $\geq 30\%$ ), chills ( $\geq 20\%$ ) and arthralgia ( $\geq 20\%$ ).
- In a subset from Study 4 (Phase 3), 300 adults  $\geq 16$  years of age who had completed 3 doses of COMIRNATY, received a booster of COMIRNATY Original/OncoSim BA.1 after receiving Dose 3. The overall safety profile for the COMIRNATY Original/OncoSim BA.1 booster (fourth dose) was similar to that seen after the COMIRNATY booster (third dose). The most frequent adverse reactions in participants greater than 55 years of age were injection site pain ( $\geq 50\%$ ), fatigue ( $\geq 40\%$ ), headache ( $\geq 30\%$ ), myalgia ( $\geq 20\%$ ), chills and arthralgia ( $\geq 10\%$ ). No new adverse reactions were identified for COMIRNATY Original/OncoSim BA.1.
- The safety of booster dose of COMIRNATY Original/OncoSim BA.4-5 is inferred from safety data for a booster dose of COMIRNATY Original/OncoSim BA.1 in individuals 18 years of age and older. Data are not available for a booster dose of COMIRNATY Original/OncoSim BA.4-5 in individuals 5 years of age and older.
- The duration of protection afforded by the vaccine is unknown. It is still being determined by ongoing clinical trials. As with any vaccine, vaccination with COMIRNATY Original/OncoSim BA.1 or COMIRNATY Original/OncoSim BA.4-5 may not protect all vaccine recipients.
- For further information on the safety of COMIRNATY Original/OncoSim BA.1 and COMIRNATY Original/OncoSim BA.4-5, always make reference to the Approved Summary of Product Characteristics and Package Leaflet available in all languages of the European Union on the EMA website. The full Summary of Product Characteristics is available in English in the public version of the vaccine. The full Summary of Product Characteristics and Package Leaflet are available in all languages of the European Union on the EMA website.

## Safety Information

### AUTHORIZED USE IN THE U.S.

#### COMIRNATY® (COVID-19 Vaccine, mRNA)

- COMIRNATY® (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 coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older. It is also authorized as a third primary series dose to individuals 12 years of age and older who have certain kinds of immunocompromise.
- The COVID-19 vaccine is FDA authorized under Emergency Use Authorization (EUA) for use in individuals 6 months and older as follows:
  - the first 2 doses of the 3-dose primary series for children 6 months through 4 years of age
  - a 3-dose primary series to individuals 5 years through 11 years of age
  - a third primary series dose to individuals 5 years and older with certain kinds of immunocompromise

#### Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5)

- Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) is FDA authorized under Emergency Use Authorization (EUA) to prevent COVID-19 as:
  - the third dose of the 3-dose primary series following 2 doses of the monovalent Pfizer-BioNTech COVID-19 Vaccine in children 6 months through 4 years of age; or
  - a single booster dose in children 6 months through 4 years of age at least 2 months after completion of primary vaccination with 3 doses of the monovalent Pfizer-BioNTech COVID-19 Vaccine; or
  - a single booster dose at least 2 months after completion of either primary vaccination with any authorized or approved COVID-19 vaccine or receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine in individuals 5 years of age and older.

### EMERGENCY USE AUTHORIZATION

Emergency uses of the vaccines listed have not been approved or licensed by FDA but have been authorized by FDA under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) in individuals aged 6 months and older for the Pfizer-BioNTech COVID-19 Vaccine and 5 years and older for the Pfizer-BioNTech COVID-19 Vaccine, Bivalent. The emergency uses are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 306(b)(1) of the FDCA Act unless the declaration is terminated or authorization revoked sooner.

### IMPORTANT SAFETY INFORMATION

#### Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5), COMIRNATY® (COVID-19 Vaccine, mRNA) and Pfizer-BioNTech COVID-19 Vaccine

- 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 or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent.
- Warnings:
  - Management of Acute Allergic Reactions: 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 or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent.
  - Monitor Pfizer-BioNTech COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention (CDC) guidelines (<https://www.cdc.gov/vaccines/imz/managing-anaphylaxis.html>)
  - Myocarditis and Pericarditis: Postmarketing safety data with Pfizer-BioNTech COVID-19 Vaccine or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent are relevant because these vaccines are manufactured using the same process. Postmarketing data with authorized or approved Pfizer-BioNTech COVID-19 Vaccine or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent, demonstrate increased risks of myocarditis and pericarditis, particularly within the first week following receipt of the second primary series dose or first booster dose, with most cases closely following administration of the second primary vaccination. For the Pfizer-BioNTech COVID-19 Vaccine, the observed risk is higher among adolescent males and adult males under 40 years of age than among females and older males, and the observed risk is highest in males 12 through 19 years of age, although some cases require intensive care support. Available data from short-term follow-up suggest that most individuals have full resolution of symptoms with conservative management. Biontech® is not yet able to evaluate about potential long-term sequelae. The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (<https://www.cdc.gov/vaccines/imz/19/covid-19/covid-19-myocarditis-pericarditis.html>).
  - Syncope: Syncope (fainting) may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting.
  - Altered Immunocompetence:
    - Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer-BioNTech COVID-19 Vaccine or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent.
- Limitation of Effectiveness:
  - Pfizer-BioNTech COVID-19 Vaccine or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent may not protect all vaccine recipients.
- Adverse reactions reported with the vaccine include:
  - Allergic Reactions to Clinical Trials
    - Adverse reactions following administration of a booster dose of the Pfizer-BioNTech COVID-19 Vaccine or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent that have been reported in clinical trials include injection site pain, fatigue, headache, muscle pain, chills, joint pain, injection site swelling, fever, fatigue, sore throat, lymphadenopathy, nausea, muscle pain in extremity, rash, decreased appetite, vomiting, diarrhea (see Full EUA Prescribing Information).
  - Adverse Reactions Identified in Post-Authorization Experience
    - Severe allergic reactions, including anaphylaxis, and other hypersensitivity reactions (e.g., rash, hives, urticaria, angioedema), dizziness, vomiting, pain in extremity (arm), syncope, and dizziness have been reported following administration of the Pfizer-BioNTech COVID-19 Vaccine.
    - Myocarditis and pericarditis have been reported following administration of the Pfizer-BioNTech COVID-19 Vaccine or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent.
    - Additional adverse reactions, some of which may be serious, may become apparent with post-authorization use of the Pfizer-BioNTech COVID-19 Vaccine or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent.
- Use with Other Vaccines:
  - There is no information on the co-administration of the Pfizer-BioNTech COVID-19 Vaccine or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent, with other vaccines.

**1** 1st Quarter 2023 Highlights  
Ugur Sahin, Chief Executive Officer

**2** Pipeline Update  
Özlem Türeci, Chief Medical Officer

**3** Financial Results  
Jens Holstein, Chief Financial Officer

**4** Strategic Outlook  
Ryan Richardson, Chief Strategy Officer

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# 1 1st Quarter 2023 Highlights

Ugur Sahin, Chief Executive Officer

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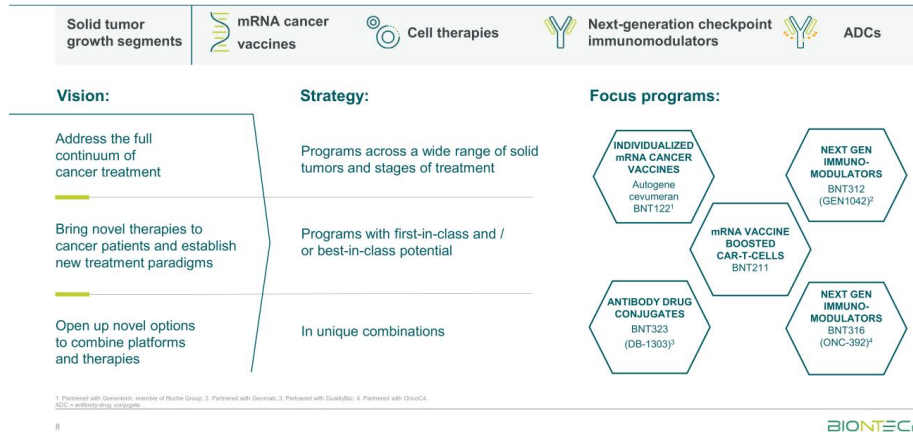
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2023 Strategic Priorities and Achievements in Q1 2023

COVID-19 franchise <sup>1</sup>	Immuno-oncology	Infectious diseases
<b>2023 Strategic Priorities</b>		
Sustain leadership in COVID-19 vaccines Advance next-gen vaccines	Advance platforms for solid tumors Initiate multiple potentially registrational trials	Initiate and accelerate clinical programs for high need indications
<b>Q1 Achievements</b>		
<p><b>Label Expansion:</b></p> <p><b>BA.4-5 in young children</b></p> <p>Next-generation vaccine candidate programs</p> <p><b>New manuscript in Cell</b></p> <p>Preclinical data on T cell string (BNT162b4)</p>	<p>Significantly expanded technology platform portfolio</p> <p><b>2 new collaborations</b></p> <p><b>DualityBio:</b> ADCs – A promising combination backbone to our pipeline</p> <p><b>OncoC4:</b> A differentiated anti-CTLA-4 antibody program</p>	 <p><b>2 new clinical programs</b></p> <p>Tuberculosis<sup>2</sup> BNT164 Shingles<sup>3</sup> BNT167</p>

<sup>1</sup> Partnered with Pfizer; <sup>2</sup> Collaboration with Bill & Melinda Gates Foundation; <sup>3</sup> Partnered with Pfizer  
ADC = Antibody-drug conjugate; CTLA-4 = Cytotoxic T Lymphocyte-Associated Protein 4

Long-Term Strategy: Expand Treatment Options for Solid Tumor Patients



## A New Drug Class – ADCs: Now Part of our Disruptive Technology Toolkit to Fight Human Diseases

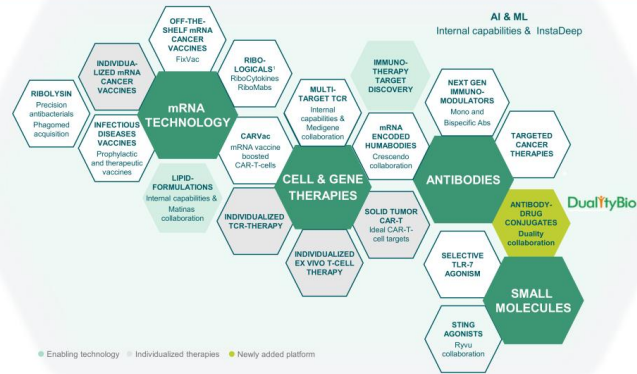
### Core principles of our technology strategy

Technology agnostic approach rooted in deep fundamental understanding of biology

Build novel platforms with the ability to produce multiple product candidates

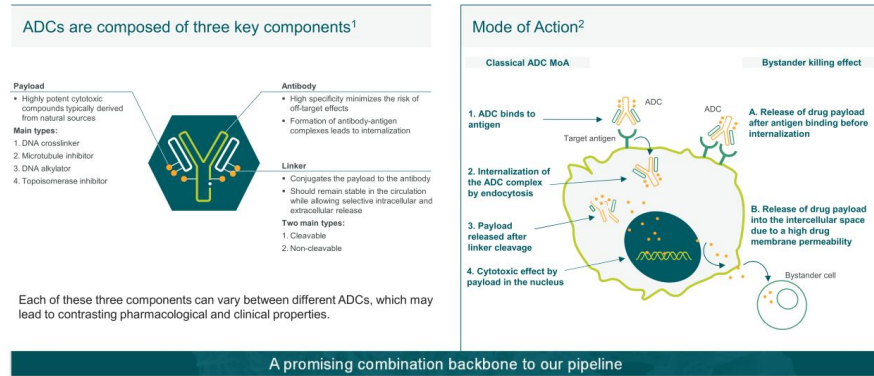
Open up new combination opportunities which leverage synergistic modes of action

Enable individualization of treatment



\* mRNA encoded cancer-targeting antibodies and cytokines.  
AI = Artificial intelligence, ML = Machine learning, CAR = chimeric antigen receptor, TLR = Toll-like receptor, STING = stimulator of interferon genes.

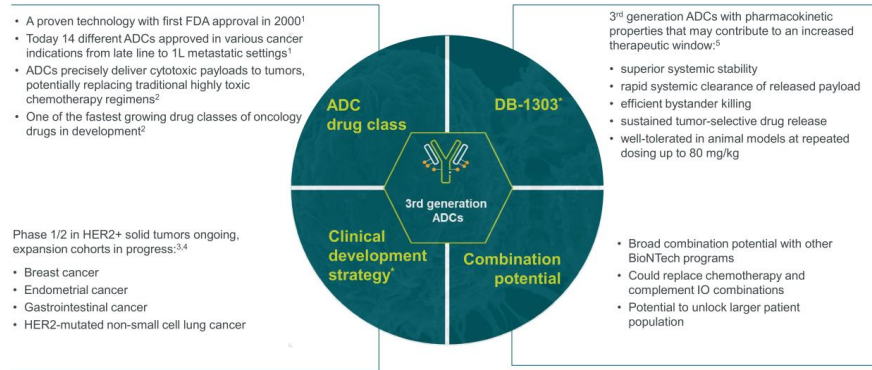
## Antibody-Drug Conjugates: A Proven Technology with Untapped Potential



<sup>1</sup> Jabbour E. et al. *Nat Rev Clin Oncol.* 2021. <sup>2</sup> Coleman N. et al. *npj Precis. Onc.* 2023.  
ADC = Antibody drug conjugate; Ig = Immunoglobulin; MoA = Mode of action



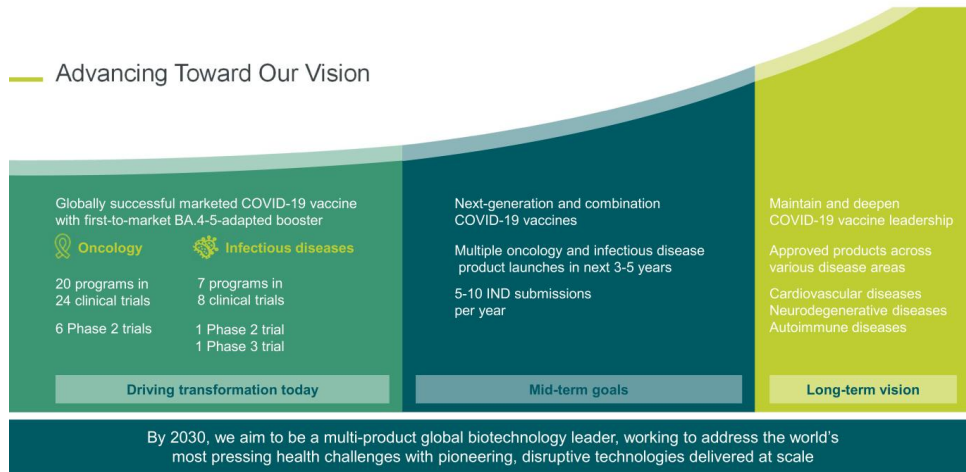
## Our 3rd Generation ADCs May Overcome Hurdles of Currently Approved ADCs



<sup>1</sup> Fu Z et al. *Sig Transduct Target Ther.* 2022. <sup>2</sup> Coleman N. et al. *npj Precis. Onc.* 2023. <sup>3</sup> NCT05150691. <sup>4</sup> Hamilton E. et al. #9504. Presented at AACR 2023. <sup>5</sup> Lin S. et al. Abstract #252. Presented at EORTC-NCI-AACR in 2022.

<sup>2</sup> Abbreviated from: ADC = Antibody drug conjugate; FDA = Food and Drug Administration; IO = Immunology; HER2 = human epidermal growth factor 2; 1L = first line.

— Advancing Toward Our Vision



ED = Infectious disease, RD = Investigational new drug

# 2 Pipeline & COVID-19 Vaccines Update

Özlem Türeci, Chief Medical Officer

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Well-Positioned with our Cancer Vaccine Portfolio Across Multiple Solid Tumors

Multiple trials ongoing (4 Phase 2) with cancer vaccine candidates in multiple disease settings

iNeST <sup>1</sup>				FixVac			
Adjuvant		1L	R/R	Multiple settings	1L	R/R	Multiple settings
CRC	PDAC	Melanoma	Multiple Solid Tumors	Prostate Cancer	HPV16+ HNSCC	Melanoma	NSCLC
Autogene cevumeran (BNT122) Monotherapy	Autogene cevumeran (BNT122) + 1x Atezolizumab	Autogene cevumeran (BNT122) + Pembrolizumab	Autogene cevumeran (BNT122) + Atezolizumab	BNT112 Monotherapy & + Cemiplimab + ADT	Pembrolizumab +/- BNT113	BNT111 +/- Cemiplimab	BNT116 Monotherapy & Cemiplimab or CTX
<ul style="list-style-type: none"> <li>Ph 2 study is ongoing</li> <li>Data presented from investigator-initiated Ph 1 study at ASCO 2022</li> <li>Ph 2 study planned to start in 2023</li> </ul>		<ul style="list-style-type: none"> <li>Ph 2 enrollment completed</li> <li>Analysis of PFS as primary endpoint will be triggered event-based and defines when we will report results</li> <li>Ph 1 data presented</li> <li>Publication in preparation</li> </ul>		<ul style="list-style-type: none"> <li>Ph 1/2 is ongoing</li> <li>Ph 2 study is ongoing</li> </ul>		<ul style="list-style-type: none"> <li>Ph 2 study is ongoing</li> <li>Ph 1 basket study is ongoing</li> <li>Ph 2 in 1L NSCLC planned to start in 2023</li> </ul>	

<sup>1</sup> Partnered with Genentech, member of Roche Group.  
iNeST = Individualized Neoantigen Specific Immunotherapy; ADT = androgen deprivation therapy; 1L = First line; R/R = relapsed/refractory; NSCLC = Non-small cell lung cancer; HPV = Human papillomavirus; CRC = Colorectal cancer; HNSCC = head and neck squamous carcinoma; PDAC = pancreatic ductal adenocarcinoma; PFS = Progression-free survival; Pembres = Pembrolizumab; CTX = capecitabine; FOLFOX = fluorouracil, leucovorin, and oxaliplatin.

## Oncology Pipeline: Achievements in Q1 2023

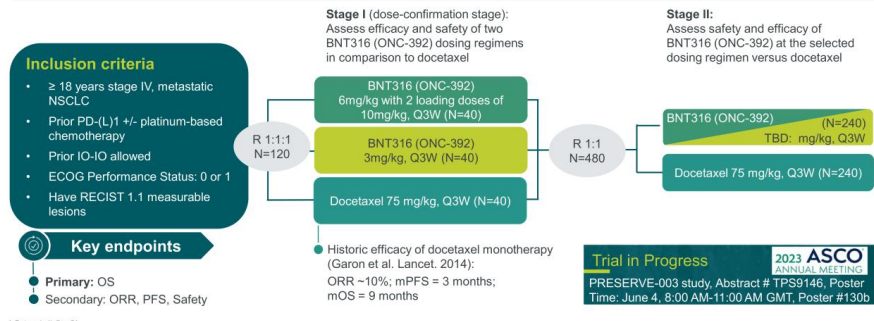
Drug Class	Phase 1 (5 First-in-Human)	Phase 1/2	Phase 2
mRNA	BNT111 Advanced melanoma	BNT112 Prostate cancer	BNT111 aPD1-R/R melanoma, + Pembrolizumab
	BNT116 2L NSCLC	BNT113 <sup>1</sup> HPV16+ head and neck cancer	BNT113 1L rec./met. HPV16+ PD-L1+ head and neck cancer, + Pembrolizumab
	Autogene cevumeran (BNT122) <sup>2</sup> Multiple solid tumors	BNT141 (CLDN18.2) Multiple solid tumors	Autogene cevumeran (BNT122) <sup>2</sup> 1L Adv. melanoma, + Pembrolizumab
	BNT131 (SAR441000) <sup>3</sup> Solid tumors (IL-12 $\alpha$ c, IL15-sushi, GM-CSF, IFN $\alpha$ )	BNT142 (CLDN6) Multiple solid tumors	Autogene cevumeran (BNT122) <sup>2</sup> Adjuvant colorectal cancer
	BNT152 + BNT153 Multiple solid tumors (IL-7, IL-2)	BNT151 (IL-2 variant) Multiple solid tumors	
Cell therapy	BNT221 Refractory metastatic melanoma	BNT218 (CLDN8) Multiple solid tumors	
Protein-based Therapeutics	BNT321 Pancreatic cancer (sLea)	BNT311 (GEN1046) <sup>4</sup> (PD-L1 $\alpha$ -1B8) Multiple solid tumors	BNT311 (GEN1046) <sup>4</sup> (PD-L1 $\alpha$ -1B8) aPD1-R/R NSCLC, + Pembrolizumab
	BNT322 (GEN1056) <sup>4</sup> Multiple solid tumors (undisclosed)	BNT312 (GEN1042) <sup>4</sup> (CD40 $\alpha$ -1B8) Multiple solid tumors	BNT316 (ONC-392) <sup>5</sup> (CTLA-4) Plat.-R ovarian cancer, + Pembrolizumab <b>NEW</b>
		BNT313 (GEN1053) <sup>4</sup> (CD27) Multiple solid tumors	
		BNT318 (ONC-392) <sup>5</sup> (CTLA-4) Multiple solid tumors <b>NEW</b>	
		BNT323 (DB-1303) <sup>6</sup> (HER2) Multiple solid tumors <b>NEW</b>	
SMIM		BNT411 (TLR7) Multiple solid tumors	

<sup>1</sup> Investigator-initiated | Investigator-initiated and sponsored | <sup>2</sup> Partnered with Genentech, member of Roche Group | <sup>3</sup> Partnered with Sanofi | <sup>4</sup> Partnered with Genentech | <sup>5</sup> Partnered with Genentech | <sup>6</sup> Partnered with Genentech | NSCLC = non-small cell lung cancer; HPV = human papillomavirus; CLDN = Claudin; IL = interleukin; 1L = first line; TLR = toll-like receptor; R/R = Relapsed/Refractory; Plat.-R = Platinum-mediated; ADC = Antibody-Drug conjugate; SMIM = small molecule immunomodulator.



— First Phase 3 Study planned: BNT316 (ONC-392) in IO R/R NSCLC<sup>1</sup>

**PRESERVE-003 (NCT05671510)**  
Randomized, open-label, active controlled, multi-center Phase 3 trial



<sup>1</sup> Referenced with OncoCell.  
PD-1 = Programmed cell death protein 1; IO = immunotherapy; NSCLC = Non-small cell lung cancer; R/R = Relapsed/Refractory; Q3W = Every three weeks; OS = Overall survival; ORR = Objective response rate; PFS = Progression free survival; ECOG = Eastern Cooperative Oncology Group.

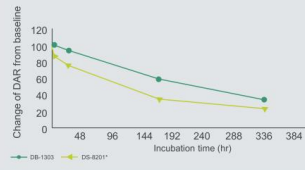
3rd-generation ADCs with improved safety and efficacy may bring added survival benefit to cancer patients

**BNT323 (DB-1303)<sup>1</sup>** pharmacokinetic and -dynamic properties may contribute to an increased therapeutic window

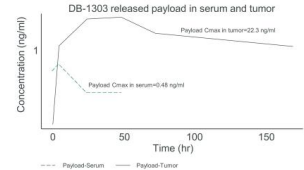


Lin S. et al. Abstract #252. Presented at EORTC-NCI-AACR in 2022.  
<sup>1</sup> Conjugated with Duquatro. ADC = Antibody-drug conjugate. HER = human epidermal growth factor receptor; payload = trastuzumab denantecan. Link = Drug-antibody ratio.

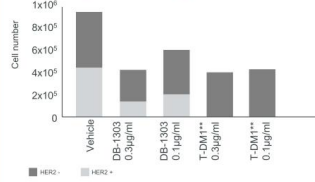
**Superior *in vitro* plasma stability in human plasma**



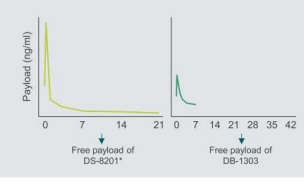
**Sustained tumor-selective drug release in tumor-bearing mice**



**Efficient bystander killing in tumor cell lines**



**Rapid systemic clearance in monkeys**



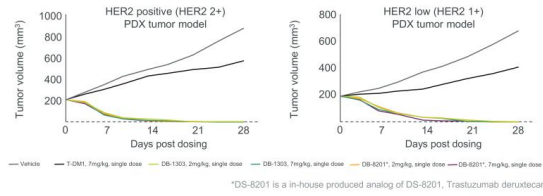
\*DS-8201 is an in-house produced analog of DS-8201, Trastuzumab denantecan.  
 \*\*Trastuzumab-Emtansin.



## BNT323 (DB-1303): Preclinical Data Show Anti-Tumor Effect and Favorable Safety Profile in HER2 Positive & HER2 Low Tumor Models and Toxicity Studies<sup>1</sup>

### Efficacy data

- BNT323 (DB-1303) induced dose-dependent tumor growth inhibition and tumor regression
- Potent anti-tumor effect in both, HER2 positive and HER2 low tumor models with a wide therapeutic window



### Safety data

- Toxicity studies in cynomolgus monkey showed improved safety profile compared to published profile of DS-8201
  - Highest non-severely toxic dose 80mg/kg
- DB-1303 showed lowered risk of causing lung inflammation compared to published profile of DS-8201
  - No ILD-like lung toxicity
- Stable linker and fast clearance may contribute to the superior safety profile of DB-1303

Lin S, et al. Abstract #252. Presented at EORTC-NCI-AACR in 2022.

<sup>1</sup> Publications are available.

HER2 = human epidermal growth factor receptor 2; ILD = interstitial lung disease; PDX = patient-derived xenograft

# FIH Phase 1/2 to Evaluate Safety and Tolerability of BNT323 (DB-1303) in Patients with Advanced HER2+ Solid Tumors<sup>1</sup>

## Phase 1/2a study design (NCT05150691), multicenter, non-randomized, open-label, multiple-dose, FIH study

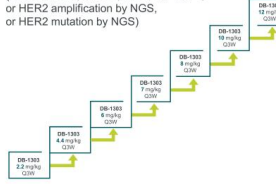
Hamilton E. et al. TIP #9504. Presented at AACR 2023

### Inclusion criteria

- Pretreated advanced or metastatic solid tumors
- Histologically confirmed HER2-positive or HER2-expressing cancers
- Previous systemic therapies
- ECOG 0-1
- Adequate organ function

### Part 1: Dose Escalation (n=88 patients)

(HER2 IHC 3+, IHC 2+, IHC 1+ or ISH +, or HER2 amplification by NGS, or HER2 mutation by NGS)



### Part 2a: Dose expansion (n=165 patients)

#### Indications

- HER2+ gastric, esophageal or gastroesophageal junction adenocarcinoma, CRC
- HR+/HER2-low breast cancer
- HER2+ breast cancer
- HER2 overexpression and HER2-low endometrial cancer
- HER2-mutated NSCLC

Disease progression, withdrawal of consent, unacceptable toxicity

3 weeks DLT window

FPI: Jan 2022

**Objective:** To assess safety, tolerability, pharmacokinetic, preliminary anti-tumor activity at the selected MTD/RP2D

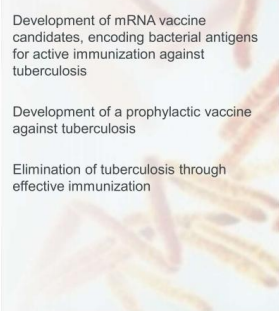


<sup>1</sup> Patented with DuPont. IHC = immunohistochemistry; FIH = First in human; Q3W = every three weeks; DLT = dose limiting toxicity; HER2 = human epidermal growth factor 2; HR = hormone receptor; CRC = colorectal cancer; NSCLC = non-small cell lung cancer; MTD = maximum tolerated dose; RP2D = recommended phase 2 dose; ECOG = Eastern Cooperative Oncology Group; FPI = First patient in LPD = Last patient out; ISH = in-situ hybridization; NGS = next-generation sequencing.

## Infectious Disease Pipeline: Achievements in Q1 2023

	Phase 1	Phase 2	Phase 3	Commercial
Pfizer Partnered Programs	BNT162b4 + BNT162b2 <sup>1</sup> (T-cell enhancing) COVID-19	BNT162b5 <sup>1</sup> (Enhanced spike antigen) COVID-19	BNT161 <sup>1</sup> Influenza	COMIRNATY <sup>1</sup> COVID-19
	BNT162b2+BNT161 <sup>2</sup> (qFlu + BA.4-5-adapted bivalent) COVID-19/Influenza combination			BNT162b2 (Original/Omicron BA.4-5-adapted bivalent) <sup>3</sup> COVID-19
	BNT167 <sup>4</sup> Shingles 			BNT162b2 (Original/Omicron BA.1-adapted bivalent) <sup>5</sup> COVID-19
Proprietary Vaccines	BNT163 <sup>3</sup> HSV-2			
Global Health Programs	BNT165 Malaria			
	BNT164 <sup>4</sup> Tuberculosis 			

<sup>1</sup> Partnership with Pfizer; <sup>2</sup> Collaboration with PFE and subject to reaching agreement with our partners; <sup>3</sup> Collaboration with University of Pennsylvania; <sup>4</sup> In collaboration with BB & Meritxida Gates Foundation; <sup>5</sup> Exclusive license to Pfizer; <sup>6</sup> H5N1 + H7N9 influenza virus.

Initiated Phase 1/2 Trial of Tuberculosis mRNA-LNP Vaccine Candidates<sup>1</sup>

<p><b>Unmet medical need</b></p>	<p><b>Objective of vaccine development</b></p>	<p><b>Target population &amp; trial design<sup>3</sup></b></p>
<p>Tuberculosis is the second leading infectious killer worldwide after COVID-19 (above HIV/AIDS)<sup>2</sup></p>	 <p>Development of mRNA vaccine candidates, encoding bacterial antigens for active immunization against tuberculosis</p> <p>Development of a prophylactic vaccine against tuberculosis</p> <p>Elimination of tuberculosis through effective immunization</p>	<p> <b>Target population:</b> IGRA-negative and positive, BCG naive and vaccinated healthy adults. Clinical trials in Germany (non-endemic) and South Africa (endemic)</p>
<p>Current prophylaxis treatment has seen limited uptake due to variable efficacy and pathogen drug-resistance</p>		<p> <b>Trial design:</b> Three-dose schedule (0 / ~8 W / ~16 W), 2 candidates, 6 dose levels</p>
<p>Ending tuberculosis epidemic by 2030 still one of the health targets of the United Nations Sustainable Development Goals<sup>2</sup></p>		<p><b>Primary endpoints:</b> Safety <b>Exploratory endpoints:</b> Immune response</p>

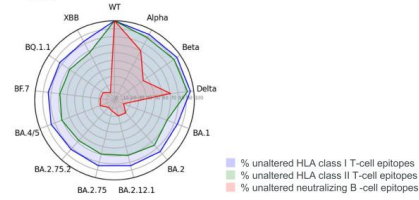
<sup>1</sup> Collaboration with BRACF, <sup>2</sup> WHO, Tuberculosis Report 2021, <sup>3</sup> NCT05537028

## COVID-19 Franchise: Being Actionable in the Face of a Dynamic Virus Evolution and Building for Continued Success

T cell immune response may continue to contribute to prevention or limitation of severe disease  
 Muik A. et al. bioRxiv pre-print. 2022



- Progressive loss of conserved B cell epitopes for spike protein neutralizing antibody sites in Omicron sublineages
- Preservation of HLA class I and class II presented T-cell epitopes across the evolution of SARS-CoV-2 spike protein
- T-cell recognition of newly occurring variants of concern may be largely intact



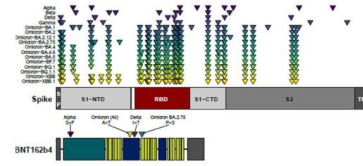
23

Induction of T cell responses to non-spike SARS-CoV-2 antigens to broaden the immune response and address immune evasion of new variants of concern  
 Arieta C. et al. Cell. 2023. DOI: 10.1016/j.cell.2023.04.007



The cell string (BNT162b4) encodes variant-conserved, immunogenic segments of the SARS-CoV-2 nucleocapsid, membrane, and ORF1ab proteins, targeting diverse HLA alleles

- mRNA vaccine component designed to enhance T cell immunity
- variant-conserved, immunogenic segments of SARS-CoV-2 proteins
- Intended to be combined with the variant-adapted spike protein vaccine component (BNT162b2)



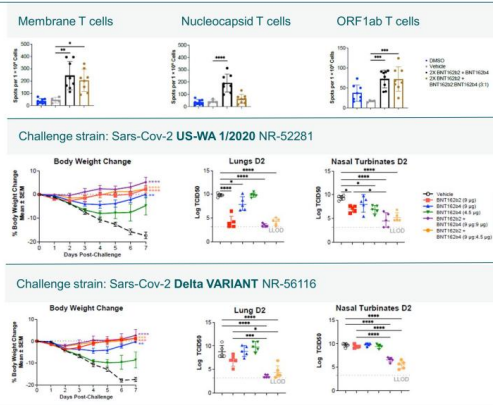
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# Next-Generation COVID-19 Vaccine Component Candidate BNT162b4 Encoding Conserved Non-Spike Antigens Protects Animals from Severe COVID-19<sup>1</sup>

In animal models

- Elicits polyfunctional CD4+ and CD8+ T cell responses
- Non-spike specific T cells increased by both BNT162b4 monovalent vaccination and in combination with spike protein component BNT162b2
- Protects hamsters from severe disease, reduces viral titers with viral variants
- Effective alone or when co-administered with BNT162b2

BNT162b4 is currently being evaluated in a clinical trial with BA.4-5 Omicron-updated bivalent BNT162b2 (NCT05541861)<sup>1</sup>



Ariela C. et al. Cell. 2023. DOI: 10.1016/j.cell.2023.04.007  
 1. Pre-proof with Pfizer

# 3 Financial Results

Jens Holstein, Chief Financial Officer

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## Q1 2023 Key Highlights<sup>1</sup>

Total revenues<sup>2</sup>

€ **1.3** bn

Operating result

€ **0.7** bn

Diluted EPS

€ **2.05**

Total cash plus security investments<sup>3</sup>

€ **12.8** bn

<sup>1</sup> Financial information is prepared and presented in Euros and numbers are rounded to millions and billions of Euros in accordance with standard commercial practice.

<sup>2</sup> BionTech's profit shown 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, 2022 as well as the Quarterly Report as of and for the three months ended March 31, 2023. Not as an audit by BionTech's Current Report on Form 10-K filed on May 10, 2023.

<sup>3</sup> Consists of cash and cash equivalents of €12,143.9 million and security investments of €671.9 million, as of March 31, 2023. The payment settling our gross profit share for the fourth quarter of 2022 (as defined by the contracts) in the amount of €2,985 million was received from our collaboration partner subsequent to the end of the reporting period on April 14, 2023. M&A activities and recent collaboration and license agreements announced in the first quarter did not lead to cash outflows until March 31, 2023. Cash outflows are shown as outflows in connection with the planned acquisition of InhibiData and the upfront payments of the collaboration and license agreements with Chiesi and Duality Biologics of approximately €0.8 billion are expected subject to charge and according future potential earn-out and milestone payments.

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## Q1 2023 Financial Results: Profit or Loss

(in millions €, except per share data) <sup>1</sup>	Three months ended March 31,	
	2023	2022
Commercial revenues <sup>2</sup>	1,276.5	6,362.2
Research & development revenues	0.5	12.4
<b>Total revenues</b>	<b>1,277.0</b>	<b>6,374.6</b>
Cost of sales	(96.0)	(1,294.1)
Research and development expenses	(334.0)	(285.8)
Sales and marketing expenses	(12.2)	(14.3)
General and administrative expenses	(119.4)	(90.8)
Other operating income less expenses	(61.0)	63.1
<b>Operating income</b>	<b>654.4</b>	<b>4,752.7</b>
Finance income less expenses	53.3	265.4
Income taxes	(205.5)	(1,319.3)
<b>Profit for the period</b>	<b>502.2</b>	<b>3,698.8</b>
<b>Earnings per share</b>		
Basic profit for the period per share	2.07	15.13
Diluted profit for the period per share	2.05	14.24

<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 content. Presentation of the unaudited interim consolidated statements of profit or loss has been condensed.

<sup>2</sup> Biontech's profit share is estimated based on preliminary data shared between Pfizer and BionTech as to that reported in the Annual Report on Form 20-F for the year ended December 31, 2022, as well as the Quarterly Report as of and for the three months ended March 31, 2023. Refer us an exhibit to BionTech's Current Report on Form 6-K filed on May 8, 2023. Any changes in the estimated share of the collaboration partner's gross profit will be recognized prospectively.

## 2023 Financial Year Guidance Reiterated<sup>1</sup>

<b>COVID-19 vaccine revenues for FY 2023</b>	Estimated BioNTech COVID-19 vaccine revenues	~ €5 bn
<b>Planned FY 2023 expenses and capex</b>	R&D expenses <sup>2</sup>	€2,400 – 2,600 m
	SG&A expenses	€650 – 750 m
	Capital expenditure for operating activities <sup>3</sup>	€500 – 600 m
<b>Estimated FY 2023 tax assumptions</b>	BioNTech Group estimated annual cash effective income tax rate	~ 27%

<sup>1</sup> Numbers reflect current base case projections and are calculated based on constant currency rates.  
<sup>2</sup> Numbers exclude effects specified from additional collaborations or potential M&A transactions to the extent disclosed and will be updated as needed.  
<sup>3</sup> Numbers exclude potential effects caused by or arising from collaborations or M&A transactions.

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# 4 Strategic Outlook

Ryan Richardson, Chief Strategy Officer

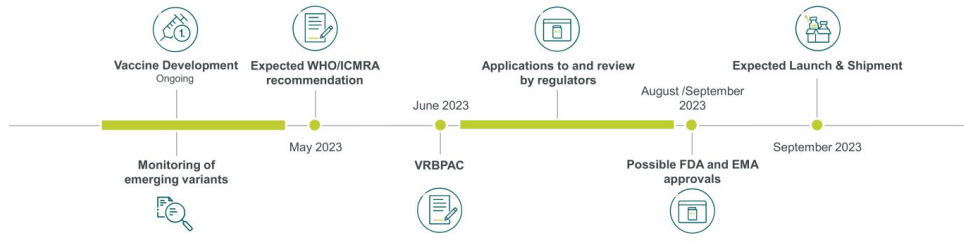
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## Outlook for COVID-19 Vaccine Franchise in 2023

- Launch Comirnaty vaccine adapted to the 2023 seasonal SARS-CoV-2 variant, as recommended by regulatory authorities
- Introduce single-dose ready to use vial
- Advance key Comirnaty features (e.g., extension of shelf-life)
- Advance next generation COVID-19 vaccines

Expected timeline for variant-adapted vaccine development:



WHO = World Health Organization; ICMRA = International Coalition of Medicines Regulatory Authorities; VRBPAC = Vaccines and Related Biological Products Advisory Committee; FDA = Food and Drug Administration; EMA = European Medicines Agency.

## COVID-19 Market Outlook

### 2023 market dynamics & outlook

- Doses already shipped to >70 countries and regions
- Increased deliveries in middle-income and low-income countries in Q1 2023
- Increased contribution from pediatric segment in Q1 2023
- U.S. commercial market opening expected in 2H 2023 in conjunction with launch of variant-adapted vaccine

### Potential mid-term growth drivers



Value proposition could support increased vaccination rate in at-risk populations once global seasonal market is established



#### Continued product innovation

- Variant adapted vaccines
- Next-generation vaccines
- Vaccine combinations



#### Commercial pricing

## Multiple Late- and Early-Stage Pipeline Milestones Expected in 2023

Modality	Indication	Program	Select milestones	Anticipated timing	
mRNA vaccines for infectious disease	COVID-19 <sup>1</sup>	BA.4-5-adapted bivalent	Pediatric label expansion	2H 2023	✓
	COVID-19 – influenza Combination <sup>1,2</sup>	BA.4-5-adapted bivalent+ BNT161	Phase 1 data update	2023	
	Malaria	BNT163	Phase 1 data update	2H 2023	
	HSV-2 <sup>3</sup>	BNT165	Phase 1 data update	2H 2023	
	Shingles <sup>1</sup>	BNT167	Phase 1 data update	2023	✓
	Tuberculosis <sup>4</sup>	BNT164	Phase 1 FPD April 2023		✓
iNeST individualized mRNA vaccines	1L melanoma <sup>5</sup>	Autogene Cevumeran (BNT122)	Phase 2 data update	2H 2023	
	Adjuvant CRC <sup>6</sup>	Autogene Cevumeran (BNT122)	Phase 2 data update	-	
	Adjuvant PDAC <sup>6</sup>	Autogene Cevumeran (BNT122)	Phase 2 FPD	2023	
Next-gen immune checkpoint modulators	Multiple solid tumors <sup>7</sup>	BNT311 (PD-L1x4-1BB)	Expansion cohort data update	2023	
	Multiple solid tumors <sup>7</sup>	BNT312 (CD40x4-1BB)	Expansion cohort data update	2023	
	2L NSCLC <sup>8</sup>	BNT316 (CTLA-4)	Phase 3 FPD	2023	
Cell therapies	CLDN6+ solid tumors	BNT211	Phase 1 data update	2023	
	2L+ testicular cancer	BNT211	Phase 2 FPD	2024	

### Clinical Data at ASCO

BNT316 (ONC-392)  
Abstract #9024  
Poster Presentation

BNT211  
Abstract #2518  
Poster Presentation

BNT323 (DB-1303)  
Abstract #3023  
Poster

1. Partnered with Pfizer; 2. Collaboration with Pfizer and subject to reaching agreement with our partners; 3. Partnered with University of Pennsylvania; 4. Collaboration with Bill & Melinda Gates Foundation; 5. Partnered with Genentech, a member of Roche Group; 6. Collaboration with AstraZeneca; 7. Collaboration with Genentech; 8. Collaboration with Genentech.  
FPD = First Patient Dosed; CRC = Colorectal cancer; PDAC = Pancreatic ductal adenocarcinoma; HSV = Herpes simplex virus; NSCLC = Non-small cell lung cancer; CLDN6 = Claudin 6; 1L = first line; 2L = second line

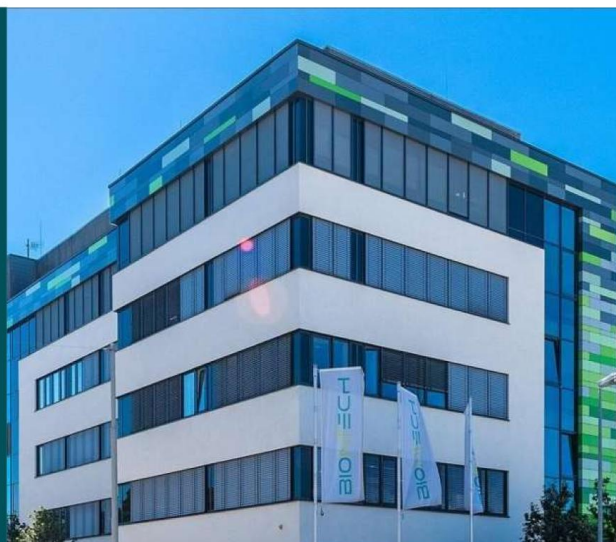
**SAVE THE DATE**  
**BIONTECH**



Annual General Meeting  
**May 25, 2023**



Innovation Series Day  
**November 7, 2023**



Thank you

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