UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

PLAINTIFF, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. BIONTECH SE, UGUR SAHIN, and JENS HOLSTEIN, Defendants.	Case No. CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS DEMAND FOR JURY TRIAL

Plaintiff, individually and on behalf of all others similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's complaint against Defendants, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through

Plaintiff's attorneys, which included, among other things, a review of the

Defendants' public documents, conference calls and announcements made by Defendants, United States ("U.S.") Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding BioNTech SE ("BioNTech" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial, additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons and entities other than Defendants that purchased or otherwise acquired BioNTech securities between March 30, 2022 and October 13, 2023, both dates inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

2. BioNTech is a biotechnology company that develops and commercializes immunotherapies for cancer and other infectious diseases. The Company has developed and continues to develop, among other products and product candidates, Comirnaty, a COVID-19 vaccine, in collaboration with Pfizer Inc. ("Pfizer"). As part of BioNTech's collaboration agreement with Pfizer, the two

companies share gross profits from COVID-19 vaccine sales in their respective territories. In addition, Pfizer's inventory write-offs for COVID-19 products reduce BioNTech's gross profit share, thereby reducing BioNTech's vaccine revenues.

3. During the Class Period, as the number of COVID-19 cases began to decline, one variant of the virus, namely, the Omicron XBB.1.5 subvariant, increasingly began to account for the majority of reported cases. Despite not yet having a version of Comirnaty approved by the U.S. Food and Drug Administration ("FDA") to treat this subvariant, BioNTech represented to the market and investors during the Class Period that Comirnaty remained relevant and in-demand.

4. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company's business, operations, and prospects. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) BioNTech overstated demand for Comirnaty and/or its commercial prospects; (ii) the Company and/or Pfizer had accumulated excess inventory of raw materials for Comirnaty, as well as COVID-19 vaccine doses adapted to other, non-XBB.1.5 variants that were produced at risk; (iii) accordingly, BioNTech was at an increased risk of recording significant inventory write-offs and other charges related to Comirnaty; and (iv) as a result, Defendants' public statements were materially false and/or misleading at all relevant times.

5. On August 8, 2022, during pre-market hours, BioNTech issued a press release announcing the Company's second quarter 2022 financial results, including,

inter alia, earnings-per-share ("EPS") under generally accepted accounting principles ("GAAP") of €6.45, missing consensus estimates by €0.63, and revenue of €3.2 billion, missing consensus estimates by €910 million, and representing a 39.7% year-over-year ("Y/Y") decrease. The Company attributed the result, in part, to the "dynamic" development of the pandemic, which "caus[ed] a re-phasing of orders and . . . le[d] to fluctuations in quarterly revenues." According to BioNTech, "[t]his revenue fluctuation caused by the re-phasing of orders is expected to remain over the rest of the financial year with an uptake in demand in key markets in the fourth quarter of 2022 related to the Omicron-adapted bivalent vaccine, subject to regulatory approval."

6. On this news, BioNTech's American Depositary Share ("ADS") price fell $13.81 per ADS, or 7.54%, to close at $169.30 per ADS on August 8, 2022.

7. On March 27, 2023, during pre-market hours, BioNTech issued a press release announcing the Company's fourth quarter and full year 2022 financial results, which, among other things, forecasted approximately €5 billion in COVID-19 vaccine revenues for the 2023 financial year, significantly below market estimates of over €8 billion. As investment research firm Third Bridge noted, "the [C]ompany's guidance for full year 2023 COVID-19 vaccine revenue of approximately EUR 5.0B is significantly below current consensus of over EUR $8.0B, reflecting the plummeting demand for population-wide levels of booster vaccinations[.]"

8. On this news, BioNTech's ADS price fell $4.60 per ADS, or 3.59%, to close at $123.60 per ADS on March 27, 2023.

9. On Friday, October 13, 2023, during after-market hours, Pfizer issued a press release announcing, among other things, that "[d]ue to lower-than-expected utilization for our COVID products, Pfizer recorded a non-cash charge of $5.5 billion to Cost of Goods Sold in the third quarter of 2023 . . . related to [*inter alia*] . . . inventory write-offs and other charges for Comirnaty of $0.9 billion." Pfizer further disclosed that it "is . . . reducing its full-year 2023 revenue expectations for Comirnaty by approximately $2.0 billion due to lower-than-expected vaccination rates."

10. On Monday, October 16, 2023, during pre-market hours, BioNTech issued a press release announcing that, as a result of Pfizer's inventory write-offs and other charges related to Comirnaty, BioNTech, too, would likely recognize up to €0.9 billion in inventory write-offs and other charges related to Comirnaty in the third quarter of 2023, which represents BioNTech's half under the gross profit-sharing agreement with Pfizer, and that "[a]ny such write-offs will reduce the revenues the Company would report for 2023." According to BioNTech, Pfizer informed that Company "that the majority of the write-offs relate to raw materials, mainly formulation-related lipids, purchased during the pandemic, as well as COVID-19 vaccine doses adapted to other, non-XBB.1.5 variants produced at risk."

11. On this news, BioNTech's ADS price fell $6.61 per ADS, or 6.38%, to close at $96.97 per ADS on October 16, 2023.

12. Then, on November 16, 2023, BioNTech issued a press release announcing its third quarter 2023 financial results. Among other items, the Company confirmed that "[i]nventory write-downs by BioNTech's collaboration partner Pfizer . . . [in connection with Comirnaty] reduced BioNTech's revenues by €507.9 million and €615.4 million for the three and nine months ended September 30, 2023, respectively."

13. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

14. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

15. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act.

16. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Pursuant to BioNTech's most recent annual report on Form 20-F, as of March 20, 2023, there were 240,993,998 of the Company's ordinary shares outstanding. BioNTech's ADSs,

each representing one of the Company's ordinary shares, trade in the U.S. on the Nasdaq Stock Market ("NASDAQ"). Accordingly, there are presumably hundreds, if not thousands, of investors in BioNTech's ADSs located in the U.S., some of whom undoubtedly reside in this Judicial District.

17. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

18. Plaintiff, as set forth in the attached Certification, acquired BioNTech securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

19. Defendant BioNTech is organized under the laws of the Federal Republic of Germany ("Germany") with principal executive offices located at An der Goldgrube 12, D-55131 Mainz, Germany. The Company's ADSs trade in an efficient market on the NASDAQ under the ticker symbol "BNTX".

20. Defendant Ugur Sahin ("Sahin") has served as BioNTech's Chief Executive Officer at all relevant times. Defendant Sahin is also BioNTech's Co-Founder.

21. Defendant Jens Holstein ("Holstein") has served as BioNTech's Chief Financial Officer at all relevant times.

22. Defendants Sahin and Holstein are collectively referred to herein as the "Individual Defendants".

23. The Individual Defendants possessed the power and authority to control the contents of BioNTech's SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of BioNTech's SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with BioNTech, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

24. BioNTech and the Individual Defendants are collectively referred to herein as "Defendants".

SUBSTANTIVE ALLEGATIONS

Background

25. BioNTech is a biotechnology company that develops and commercializes immunotherapies for cancer and other infectious diseases. The Company has developed and continues to develop, among other products and

product candidates, Comirnaty, a COVID-19 vaccine, in collaboration with Pfizer. The commercial name "Comirnaty" originally referred to the Company's vaccine product BNT162b2 and now also encompasses the Company's Original/BA.1- and Original/Omicron BA.4-5-adapted bivalent vaccines, all of which are referred to as "Comirnaty" by the Company.

26. As part of BioNTech's collaboration agreement with Pfizer, the two companies share gross profits from COVID-19 vaccine sales in their respective territories. In addition, Pfizer's inventory write-offs for COVID-19 products reduce BioNTech's gross profit share, thereby reducing BioNTech's vaccine revenues.

27. During the Class Period, as the number of COVID-19 cases began to decline, one variant of the virus, namely, the Omicron XBB.1.5 subvariant, increasingly began to account for the majority of reported cases. Despite not yet having a version of Comirnaty approved by the FDA to treat this subvariant, BioNTech represented to the market and investors during the Class Period that Comirnaty remained relevant and in-demand.

Materially False and Misleading Statements Issued During the Class Period

28. The Class Period begins on March 30, 2022, when BioNTech issued a press release during pre-market hours announcing the Company's fourth quarter and full year 2021 financial results (the "4Q/FY21 Earnings Release"). That press release stated, *inter alia*:

> BNT162b2 . . . is ushering in a new class of medicines. This was one of the fastest pharmaceutical products ever developed and one of the most successful pharmaceutical product launches. BioNTech's efforts resulted in more than one billion people being vaccinated with BNT162b2 around the globe. BioNTech and Pfizer continue to execute on plans for global COVID-19 vaccine leadership with multiple new product launches, including label expansions, pediatric dosage forms and potentially variant-based vaccines.

29. The 4Q/FY21 Earnings Release also provided updates on Comirnaty's commercial activity and prospects, stating, in relevant part:

> As of the beginning of March 2022, BioNTech and Pfizer delivered more than 3.1 billion doses of BNT162b2 to more than 170 countries and regions around the world. By early March 2022 . . . approximately 1.3 billion doses had been delivered to low- and middle-income countries. As of mid-March 2022, BioNTech and Pfizer have signed orders for approximately 2.4 billion doses in 2022. Further discussions for additional dose commitments are ongoing for 2022 and beyond.
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> - BioNTech and Pfizer launched a new product formulation of their COVID-19 vaccine that simplifies vaccine handling and has improved storage and transport conditions . . . . To date, this formulation has been delivered to more than 50 countries.
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> - In December 2021, BioNTech and Pfizer announced an agreement with the European Commission (EC) and its member states, pursuant to which the EC exercised its option to purchase more than 200 million additional doses of vaccine. The 200 million doses are in addition to the 450 million doses already planned to be delivered in 2022, based on an agreement signed in May 2021. The number of doses to be delivered to EC member states in 2022 will now total more than 650 million doses. In sum, the total number of potential doses delivered to the EC, inclusive of all agreements, is expected to be up to 2.4 billion by end of 2023.

30. Also on March 30, 2022, BioNTech filed an annual report on Form 20-F with the SEC, reporting the Company's financial and operational results for the

quarter and year ended December 31, 2021 (the "2021 20-F"). The 2021 20-F discussed Comirnaty's widespread adoption and use in commercial markets, while simultaneously touting the vaccine's continued demand prospects, stating, in relevant part:

> As of February 2022, based on data from the Centers for Disease Control and Prevention, or CDC, approximately six out of each ten doses administered in the United States were our COVID-19 vaccine. For Europe and the United States combined, our COVID-19 vaccine has accounted for approximately 70% of doses distributed as of February 5, 2022, according to "Our World in Data Coronavirus (COVID-19) Vaccinations."
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> We seek to drive long-term value in our COVID-19 vaccine program by increasing patient access through enhancing manufacturing and supply capacities, conducting a global clinical program to generate data to support additional label expansions, gaining regulatory advancement across further geographies, optimizing the formulation to simplify vaccine access worldwide, and by addressing waning immune responses and emerging SARS-CoV-2 variants.

31. The 2021 20-F also provided an update on Comirnaty's commercial activity, which similarly attested to the strong demand for, as well as continued commercial prospects of, Comirnaty, stating, in relevant part:

> As of mid March 2022, we and our partner Pfizer have signed orders for approximately 2.4 billion doses to be delivered in 2022. This includes agreements with the governments in the United States, United Kingdom, Japan, Canada and the European Union. Further discussions for additional dose commitments are ongoing and the order book is expected to further grow. ***Based on our order book and the expected continued need for booster vaccinations and vaccinations in the pediatric population, we and Pfizer are well positioned to continue to be a global leader in vaccines for the prevention of COVID-19.***

> We and Pfizer have an agreement with the European Commission, or the EC, that includes supplying 600 million doses of our COVID-19 vaccine to the 27 EU member states by the end of 2021, and to supply 900 million doses in 2022 and 2023, with option to request up to an additional 900 million doses. ***This would also cover potential vaccines adapted to variants without additional costs, if a variant vaccine is determined to be needed and subsequently authorized or approved*** . . . . In December 2021, we and Pfizer announced an agreement with the EC and its member states, pursuant to which the EC exercised its option to purchase more than 200 million additional doses of vaccine. The 200 million doses are in addition to the 450 million doses already planned to be delivered in 2022, based on an agreement signed in May 2021. The number of doses to be delivered to EC member states in 2022 will now total more than 650 million doses. In sum, the total number of potential doses delivered to the EC, inclusive of all agreements, is expected to be up to 2.4 billion by end of 2023.
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> The U.S. government has secured a total of 600 million doses under a supply agreement with us and Pfizer, including doses for pediatric vaccinations, and excluding one billion doses to be supplied at a not-for-profit price for donation. The U.S. government also has the option to acquire an updated version of the vaccine that includes new formulations or addresses potential viral variants, if available and authorized.

(Emphases added.)

32. The 2021 20-F's discussion of the scale of manufacturing operations for Comirnaty similarly attested to the strong demand for, as well as continued commercial prospects of, Comirnaty, stating, *inter alia*:

> Together with Pfizer we have developed a global COVID-19 vaccine supply chain and manufacturing network, which now spans four continents and includes more than 20 manufacturing facilities.
>
> Our manufacturing facility in Marburg is one of the largest mRNA vaccine manufacturing sites worldwide. The facility reached an annual capacity of up to 1 billion doses mRNA drug substance in 2021. The first batches of vaccines manufactured at the Marburg facility were

> delivered in mid-April 2021. For 2022 we and Pfizer plan to expand the global manufacturing capacity to four billion doses. The companies have developed a global COVID-19 vaccine supply chain and manufacturing network, which now spans four continents and includes more than 20 manufacturing facilities.
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> We and Pfizer are also leveraging Pfizer's manufacturing site in Puurs, Belgium, one of Pfizer's largest sterile injectable sites, for European supply and as back up supply to the primary manufacturing site for the U.S. market, which is in Kalamazoo, Michigan.
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> As our global footprint continues to grow we are also upscaling our manufacturing capacity by establishing new manufacturing sites.

33. With respect to inventory write-offs and reserves relating to Comirnaty, the 2021 20-F stated, in relevant part:

> During the year ended December 31, 2021, inventory write-offs and reserves related to our COVID-19 vaccine amounting to €194.6 million were recognized in cost of sales as a result of the respective inventories not fulfilling the predefined quality-specifications (GMP) and / or regulatory requirements (approval of the respective authorities, i.e. FDA) and / or shelf-life expiration, compared to nil in the previous period . . . . During the years ended December 31, 2021 and 2020, €1,255.1 million and €32.1 million, respectively costs of inventories were recognized as cost of sales.

34. On May 9, 2022, BioNTech issued a press release announcing the Company's first quarter 2022 financial results (the "1Q22 Earnings Release"). That press release contained substantively the same statements as reference in ¶ 28, *supra*, regarding Comirnaty's widespread use, as well as BioNTech and Pfizer's continued execution on plans for global COVID-19 vaccine leadership.

35. The 1Q22 Earnings Release also provided updates on Comirnaty's commercial activity and prospects, stating, in relevant part, that "[i]n the first

quarter of 2022, BioNTech and Pfizer have invoiced approximately 750 million COVID-19 vaccine doses"; and that, "[a]s of end-April 2022, the Companies have signed orders for approximately 2.4 billion doses in 2022."

36. In addition, with respect to the impact of inventory write-offs on cost of sales incurred in the quarter, the 1Q22 Earnings Release stated, in relevant part:

> Cost of sales was €1,294.1 million for the three months ended March 31, 2022, compared to €233.1 million for the comparative prior year period . . . . This increase in cost of sales is [parti]ally attributed to expenses arising from inventory write-offs and for production capacities derived from contracts with Contract Manufacturing Organizations.

37. Also on May 9, 2022, BioNTech filed a report of foreign issuer on Form 6-K with the SEC, appended to which as an exhibit was the Company's Quarterly Report for the Three Months Ended March 31, 2022 (the "1Q22 6-K"). The 1Q22 6-K contained substantively the same statements as referenced in ¶¶ 28 and 35, *supra*, regarding BioNTech and Pfizer's continued execution on plans for global COVID-19 vaccine leadership and updates on Comirnaty's commercial activity and prospects.

38. The 1Q22 6-K also stated, in relevant part, that "[d]uring the three months ended March 31, 2022 and 2021, inventory write-offs and reserves related to our COVID-19 vaccine amount[ed] to €156.0 million and nil, respectively, and were recognized in cost of sales as a result of the introduction of a new COVID-19 vaccine formulation."

39. The statements referenced in ¶¶ 28-38 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) BioNTech overstated demand for Comirnaty and/or its commercial prospects; (ii) the Company and/or Pfizer had accumulated excess inventory of raw materials for Comirnaty, as well as COVID-19 vaccine doses adapted to other, non-XBB.1.5 variants that were produced at risk; (iii) accordingly, BioNTech was at an increased risk of recording significant inventory write-offs and other charges related to Comirnaty; and (iv) as a result, Defendants' public statements were materially false and/or misleading at all relevant times.

The Truth Begins to Emerge

40. On August 8, 2022, during pre-market hours, BioNTech issued a press release announcing the Company's second quarter 2022 financial results (the "2Q22 Earnings Release"). For the quarter, the 2Q22 Earnings Release reported GAAP EPS of €6.45, missing consensus estimates by €0.63, and revenue of €3.2 billion, missing consensus estimates by €910 million, and representing a 39.7% Y/Y decrease. The Company attributed the result, in part, to the "dynamic" development of the pandemic, which "caus[ed] a re-phasing of orders and . . . le[d] to fluctuations in quarterly revenues." According to BioNTech, "[t]his revenue fluctuation caused by the re-phasing of orders is expected to remain over the rest of the financial year

with an uptake in demand in key markets in the fourth quarter of 2022 related to the Omicron-adapted bivalent vaccine, subject to regulatory approval."

41. The market quickly understood the foregoing disclosures for what they were—sales of Comirnaty were declining. As reported, in relevant part, by *Seeking Alpha* that day, in a press release entitled "BioNTech stock falls on Q2 miss as vaccine sales slump; eyes uptick in Q4 with Omicron shot delivery in October":

> BioNTech (NASDAQ:BNTX) stock fell ~5% premarket Aug. 8 after the company's Q2 results missed analysts estimates, however the company reaffirmed its COVID-19 vaccine revenues outlook for 2022.
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> Q2 EPS slumped -40.11% Y/Y to €6.45, while revenue fell -39.79% Y/Y to ~€3.2B.
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> Revenue from direct COVID-19 vaccine sales to customers in BioNTech's territory, Germany and Turkey, declined to €557M, compared to ~€1.04B in Q1 2021. Meanwhile, sales from products manufactured by BioNTech for its collaboration partners increased to €608.3M, compared to €138.1M in the prior year period.
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> The German company said that due to the dynamic nature of the pandemic there was a re-phasing of orders causing fluctuations in quarterly revenues, which is expected to remain over the rest of the year with an uptake in demand in key markets in Q4 related to the Omicron-adapted bivalent vaccine, if approved.
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> Net Profit declined to €1,67B, compared to €2,.79B in Q2 2021. Research and development expenses were €399.6M, compared to €201.1M in Q2 2021.

42. On this news, BioNTech's ADS price fell $13.81 per ADS, or 7.54%, to close at $169.30 per ADS on August 8, 2022. Despite this decline in the

Company's ADS price, BioNTech securities continued trading at artificially inflated prices throughout the remainder of the Class Period because of Defendants' continued misstatements and omissions with respect to demand and inventory for Comirnaty, as well as the vaccine's commercial prospects.

43. For example, the 2Q22 Earnings Release quoted Defendant Sahin, who stated, in relevant part:

> In the first half of 2022, we achieved important milestones as we have further strengthened our COVID-19 vaccine leadership and have expanded our broad pipeline and accelerated its maturation. Our COVID-19 product pipeline includes variant-adapted and next-generation vaccine candidates, aimed at prolonged and broad protection[.]

44. The 2Q22 Earnings Release also quoted Defendant Holstein, who stated, in relevant part:

> With our initiatives around variant-adapted COVID-19 vaccine candidates, we expect an uptake in demand in our key markets in the fourth quarter of 2022, subject to regulatory approval. We . . . remain focused on . . . driving our leadership in COVID-19 vaccine development.

45. The 2Q22 Earnings Release also provided updates on Comirnaty's commercial activity and prospects, stating, in relevant part:

> As of the beginning of July 2022, BioNTech and Pfizer have delivered in total more than 3.6 billion doses to 180 countries or territories. The companies have signed orders for approximately 2.5 billion doses for 2022, and, in the first half of the year, invoiced approximately 1.2 billion doses. The cumulative share of doses[] increased in the period between January 1, 2022 to July 20, 2022 from approximately 52% to 63% in all markets[]. In developed markets[], the share of doses for the same time period increased from approximately 59% to 68%.

* * *

- In May 2022, BioNTech and Pfizer announced an agreement with the European Commission, or EC, to amend their originally agreed contractual delivery schedules for the COVID-19 vaccine. The amendment rephases planned deliveries to help support the EC and Member States' ongoing immunization programs . . . . Doses scheduled for delivery in June through August 2022 will now be delivered in September through to the fourth quarter of 2022. This change of delivery schedule did not impact the companies' full-year 2022 revenue guidance or the full-year commitment of doses to be delivered to EC Member States in 2022.

- In June 2022, BioNTech and Pfizer entered into a new vaccine supply agreement with the U.S. government. Under the terms of the agreement, the U.S. government will receive 105 million doses . . . potentially including the Omicron-adapted adult vaccine, subject to granting of U.S. FDA Emergency Use Authorization, or EUA. The U.S. government also has the option to purchase up to an additional 195 million doses, bringing the potential total to 300 million vaccine doses. Delivery of the vaccine doses is scheduled to begin in late summer 2022 and will continue into the fourth quarter of this year. The U.S. government will pay the two companies $3.2 billion after receiving the first 105 million doses of vaccine.

46. In addition, with respect to the impact of inventory write-offs on cost of sales incurred in the quarter, the 2Q22 Earnings Release stated, in relevant part:

> Cost of sales were €764.6 million for the three months ended June 30, 2022, compared to €883.8 million for the comparative prior year period . . . . [C]ost of sales was [partially] impacted by expenses arising from inventory write-offs and expenses for production capacities derived from contracts with contract manufacturing organizations.

47. Also on August 8, 2022, BioNTech filed a report of foreign issuer on Form 6-K with the SEC, appended to which as an exhibit was the Company's

Quarterly Report for the Three and Six Months Ended June 30, 2022 (the "2Q22 6-K"). The 2Q22 6-K contained substantively the same statements as referenced in ¶¶ 28 and 45, *supra*, regarding BioNTech and Pfizer's continued execution on plans for global COVID-19 vaccine leadership and updates on Comirnaty's commercial activity and prospects.

48. With respect to inventory write-offs, reserves, and provisions related to Comirnaty, the 2Q22 6-K stated, in relevant part:

> During three and six months ended June 30, 2022, inventory write-offs and reserves related to our COVID-19 vaccine amounting to €247.1 million and €403.1 million, respectively, were recognized in cost of sales as a result of the planned introduction of a new COVID-19 vaccine formulation and the potential switch from the BNT162b2 vaccine to an Omicron-adapted bivalent vaccine. During the comparative periods, three and six months ended June 30, 2021 no inventory write-offs were recorded.
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> * * *
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> As of June 30, 2022, our current provisions include €207.8 million (nil as of December 31, 2021) of obligations for production capacities derived from contracts with Contract Manufacturing Organizations, or CMOs, that became redundant as a direct result of the planned introduction of a new COVID-19 vaccine formulation, the potential switch from the BNT162b2 vaccine to an Omicron-adapted bivalent vaccine and due to increased internal manufacturing capacities during the three and six months ended June 30, 2022. The related expenses were recognized in cost of sales in our unaudited interim condensed consolidated statements of profit or loss.

49. The 2Q22 6-K also reiterated that "[w]e believe the development of the pandemic remains dynamic which influences the potential switch from the BNT162b2 vaccine to an Omicron-adapted bivalent vaccine, subject to regulatory

approval, thereby causing a re-phasing of orders from those made earlier in the year to a later time in the year"; and that "[t]hese developments are leading to fluctuations in quarterly revenues which we expect to remain over the rest of the financial year with an uptake in demand in our key markets in the fourth quarter of 2022 related to the Omicron-adapted bivalent vaccine, subject to regulatory approval."

50. On October 26, 2022, BioNTech filed an amendment on Form 20-F/A with the SEC, amending the 2021 20-F to attach as exhibits previously omitted signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX"), signed by the Individual Defendants, wherein the Individual Defendants certified that the 2021 20-F "does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by" the 2021 20-F, and that "the financial statements, and other financial information included in th[e 2021 20-F], fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in th[e 2021 20-F.]"

51. On November 7, 2022, BioNTech issued a press release announcing the Company's third quarter 2022 financial results (the "3Q22 Earnings Release"). Therein, the Company highlighted, in relevant part, that "BioNTech (NTGN) and Pfizer continue to build on global COVID-19 vaccine leadership with first-to-

market Original/Omicron BA.4/BA.5-adapted bivalent vaccine launches across multiple countries and regions worldwide" and that "[a]pproximately 300 million doses of the Original/Omicron BA.1- and BA.4/BA.5-adapted bivalent vaccines invoiced as of mid-October 2022[.]"

52. The 3Q22 Earnings Release also stated, in relevant part, that BioNTech and Pfizer "have now three commercial stage COVID-19 vaccine products on the market that include the original COVID-19 vaccine and two Omicron adapted vaccines: Original/BA.1- and BA.4/5.-adapted bivalent vaccines" and that "BioNTech believes its COVID-19 vaccine franchise will remain a long-term sustainable business opportunity."

53. With respect to updates on Comirnaty's commercial activity and prospects, the 3Q22 Earnings Release stated, in relevant part:

> Following regulatory approvals, BioNTech and Pfizer immediately began shipping Original/Omicron BA.1 and BA.4/BA.5-adapted bivalent COVID-19 vaccines in September 2022 in time for fall and winter booster campaigns. Shipments in the United States began approximately two months after the [FDA] provided its guidance for the BA.4/BA.5-adapted bivalent COVID-19 vaccine.
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> As of mid-October 2022, BioNTech and Pfizer have invoiced approximately 300 million doses of Original/Omicron-adapted bivalent vaccine.
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> * * *
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> BioNTech expects to invoice up to 2.1 billion doses of the COVID-19 vaccine in 2022. Some dose deliveries have been shifted into 2023 due to the evolving dynamics of demand.

54. In addition, with respect to the impact of inventory write-offs on cost of sales incurred in the quarter, the 3Q22 Earnings Release stated, in relevant part:

> Cost of sales were €752.8 million for the three months ended September 30, 2022 (Q3 2021: €1,211.4 million) . . . . [C]ost of sales were [partially] impacted by expenses arising from inventory write-offs and expenses for production capacities derived from contracts with contract manufacturing organizations.

55. Also on November 7, 2022, BioNTech filed a report of foreign issuer on Form 6-K with the SEC, appended to which as an exhibit was the Company's Quarterly Report for the Three and Nine Months Ended November 30, 2022 (the "3Q22 6-K"). The 3Q22 6-K contained substantively the same statements as referenced in ¶¶ 28 and 53, *supra*, regarding BioNTech and Pfizer's continued execution on plans for global COVID-19 vaccine leadership and updates on Comirnaty's commercial activity and prospects.

56. With respect to inventory write-offs, reserves, and provisions related to Comirnaty, the 3Q22 6-K stated, in relevant part:

> During three and nine months ended September 30, 2022, inventory write-offs and reserves related to our COVID-19 vaccine amounting to €138.4 million and €559.4 million, respectively, were recognized in cost of sales due to the switch from the BNT162b2 vaccine to an Omicron-adapted bivalent vaccine and further raw materials reserves. During the comparative periods, three and nine months ended September 30, 2021, inventory write-offs amounting to €88.0 million and €107.8 million, respectively, were recognized in cost of sales.
>
> * * *
>
> As of September 30, 2022, our current provisions include €321.2 million (nil as of December 31, 2021) of obligations for

> production capacities derived from contracts with Contract Manufacturing Organizations, or CMOs, that became redundant as a direct result of the introduction of a new COVID-19 vaccine formulation, the switch from the BNT162b2 vaccine to an Omicron-adapted bivalent vaccine and due to increased internal manufacturing capacities during the three and nine months ended September 30, 2022. The related expenses were recognized in cost of sales in our unaudited interim condensed consolidated statements of profit or loss.

57. The statements referenced in ¶¶ 40 and 43-56 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) BioNTech overstated demand for Comirnaty and/or its commercial prospects; (ii) the Company and/or Pfizer had accumulated excess inventory of raw materials for Comirnaty, as well as COVID-19 vaccine doses adapted to other, non-XBB.1.5 variants that were produced at risk; (iii) accordingly, BioNTech was at an increased risk of recording significant inventory write-offs and other charges related to Comirnaty; and (iv) as a result, Defendants' public statements were materially false and/or misleading at all relevant times.

58. On March 27, 2023, during pre-market hours, BioNTech issued a press release announcing the Company's fourth quarter and full year 2022 financial results (the "4Q/FY22 Earnings Release"). Among other results, 4Q/FY22 Earnings Release forecasted approximately €5 billion in COVID-19 vaccine revenues for the 2023 financial year, significantly below market estimates of over

€8 billion. As investment research firm Third Bridge noted, "the [C]ompany's guidance for full year 2023 COVID-19 vaccine revenue of approximately EUR 5.0B is significantly below current consensus of over EUR $8.0B, reflecting the plummeting demand for population-wide levels of booster vaccinations[.]"

59. On this news, BioNTech's ADS price fell $4.60 per ADS, or 3.59%, to close at $123.60 per ADS on March 27, 2023. Despite this decline in the Company's ADS price, BioNTech securities continued trading at artificially inflated prices throughout the remainder of the Class Period because of Defendants' continued misstatements and omissions with respect to demand and inventory for Comirnaty, as well as the vaccine's commercial prospects.

60. For example, with respect to updates on Comirnaty's commercial activity and prospects, the 4Q/FY22 Earnings Release stated, in relevant part:

- In December 2022, BioNTech and Pfizer announced that approximately 2 billion doses of COMIRNATY were invoiced globally in 2022 between the two companies, including approximately 550 million doses of the Original/Omicron BA.4-5-adapted bivalent COVID-19 vaccine, as of mid-December 2022.

- In January 2023, BioNTech and Pfizer announced that negotiations were ongoing for the re-phasing of delivery timelines for the COMIRNATY supply agreement with the European Commission (EC). The agreement with the EC was signed in May 2021 and a rephasing agreement was previously reached in May 2022.

61. In addition, with respect to the impact of inventory write-offs on cost of sales incurred in the quarter and year, the 4Q/FY22 Earnings Release stated, in relevant part:

> Cost of sales were €183.5 million for the three months ended December 31, 2022, compared to €583.2 million for the comparative prior year period. For the year ended December 31, 2022, cost of sales were €2,995.0 million, compared to €2,911.5 million for the comparative prior year period. Cost of sales were impacted by expenses arising from inventory write-offs and expenses for production capacities derived from agreements with contract manufacturing organizations that became redundant. In addition, during the three months ended December 31, 2022, cost of sales were impacted by the release of provisions.

62. Also on March 27, 2023, BioNTech filed an annual report on Form 20-F with the SEC, reporting the Company's financial and operational results for the quarter and year ended December 31, 2022 (the "2022 20-F"). The 2022 20-F stated, *inter alia*, that "[w]e and Pfizer developed and launched two Original/Omicron-adapted bivalent vaccines, expanded *Comirnaty's* label to include pediatrics and other populations for primary and booster vaccination, converted conditional or emergency approvals to full marketing authorizations, and between us invoiced sales of approximately 2 billion doses of *Comirnaty*."

63. In addition, the 2022 20-F touted Comirnaty's widespread adoption and use in commercial markets and continued demand prospects, stating, in relevant part, that "[a]s of December 2022, our original COVID-19 vaccine product has been authorized or approved for emergency or temporary use or granted marketing

authorization in more than 100 countries and regions worldwide and our efforts have resulted in more than 4 billion doses shipped globally."

64. The 2022 20-F also provided an update on Comirnaty's commercial activity, which similarly attested to the strong demand for, as well as continued commercial prospects of, Comirnaty, stating, in relevant part:

> In 2022, we and Pfizer continued our global COVID-19 vaccine leadership with the first-to-market Original/Omicron BA.4-5-adapted bivalent COVID-19 vaccine directed against both the original COVID-19 virus and the Omicron BA.4-5 adapted COVID-19 virus. We now have three commercial COVID-19 vaccine products on the market: the original COVID-19 vaccine, and two Original/Omicron-adapted bivalent vaccines: Original/BA.1- and Original/Omicron BA.4-5-adapted bivalent vaccines, which are all referred to as *Comirnaty*.
>
> In 2022, together with Pfizer, we invoiced approximately two billion doses of *Comirnaty*. As part of our and Pfizer's two-billion-doses pledge to support equitable access to medicines, we and Pfizer have delivered approximately 1.7 billion doses of *Comirnaty* to low- and middle-income countries in line with demand.
>
> In June 2022, Pfizer entered into a new vaccine supply agreement with the U.S. government. Under the terms of the agreement, the U.S. government received 105 million doses . . . including the Original/Omicron BA.4-5-adapted bivalent COVID-19 vaccine for adults. The U.S. government also has the option to purchase up to an additional 195 million doses, bringing the potential total to 300 million vaccine doses. Delivery of the vaccine doses began in late summer 2022. The U.S. government was contractually required to pay the two companies $3.2 billion after receiving the first 105 million doses of vaccine.
>
> In September 2022, following regulatory approvals, we and Pfizer began shipping Original/Omicron BA.1- and BA.4-5-adapted bivalent COVID-19 vaccines in time for fall and winter booster campaigns. Shipments to the U.S. began approximately two months after the FDA provided its guidance for the Original/Omicron BA.4-5-adapted

bivalent COVID-19 vaccines. As of mid-December 2022, we and Pfizer have shipped approximately 550 million doses of Original/Omicron-adapted bivalent vaccine.

In December 2022, we and Fosun Pharma provided approximately 11,500 doses of *Comirnaty* which were delivered to Mainland China to enable a vaccination campaign for German expatriates. The delivery contained both the Original/Omicron BA.4-5-adapted bivalent COVID-19 vaccine and the original COVID-19 vaccine.

We believe that we and Pfizer are well positioned for the future as leading COVID-19 vaccine providers. We expect that as the market dynamics evolve, there will be continued vaccine boosting and vaccinations of immunologically naive populations. To meet this need, in 2023, we plan to deliver doses originally scheduled for delivery in 2022 in some geographies. We also expect that in 2023, some governments will no longer be the main COVID-19 vaccine purchasers for their populations, and that commercial buyers will assume that role. In the U.S., for example, we expect that shift to happen in the third quarter of 2023.

65. With respect to the impact of inventory write-offs on cost of sales incurred in the year, the 2022 20-F stated, in relevant part:

From the year ended December 31, 2021 to the year ended December 31, 2022, cost of sales increased by €83.5 million or 3% from €2,911.5 million to €2,995.0 million . . . . [C]ost of sales was [partially] impacted by expenses arising from inventory write-offs and expenses for production capacities derived from contracts with Contract Manufacturing Organizations, or CMOs, that became redundant. The effects were driven by the introduction of a new COVID-19 vaccine formulation, the switch from the monovalent vaccine to our Omicron-adapted bivalent COVID-19 vaccines and due to accelerating internal manufacturing capacities during the year ended December 31, 2022.

* * *

During the year ended December 31, 2022, inventory write-offs to net realizable value and reserves related to our COVID-19 vaccine amounting to €484.6 million were recognized in cost of sales due to the

> switch from the BNT162b2 vaccine to an Omicron-adapted bivalent vaccine and further raw materials reserves recognized with respect to our excess stock, compared to €194.6 million in the previous period. The inventories valued at net realizable value in our consolidated statements of financial position as of December 31, 2022, consider contractual compensation payments . . . . During the years ended December 31, 2022, and 2021, costs of inventories in the amount of €1,550.6 million and €1,255.1 million, respectively, were recognized as cost of sales.

66. Appended as exhibits to the 2022 20-F were substantively the same SOX certifications as referenced in ¶ 50, *supra*, signed by the Individual Defendants.

67. On May 8, 2023, BioNTech issued a press release announcing the Company' first quarter 2023 financial results, stating, in relevant part:

> [E]stimated BioNTech COVID-19 vaccine revenues reflect expected deliveries under existing or committed supply contracts and anticipated sales through traditional commercial orders. A re-negotiation of the existing supply contract with the European Commission is ongoing, with the potential for a rephasing of deliveries of doses across multiple years and/or a volume reduction. While a ***vaccine adaptation is expected to lead to increased demand***, fewer primary vaccinations and lowered population-wide levels of boosting are anticipated. Seasonal demand is assumed, moving expected revenue generation significantly to the second half of the year 2023.

(Emphasis added.)

68. Also on May 8, 2023, BioNTech filed a report of foreign issuer on Form 6-K with the SEC, appended to which as an exhibit was the Company's Quarterly Report for the Three Months Ended March 31, 2023 (the "1Q23 6-K").

With respect to updates on Comirnaty's commercial activity and prospects, the 1Q23 6-K stated, in relevant part:

> We expect that as SARS-CoV-2 continues to evolve, and the risk of severe COVID-19 disease and deaths continues especially for high risk populations, there will be continued demand for vaccine boosting and vaccinations, especially for at-risk and immunocompromised groups. To meet this need, in 2023, we plan to deliver doses originally scheduled for delivery in 2022 in some geographies. We also expect that in 2023, the transition from an advanced purchase agreement environment to commercial market ordering will start in some geographies and that there may be a regulatory recommendation to adapt the COVID-19 vaccines to address newly circulating variants or sublineages of SARS-CoV-2. Our estimated COVID-19 vaccine revenues reflect expected deliveries under existing or committed supply contracts and anticipated sales through traditional commercial orders. A re-negotiation of the existing supply contract with the European Commission is ongoing, with the potential for rephasing deliveries of doses across multiple years and/or a volume reduction.

69. In addition, with respect to the impact of inventory write-offs on cost of sales incurred in the quarter, the 1Q23 6-K stated, in relevant part:

> During the three months ended March 31, 2023 and 2022 expenses from inventory write-downs to net realizable value and inventory write-offs due to inventories expected to be unsaleable, not fulfilling the specification defined by our quality standards, shelf-life expiry or disposals resulted in €73.7 million and €156.0 million, respectively, included in cost of sales.

70. The 1Q23 6-K also purported to warn that uncertainty in demand for COVID-19 vaccines "may" lead to significant inventory write-downs that "could" materially affect BioNTech's COVID-19-related revenues, stating, in relevant part:

> We cannot accurately predict the revenues our COVID-19 vaccine will generate in future periods or for how long our COVID-19 vaccine will continue to generate material revenues and we cannot ensure it will

> maintain its competitive position. Uncertainty in the demand for our COVID-19 vaccine and difficulties in targeting appropriate supply of our COVID-19 vaccines have in the past resulted, and ***may*** in the future result, in significant inventory write-offs and cancellations of contract manufacturing orders. Our business and financial condition ***could*** be materially affected by lowered COVID-19 vaccine revenues resulting from any of the above factors, or by production and supply chain difficulties. In addition, ***if*** our revenues or market share of, or other financial metrics relating to our COVID-19 vaccine do not meet the expectations of investors or securities analysts, the market price of the ADSs representing our ordinary shares may decline.

(Emphases added.) Plainly, the foregoing risk warning was a generic, boilerplate provision that was not tailored to BioNTech's actual known risks related to demand for Comirnaty and the likelihood of attendant inventory write-downs.

71. On August 7, 2023, BioNTech issued a press release announcing the Company's second quarter 2023 financial results (the "2Q23 Earnings Release"). Therein, the Company highlighted its "[p]reparation for launch of Omicron XBB.1.5-adapted monovalent COVID-19 vaccine as recommended by the [FDA], European Medicines Agency (EMA) and other health authorities" with "deliveries expected to start as early as September, subject to regulatory approval"; while "[r]eiterat[ing] COVID-19 vaccine revenue guidance of approximately €5 billion in 2023[.]"

72. With respect to the impact of inventory write-downs on BioNTech's COVID-19 vaccine revenues, the 2Q23 Earnings Release merely stated, in relevant part, that revenue estimates for full year 2023 "***may*** be influenced by costs such as

inventory write-offs once materialized and shared with the collaboration partner Pfizer" (emphasis added).

73. Also on August 7, 2023, BioNTech filed a report of foreign issuer on Form 6-K with the SEC, appended to which as an exhibit was the Company's Quarterly Report for the Three and Six Months Ended June 30, 2023 (the "2Q23 6-K"). With respect to updates on Comirnaty's commercial activity and prospects, the 2Q23 6-K stated, in relevant part:

> In May 2023, we and Pfizer announced an agreement had been reached with the European Commission, or the EC, to amend the previous COVID-19 Vaccine Purchase Agreement to deliver COVID-19 vaccines to the European Union, or the EU. The amended agreement reflects ours and Pfizer's commitment to working collaboratively to help address ongoing public health needs, while respecting the principles of the original agreement. The agreement rephased 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.
>
> We expect that as SARS-CoV-2 continues to evolve, and the risk of severe COVID-19 disease and deaths continues, especially for high risk populations, there will be continued demand for vaccine boosting and vaccinations, especially for at-risk and immunocompromised groups. We also expect to begin the transition from an advanced purchase agreement environment to commercial market ordering in some geographies, driven by regulatory recommendations to adapt COVID-19 vaccines to newly circulating variants or sublineages of SARS-CoV-2, namely XBB.1.5 for the fall and winter seasons in 2023 and 2024.

74. In addition, with respect to the impact of inventory write-offs on cost of sales incurred in the quarter, the 2Q23 6-K stated, in relevant part:

> During the three and six months ended June 30, 2023 expenses from inventory write-downs to net realizable value and inventory write-offs due to inventories expected to be unsaleable, not fulfilling the specification defined by our quality standards, shelf-life expiry or disposals resulted in €40.2 million and €113.9 million, respectively, included in cost of sales. (€247.1 million and €403.1 million with respect to write-offs during the three and six months ended June 30, 2022).

75. The 2Q23 6-K also contained the same generic, boilerplate risk warning as referenced in ¶ 70, *supra*, purporting to warn that uncertainty in demand for COVID-19 vaccines "may" lead to significant inventory write-downs that "could" materially affect BioNTech's COVID-19-related revenues, which was not tailored to BioNTech's actual known risks related to demand for Comirnaty and the likelihood of attendant inventory write-downs.

76. The statements referenced in ¶¶ 58 and 60-75 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) BioNTech overstated demand for Comirnaty and/or its commercial prospects; (ii) the Company and/or Pfizer had accumulated excess inventory of raw materials for Comirnaty, as well as COVID-19 vaccine doses adapted to other, non-XBB.1.5 variants that were produced at risk; (iii) accordingly, BioNTech was at an increased risk of recording significant inventory write-offs and

other charges related to Comirnaty; and (iv) as a result, Defendants' public statements were materially false and/or misleading at all relevant times.

The Truth Fully Emerges

77. On Friday, October 13, 2023, during after-market hours, Pfizer issued a press release announcing, among other things, that "[d]ue to lower-than-expected utilization for our COVID products, Pfizer recorded a non-cash charge of $5.5 billion to Cost of Goods Sold in the third quarter of 2023 . . . related to [*inter alia*] . . . inventory write-offs and other charges for Comirnaty of $0.9 billion." Pfizer further disclosed that it is "reducing its full-year 2023 revenue expectations for Comirnaty by approximately $2.0 billion due to lower-than-expected vaccination rates."

78. Then, on Monday, October 16, 2023, during pre-market hours, BioNTech issued a press release announcing that, as a result of Pfizer's inventory write-offs and other charges related to Comirnaty, BioNTech, too, would likely recognize up to €0.9 billion in inventory write-offs and other charges related to Comirnaty in the third quarter of 2023, which represents BioNTech's half under the gross profit-sharing agreement with Pfizer, stating, in relevant part:

> On October 13, 2023, Pfizer Inc. (NYSE: PFE, "Pfizer"), a collaboration partner of BioNTech SE (Nasdaq: BNTX, "BioNTech" or "the Company"), announced a non-cash charge for inventory write-offs and other charges related to COMIRNATY of $0.9 billion. The Company has been informed by Pfizer that the majority of the write-offs relate to raw materials, mainly formulation-related lipids, purchased during the pandemic, as well as COVID-19 vaccine doses

> adapted to other, non-XBB.1.5 variants produced at risk. According to Pfizer, the write-offs do not address the Pfizer-BioNTech COVID-19 Vaccine adapted to the XBB.1.5 variant, which has been approved and is being marketed in key geographies.
>
> BioNTech is evaluating the potential impact of Pfizer's write-offs and other charges related to COMIRNATY on the Company's financial results. ***BioNTech's current expectation is that the Company is likely to recognize the effect of Pfizer's inventory write-offs and other charges related to COMIRNATY in the third quarter of 2023 up to €0.9 billion***, which represents BioNTech's half under the gross profit-sharing agreement with Pfizer. ***Any such write-offs will reduce the revenues the Company would report for 2023.*** BioNTech expects to release its financial report for the third quarter of 2023 on November 6, 2023.

(Emphases added.)

79. On this news, BioNTech's ADS price fell $6.61 per ADS, or 6.38%, to close at $96.97 per ADS on October 16, 2023.

Post-Class Period Developments

80. On November 16, 2023, BioNTech issued a press release announcing its third quarter 2023 financial results. Among other items, the Company confirmed that "[i]nventory write-downs by BioNTech's collaboration partner Pfizer . . . [in connection with Comirnaty] reduced BioNTech's revenues by €507.9 million and €615.4 million for the three and nine months ended September 30, 2023, respectively." The Company explained, in relevant part:

> 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.

81. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

SCIENTER ALLEGATIONS

82. During the Class Period, Defendants had both the motive and opportunity to commit fraud. They also had actual knowledge of the misleading nature of the statements they made, or acted in reckless disregard of the true information known to them at the time. In so doing, Defendants participated in a scheme to defraud and committed acts, practices, and participated in a course of business that operated as a fraud or deceit on purchasers of the Company's securities during the Class Period.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

83. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired BioNTech securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective

disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

84. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, BioNTech securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by BioNTech or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

85. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

86. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

87. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of BioNTech;
- whether the Individual Defendants caused BioNTech to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of BioNTech securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

88. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

89. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- BioNTech securities are traded in an efficient market;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NASDAQ and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiff and members of the Class purchased, acquired and/or sold BioNTech securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

90. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

91. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

92. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

93. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

94. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of BioNTech securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire BioNTech securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan

and course of conduct, Defendants, and each of them, took the actions set forth herein.

95. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for BioNTech securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about BioNTech's finances and business prospects.

96. By virtue of their positions at BioNTech, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

97. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of BioNTech, the Individual Defendants had knowledge of the details of BioNTech's internal affairs.

98. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of BioNTech. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to BioNTech's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of BioNTech securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning BioNTech's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired BioNTech securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

99. During the Class Period, BioNTech securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the

materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of BioNTech securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of BioNTech securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of BioNTech securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

100. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

101. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against the Individual Defendants)

102. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

103. During the Class Period, the Individual Defendants participated in the operation and management of BioNTech, and conducted and participated, directly and indirectly, in the conduct of BioNTech's business affairs. Because of their senior positions, they knew the adverse non-public information about BioNTech's misstatement of income and expenses and false financial statements.

104. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to BioNTech's financial condition and results of operations, and to correct promptly any public statements issued by BioNTech which had become materially false or misleading.

105. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which BioNTech disseminated in the marketplace during the Class Period concerning BioNTech's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause BioNTech to engage in the wrongful acts complained of herein.

The Individual Defendants, therefore, were "controlling persons" of BioNTech within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of BioNTech securities.

106. Each of the Individual Defendants, therefore, acted as a controlling person of BioNTech. By reason of their senior management positions and/or being directors of BioNTech, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, BioNTech to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of BioNTech and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

107. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by BioNTech.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.