



BioNTech Announces Third Quarter 2023 Financial Results and Corporate Update

November 6, 2023

- Positive clinical data updates across multiple drug classes including antibody-drug conjugate (ADC) candidates BNT323/DB-1303, BNT325/DB-1305, CAR-T candidate BNT211, T cell therapy candidate BNT221 and mRNA cancer vaccine candidate BNT116
- Progress across the oncology pipeline with multiple late-stage trials initiated since third quarter start
- New and expanded strategic collaborations reflect BioNTech's commitment to delivering transformational therapies for oncology and infectious diseases
- Successful launches of Omicron XBB.1.5-adapted monovalent COVID-19 vaccine in markets worldwide
- Updated 2023 COVID-19 vaccine revenue guidance of around €4 billion
- Guidance reduction of planned 2023 R&D expenses to €1.8-2.0 billion and SG&A expenses to €600-650 million
- First nine months of 2023¹ revenues of €2.3 billion², net profit of €472 million and diluted earnings per share of €1.94 (\$2.11³)

Conference call and webcast scheduled for November 6, 2023, at 8:00 am ET (2:00 pm CET)

MAINZ, Germany, November 6, 2023 (GLOBE NEWSWIRE) -- [BioNTech SE](#) (Nasdaq: BNTX, "BioNTech" or "the Company") today reported financial results for the three and nine months ended September 30, 2023, and provided an update on its corporate progress.

"Over the last quarter, we complemented our investigational pipeline with ADC candidates, initiated later-stage clinical trials and presented significant data across modalities including cancer vaccines, cell therapies, ADCs and immune checkpoint modulators. Our strategy focuses on assembling a diverse toolbox of complementary technologies to deliver novel therapies, aiming to improve the standard-of-care for cancer patients," said **Prof. Ugur Sahin, M.D., CEO and Co-Founder of BioNTech**. "We combine our internal innovation engine with a high-performance partnership model to transform healthcare and improve patients' quality of life."

Financial Review for the Third Quarter and First Nine Months of 2023

in millions €, except per share data	Third Quarter 2023	Third Quarter 2022	Nine Months 2023	Nine Months 2022
Total Revenues ²	895.3	3,461.2	2,340.0	13,032.3
Net Profit	160.6	1,784.9	472.4	7,155.7
Diluted Earnings per Share	0.67	6.98	1.94	27.70

Total revenues reported were €895.3 million² for the three months ended September 30, 2023, compared to €3,461.2 million for the comparative prior year period. For the nine months ended September 30, 2023, total revenues were €2,340.0 million², compared to €13,032.3 million for the comparative prior year period. Inventory write-downs by BioNTech's collaboration partner Pfizer, Inc. ("Pfizer") reduced BioNTech's revenues by €507.9 million and €615.4 million for the three and nine months ended September 30, 2023, respectively.

Cost of sales were €161.8 million for the three months ended September 30, 2023, compared to €752.8 million for the comparative prior year period. For the nine months ended September 30, 2023, cost of sales were €420.7 million, compared to €2,811.5 million for the comparative prior year period. The change was in line with decreasing COVID-19 vaccine revenues.

Research and development (R&D) expenses were €497.9 million for the three months ended September 30, 2023, compared to €341.8 million for the comparative prior year period. For the nine months ended September 30, 2023, research and development expenses were €1,205.3 million, compared to €1,027.2 million for the comparative prior year period. Research and Development 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 (G&A) expenses were €144.5 million for the three months ended September 30, 2023, compared to €141.0 million for the comparative prior year period. For the nine months ended September 30, 2023, G&A expenses were €386.6 million, compared to €361.8 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 accrued in an amount of €66.8 million for the three months ended September 30, 2023, compared to €659.2 million accrued for the comparative prior year period. For the nine months ended September 30, 2023, income taxes were accrued with an amount of €50.5 million, compared to €2,625.8 million accrued for the comparative prior year period. The derived annual effective income tax rate for the nine months ended September 30, 2023, was 9.7% 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 profit was €160.6 million for the three months ended September 30, 2023, compared to €1,784.9 million for the comparative prior year period. For the nine months ended September 30, 2023, net profit was €472.4 million, compared to €7,155.7 million net profit for the comparative prior year period.

Cash and cash equivalents as well as security investments were €16,967.6 million, comprising €13,495.8 million cash and cash equivalents and €3,471.8 million security investments, respectively, as of September 30, 2023. Subsequent to the end of the reporting period, as of October 16, 2023,

a payment of €565.0 million was received from BioNTech's collaboration partner, settling BioNTech's gross profit share for the second quarter of 2023 (as defined by the contract with Pfizer).

Diluted earnings per share was €0.67 for the three months ended September 30, 2023, compared to a diluted earnings per share €6.98 for the comparative prior year period. For the nine months ended September 30, 2023, diluted earnings per share was €1.94, compared to €27.70 diluted earnings per share for the comparative prior year period.

Shares outstanding as of September 30, 2023, were 237,715,500, excluding 10,836,700 shares in treasury.

In March 2023, BioNTech initiated a new share repurchase program pursuant to which the Company was able to 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 September 30, 2023, 3,114,280 ADSs were repurchased under the share repurchase program at an average price of €97.15 (\$106.92³), for total consideration of €302.5 million (\$333.1 million³). The trading plan for BioNTech's 2023 program concluded on September 18, 2023.

"In the third quarter, we continued to invest in our capabilities and our portfolio of innovative product candidates while strengthening the financial position of BioNTech. About €17 billion in cash and security investments provide strategic flexibility and is a major strength, especially in these days, where financial stability is key," said **Jens Holstein, CFO of BioNTech**. "We updated our financial guidance for the full year 2023. In line with anticipated revenues of around €4 billion, we reduced relevant cost drivers for 2023 as we effectively manage our expenditures."

Outlook updated for the 2023 Financial Year

The Company updated 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:

	Initial Guidance Mar 2023	Updated Guidance Nov 2023
Estimated BioNTech COVID-19 vaccine revenues for the full 2023 financial year	~ €5 billion	~ €4 billion

The revenues 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.

Revenue guidance is based on various assumptions. These include, but are not limited to, expectations regarding: transitions in the purchasing environment; the timing and receipt of regulatory approvals and recommendations; the progress of vaccination campaigns; and seasonal variations in SARS-CoV-2 circulation and vaccination uptake.

Several factors drive the Company's adjusted revenue guidance. Such factors include BioNTech's and Pfizer's lower than previously forecast revenue expectations for the full 2023 financial year, which take into account delays in the expected timing of regulatory approvals, as well as the effects of Pfizer's recently-announced write-downs and other charges.

While fewer primary vaccinations and lower population-wide levels of boosting are anticipated overall compared to the same period in prior years, vaccine adaptation and seasonal trends are expected to lead to demand peaks in the autumn and winter compared to other seasons. As a result of later-than-anticipated regulatory approvals and their effect on national vaccination campaign timelines, expected sales have shifted to future periods. In general, the Company continues to remain largely dependent on revenues generated in its collaboration partner's territories.

In addition, BioNTech's revenues have been affected by the inventory write-downs and other charges related to COMIRNATY that were previously announced by the Company's collaboration partner Pfizer. As a result of the Company's continued assessment of these write-downs and other charges, the Company has determined that the charges originating on BioNTech's end had largely already been reflected in the Company's financial results for the 2022 financial year, and to a smaller extent, continued to be reflected during 2023. Ultimately, the initial estimate of "up to €0.9 billion" impact has been refined by the Company. The impact from the collaboration partner's charges onto the Company's revenues has been identified to be €0.6 billion for the nine months ended September 30, 2023 and €0.5 billion for the three months ended September 30, 2023, which is reflected in the revised revenues guidance.

Planned 2023 Financial Year Expenses and Capex⁴:

	Initial Guidance Mar 2023	Updated Guidance Nov 2023
R&D expenses ⁵	€2,400m - €2,600m	€1,800m - €2,000m
SG&A expenses	€650m - €750m	€600m - €650m
Capital expenditures for operating activities ⁶	€500m - €600m	€200m - €300m

Estimated 2023 Financial Year Tax Assumptions:

	Initial Guidance Mar 2023	Updated Guidance Nov 2023
BioNTech Group estimated annual cash effective income tax rate ⁷	~ 27%	~ 21%

The full interim unaudited condensed consolidated financial statements can be found in BioNTech's Report on Form 6-K for the period ended September 30, 2023, filed today with the United States Securities and Exchange Commission ("SEC") and available at <https://www.sec.gov/>.

Endnotes

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

²BioNTech'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.

³Calculated applying the average foreign exchange rate for the nine months ended September 30, 2023, as published by the German Central Bank (Deutsche Bundesbank).

⁴Numbers reflect current base case projections and are calculated based on constant currency rates. Excluding external risks that are not yet known and/or quantifiable, including, but not limited to, the effects of ongoing and/or future legal disputes or related activity.

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

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

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

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

COVID-19 Vaccine Marketed Products

- In August, BioNTech and Pfizer received a positive opinion from the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) recommending marketing authorization for the companies' Omicron XBB.1.5-adapted monovalent COVID-19 vaccine for individuals 6 months of age and older.
- In September, BioNTech and Pfizer received approval of their supplemental Biologics License Application by the U.S. Food and Drug Administration (FDA) for their Omicron XBB.1.5-adapted monovalent COVID-19 vaccine for individuals 12 years and older, and emergency use authorization for individuals 6 months through 11 years of age.
- Several other national healthcare regulatory bodies, including in the United Kingdom (UK), Japan, Canada and South Korea, have approved BioNTech and Pfizer's monovalent XBB.1.5-adapted vaccine.
- In October, BioNTech and Pfizer announced an agreement between the Japanese government and Pfizer Japan Co., Ltd. to supply an additional 9 million doses of the Omicron XBB.1.5-adapted COVID-19 vaccine for the special vaccination program in Japan which started this autumn. This follows an agreement between the Japanese government and Pfizer Inc. in July to supply 20 million doses and additional supplies as needed, and an agreement announced in September to provide additional 10 million doses of the companies' Omicron XBB.1.5-adapted COVID-19 vaccine for the special vaccination program in Japan.

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

Antibody-Drug Conjugate (ADC) Pipeline

BioNTech's pipeline comprises several ADCs that are based on a topoisomerase I inhibitor as payload.

BNT323/DB-1303 is an HER2-targeted ADC candidate being developed in collaboration with Duality Biologics (Suzhou) Co. Ltd. ("DualityBio").

- An open-label, multi-center, randomized Phase 3 clinical trial ([NCT06018337](#)) is planned to evaluate BNT323/DB-1303 versus investigator's choice of chemotherapy in advanced or metastatic Hormone Receptor (HR)+, HER2-low breast cancer subjects whose disease has progressed on at least two lines of prior endocrine therapy (ET) or within six months of first line ET plus CDK4/6 inhibitor in the metastatic setting, and no prior chemotherapy. The study aims to enroll approximately 532 patients.
- In September, clinical data from the ongoing Phase 1/2 clinical trial ([NCT05150691](#)) evaluating BNT323/DB-1303 in patients with advanced/unresectable, recurrent, or metastatic HER2-expressing solid tumors were presented at the 2023 European Congress on Gynaecological Oncology Annual Meeting. BNT323/DB-1303 showed a manageable safety profile and no new safety signals were observed. BNT323/DB-1303 demonstrated encouraging antitumor activity in patients (n=17) with advanced, recurrent or metastatic HER2-expressing endometrial cancer with an objective response rate ("ORR"; confirmed and unconfirmed) of 58.8% and disease control rate ("DCR") of 94.1%.

BNT324/DB-1311 is an ADC candidate being developed in collaboration with DualityBio.

- In September, the first patient was dosed in a first-in-human, open-label Phase 1/2 clinical trial ([NCT05914116](#)) evaluating BNT324/DB-1311 in multiple advanced solid tumors.

BNT325/DB-1305 is a TROP-2-targeted ADC candidate being developed in collaboration with DualityBio.

- In October, clinical data from the ongoing Phase 1/2 clinical trial ([NCT05438329](#)) in patients with advanced solid tumors were presented at the 2023 European Society of Medical Oncology (ESMO) Annual Meeting suggesting a manageable safety profile at lower dose levels. Encouraging preliminary activity of BNT325/DB-1305 was observed with an ORR of 30.4% (7/23), and DCR of 87.0% (20/23) (both unconfirmed) across overall study population. Encouraging efficacy signals

were observed in non-small cell lung cancer (NSCLC) patients with an ORR of 46.2% (6/13) and an DCR of 92.3% (12/13) (both unconfirmed).

BNT326/YL202 is a HER3-targeted ADC candidate being developed in collaboration with MediLink Therapeutics (Suzhou) Co., Ltd. ("MediLink").

- A multicenter, open-label, first-in-human Phase 1 clinical trial ([NCT05653752](#)) evaluating YL202 as a later-line treatment in patients with locally advanced or metastatic epidermal growth factor receptor (EGFR)-mutated NSCLC or HR-positive and HER2-negative breast cancer is ongoing.

Next-Generation Immune Checkpoint Immunomodulator Pipeline

BNT316/ONC-392 (gotistobart) is an anti-CTLA-4 monoclonal antibody candidate being developed in collaboration with OncoC4, Inc. ("OncoC4"). BNT316/ONC-392 (gotistobart) is designed to offer a differentiated safety profile that may allow for higher dosing and longer duration of treatment both as monotherapy and in combination with other therapies.

- In November, clinical data were presented at the 2023 Society for Immunotherapy of Cancer (SITC) Annual Meeting from the ongoing Phase 1/2 trial ([NCT04140526](#)) showing that BNT316/ONC-392 (gotistobart) monotherapy has a manageable safety profile. Early readout of the expansion cohort showed encouraging clinical activity in patients with immunotherapy-resistant NSCLC. A Phase 3 trial evaluating BNT316/ONC-392 (gotistobart) monotherapy in this patient population is ongoing.
- A Phase 2 clinical trial ([NCT05682443](#)) is planned to evaluate the safety and efficacy of BNT316/ONC-392 in combination with lutetium Lu-177 vipivotide tetraxetan in metastatic castration resistant prostate cancer patients who have disease progressed on androgen receptor pathway inhibition.

BNT312/GEN1042 is a bispecific antibody candidate based on Genmab A/S ("Genmab")'s DuoBody technology and designed to induce conditional immune activation by crosslinking CD40 and 4-1BB positive cells.

- In November, preclinical data demonstrating *in vivo* antitumor activity and peripheral immune modulation of a chimeric variant of BNT312/GEN1042 were presented at the 2023 SITC Annual Meeting. These data support ongoing Phase 1/2 clinical studies evaluating the combination of BNT312/GEN1042 with pembrolizumab and chemotherapy in patients with advanced solid tumors ([NCT04083599](#), [NCT05491317](#)).

BNT314/GEN1059 is a bispecific antibody candidate designed to boost antitumor immune responses through EpCAM-dependent 4-1BB agonistic activity. This is the fifth drug candidate under BioNTech's collaboration with Genmab where the development costs and potential future profits will be shared equally.

- In October, preclinical data characterizing the mechanism of action of BNT314/GEN1059 were presented at the 2023 ESMO Annual Meeting.
- A first-in-human trial sponsored by BioNTech is planned to investigate the clinical safety and preliminary antitumor activity of BNT314/GEN1059 in patients with solid tumors.

Cancer Vaccines Pipeline

BNT116 is based on BioNTech's FixVac platform, and is 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, 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 in patients with advanced NSCLC whose tumors express PD-L1 in $\geq 50\%$ of tumor cells.
- In November, clinical data from the ongoing Phase 1 clinical trial ([NCT05142189](#)) evaluating the safety, tolerability and preliminary efficacy of BNT116 alone and in combination with cemiplimab (Regeneron's Libtayo) or chemotherapy across various cohorts of patients were presented at the 2023 SITC Annual Meeting. BNT116 was generally well tolerated with an expected safety profile as monotherapy and in combination with cemiplimab. In heavily pretreated NSCLC patients, treatment with BNT116 with cemiplimab from cycle 3 onwards showed early clinical activity.

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

- In October, the first patient was dosed in a randomized Phase 2 clinical trial ([NCT05968326](#)) evaluating the safety and efficacy of BNT122 in combination with atezolizumab (Roche's Tecentriq) followed by adjuvant standard-of-care chemotherapy (mFOLFIRINOX) in patients with resected pancreatic ductal adenocarcinoma (PDAC) compared to chemotherapy alone. The Phase 2 study is expected to enroll 260 patients with resected PDAC, who have not received prior systemic anti-cancer treatment and showed no evidence of disease after surgery.

Cell Therapy Pipeline

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 a CAR-T cell Amplifying RNA Vaccine (“CARVac”), encoding CLDN6.

- In October, clinical data from the ongoing Phase 1/2 clinical trial ([NCT04503278](#)) were presented at the 2023 ESMO 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 ± CLDN6 CARVac demonstrated encouraging signs of clinical activity. In several patients treated with CARVac, an increased persistence of cancer-specific CAR-T cells was observed. The rate of treatment-dependent adverse events was dose-dependent. After determination of the recommended Phase 2 dose, BioNTech plans to initiate a pivotal trial in germ cell tumors.

BNT221 is an autologous, fully personalized, polyspecific T-cell therapy candidate directed against selected sets of individual neoantigens. BNT221 is based on expanded neoantigen-specific memory T cells and induced naive T cells.

- In October and November, first monotherapy clinical data from the ongoing first-in-human Phase 1 dose escalation clinical trial ([NCT04625205](#)) in patients with checkpoint inhibitor unresponsive or refractory metastatic melanoma were presented at the 2023 ESMO and SITC Annual Meetings. These initial results showed a manageable safety profile and encouraging activity signs of tumor regression in several patients with anti-PD-1/anti-CTLA-4 pretreated advanced or metastatic melanoma.

Select Infectious Pipeline Highlights - Recent trial starts and data readouts

COVID-19-Influenza Combination mRNA Vaccine Program – BNT162b2 + BNT161

- In October, BioNTech and Pfizer announced top-line results from a Phase 1/2 clinical trial ([NCT05596734](#)) evaluating the safety, tolerability and immunogenicity of mRNA-based combination vaccine candidates for influenza and COVID-19 in healthy adults 18 to 64 years of age. In the clinical trial, the vaccine candidates were compared to licensed influenza vaccines and the Pfizer-BioNTech COVID-19 Omicron BA.4/BA.5 adapted bivalent vaccine given separately at the same visit. The data from the trial demonstrated robust immune responses to influenza A, influenza B, and SARS-CoV-2 strains, as well as a safety profile consistent with the safety profile of the companies’ COVID-19 vaccine. A pivotal Phase 3 trial is expected to be initiated in the coming months.

Mpox Program - BNT166

The BNT166 vaccine candidates encode surface antigens that are expressed in the two infectious forms of the mpox virus (MPXV) with the aim to efficiently fight virus replication and infectivity. In partnership with the Coalition for Epidemic Preparedness Innovations (CEPI), BNT166 is part of BioNTech’s infectious disease vaccine programs aiming to help provide equitable access to effective and well-tolerated vaccines for high medical need indications.

- In October, the first patient was dosed in a Phase 1/2 clinical trial ([NCT05988203](#)) evaluating the safety, tolerability, reactogenicity and immunogenicity of two mRNA-based multivalent vaccine candidates against mpox. The trial aims to enroll 96 healthy participants with and without prior history of known or suspected smallpox vaccination.

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

- In July, BioNTech successfully completed its previously announced acquisition of InstaDeep Ltd. (“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 existing bioinformatics and data science workforce, including teams in AI, machine learning, bioengineering, data science, and software development.
- In September, BioNTech and CEPI announced a strategic partnership to advance mRNA-based vaccine candidates with the development of BNT166 for the prevention of mpox, an infectious disease that can lead to severe, life-threatening complications. The strategic partnership aims to contribute to CEPI’s 100 Days Mission, a goal to accelerate development of well-tolerated and effective vaccines against a potential future pandemic virus so that a vaccine can be ready for regulatory authorization and manufacturing at scale within 100 days of recognition of a pandemic pathogen. This mission is spearheaded by CEPI and embraced by the G7, G20, and industry leaders. The partnership between BioNTech and CEPI could help accelerate responses to future outbreaks caused by viruses of the Orthopoxvirus viral family. CEPI will provide funding of up to \$90 million to support the development of mRNA-based vaccine candidates.
- Post period-end, in October, BioNTech and MediLink entered into a strategic research collaboration and worldwide license agreement to develop a next-generation ADC candidate against Human Epidermal Growth Factor Receptor 3 (HER3). Under the terms of the agreement, MediLink will grant BioNTech exclusive global rights, excluding Mainland China, Hong Kong Special Administrative Region, and Macau Special Administrative Region, for the development, manufacturing, and commercialization of one of MediLink’s ADC assets. In exchange, BioNTech will provide MediLink with an upfront payment totaling of \$70 million and additional development, regulatory and commercial milestone payments potentially totaling over \$1 billion. The completion of the agreement is subject to customary closing conditions.

- Also, post period-end in November, BioNTech and Biotheus Inc. (“Biotheus”), announced an exclusive license and collaboration agreement under which BioNTech will have the rights to develop, manufacture and commercialize PM8002, a bispecific antibody candidate targeting PD-L1 and VEGF, globally except in Greater China, where Biotheus retains the rights to PM8002. PM8002 is currently being tested in a Phase 2/3 study in China to evaluate the efficacy and safety of the candidate as a monotherapy or in combination with chemotherapy in patients with NSCLC.

Upcoming Investor and Analyst Events

- BioNTech’s Innovation Series Day will take place tomorrow, Tuesday, November 7, 2023, from 9.00 a.m. ET (3.00 p.m. CET) in Boston, USA. The event will provide an update on BioNTech’s clinical progress across its pipeline and provide a deep dive into scientific and technological innovations from its research engine. The slide presentation and audio of the webcast will be available via this [link](#).
- BioNTech’s fourth quarter and full year 2023 financial results and corporate update are scheduled for Wednesday, March 20, 2024.

Conference Call and Webcast Information

BioNTech invites investors and the general public to join a conference call and webcast with investment analysts today, November 6, 2023, at 8.00 a.m. ET (2.00 p.m. CET) to report its financial results and provide a corporate update for the third 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 (CAR) T cells, several protein-based therapeutics, including bispecific immune checkpoint modulators, targeted cancer antibodies and antibody-drug conjugate (ADC) therapeutics, as well as 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 Duality Biologics, Fosun Pharma, Genentech, a member of the Roche Group, Genevant, Genmab, OncoC4, Regeneron, Sanofi and Pfizer.

For more information, please visit 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 the Company’s collaboration and licensing agreements; 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 September 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 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 September 30,		Nine months ended September 30,	
	2023 <i>(unaudited)</i>	2022 <i>(unaudited)</i>	2023 <i>(unaudited)</i>	2022 <i>(unaudited)</i>
<i>(in millions €, except per share data)</i>				
Revenues				
Commercial revenues	893.7	3,394.8	2,336.6	12,923.3
Research & development revenues	1.6	66.4	3.4	109.0
Total revenues	895.3	3,461.2	2,340.0	13,032.3
Cost of sales	(161.8)	(752.8)	(420.7)	(2,811.5)
Research and development expenses	(497.9)	(341.8)	(1,205.3)	(1,027.2)
Sales and marketing expenses	(14.4)	(12.8)	(44.7)	(44.9)
General and administrative expenses	(144.5)	(141.0)	(386.6)	(361.8)
Other operating expenses	(31.4)	(285.1)	(223.7)	(594.6)
Other operating income	27.8	459.8	105.2	1,157.5
Operating income	73.1	2,387.5	164.2	9,349.8
Finance income	156.3	60.9	363.2	448.5
Finance expenses	(2.0)	(4.3)	(4.5)	(16.8)
Profit before tax	227.4	2,444.1	522.9	9,781.5
Income taxes	(66.8)	(659.2)	(50.5)	(2,625.8)
Profit for the period	160.6	1,784.9	472.4	7,155.7
Earnings per share				
Basic earnings for the period per share	0.67	7.43	1.96	29.47
Diluted earnings for the period per share	0.67	6.98	1.94	27.70

Interim Consolidated Statements of Financial Position

	September 30, 2023 <i>(unaudited)</i>	December 31, 2022
<i>(in millions €)</i>		
Assets		
Non-current assets		
Intangible assets	665.5	158.5
Goodwill	365.6	61.2

Property, plant and equipment	728.9	609.2
Right-of-use assets	197.0	211.9
Other financial assets	1,292.7	80.2
Other non-financial assets	0.3	6.5
Deferred tax assets	208.1	229.6
Total non-current assets	3,458.1	1,357.1
Current assets		
Inventories	415.7	439.6
Trade and other receivables	2,002.0	7,145.6
Contract assets	6.8	—
Other financial assets	2,253.3	189.4
Other non-financial assets	286.2	271.9
Income tax assets	289.3	0.4
Cash and cash equivalents	13,495.8	13,875.1
Total current assets	18,749.1	21,922.0
Total assets	22,207.2	23,279.1
Equity and liabilities		
Equity		
Share capital	248.6	248.6
Capital reserve	1,228.4	1,828.2
Treasury shares	(10.8)	(5.3)
Retained earnings	19,305.4	18,833.0
Other reserves	(904.8)	(848.9)
Total equity	19,866.8	20,055.6
Non-current liabilities		
Lease liabilities, loans and borrowings	161.9	176.2
Other financial liabilities	38.5	6.1
Income tax liabilities	—	10.4
Provisions	8.6	8.6
Contract liabilities	268.0	48.4
Other non-financial liabilities	13.1	17.0
Deferred tax liabilities	43.1	6.2
Total non-current liabilities	533.2	272.9
Current liabilities		
Lease liabilities, loans and borrowings	40.0	36.0
Trade payables and other payables	222.7	204.1
Other financial liabilities	321.6	785.1
Refund liabilities	—	24.4
Income tax liabilities	545.2	595.9
Provisions	318.0	367.2
Contract liabilities	167.1	77.1
Other non-financial liabilities	192.6	860.8
Total current liabilities	1,807.2	2,950.6
Total liabilities	2,340.4	3,223.5
Total equity and liabilities	22,207.2	23,279.1

Interim Consolidated Statements of Cash Flows

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2023	2022	2023	2022
(in millions €)	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Operating activities				
Profit for the period	160.6	1,784.9	472.4	7,155.7
Income taxes	66.8	659.2	50.5	2,625.8
Profit before tax	227.4	2,444.1	522.9	9,781.5
Adjustments to reconcile profit before tax to net cash flows:				

Depreciation and amortization of property, plant, equipment, intangible assets and right-of-use assets	41.3	33.5	104.6	94.3
Share-based payment expenses	15.5	61.4	37.2	86.4
Net foreign exchange differences	(20.4)	116.2	(364.3)	(222.3)
Loss on disposal of property, plant and equipment	3.3	0.2	3.6	0.4
Finance income excluding foreign exchange differences	(148.5)	(7.7)	(357.4)	(226.5)
Finance expense excluding foreign exchange differences	2.0	4.3	4.5	16.8
Movements in government grants	—	—	(3.0)	—
Unrealized net (gain) / loss on derivative instruments at fair value through profit or loss	(3.5)	(2.3)	84.7	82.3
Working capital adjustments:				
Decrease in trade and other receivables, contract assets and other assets	631.2	2,245.4	6,648.6	5,016.7
Decrease in inventories	33.2	72.9	23.9	207.7
(Decrease) / increase in trade payables, other financial liabilities, other liabilities, contract liabilities, refund liabilities and provisions	(25.0)	565.9	(293.9)	760.3
Interest received	70.3	4.3	166.4	6.5
Interest paid	(1.2)	(4.3)	(3.7)	(16.5)
Income tax paid	(10.2)	(753.3)	(1,292.4)	(2,834.7)
Share-based payments	(4.2)	(1.7)	(761.2)	(4.7)
Net cash flows from operating activities	811.2	4,778.9	4,520.5	12,748.2
Investing activities				
Purchase of property, plant and equipment	(53.2)	(77.9)	(165.6)	(192.6)
Proceeds from sale of property, plant and equipment	(0.8)	0.4	(0.8)	0.4
Purchase of intangible assets and right-of-use assets	(97.2)	(4.7)	(348.9)	(26.2)
Acquisition of subsidiaries and businesses, net of cash acquired	(336.9)	—	(336.9)	—
Investment in other financial assets	(744.1)	(1.1)	(3,407.2)	(31.1)
Proceeds from maturity of other financial assets	—	—	—	375.2
Net cash flows from / (used in) investing activities	(1,232.2)	(83.3)	(4,259.4)	125.7
Financing activities				
Proceeds from issuance of share capital and treasury shares, net of costs	—	—	—	110.5
Proceeds from loans and borrowings	0.1	0.4	0.1	0.6
Repayment of loans and borrowings	(0.1)	—	(0.1)	(18.8)
Payments related to lease liabilities	(9.3)	(10.0)	(28.0)	(31.9)
Share repurchase program	(301.7)	(643.8)	(737.7)	(930.7)
Dividends	—	—	—	(484.3)
Net cash flows used in financing activities	(311.0)	(653.4)	(765.7)	(1,354.6)
Net increase / (decrease) in cash and cash equivalents	(732.0)	4,042.2	(504.6)	11,519.3
Change in cash and cash equivalents resulting from exchange rate differences and other valuation effects	61.2	46.7	125.3	211.7
Cash and cash equivalents at the beginning of the period	14,166.6	9,334.8	13,875.1	1,692.7
Cash and cash equivalents as of September 30	13,495.8	13,423.7	13,495.8	13,423.7