

**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 AUGUST 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 August 7, 2023, BioNTech SE (the “Company”) issued a press release announcing its second quarter 2023 financial results and corporate update and details of a conference call to be held at 8:00 am EDT on August 7, 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: August 7, 2023

**EXHIBIT INDEX**

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

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

- Significant pipeline advancement highlighted by the initiation of BNT316/ONC-392 Phase 3 pivotal trial and multiple trials planned to start across the oncology portfolio
- Positive data updates across multiple technology platforms including ADC candidate BNT323/DB-1303, anti-CTLA4 monoclonal antibody candidate BNT316/ONC-392 and CAR-T candidate BNT211
- Preparation for launch of Omicron XBB.1.5-adapted monovalent COVID-19 vaccine as recommended by the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA) and other health authorities; deliveries expected to start as early as September, subject to regulatory approval
- Reiterates COVID-19 vaccine revenue guidance of approximately €5 billion in 2023
- First half<sup>1</sup> of 2023 revenues of €1.4 billion<sup>2</sup>, net profit of €311.8 million and fully diluted earnings per share of €1.28 (\$1.38<sup>3</sup>)

Conference call and webcast scheduled for August 7, 2023, at 8:00 am EDT (2:00 pm CEST)

**MAINZ, Germany, August 7, 2023 (GLOBE NEWSWIRE)** -- BioNTech SE (Nasdaq: BNTX, "BioNTech" or "the Company") today reported financial results for the three and six months ended June 30, 2023, and provided an update on its corporate progress.

"We are progressing our oncology pipeline into late-stage development, having launched a pivotal Phase 3 trial and preparing for additional trials with registrational potential in the coming months," said **Prof. Ugur Sahin, M.D., CEO and Co-Founder of BioNTech**. "Simultaneously, we are enhancing our infectious disease pipeline to address global health needs and are developing an Omicron XBB.1.5-adapted monovalent COVID-19 vaccine to become available for the upcoming fall-winter season, subject to regulatory approvals."

### Financial Review for the Second Quarter and First Half of 2023

in millions €, except per share data	Second Quarter 2023	Second Quarter 2022	First Half 2023	First Half 2022
Total Revenues <sup>2</sup>	167.7	3,196.5	1,444.7	9,571.1
Net Profit / (Loss)	(190.4)	1,672.0	311.8	5,370.8
Diluted Earnings / (Loss) per Share	(0.79)	6.45	1.28	20.69

**Total revenues** reported were €167.7 million<sup>2</sup> for the three months ended June 30, 2023, compared to €3,196.5 million for the comparative prior year period. For the six months ended June 30, 2023, total revenues were €1,444.7 million<sup>2</sup>, compared to €9,571.1 million for the comparative prior year period. Write-offs by BioNTech's collaboration partner Pfizer, Inc. ("Pfizer") significantly reduced the Company's gross profit share in the second quarter and hence negatively influenced its revenues for the three months ended June 30, 2023.

**Cost of sales** were €162.9 million for the three months ended June 30, 2023, compared to €764.6 million for the comparative prior year period. For the six months ended June 30, 2023, cost of sales were €258.9 million, compared to €2,058.7 million for the comparative prior year period. The change was in line with decreasing COVID-19 vaccine sales.

**Research and development** expenses were €373.4 million for the three months ended June 30, 2023, compared to €399.6 million for the comparative prior year period. For the six months ended June 30, 2023, research and development expenses were €707.4 million, compared to €685.4 million

for the comparative prior year period. Research and Development (R&D) expenses are mainly influenced by progressing clinical studies for pipeline candidates, the development of variant adapted as well as next generation COVID-19 vaccines and expanding R&D headcount.

**General and administrative** expenses were €122.7 million for the three months ended June 30, 2023, compared to €130.0 million for the comparative prior year period. For the six months ended June 30, 2023, general and administrative expenses were €242.1 million, compared to €220.8 million for the comparative prior year period. G&A expenses were mainly influenced by increased expenses for IT services as well as expanding the G&A headcount.

**Income taxes** were realized with an amount of €221.8 million tax income for the three months ended June 30, 2023, compared to €647.3 million of tax expenses accrued for the comparative prior year period. For the six months ended June 30, 2023, income taxes were realized with an amount of €16.3 million tax income, compared to €1,966.6 million tax expenses accrued for the comparative prior year period. The derived annual effective income tax rate for the six months ended June 30, 2023, was minus 5.5% which is expected to change over the 2023 financial year to be in line with the updated estimated annual cash effective income tax rate of somewhere around 21% for the BioNTech Group.

**Net loss** was €190.4 million for the three months ended June 30, 2023, compared to €1,672.0 million net profit for the comparative prior year period. For the six months ended June 30, 2023, **net profit** was €311.8 million, compared to €5,370.8 million net profit for the comparative prior year period.

**Cash and cash equivalents as well as security investments** were €14,166.6 million as well as €2,667.0 million, respectively, as of June 30, 2023. Subsequent to the end of the reporting period, the payment settling BioNTech's gross profit share for the first quarter of 2023 (as defined by the contract with Pfizer) in the amount of €1,059.2 million was received from BioNTech's collaboration partner as of July 17, 2023. In addition, until early August 2023, €437.7 million was received in connection with the amended COVID-19 Vaccine Purchase Agreement with the European Commission (EC).

**Loss per share** was €0.79 for the three months ended June 30, 2023, compared to a diluted earnings per share €6.45 for the comparative prior year period. For the six months ended June 30, 2023, diluted **earnings per share** was €1.28, compared to €20.69 diluted earnings per share for the comparative prior year period.

**Shares outstanding** as of June 30, 2023, were 239,771,156, excluding 8,781,044 shares in treasury.

In March 2023, BioNTech initiated a new share repurchase program pursuant to which the Company may purchase American Depositary Shares, or ADSs, each representing one ordinary share of the Company, in the amount of up to \$0.5 billion during the remainder of 2023. During the three months ended June 30, 2023, 1,532,685 American Depositary Shares were repurchased under the share repurchase program of ADSs at an average price of €100.45 (\$108.92<sup>3</sup>), for total consideration of €154.0 million (\$166.9 million<sup>3</sup>).

**Cash outflows and share consideration** in connection with the acquisition of InstaDeep Ltd. ("InstaDeep") on July 31, BioNTech invested approximately €450 million not including potential future milestones.

"We enter the second half of 2023 with a strong financial position, on track to launch our new variant-adapted COVID-19 vaccine and to conduct multiple clinical trials with registrational potential across our oncology and infectious disease pipeline. The COVID-19 vaccine market remains highly dynamic and difficult to fully predict. Along with our partner Pfizer, the Company continues to focus on supporting successful vaccinations during the autumn respiratory infection season," **said Jens Holstein, CFO of BioNTech.** "It is our goal to become a multi-product company by investing in our own clinical programs and by complementing them with additional compounds from our partners. With

some uncertainty on the revenue line, we are also carefully watching our spending by revisiting our cost base while remaining focused on executing against our strategic goals and providing value to the public and our shareholders."

#### Outlook for the 2023 Financial Year

The Company reiterates its COVID-19 vaccine revenue guidance and updates its previous expense and capex guidance for the 2023 financial year:

#### 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 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. While vaccine adaptation is expected to lead to increased demand, fewer primary vaccinations and lowered population-wide levels of boosting are anticipated. In addition, seasonal demand is assumed, moving expected revenue generation to the second half of the year 2023 as previously reported. The revenues guidance reflects the revenues as specified by the amendment of the contractual agreement with the EC on behalf of the member states while it largely remains dependent on revenues generated in BioNTech's collaboration partner's territories. The market dynamics for COVID-19 vaccines are influenced by various factors which underlie substantial uncertainties and might affect the demand for COVID-19 vaccines in general as well as the Company's estimated revenues.

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

	Previous Guidance	Updated Guidance
R&D expenses <sup>5</sup>	€2,400m - €2,600m	€2,000m - €2,200m
SG&A expenses	€650m - €700m	€600m - €700m
Capital expenditures for operating activities <sup>6</sup>	€500m - €600m	€350m - €450m

#### Estimated 2023 Financial Year Tax Assumptions:

	Previous Guidance	Updated Guidance
BioNTech Group estimated annual cash effective income tax rate <sup>7</sup>	~ 27%	~ 21%

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

#### Endnotes

<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 and six months ended June 30, 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.

<sup>7</sup> Numbers exclude potential effects caused by or driven from share-based payment settlements in the course of 2023.

## Operational Review and Pipeline Update for the Second Quarter 2023 and Key Post Period-End Events

### COVID-19 Marketed Products

- In May, BioNTech and Pfizer announced an agreement with the EC to amend the previous COVID-19 Vaccine Purchase Agreement to deliver COVID-19 vaccines doses to the European Union. The amended agreement reflects BioNTech and Pfizer's commitment to working collaboratively to help address ongoing public health needs, while respecting the principles of the original agreement. It includes re-phasing of delivery of doses annually through 2026. In addition, the agreement includes an aggregate volume reduction, providing additional flexibility for EU Member States. The EC will maintain access to future adapted COVID-19 vaccines and the ability to donate doses, in alignment with the original agreement.
- In June, BioNTech and Pfizer submitted regulatory applications to the EMA and to the U.S. FDA for their Omicron XBB.1.5-adapted monovalent COVID-19 vaccine for individuals 6 months of age and older in line with recommendations from both regulatory agencies. Regulatory submissions in other territories have also been initiated.
- BioNTech and Pfizer have manufactured Omicron XBB.1.5-adapted monovalent COVID-19 vaccine doses at risk to ensure readiness ahead of the fall and winter seasons in various regions worldwide. The companies plan to prepare shipments of Omicron XBB.1.5-adapted monovalent COVID-19 vaccine doses for fast delivery following potential regulatory approval.

### Oncology Pipeline Highlights - Recent and upcoming trial starts and data readouts

**BNT316/ONC-392 (gotistobart)** is a next-generation anti-CTLA-4 monoclonal antibody candidate jointly developed by BioNTech and OncoC4, Inc. ("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.

- In June, BioNTech and OncoC4 initiated a Phase 3 clinical trial ([NCT05671510](#)) to evaluate BNT316/ONC-392 as monotherapy in non-small cell lung cancer (NSCLC) patients whose disease progressed on anti-PD-1/PD-L1 antibody-based therapy. The program received Fast Track Designation from the FDA in 2022.
- Data from a dose escalation and an expansion cohort evaluating BNT316/ONC-392 as monotherapy in NSCLC patients that had progressed on prior immune-checkpoint inhibitor (ICI) therapy as part of the ongoing Phase 1/2 clinical trial ([NCT04140526](#)) were presented at the American Society of Clinical Oncology (ASCO) Annual Meeting in June 2023. BNT316/ONC-392 was generally well-tolerated with a manageable safety profile. Early readout of the expansion cohort showed encouraging clinical activity in patients with ICI-resistant NSCLC.

**BNT323/DB-1303** is a HER2-targeted antibody-drug conjugate (ADC) candidate, being developed in collaboration with Duality Biologics (Suzhou) Co. Ltd. ("DualityBio").

- BNT323/DB-1303 is being evaluated in a Phase 1/2 clinical trial ([NCT05150691](#)) in patients with advanced/unresectable, recurrent, or metastatic HER2-expressing solid tumors. Data

from the ongoing trial were presented at the 2023 ASCO Annual Meeting suggesting that BNT323/DB-1303 was well tolerated and adverse events (AEs) were manageable. Preliminary antitumor activity was observed in heavily pretreated HER2-expressing patients with a median of seven prior systemic treatment regimens, including other HER2 ADCs.

**BNT324/DB-1311** is a topoisomerase-1 inhibitor-based ADC candidate being developed in collaboration with DualityBio.

- A first-in-human, open-label Phase 1/2 clinical trial evaluating BNT324/DB-1311 in multiple advanced solid tumors is planned to start this year.

**BNT116** is based on BioNTech's FixVac platform, a wholly owned, systemically administered, off-the-shelf mRNA-based cancer vaccine candidate. This candidate is being evaluated for the treatment of advanced NSCLC.

- In July 2023, BioNTech and Regeneron Pharmaceuticals Inc. ("Regeneron") initiated a randomized, controlled, Phase 2 clinical trial ([NCT05557591](#)) to evaluate BNT116 in combination with cemiplimab (Regeneron's Libtayo) and cemiplimab alone as first-line treatment of patients with advanced NSCLC whose tumors express PD-L1 in  $\geq 50\%$  of tumor cells.

**BNT122 (Autogene cevumeran)** 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 ("Roche").

- A randomized Phase 2 clinical trial ([NCT05968326](#)) is planned to start in 2H 2023 to further evaluate the safety and efficacy of BNT122 in the adjuvant setting in combination with atezolizumab (Genentech's Tecentriq) followed by chemotherapy in patients with resected pancreatic ductal adenocarcinoma (PDAC) supported by data from an investigator-initiated Phase 1 trial ([NCT04161755](#)). In May 2023, results from the Phase 1 trial were published in the peer-reviewed journal *Nature*. Trials in other indications are ongoing.

**BNT211** is an autologous Claudin-6 (CLDN6)-targeting chimeric antigen receptor (CAR) T cell therapy candidate that is being tested alone and in combination with an investigational CAR-T cell Amplifying RNA Vaccine compound, or CARVac, encoding CLDN6.

- A data update from the ongoing Phase 1/2 clinical trial ([NCT04503278](#)) was provided at the 2023 ASCO Annual Meeting detailing the new dose escalation of CLDN6 CAR-T cells with and without a CLDN6-encoding mRNA vaccine for the treatment of CLDN6-positive relapsed/refractory solid tumors using an automated manufacturing process. CLDN6 CAR-T cells  $\pm$  CLDN6 CARVac showed a moderate safety profile in line with that of manually produced CLDN6 CAR-T cells. Encouraging signs of clinical activity for dose level 1 and 2 were confirmed, including dose-dependent expansion of CAR-T cells demonstrated by an objective response rate (ORR) of 41% in all 17 evaluable patients and an ORR of 75% in patients at dose level 2. Follow-up of treated patients and further enrollment of patients into dose level 2 and 3 are ongoing. After determination of a recommended Phase 2 dose for CLDN6 CAR-T cells, a pivotal trial in germ cell tumors is planned to start in 2024.

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

- 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. In August 2023, BioNTech

- signed another agreement with DualityBio to develop, manufacture and commercialize an additional antibody-drug conjugate, DB-1305.
- In July, following on a memorandum of understanding announced in January, BioNTech signed a long-term strategic partnership agreement with the UK Government, NHS England and Genomics England Limited with the aim to provide access to personalized treatments for up to 10,000 patients by 2030, either in clinical trials or as authorized treatment. To execute this, BioNTech plans to set up new laboratories in Cambridge with an expected capacity of more than 70 highly skilled scientists as well as a new regional hub for the United Kingdom.
- In July, BioNTech also successfully completed its previously announced acquisition of InstaDeep, following the satisfaction of all customary closing conditions. The acquisition supports the Company's strategy to build world-leading capabilities in Artificial Intelligence ("AI")-driven drug discovery and development. InstaDeep will operate as a UK-based global subsidiary of BioNTech. The transaction adds approximately 290 highly skilled professionals to BioNTech's workforce, including teams in AI, machine learning ("ML"), bioengineering, data science, and software development.

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

BioNTech was founded out of a responsibility to patients and to society and this is still the vision that drives the Company. It gives grounds for BioNTech's enhanced responsibility: for translating the Company's science into the health of people worldwide and democratizing access to innovative medicines, for environmental and climate protection, for respecting human rights and for fostering the full potential of all employees.

In March 2023, BioNTech published its third ESG report (Sustainability Report 2022). The report highlights the Company's progress in developing novel medicines and introducing scalable technological innovations. It describes BioNTech's science-based climate goals (under SBTi review), actions and climate risk management as well as the status of the Companies' human rights strategy and due diligence. The report addresses diversity, inclusion, equity and belonging, and highlights the importance of BioNTech's values and culture.

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

**Upcoming Investor and Analyst Events**

- BioNTech's third quarter 2023 financial results and corporate update are scheduled for Monday, November 6, 2023.
- BioNTech will host its 2nd Innovation Day on Tuesday, November 7, 2023, in Boston, USA.

**Conference Call and Webcast Information**

BioNTech invites investors and the general public to join a conference call and webcast with investment analysts today, August 7, 2023, at 8.00 a.m. EDT (2.00 p.m. CEST) to report its financial results and provide a corporate update for the second 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 DualityBio, Fosun Pharma, Genentech, a member of the Roche Group, Genevant, Genmab, OncoC4, Regeneron, Sanofi, 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; our expectations with respect to our intellectual property; the impact of the Company's 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 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 June 30, 2023 and in subsequent filings made by BioNTech with the SEC, which are available on the SEC's website at [www.sec.gov](http://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

	Three months ended June 30,		Six months ended June 30,	
	2023 (unaudited)	2022 (unaudited)	2023 (unaudited)	2022 (unaudited)
<i>(in millions €, except per share data)</i>				
Revenues				
Commercial revenues	166.4	3,166.3	1,442.9	9,528.5
Research & development revenues	1.3	30.2	1.8	42.6
<b>Total revenues</b>	<b>167.7</b>	<b>3,196.5</b>	<b>1,444.7</b>	<b>9,571.1</b>
Cost of sales	(162.9)	(764.6)	(258.9)	(2,058.7)
Research and development expenses	(373.4)	(399.6)	(707.4)	(685.4)
Sales and marketing expenses	(18.1)	(17.8)	(30.3)	(32.1)
General and administrative expenses	(122.7)	(130.0)	(242.1)	(220.8)
Other operating expenses	(74.2)	(240.7)	(192.3)	(309.5)
Other operating income	20.3	565.8	77.4	697.7
<b>Operating income / (loss)</b>	<b>(563.3)</b>	<b>2,209.6</b>	<b>91.1</b>	<b>6,962.3</b>
Finance income	152.4	115.5	208.9	387.6
Finance expenses	(1.3)	(5.8)	(4.5)	(12.5)
<b>Profit / (loss) before tax</b>	<b>(412.2)</b>	<b>2,319.3</b>	<b>295.5</b>	<b>7,337.4</b>
Income taxes	221.8	(647.3)	16.3	(1,966.6)
<b>Profit / (Loss) for the period</b>	<b>(190.4)</b>	<b>1,672.0</b>	<b>311.8</b>	<b>5,370.8</b>
<b>Earnings per share</b>				
Basic profit / (loss) for the period per share	(0.79)	6.86	1.29	22.00
Diluted profit / (loss) for the period per share	(0.79)	6.45	1.28	20.69

### Interim Consolidated Statements of Financial Position

<i>(in millions €)</i>	June 30, 2023 <i>(unaudited)</i>	December 31, 2022
<b>Assets</b>		
<b>Non-current assets</b>		
Intangible assets	501.4	219.7
Property, plant and equipment	691.1	609.2
Right-of-use assets	202.9	211.9
Other financial assets	1,374.3	80.2
Other non-financial assets	2.5	6.5
Deferred tax assets	239.5	229.6
<b>Total non-current assets</b>	<b>3,011.7</b>	<b>1,357.1</b>
<b>Current assets</b>		
Inventories	448.9	439.6
Trade and other receivables	2,657.9	7,145.6
Contract assets	5.9	—
Other financial assets	1,390.7	189.4
Other non-financial assets	212.3	271.9
Income tax assets	331.6	0.4
Cash and cash equivalents	14,166.6	13,875.1
<b>Total current assets</b>	<b>19,213.9</b>	<b>21,922.0</b>
<b>Total assets</b>	<b>22,225.6</b>	<b>23,279.1</b>
<b>Equity and liabilities</b>		
<b>Equity</b>		
Share capital	248.6	248.6
Capital reserve	1,424.4	1,828.2
Treasury shares	(8.8)	(5.3)
Retained earnings	19,144.8	18,833.0
Other reserves	(902.5)	(848.9)
<b>Total equity</b>	<b>19,906.5</b>	<b>20,055.6</b>
<b>Non-current liabilities</b>		
Lease liabilities, loans and borrowings	167.1	176.2
Other financial liabilities	6.1	6.1
Income tax liabilities	—	10.4
Provisions	8.6	8.6
Contract liabilities	302.1	48.4
Other non-financial liabilities	11.7	17.0
Deferred tax liabilities	4.5	6.2
<b>Total non-current liabilities</b>	<b>500.1</b>	<b>272.9</b>
<b>Current liabilities</b>		
Lease liabilities, loans and borrowings	38.6	36.0
Trade payables and other payables	228.6	204.1
Other financial liabilities	172.5	785.1
Refund liabilities	—	24.4
Income tax liabilities	554.9	595.9
Provisions	374.8	367.2
Contract liabilities	201.2	77.1
Other non-financial liabilities	248.4	860.8
<b>Total current liabilities</b>	<b>1,819.0</b>	<b>2,950.6</b>
<b>Total liabilities</b>	<b>2,319.1</b>	<b>3,223.5</b>
<b>Total equity and liabilities</b>	<b>22,225.6</b>	<b>23,279.1</b>

### Interim Consolidated Statements of Cash Flows

(in millions €)	Three months ended June 30,		Six months ended June 30,	
	2023 (unaudited)	2022 (unaudited)	2023 (unaudited)	2022 (unaudited)
<b>Operating activities</b>				
Profit / (Loss) for the period	(190.4)	1,672.0	311.8	5,370.8
Income taxes	(221.8)	647.3	(16.3)	1,966.6
<b>Profit / (Loss) before tax</b>	<b>(412.2)</b>	<b>2,319.3</b>	<b>295.5</b>	<b>7,337.4</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	31.9	33.2	63.3	60.8
Share-based payment expenses	13.1	14.8	21.7	25.0
Net foreign exchange differences	(397.0)	(344.6)	(343.9)	(338.5)
Loss on disposal of property, plant and equipment	0.1	0.2	0.3	0.2
Finance income excluding foreign exchange differences	(126.6)	(1.5)	(208.9)	(218.8)
Finance expense excluding foreign exchange differences	1.3	5.8	2.5	12.5
Movements in government grants	—	—	(3.0)	—
Net loss on derivative instruments at fair value through profit or loss	12.0	86.5	88.2	84.6
Working capital adjustments:				
Decrease in trade and other receivables, contract assets and other assets	5,123.6	3,174.8	6,017.4	2,771.3
Decrease / (increase) in inventories	(24.8)	91.6	(9.3)	134.8
(Decrease) / increase in trade payables, other financial liabilities, other liabilities, contract liabilities, refund liabilities and provisions	592.7	(663.1)	(268.9)	194.4
Interest received	42.5	1.5	96.1	2.2
Interest paid	(1.3)	(5.8)	(2.5)	(12.2)
Income tax paid	(437.3)	(791.4)	(1,282.2)	(2,081.4)
Share-based payments	(31.3)	(2.2)	(757.0)	(3.0)
<b>Net cash flows from operating activities</b>	<b>4,386.7</b>	<b>3,919.1</b>	<b>3,709.3</b>	<b>7,969.3</b>
<b>Investing activities</b>				
Purchase of property, plant and equipment	(67.2)	(70.6)	(112.4)	(114.7)
Purchase of intangible assets and right-of-use assets	(242.1)	(4.8)	(251.7)	(21.5)
Investment in other financial assets	(1,982.5)	(3.0)	(2,663.1)	(30.0)
Proceeds from maturity of other financial assets	—	—	—	375.2
<b>Net cash flows from / (used in) investing activities</b>	<b>(2,291.8)</b>	<b>(78.4)</b>	<b>(3,027.2)</b>	<b>209.0</b>
<b>Financing activities</b>				
Proceeds from issuance of share capital and treasury shares, net of costs	—	—	—	110.5
Proceeds from loans and borrowings	—	0.2	—	0.2
Repayment of loans and borrowings	—	—	—	(18.8)
Payments related to lease liabilities	(9.4)	(10.5)	(18.7)	(21.9)
Share repurchase program	(154.0)	(286.9)	(436.0)	(286.9)
Dividends	—	(484.3)	—	(484.3)
<b>Net cash flows used in financing activities</b>	<b>(163.4)</b>	<b>(781.5)</b>	<b>(454.7)</b>	<b>(701.2)</b>
Net increase in cash and cash equivalents	1,931.5	3,059.2	227.4	7,477.1
Change in cash and cash equivalents resulting from exchange rate differences	91.2	111.5	64.1	165.0
Cash and cash equivalents at the beginning of the period	12,143.9	6,164.1	13,875.1	1,692.7
<b>Cash and cash equivalents as of June 30</b>	<b>14,166.6</b>	<b>9,334.8</b>	<b>14,166.6</b>	<b>9,334.8</b>

# 2<sup>nd</sup> Quarter 2023 Financial Results & Corporate Update

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August 7, 2023

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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 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; our expectations with respect to our intellectual property; the impact of the Company's 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 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 June 30, 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.

**1** 2<sup>nd</sup> Quarter 2023 Highlights  
Ugur Sahin, Chief Executive Officer

**2** COVID-19 & 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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# 2<sup>nd</sup> Quarter 2023 Highlights

Ugur Sahin, Chief Executive Officer

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## 2023 Strategic Priorities and Achievements in Q2 2023

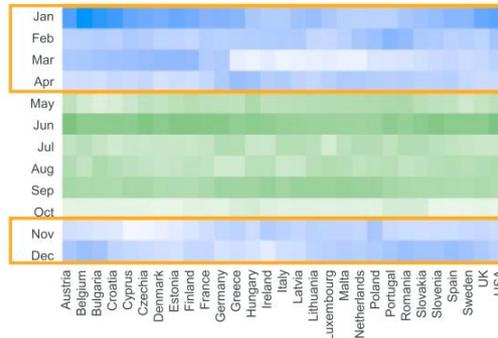
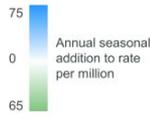
COVID-19 franchise <sup>1</sup>	Immuno-oncology	Infectious diseases
<b>2023 Strategic Priorities</b>		
Sustain leadership in COVID-19 vaccines Advance next-gen vaccines	Advance platforms for solid tumors Initiate multiple trials with registrational potential	Initiate and accelerate clinical programs for high medical need indications
<b>Q2 Achievements</b>		
<p><b>Prepare launch activities for variant-adapted vaccine</b></p> <p>Submitted application to EU and U.S. regulators for variant-adapted COVID-19 vaccine</p> <p>Initiated development &amp; manufacturing of COVID-19 vaccines better matched to currently circulating sublineages for 2023/2024 season</p>	<p><b>Two new collaborations</b></p> <p>DualityBio ADCs – A promising combination backbone to our pipeline</p> <p>OncoC4 A differentiated anti CTLA-4 antibody program</p> <p><b>Three clinical data updates at ASCO</b></p> <p>BNT211 BNT316/ONC-392 (gotistobart)<sup>2</sup> BNT323/DB-1303<sup>3</sup></p> <p><b>Phase 3 Trial Start</b></p> <p>BNT316/ONC-392 (gotistobart)<sup>2</sup></p>	<p><b>Trial Start</b></p> <p>Tuberculosis<sup>4</sup> BNT164</p> <p><b>Multiple data updates expected in 2H 2023</b></p> <p>HSV<sup>5</sup> BNT163</p> <p>Malaria BNT165</p>

1. Partnered with Pfizer; 2. Partnered with OncoC4; 3. Partnered with DualityBio; 4. In collaboration with Bill & Melinda Gates Foundation; 5. Collaboration with University of Pennsylvania.  
HSV = Herpes simplex virus; ADC = antibody-drug conjugate; CTLA = cytotoxic T-lymphocyte-associated protein.

# SARS-CoV-2 Activity is Expected to Increase Again this Fall/Winter and Become a Seasonal Disease

Disease activity has peaked between November and April<sup>1</sup>  
 Similar patterns seen for influenza, RSV, and other respiratory viruses<sup>2</sup>

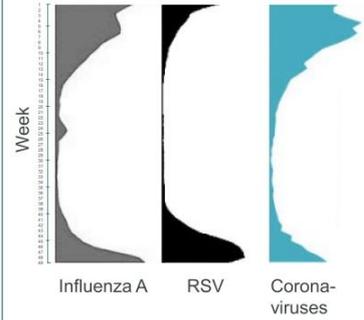
Heatmap of monthly COVID-19-related hospitalizations per million population, Northern hemisphere, Mar 2020 – Dec 2022<sup>1</sup>



1 Wiemken et al. Sci Rep. 2023 Mar 8;13(1):3886. doi: 10.1038/s41598-023-31057-1  
 2 Nichols et al. BMC Infect Dis. 2021 Oct 26;21(1):1101. doi: 10.1186/s12879-021-06785-2

RSV = respiratory syncytial virus.

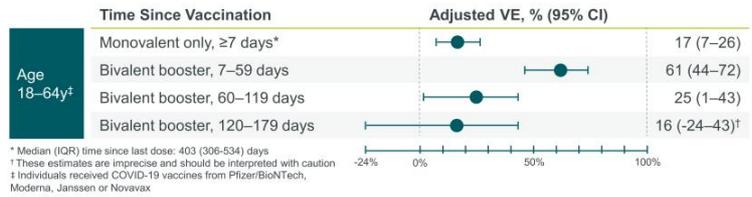
Weekly Seasonality of Confirmed Viral Infections  
 England and Wales, 1989 – 2019<sup>2</sup>



# Better-Matched Vaccines are Required to Improve Protection Against Severe COVID-19

- XBB sublineages are dominant globally and antigenically distant from prior Omicron strains<sup>1,2</sup>
- Current bivalent vaccines maintain effectiveness<sup>3-11</sup> but show signs of waning, including against severe COVID-19<sup>3,9-11</sup>
- Immunity likely to be further reduced by the fall
- COVID-19 vaccines better matched to currently circulating sublineages could improve protection<sup>3</sup>

## Absolute vaccine effectiveness against hospitalization<sup>11</sup> Immunocompetent adults, VISION Network, Sep 2022 – Apr 2023, U.S. CDC

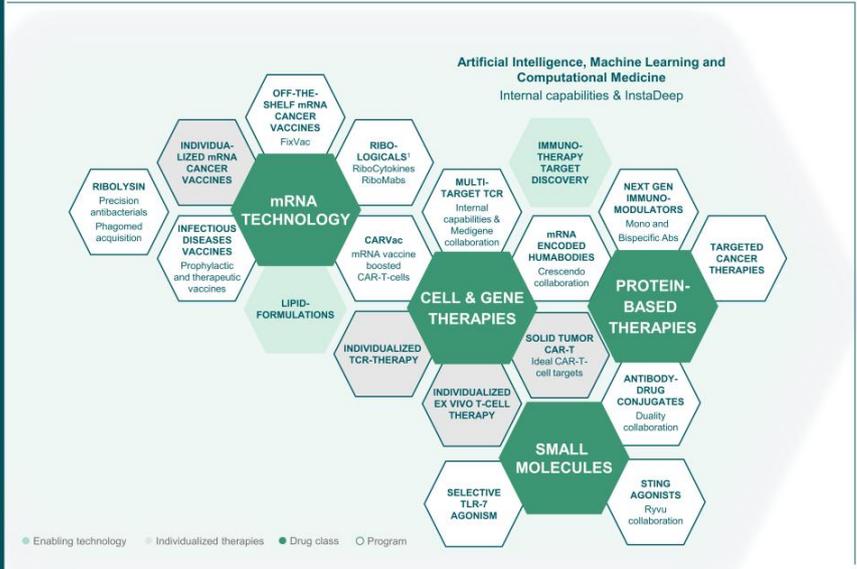


1. World Health Organization. Weekly epidemiological update on COVID-19 – April 2023. Available at: Weekly epidemiological update on COVID-19 – April 2023 (who.int)  
 2. covid19ECTRN dashboard. Available at: <https://www.eurosurveillance.org/en/diseases/19504>  
 3. Lin et al. N Engl J Med. 2023 Feb 23;368(8):764–766. DOI: 10.1056/NEJM2023022376477  
 4. Link-Gelles et al. MMWR Morb Mortal Wkly Rep. 2023;72(11):119–124. doi: 10.15585/mmwr.mm7201a1  
 5. Suris et al. MMWR Morb Mortal Wkly Rep. 2022;71:1625–1630. DOI: 10.15585/mmwr.mm71515a2  
 6. Tenforde et al. MMWR Morb Mortal Wkly Rep. 2023;71:1637–1646. DOI: 10.15585/mmwr.mm7153a1  
 7. Fabiani et al. Euro Surveill. 2023 Feb;28(2):2303105. doi: 10.2807/1565-7917.ES.2023.28.2.2303105  
 8. Tartof et al. Unpublished analysis, under review.  
 9. Pouskka et al. medRxiv. 2023. DOI:10.1101/2023.03.02.23280561  
 10. Link-Gelles R. CDC. Data presented at the ACIP meeting (April 19, 2023). Available at: ACIP meeting (CDC.gov)  
 11. Link-Gelles R. MMWR Morb Mortal Wkly Rep. 2023;72(7):6–68. DOI: <https://dx.doi.org/10.15585/mmwr.mm7207a3>.

# Multi-Technology Innovation Engine

## Core principles of our technology strategy

- Multi-technology-driven 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 and accelerate individualization of treatment
- Leverage AI-powered drug discovery, design and development



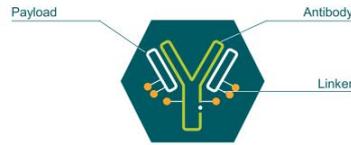
1 mRNA encoded cancer-targeting antibodies and cytokines.  
CAR = chimeric antigen receptor, TLR = Toll-like receptor, TCR = T-cell receptor, Abs = Antibodies, STING = stimulator of interferon genes.

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

## ADCs are composed of three key components

Jabbour E. et al. Nat Rev Clin Oncol. 2021

Each of these three components can vary between different ADCs, which may lead to contrasting pharmacological and clinical properties.



## Growing ADC Pipeline

BNT323/DB-1303 <sup>1</sup>	Phase 1/2 ongoing
BNT324/DB-1311 <sup>1</sup>	Phase 1/2 planned
DB-1305 <sup>1</sup>	Phase 1/2 ongoing

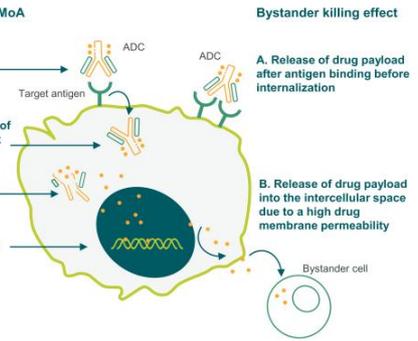
ADCs – A promising combination backbone to our pipeline

## Mode of Action

Coleman N. et al. npj Precis. Onc. 2023

### Classical ADC MoA

1. ADC binds to antigen
2. Internalization of the ADC complex by endocytosis
3. Payload released after linker cleavage
4. Cytotoxic effect by payload in the nucleus



<sup>1</sup> Partnered with DualityBio  
ADC = Antibody-drug conjugate; Ig = Immunoglobulin; MoA = Mode of Action.

# 2 COVID-19 Vaccine & Pipeline Update

Özlem Türeci, Chief Medical Officer

BIONTECH

# The Current COVID-19 Epidemiologic Landscape is Dominated by XBB Sublineages

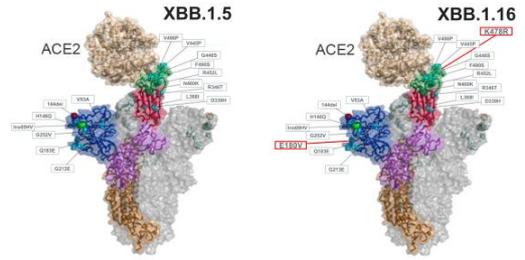
XBB sublineages remain dominant across all the territories<sup>1,2</sup>

Dominant XBB sublineages: XBB.1.5, XBB.1.9.2, XBB.1.16 and XBB.2.3

Global 28-day prevalence of variants of interest XBB.1.5 (A) and XBB.1.16 (B), between 12 June to 9 July 2023



Circulating XBB sublineages are antigenically similar and have greater immune escape than prior circulating lineages

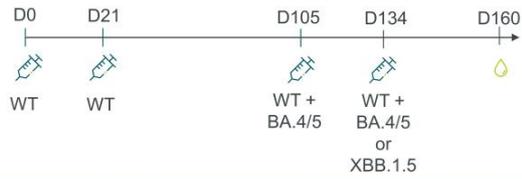


Variant-adapted vaccines should be designed to induce a cross-neutralizing immune response against other circulating variants to improve durability in an ever-shifting epidemiological landscape.

<sup>1</sup> World\_covid19\_SPECTRUM (covid-spectrum.org) <sup>2</sup> Weekly epidemiological update on COVID-19 - 6 July 2023 (who.int)

## Monovalent XBB.1.5 Booster Elicits Highest XBB Sublineage Neutralization Response in Mice

### Experimental Design



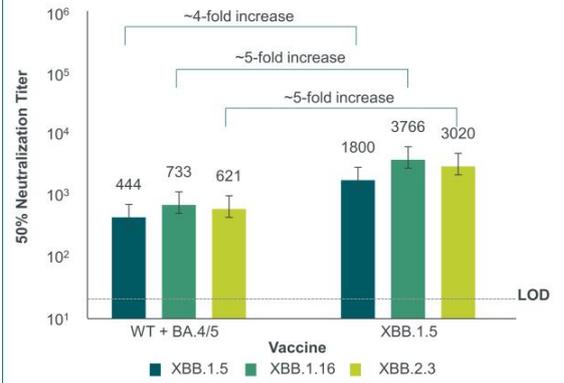
### Preclinical Results

#### XBB.1.5 vaccine



~ 4- to 5-fold increased neutralization when vaccinated with XBB.1.5-adapted monovalent vaccine compared to BA.4/5-adapted bivalent

XBB.1.5-adapted monovalent vaccine elicited **potent neutralization against all tested sublineages**



A Phase 2/3 trial is planned to investigate the safety, tolerability, and immunogenicity of the Omicron XBB.1.5-adapted monovalent COVID-19 vaccine. Safety and immunogenicity data expected by the end of this year.

Pseudovirus neutralization assay; Reference strain, Wuhan-HU-1.  
LOD = Limit of detection, the lowest serum dilution of 1:20. N = 10 mice per vaccine group.

## Oncology Pipeline: Achievements in Q2 2023

Drug Class	Phase 1	Phase 1/2	Phase 2	Phase 3
mRNA	BNT116 Metastatic NSCLC	BNT112 <sup>1</sup> Prostate cancer	BNT111 <sup>1</sup> aPD(L)1+R/R melanoma, + cemiplimab	Autogene cevumeran (BNT122) <sup>2</sup> 1L Adv. melanoma, + Pembrolizumab
	BNT122 (Autogene cevumeran) <sup>2</sup> Multiple solid tumors	BNT142 (CLDN6) Multiple solid tumors	BNT113 1L rec./met. HPV16+ PD-L1+ head and neck cancer, + Pembrolizumab	Autogene cevumeran (BNT122) <sup>2</sup> Adj. CRC
	BNT122 (Autogene cevumeran) <sup>1, 2</sup> Adj. PDAC	BNT151 (IL-2 variant) Multiple solid tumors	BNT116 <sup>3</sup> 1L NSCLC <b>NEW</b>	Autogene cevumeran (BNT122) <sup>2</sup> Adj. PDAC <b>PLANNED</b>
	BNT152 + BNT153 (IL-7, IL-2) Multiple solid tumors			
	BNT131 (SAR441000) <sup>7</sup> Solid tumors (IL-12sc, IL15-sushi, GM-CSF, IFN $\gamma$ )			
Cell therapy	BNT221 Refractory metastatic melanoma	BNT211 (CLDN6) Multiple solid tumors		
Protein-based therapeutics	BNT321 (sLea) Pancreatic cancer	BNT311/GEN1046 <sup>4</sup> (PD-L1x4-1BB) Multiple solid tumors	BNT311/GEN1046 <sup>4</sup> (PD-L1x4-1BB) aPD(L)1+R/R NSCLC, + Pembrolizumab	BNT316/ONC-392 (gotistobart) <sup>5</sup> (CTLA-4) Plat.-R ovarian cancer, + Pembrolizumab
	BNT322/GEN1056 <sup>4</sup> Multiple solid tumors	BNT312/GEN1042 <sup>4</sup> (CD40x4-1BB) Multiple solid tumors		BNT316/ONC-392 (gotistobart) <sup>5</sup> (CTLA-4) <b>NEW</b>
		BNT313/GEN1053 <sup>4</sup> (CD27) Multiple solid tumors		
		BNT316/ONC-392 (gotistobart) <sup>5</sup> (CTLA-4) Multiple solid tumors		
		BNT323/DB-1303 <sup>6</sup> (HER2) Multiple solid tumors		
		BNT324/DB-1311 <sup>6</sup> Advanced solid tumors <b>PLANNED</b>		
SMIM		DB-1305 <sup>6</sup> Multiple solid tumors <b>NEW</b>		
		BNT411 (TLR7) Multiple solid tumors		

Data announced in Q2

1. Investigator-initiated / investigator-initiated and sponsored trial; 2. Partnered with Genentech, member of Roche Group; 3. Partnered with Regeneron; 4. Partnered with Genmab; 5. Partnered with Oncoc4; 6. Partnered with DualyBio; 7. Partnered with Sanofi, study status active, recruitment stopped, program discontinued. 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-resistant; ADC = Antibody-drug conjugate; SMM = small molecule immunomodulator; \*2 Phase 1/2 clinical trials in patients with solid tumors are ongoing in combination with IC1 + chemotherapy



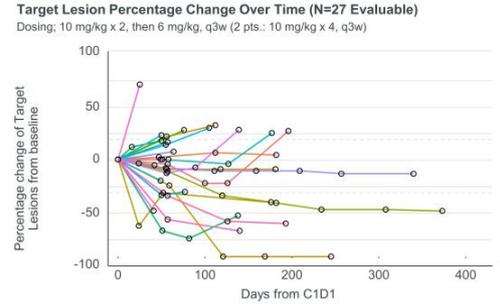
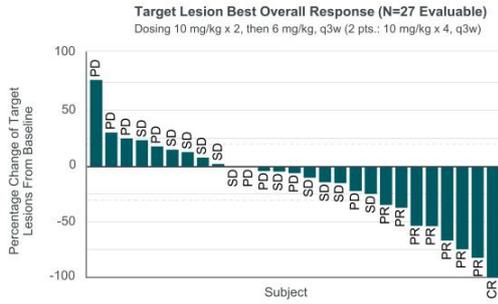
# ASCO 2023: Results Support Initiation of a Pivotal Phase 3 Study Evaluating BNT316/ONC-392 (gotistobart)<sup>1</sup> in ICI-resistant NSCLC

**PRESERVE-001: Phase 1/2a multicenter, non-randomized, open-label, multiple-dose, FIH study (NCT04140526)**  
 He K. et al. presented at ASCO 2023, Abstract #9024.

Anti-tumor activity observed in ICI-resistant NSCLC patients (n=27)

ORR: 29.6% (22.2% confirmed & 7.4% unconfirmed)  
 DCR: 70.4%

Manageable adverse events



**Initiated Phase 3 trial (PRESERVE-003) evaluating BNT316/ONC-392 (gotistobart) as monotherapy in patients with metastatic, ICI-resistant NSCLC**

<sup>1</sup> Partnered with OncoC4.  
 ICI = Immune checkpoint inhibitor, NSCLC = non-small cell lung cancer, FIH = first in human, ID = immunology, ORR = objective response rate, DCR = disease control rate, pts = patients, q3w = 3-week schedule, C1D1 = Cycle 1 Day 1.

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

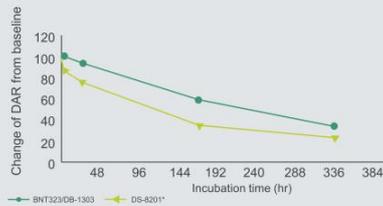


3rd generation ADCs

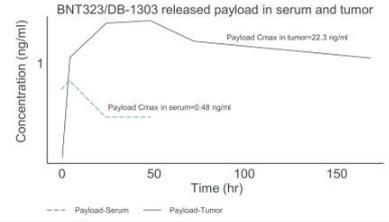
Lin S. et al. Abstract #252. Presented at EORTC-NCI-AACR in 2022.

<sup>1</sup> Formulated with DualyBio. ADC = Antibody drug conjugate; HER = human epidermal growth factor receptor; cmax = maximum concentration; DAR = Drug antibody ratio.

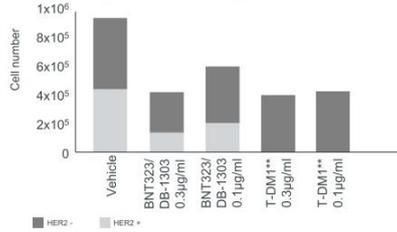
### Superior *in vitro* plasma stability in human plasma



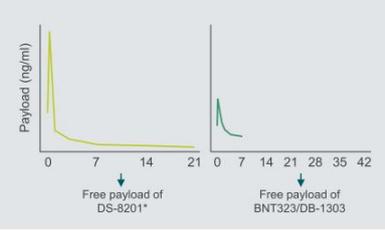
### Sustained tumor-selective drug release in tumor-bearing mice



### Efficient bystander killing in tumor cell lines



### Rapid systemic clearance in monkeys



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

# ASCO 2023: First Clinical Data for BNT323/DB-1303<sup>1</sup> Demonstrated Anti-Tumor Activity in Heavily Pretreated HER2-Expressing Patients

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

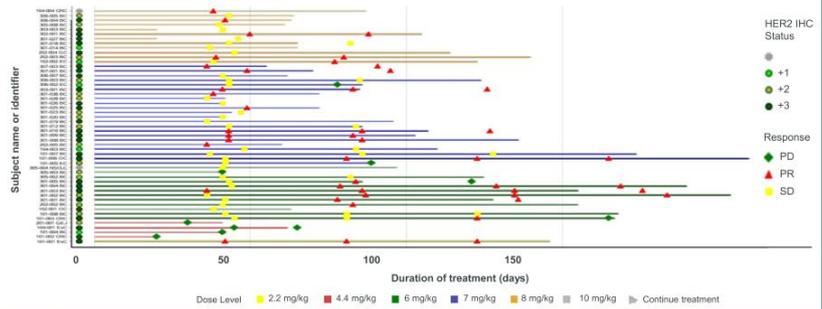
Moore K. et al. Presented at ASCO 2023. Abstract #3023.

### Anti-tumor activity in heavily pretreated HER2-expressing patients

	ORR, %	DCR, %
All patients (n=52)	44.2	88.5
HER2+ breast cancer (n=26)	50	96.2
HER2 low breast cancer (n=13)	38.5	84.6

**BNT323/DB-1303 was well-tolerated and all adverse events were manageable**

### Response over time in heavily pretreated HER-2 expressing patients treated with different dose levels and HER2 IHC status:



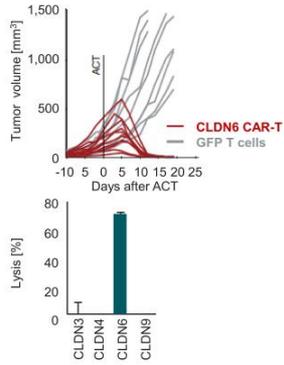
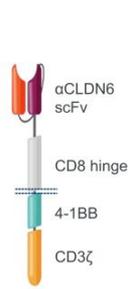
Expansion is ongoing in selected tumor patients treated at the RP2D

<sup>1</sup> Partnered with DualligBio.  
 HER2 = human epidermal growth factor receptor 2; ORR = objective response rate; DCR = disease control rate; FIH = first in human; ADC = antibody drug conjugate; IHC = immune histo chemistry test; PD = progressive disease; PR = partial response; SD = stable disease; DLT = dose limiting toxicities; RP2D = recommended phase 2 dose.

# BNT211: A CLDN6 CAR T-cell Therapy + CLDN6-Encoding CARVac That Enhances Expansion and Persistence of the Infused CAR T Cells

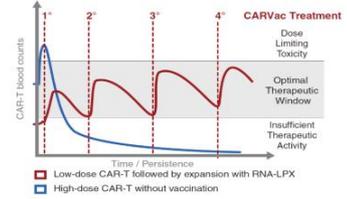
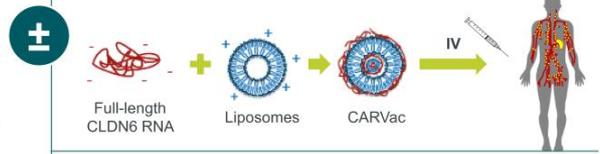
Potent 2<sup>nd</sup>-generation CAR T cells with high sensitivity and specificity

Reinhard K, et al. *Science* 2020; 367:446–453



Combined with CARVac (CAR-T cell amplifying RNA vaccine) to target APCs

Reinhard K, et al. *Science* 2020; 367:446–453  
Kranz LM, et al. *Nature* 2016; 534:396–401



ACT = adoptive cell transfer; APC = antigen-presenting cell; CAR = chimeric antigen receptor; CARVac = CAR T cell-amplifying RNA vaccine; CLDN6 = claudin 6.

# ASCO 2023: BNT211 – A Potential First-in-Class Approach for CLDN6+ Solid Tumors

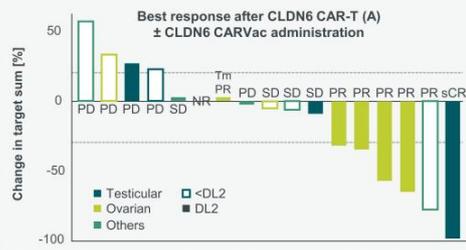
## BNT211 in multiple solid tumors

Mackensen A et al. presented at ASCO 2023. Abstract #2518.

### Aim of the current analysis:

Determine the safety and preliminary efficacy of the BNT211 product, manufactured using an **automated manufacturing process (A)**.

### Clinical activity (n=17)



ORR all pts:  
**41%**  
ORR DL2:  
**75%**

### Safety and efficacy:

CLDN6 CAR-T (A) cells ± CLDN6 CARVac has a moderate safety profile.

Encouraging signs of activity, with dose-dependent expansion of CAR-T cells translating into ORR of 41% with 7 responders in 17 evaluable patients

Follow-up on treated patients and further recruitment to DL2 and DL3 is ongoing and additional data readouts expected in 2H 2023. After determination of RP2D, a pivotal trial in germ cell tumors is planned to be initiated (PRIME designation) in 2024.

CLDN6 = Claudin 6, CAR = chimeric antigen receptor, scFv = single-chain variable fragment, CD = cluster of differentiation, ORR = objective response rate, pts = patients, DL = dose level, DLT = dose limiting toxicities, RP2D = recommended phase 2 dose, PRIME = Priority Medicines.



# 3 Financial Results

Jens Holstein, Chief Financial Officer

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— YTD 2023 Key Financial Figures<sup>1</sup>

<p>Total revenues<sup>2</sup></p> <p>— € <b>1.4</b> bn</p>	<p>Operating result</p> <p>€ <b>91</b> mn —</p>
<p>Diluted EPS</p> <p>— € <b>1.28</b></p>	<p>Total cash plus security investments<sup>3</sup></p> <p>€ <b>16.8</b> bn —</p>

<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 on Form 20-F for the year ended December 31, 2022 as well as the Quarterly Report as of and for the three and six months ended June 30, 2023, filed as an exhibit to BioNTech's Current Report on Form 6-K filed on August 7, 2023.

<sup>3</sup> Consists of cash and cash equivalents of €14,159.0 million and security investments of €2,687.0 million, as of June 30, 2023. Cash outflows and share considerations in connection with the acquisition of InstaDeep as of July 31, approximately €450 million are invested not including potential future milestones. The payment settling our gross profit share for the first quarter of 2023 (as defined by the contract) in the amount of €1,059 million was received from our collaboration partner subsequent to the end of the reporting period as of July 17, 2023. In addition, until early August 2023, €438 million were received in connection with the amended COVID-19 Vaccine Purchase Agreement with the European Commission.

## Q2 and YTD 2023 Financial Results: Profit or Loss

(in millions €, except per share data) <sup>1</sup>	Three months ended June 30,		Six months ended June 30,	
	2023	2022	2023	2022
Commercial revenues <sup>2</sup>	166.4	3,166.3	1,442.9	9,528.5
Research & development revenues	1.3	30.2	1.8	42.6
<b>Total revenues</b>	<b>167.7</b>	<b>3,196.5</b>	<b>1,444.7</b>	<b>9,571.1</b>
Cost of sales	(162.9)	(764.6)	(258.9)	(2,058.7)
Research and development expenses	(373.4)	(399.6)	(707.4)	(685.4)
Sales and marketing expenses	(18.1)	(17.8)	(30.3)	(32.1)
General and administrative expenses	(122.7)	(130.0)	(242.1)	(220.8)
Other operating income less expenses	(53.9)	325.1	(114.9)	388.2
<b>Operating income / (loss)</b>	<b>(563.3)</b>	<b>2,209.6</b>	<b>91.1</b>	<b>6,962.3</b>
Finance income less expenses	151.1	109.7	204.4	375.1
Income taxes	221.8	(647.3)	16.3	(1,966.6)
<b>Profit / (loss) for the period</b>	<b>(190.4)</b>	<b>1,672.0</b>	<b>311.8</b>	<b>5,370.8</b>
<b>Earnings per share</b>				
Basic profit / (loss) for the period per share	(0.79)	6.86	1.29	22.00
Diluted profit / (loss) for the period per share	(0.79)	6.45	1.28	20.69

<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 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 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 and nine months ended June 30, 2023, filed as an exhibit to BioNTech's Current Report on Form 8-K filed on August 7, 2023. Any changes in the estimated share of the collaboration partner's gross profit will be recognized prospectively.

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

			Updated Guidance
<b>COVID-19 vaccine revenues for FY 2023</b>	Estimated BioNTech COVID-19 vaccine revenues	~ €5 bn	<b>~ €5 bn</b>
<b>Planned FY 2023 expenses and capex</b>	R&D expenses <sup>2</sup>	€2,400 – 2,600 m	<b>€2,000 – 2,200 m</b>
	SG&A expenses	€650 – 750 m	<b>€600 – 700 m</b>
	Capital expenditure for operating activities <sup>3</sup>	€500 – 600 m	<b>€350 – 450 m</b>
<b>Estimated FY 2023 tax assumptions</b>	BioNTech Group estimated annual cash effective income tax rate <sup>4</sup>	~ 27%	<b>~ 21%</b>

<sup>1</sup> Numbers reflect current base case projections and are calculated based on constant currency rates.

<sup>2</sup> Numbers include effects identified from additional in-licensing arrangements, collaborations or potential MSA transactions to the extent disclosed and will be updated as needed.

<sup>3</sup> Numbers exclude potential effects caused by or driven from in-licensing arrangements, collaborations or MSA transactions.

<sup>4</sup> Numbers exclude potential effects caused by or driven from share-based payment settlements in the course of 2023.



# 4 Strategic Outlook

Ryan Richardson, Chief Strategy Officer

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## Readiness to Supply Omicron XBB.1.5-adapted Monovalent COVID-19 Vaccine Booster



### Completed key regulatory submissions

Submissions:  
USA, EU, Australia, Canada,  
Japan, New Zealand, South Korea,  
Switzerland  
Plan to launch in > 40 countries  
worldwide



### Vaccine distribution can begin immediately upon regulatory approval

Expected launch:  
September 2023



### Positioned to maintain leadership in major markets

Major contract serving the  
EU market  
Leveraging partner commercial  
launch experience in the U.S.

## — InstaDeep will Accelerate and Enhance BioNTech's AI Vision



### Immediate access to world-class AI technology

Broaden our access to world-class existing InstaDeep capabilities

### Fuel our AI research engine

Access to AI research talent already working for industry leaders such as Google and collaborating with multiple world-leading academic institutions

### Acquire and grow AI talent base

Acquisition adds >290 engineers and tech professionals  
Leverage InstaDeep's access to top AI / ML talent world-wide

### Supercharge BioNTech R&D capabilities

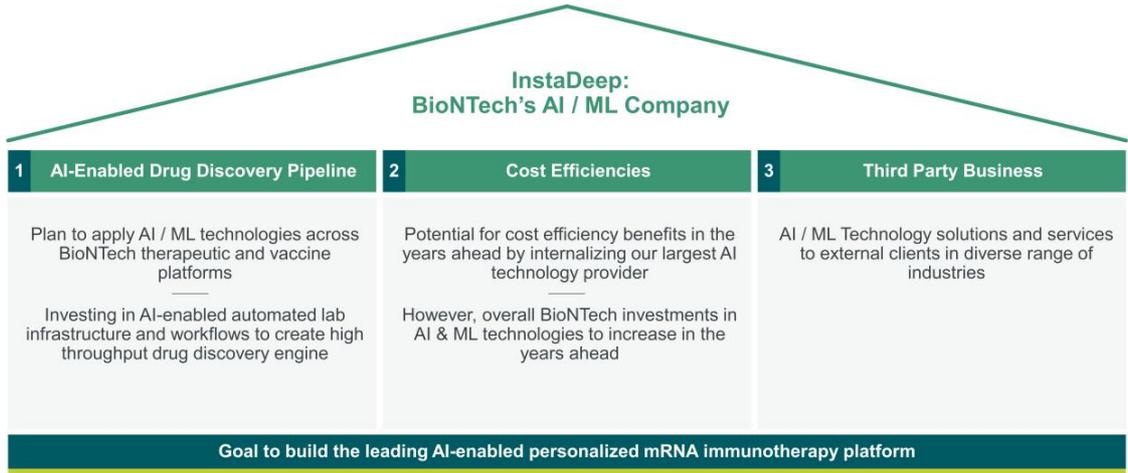
Combine InstaDeep's AI and BioNTech's research & development expertise to develop novel therapeutics & vaccine product candidates more quickly

### Quickly test AI expansion potential to other functions

Build on trusted relationship established with InstaDeep over the last 3 years and on their proven ability to learn quickly and efficiently to test their abilities in pilot projects across functions

AI = Artificial Intelligence; ML = Machine Learning; HEOR = Health Economics & Outcomes Research

— InstaDeep will Operate as an Independent Subsidiary of BioNTech



AI = Artificial Intelligence, ML = Machine Learning

## Selected Pipeline Milestones Expected in 2023 and Beyond

Modality	Indication	Program	Select Milestones	Anticipated Timing
mRNA vaccines for infectious disease	COVID-19 – influenza Combination <sup>1,2</sup>	BNT162b2 + BNT161	Trial update	2023
	Malaria	BNT165	Phase 1 data update	2H 2023
	HSV <sup>3</sup>	BNT163	Phase 1 data update	2H 2023
	Shingles <sup>1</sup>	BNT167	Trial update	2024
	Tuberculosis <sup>4</sup>	BNT164	Phase 1 FPD	2023 ✓
iNeST individualized mRNA vaccines	1L Melanoma	BNT122/Autogene Cevumeran	Phase 2 data update	2023
	Adjuvant CRC <sup>5</sup>	BNT122/Autogene Cevumeran	Phase 2 data update	-
	Adjuvant PDAC <sup>5</sup>	BNT122/Autogene Cevumeran	Phase 2 FPD	2H 2023
FixVac	1L NSCLC <sup>6</sup>	BNT116	Phase 2 FPD	2H 2023 ✓
Protein-based therapeutics	Multiple solid tumors <sup>7</sup>	BNT311/GEN-1046	Expansion cohort data update	2023
	Multiple solid tumors <sup>7</sup>	BNT312/GEN-1042	Expansion cohort data update	2023
	aPD(L)1-R/R NSCLC <sup>8</sup>	BNT316/ONC-392 (gotistobart)	Phase 3 FPD	2023 ✓
	Multiple solid tumors <sup>9</sup>	BNT323/DB-1311	Phase 1/2 data update	2H 2023
	Multiple solid tumors <sup>9</sup>	BNT324/DB-1303	Phase 1/2 FPD	2H 2023
Cell therapies	CLDN6+ solid tumors	BNT211	Phase 1 data update	2H 2023
	2L+ testicular cancer	BNT211	Phase 2 FPD	2024

<sup>1</sup> Partnered with Pfizer. <sup>2</sup> Collaboration with Pfizer and subject to reaching agreement with our partners. <sup>3</sup> Partnered with University of Pennsylvania. <sup>4</sup> Collaboration with Bill & Melinda Gates Foundation. <sup>5</sup> Partnered with Genentech, a member of Roche Group. <sup>6</sup> Partnered with Regeneron. <sup>7</sup> Collaboration with Genmab. <sup>8</sup> Collaboration with OncoC4. <sup>9</sup> Partnered with Duality Bio. 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.

## Second Half 2023 Strategic Outlook

- 1 Launch Omicron XBB.1.5-adapted monovalent COVID-19 vaccine globally
- 2 Initiate multiple potentially registrational oncology clinical trials
- 3 Expand our infectious disease pipeline with data updates expected this year
- 4 Scale up activity in highly strategic growth areas like AI / ML enabled drug discovery
- 5 Expand innovation ecosystem and in-license complimentary assets

AI = Artificial Intelligence, ML = Machine Learning

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SAVE THE DATE  
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Innovation Series Day  
**November 7, 2023**



Thank you

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