



First-Quarter 2023 Earnings Conference Call Prepared Remarks May 2, 2023

[Slide 4: Opening Remarks – Albert Bourla]

Albert Bourla – Pfizer Inc. – Chairman and Chief Executive Officer

[Slide 5: Q1 2023: A Solid, Foundational Quarter]

Q1 was a solid, foundational quarter in what we expect to be an exciting year for Pfizer and patients.

Our financial results were as we anticipated. Our non-COVID revenues grew 5% operationally compared with the year-ago quarter, while overall revenues declined 26% operationally primarily due to a previously communicated and expected decline in Comirnaty revenues. Even with Comirnaty's decline, our COVID franchises remained significant contributors to the business with a combined \$7.1 billion in revenues during the quarter.

This growth was driven primarily by:

- recently acquired products, Nurtec ODT/Vydura for migraine and Oxbryta for sickle cell disease,
- our anti-infective Sulperazon,
- Eliquis, in the non-valvular atrial fibrillation indication in the U.S., and
- our Vyndaqel family of products for the treatment of transthyretin amyloid cardiomyopathy (or ATTR-CM).

We also continue to be proud of our patient impact. During the first quarter, more than 250 million patients were treated with our medicines and vaccines.

[Slide 6: Expected 7-9% Op Growth ex-COVID in 2023 on Track]

With this solid start to the year, we remain on track to grow our non-COVID revenues by 7-9% operationally in 2023. That's because the majority of our potential near-term product launches – as you can see mapped out on this slide – are expected to occur in the second half of the year, following regulatory approvals where not yet secured. As such, we expect our non-COVID revenues to grow at a faster rate in the second half of the year than in the first.

[Slide 7: New Launches / Co-promotions and Potential Product Launches]

Overall, we are in the midst of an 18-month period in which we expect to launch up to 19 potential new products and indications.

[Slide 8: Excellent Progress toward Expected Product Launches]

Over the first four months of the year, we have made excellent progress toward this goal with the approval of Zavzpret, an expanded indication for Cibinqo to include adolescents, and last week's approval of Pevnar 20 for pediatric use — all in the U.S.

We also have secured regulatory filing acceptances for elranatamab, for Braftovi + Mektovi for non-small cell lung cancer, and for our RSV maternal vaccine candidate, which if approved would be the first vaccine for administration to pregnant individuals to help protect against the complications of RSV disease in infants from birth through six months.

In addition, the U.S. Food & Drug Administration (FDA) has granted priority review and the European Medicines Agency (EMA) has accepted our MAA filing for review of Talzenna for use in combination with Xtandi for patients with newly diagnosed metastatic castration-resistant prostate cancer, based on the TALAPRO2 results.

[Slide 9: COVID-19 Revenue Expectations Remain Unchanged]

Regarding our COVID-19 franchises, we continue to expect 2023 to be a transition year as the virus continues to mutate and we move from advance purchases under government contracts to more traditional supply arrangements in a commercial model for both Comirnaty and Paxlovid in the U.S.

As previously discussed, in 2023 and 2024 we expect vaccine utilization to decline compared with 2022. Then starting in 2025, and continuing in 2026 and beyond, we expect to see an increase in COVID-19 vaccination rates, assuming the successful development and approval of various COVID combination vaccines. Outside the U.S., we expect these general trends to be similar – with some variations from country to country.

Regarding Paxlovid, we continue to expect the government inventory that was built around the world last year to be absorbed by the end of this year. We then expect that in years 2024 and beyond, the courses sold and used will more closely align. With its robust efficacy, consistent safety profile, and potential to help mitigate the burden of COVID-19 on patients and their families, health systems and society, Paxlovid is proving to be an important and durable complementary tool to vaccination strategies for the estimated 40% of the global adult population at high risk for progressing to severe disease.

[Slide 10: Accelerating Pfizer's Battle Against Cancer]

Now let's take a look at Pfizer's next potential moonshot: the battle against cancer.

Oncology remains a core therapeutic area for Pfizer, and we believe the proposed acquisition of Seagen will enhance our position in this important space.

Integration planning is already underway, and we continue to expect the deal to close in late 2023 or early 2024, subject to the satisfaction of customary closing conditions.

By combining Seagen's category-leading antibody-drug conjugate technology with Pfizer's scale, expertise and capabilities, we believe we can accelerate potential breakthroughs in cancer medicines and introduce new solutions to patients around the world.

The potential combined commercial infrastructure for Pfizer and Seagen will be three times the size of that of Seagen alone in the U.S. – and 4-5 times larger globally. As a result, we believe acquiring Seagen could contribute more than \$10 billion in 2030 risk-adjusted revenues, with potential significant growth beyond 2030.

Even with the Seagen deal, given the strength of our balance sheet and cash flows, we continue to have the flexibility to take additional actions to create shareholder value. Dave will provide more details on this during his presentation.

[Slide 11: Continuing to Build Trust in Our Brand]

One of the key areas of focus for Pfizer in 2023 is continuing to build trust – which is a key asset for every biopharmaceuticals company. Since the beginning of the year, we have received two accolades that demonstrate we are doing just that.

In February, Pfizer was named to the top ten of Fortune's Most Admired Companies List for the second year in a row. And in March, Ethisphere recognized Pfizer as one of the world's most ethical companies – also for the second year in a row.

At Pfizer, trust is everything. It gives us our license to operate, allows us to attract the best talent and enables us to deliver breakthroughs that change patients' lives.

With that, I will turn it over to Dave. After Dave, Mikael will provide an update on our R&D pipeline.

[Slide 12: Financial Review – David Denton]

David Denton – Pfizer Inc. – Chief Financial Officer, Executive Vice President

[Slide 13: Efficient Cash Deployment Strategy Focused on Three Pillars]

Thank you, Albert, and good morning, everyone.

I want to begin with Pfizer's capital allocation strategy before we dive into additional commentary about our quarterly performance and outlook for the remainder of 2023.

As you know our strategy includes three pillars: reinvesting in the business; growing and paying dividends; and repurchasing our shares.

In the first three months of 2023, we've invested:

- \$2.5 billion in internal R&D
- And returned \$2.3 billion to shareholders via our quarterly dividend
- And importantly, allocated approximately \$43 billion for the proposed Seagen acquisition

Over the last few years, we have reinvested heavily into the business, to drive long-term growth and enhance long-term shareholder value. We have invested in Pfizer's own science, while acquiring the best external science to supplement our pipeline. Since 2022, we've invested approximately \$70 billion, including Seagen, in business development.

In addition, we have continued to grow our dividend. For the past 14 years, we have raised our dividend annually. Since 2010, our quarterly cash dividend grew from \$0.16 a share to \$0.41 a share in 2023.

Looking ahead, as we exit this unprecedented period of anticipated launches, we would expect to achieve margin improvement over time.

As we begin to de-lever our capital structure after the closing of the Seagen transaction, we expect to return to a more balanced capital allocation mix between our three pillars. While we will continue to invest in our business, we do expect more balance between that priority and returning value to our shareholders via increased dividends and value-enhancing share repurchases.

Our capital allocation strategy is squarely focused on driving shareholder value while at the same time remaining committed to a high investment grade/Tier-1 commercial paper rating.

[Slide 14: Quarterly Income Statement Highlights]

Turning to the quarter. As Albert said, our results were in line with our expectations, albeit slightly better than consensus,

As expected, overall revenues declined 26% operationally, primarily driven by the anticipated decline in Comirnaty, which was partially offset by strong Paxlovid sales.

I want to point out that our COVID-19 products produced \$7.1 billion in revenues in the first-quarter.

Our non-COVID operational revenue growth was solid at 5% year over year.

Primarily driving this growth was the inclusion of Nurtec ODT and Oxbryta, and an increase in Sulperazon revenues in China. Revenues for Eliquis in the US and the Vyndaqel family globally also contributed to this growth.

I want to remind you of the seasonality of some of our products - in the first-quarter, Nurtec ODT and Oxbryta typically have lower sales quarter-on-quarter due to annual copay reset dynamics, with higher sales anticipated in later quarters. Most important, both products continue to experience strong growth in demand.

Sulperazon revenues increased more than \$100 million year-over-year, due to higher demand in China during the quarter, which we do not expect to be sustained going forward. The demand was due to increased bacterial infections from more patients being hospitalized for COVID.

To help ensure the success of the expected launches of our large number of new and acquired products and indications, we increased our investments in SI&A. These investments are squarely focused on Pfizer's 2025 to 2030 growth aspirations.

Moving to the bottom line, reported diluted EPS this quarter declined by 29% to \$0.97, while Adjusted diluted EPS of \$1.23 declined 20% on an operational basis in the quarter.

Once again this quarter, foreign exchange movements significantly impacted our results, reducing first-quarter revenues by \$730 million, or 3%, and Adjusted diluted EPS by \$0.07, or 4%, compared to last year.

[Slide 15: Reaffirms 2023 Revenues and Adjusted Diluted EPS]

Turning now to the full-year financial outlook for the company. Our full-year 2023 guidance remains unchanged.

On a total company basis, we continue to expect revenues of \$67 to \$71 billion, reflecting an operational decline of 31% at the midpoint.

With 5% operational growth in our non-COVID revenues this quarter, we are on-track to achieve our non-COVID revenue guidance of 7-9% operational growth for the year.

Given that a large number of launches are expected to occur in the third- and fourth-quarters of 2023, we anticipate our quarterly revenues will not be linear this year, and that our non-COVID revenues will grow more quickly in the back half of the year versus the first-half of 2023.

In terms of our COVID products — Comirnaty and Paxlovid — we expect sales to trend more seasonally in 2023. Given these dynamics, we expect significantly lower sales contributions from our COVID products in the second-quarter versus the first-quarter.

In fact, given the anticipated timing of approvals for a fall vaccine with strain change, we would expect more substantial vaccine deliveries to start in September, which is late in the U.S. third-quarter and the beginning of our international fourth-quarter.

With respect to Paxlovid, we continue to expect 2023 to be a transitional year as we anticipate shifting to a commercial market in the second half of this year.

We are reaffirming our Adjusted diluted EPS guidance range of \$3.25 to \$3.45. On a full-year basis, we expect that foreign exchange will have an unfavorable impact compared with full-year 2022 of approximately \$0.13, on Adjusted diluted EPS.

We are also reaffirming the remaining components of our full-year 2023 guidance, which you can find in the Appendix of the Q1 2023 earnings presentation.

In closing, this is an exciting period for Pfizer as we continue to invest to drive long-term growth and importantly enhance long-term shareholder value.

With that, let me turn it over to Mikael.

[Slide 16: Scientific Updates – Mikael Dolsten]

Mikael Dolsten – *Pfizer Inc. – Chief Scientific Officer and President, Worldwide Research, Development and Medical*

Thank you, Dave. Today I'd like to start off with one of the four pillars of our oncology portfolio, which are breast, urogenital, blood cancers and precision medicine.

[Slide 17: Building Upon Standard of Care in Prostate Cancer]

Within urogenital, prostate cancer is an area in which we have strong momentum. Recent positive study results further strengthen our franchise, building upon the global standard of care set by XTANDI, and underscoring our long-standing commitment to the pursuit of breakthroughs that define new standards of care in prostate cancer.

I'll highlight data from two Phase 3 studies, EMBARK and TALAPRO-2, as well as early, but promising signals from our EZH2 inhibitor, each of which has the potential to reach broader patient populations across the treatment continuum in prostate cancer.

[Slide 18: TALZENNA + XTANDI Improves Final rPFS in Phase 3 mCRPC Study]

Final analysis from TALAPRO-2, evaluating our potential blockbuster PARP inhibitor TALZENNA in combination with XTANDI were presented at ASCO GU. Results showed significant and clinically meaningful improvement across the all-comers population in radiographic progression free survival, or rPFS, in men with metastatic castration resistant prostate cancer, with or without homologous recombination repair or HRR gene mutations.

There was a 37% reduction in risk of disease progression. Median rPFS in patients treated with TALZENNA and XTANDI was not reached at the time of analysis versus 21.9 months for placebo plus XTANDI.

A trend in overall survival favoring TALZENNA plus XTANDI was also observed, though these data are immature. The final OS data will be reported once the predefined number of survival events has been reached.

[Slide 19: TALZENNA + XTANDI Improves ORR in Phase 3 mCRPC Study]

Treatment with TALZENNA and XTANDI resulted in statistically significant improvement in overall response rates, which suggest a potential cooperative effect between the two treatments.

The U.S. FDA has granted Priority Review for our sNDA for TALZENNA in combination with XTANDI for metastatic castration resistant prostate cancer, with a decision expected in 2023. The ongoing TALAPRO-3 study, if successful, may further expand the reach of this potential blockbuster into the HRR-deficient metastatic castration sensitive population.

[Slide 20: XTANDI + Leuprolide Improves MFS in Phase 3 nmCSPC Study]

We recently presented data from our Phase 3 EMBARK study evaluating XTANDI plus leuprolide in men with non-metastatic hormone-sensitive prostate cancer with high-risk biochemical recurrence at the American Urological Association's 2023 Annual Meeting.

The study met its primary endpoint with statistically significant and clinically meaningful improvement in metastasis-free survival, with a 58% reduction in risk for radiographic progression or death. Key secondary endpoints were met including time to PSA progression.

These results suggest XTANDI—the only novel hormone therapy approved for three disease states of prostate cancer in the U.S.—has the potential if approved to expand to patients in the hormone-sensitive, or castration sensitive setting, for the first time.

[Slide 21: PF-06821497: Potential First-in-Class EZH2i in Prostate Cancer]

Next, I'd like to share early data from one of our next-wave candidates, a potential first-in-class and best-in-class EZH2 inhibitor, which we shorthand as '1497.

EZH2 is an epigenetic transcriptional repressor that is frequently overexpressed in prostate cancer. We believe that inhibition of EZH2 may provide synergistic effects in combination with XTANDI, with the potential to address unmet needs of patients with androgen-sensitive and resistant disease.

Here are data from our ongoing Phase 1/2 study evaluating '1497 in second line mCRPC patients with prior abiraterone and/or XTANDI, and up to one line of chemotherapy. On the left are updated data from a Phase 1 dose escalation study shared at ESMO last year.

These encouraging results show durable anti-tumor activity in both XTANDI-naïve and -experienced patients, with all XTANDI-naïve patients having received prior abiraterone. Importantly, this suggests that the addition of our EZH2 inhibitor has the potential to sensitize XTANDI-resistant tumors, which is an increasing clinical unmet need.

The early rPFS data are also highly encouraging—reaching 8.7 months in the XTANDI-experienced patients and 17.1 months in XTANDI-naïve—both of which are notably longer than historical controls. For example, in the control arm of the CARD study, rPFS for XTANDI alone was 4.8 months in XTANDI-naïve patients.

And although cross-trial comparisons cannot be made, these results, in combination with the emerging objective response rate and PSA50 response, are supportive of the contribution of our EZH2 inhibitor candidate in driving these responses.

From a safety perspective, the combination was generally well tolerated, with mostly Grade 1 and 2 events. The randomized Phase 2 study in second line mCRPC is ongoing, with data expected in early 2024.

[Slide 22: Potential Near-Term Growth in Respiratory Vaccines]

Now, we turn to the potential for near-term growth across our respiratory vaccine franchise.

Prevnar 20, our 20-valent pneumococcal conjugate vaccine, is now approved for children aged 6 weeks through 17 years. We are confident in our ability to maintain leadership in the pneumococcal vaccine space with Prevnar 20, which offers the broadest serotype coverage of any pediatric pneumococcal conjugate vaccine, helping to protect against the 20 serotypes in the vaccine.

We have strong momentum with our RSV vaccine candidate, having received a positive Vaccines and Related Biological Products Advisory Committee vote supporting potential approval to help combat RSV in older adults and PDUFA dates for our Older Adult and Maternal indications in quick succession in the

coming months. Just last month, the New England Journal of Medicine published results from the two Phase 3 studies.

Emerging data from the middle of the second RSV season in the Northern Hemisphere in the Phase 3 Older Adult study support meaningful durable vaccine efficacy; we will share the data once complete.

In the coming months, we plan to start a Phase 3 study of the RSV vaccine candidate in 18-60-year-olds at high risk for RSV and in immunocompromised adults 18 and over, and a Phase 1 study in 2-18-year-olds at high risk, with the potential to broadly expand the reach of our vaccine candidate both to those aged 18-60 with high-risk conditions as well as to pediatrics and adolescents.

Our RSV-Flu coadministration study met its primary endpoint, demonstrating non-inferiority for all four flu strains and RSV A and B strains. This suggests the RSV vaccine candidate, if approved, could be co-administered with flu vaccinations and add an important component of seasonal protection against respiratory pathogens.

Finally, the FDA recently updated the Emergency Use Authorization for our Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine to enable those at higher risk of severe COVID-19 illness, including the elderly and the immunocompromised, to partner with their healthcare providers to be proactive in helping protect themselves against COVID-19. We anticipate another update from FDA in June that will provide guidance on COVID-19 vaccine strains and vaccination timing for the 2023 fall and winter seasons.

[Slide 23: Potent and Selective 2nd Generation Oral COVID-19 Antiviral]

Beyond vaccines, antivirals are an important component of our strategy in respiratory viruses.

Here we share data for the first time from our second generation oral COVID-19 antiviral candidate, a potent and selective SARS-CoV-2 Mpro inhibitor that is currently in Phase 1 development.

We designed this candidate to achieve clinical exposures that would have similar anti-viral activity to PAXLOVID, without the need for ritonavir boosting and with the potential for reduced drug interactions.

Early results from Phase 1 dose escalation are encouraging, with no dose limiting safety or tolerability findings. Dosing achieved concentrations many-fold over in vitro EC90 and is therefore expected to have similar antiviral activity to PAXLOVID.

On the right are preliminary results from a Phase 1 pharmacokinetic study of midazolam drug interaction, which is a well-known standard for indicating CYP3A4-mediated drug-drug interactions. These data show there is a lack of such drug-drug interactions, suggesting there may be no related restrictions of co-dosing with drugs metabolized by CYP enzymes.

Based on these encouraging data, we are planning to advance to a Phase 2 dose-ranging study in the first half of 2023.

[Slide 24: Strong Launch Execution and Next Wave Pipeline Candidates]

In addition to the assets I spoke about today, we continue to make progress on the pipeline with more than 25 milestones recently achieved or anticipated through the first half of 2024.

In inflammation & immunology, the FDA has approved our sNDA for CIBINQO, enabling a label expansion for adolescents with moderate-to-severe atopic dermatitis.

In internal medicine, ZAVZPRET migraine nasal spray has received FDA approval, expanding our migraine portfolio.

Recently, the FDA Advisory Committee voted in support of PAXLOVID's favorable benefit-risk profile, with a PDUFA date in May.

In closing, we are very excited about the potentially transformative catalysts expected across the pipeline as we work with continued urgency to bring breakthroughs to patients.

Thank you. Let me turn it over to Chris to start the Q&A session.

Disclosure Notice: *This material represents prepared remarks for Pfizer Inc.'s earnings conference call and is not an official transcript. Except where otherwise noted, the information contained in these prepared remarks is as of May 2, 2023. We assume no obligation to update any forward-looking statements contained in these prepared remarks as a result of new information or future events or developments.*

These prepared remarks contains forward-looking statements about, among other topics, our anticipated operating and financial performance; reorganizations; business plans, strategy and prospects; our Environmental, Social and Governance (ESG) priorities, strategy and goals; expectations for our product pipeline, in-line products and product candidates, including anticipated regulatory submissions, data read-outs, study starts, approvals, launches, clinical trial results and other developing data, revenue contribution and projections, potential pricing and reimbursement, potential market dynamics and size, growth, performance, timing of exclusivity and potential benefits; strategic reviews; capital allocation objectives; dividends and share repurchases; plans for and prospects of our acquisitions, dispositions and other business development activities, including our proposed acquisition of Seagen, and our ability to successfully capitalize on these opportunities; manufacturing and product supply; our ongoing efforts to respond to COVID-19, including the Pfizer-BioNTech COVID-19 Vaccine (Comirnaty), the Pfizer-BioNTech COVID-19 Omicron BA.4/BA.5 Vaccine, Bivalent (the Pfizer-BioNTech COVID-19 bivalent vaccine), other vaccines that may result from the BNT162 program, including new variant-based or next-generation vaccines, Comirnaty (as defined in Q1 2023 earnings release issued on May 2, 2023) and our oral COVID-

19 treatment (Paxlovid); and our expectations regarding the impact of COVID-19 on our business, operations and financial results that involve substantial risks and uncertainties. You can identify these statements by the fact that they use future dates or use words such as “will,” “may,” “could,” “likely,” “ongoing,” “anticipate,” “estimate,” “expect,” “project,” “intend,” “plan,” “believe,” “assume,” “target,” “forecast,” “guidance,” “goal,” “objective,” “aim,” “seek,” “potential,” “hope” and other words and terms of similar meaning. Among the factors that could cause actual results to differ materially from past results and future plans and projected future results are the following:

Risks Related to Our Business, Industry and Operations, and Business Development:

- *the outcome of research and development (R&D) activities, including, the ability to meet anticipated pre-clinical or clinical endpoints, commencement and/or completion dates for our pre-clinical or clinical trials, regulatory submission dates, and/or regulatory approval and/or launch dates; the possibility of unfavorable pre-clinical and clinical trial results, including the possibility of unfavorable new pre-clinical or clinical data and further analyses of existing pre-clinical or clinical data; risks associated with preliminary, early stage or interim data; the risk that pre-clinical and clinical trial data are subject to differing interpretations and assessments, including during the peer review/publication process, in the scientific community generally, and by regulatory authorities; and whether and when additional data from our pipeline programs will be published in scientific journal publications and, if so, when and with what modifications and interpretations;*
- *our ability to successfully address comments received from regulatory authorities such as the U.S. Food and Drug Administration or the European Medicines Agency, or obtain approval for new products and indications from regulators on a timely basis or at all; regulatory decisions impacting labeling, including the scope of indicated patient populations, product dosage, manufacturing processes, safety and/or other matters, including decisions relating to emerging developments regarding potential product impurities; the impact of, or uncertainties regarding the ability to obtain, recommendations by technical or advisory committees; and the timing of pricing approvals and product launches;*
- *claims and concerns that may arise regarding the safety or efficacy of in-line products and product candidates, including claims and concerns that may arise from the outcome of post-approval clinical trials, which could impact marketing approval, product labeling, and/or availability or commercial potential, including uncertainties regarding the commercial or other impact of the results of the Xeljanz ORAL Surveillance (A3921133) study or actions by regulatory authorities based on analysis of ORAL Surveillance or other data, including on other Janus kinase (JAK) inhibitors in our portfolio;*
- *the success and impact of external business-development activities, including the ability to identify and execute on potential business development opportunities; the ability to satisfy the conditions to closing of announced transactions in the anticipated time frame or at all; the ability to realize the*

anticipated benefits of any such transactions in the anticipated time frame or at all; the potential need for and impact of additional equity or debt financing to pursue these opportunities, which could result in increased leverage and/or a downgrade of our credit ratings; challenges integrating the businesses and operations; disruption to business and operations relationships; risks related to growing revenues for certain acquired products; significant transaction costs; and unknown liabilities;

- risks and uncertainties related to Pfizer's proposed acquisition of Seagen, including, among other things, risks related to the satisfaction or waiver of the conditions to closing the proposed acquisition (including the failure to obtain necessary regulatory approvals and failure to obtain the requisite vote by Seagen stockholders) in the anticipated timeframe or at all, including the possibility that the proposed acquisition does not close; the possibility that competing offers may be made; risks related to the ability to realize the anticipated benefits of the proposed acquisition, including the possibility that the expected benefits from the acquisition will not be realized or will not be realized within the expected time period; the risk that the businesses will not be integrated successfully; disruption from the transaction making it more difficult to maintain business and operational relationships; negative effects of the announcement or the consummation of the proposed acquisition on the market price of Pfizer's common stock and/or operating results; significant transaction costs; unknown liabilities; the risk of litigation and/or regulatory actions related to the proposed acquisition or Seagen's business; risks related to the financing of the transaction; other business effects and uncertainties, including the effects of industry, market, business, economic, political or regulatory conditions; future exchange and interest rates; changes in tax and other laws, regulations, rates and policies; the impact of the proposed acquisition on future business combinations or disposals; uncertainties regarding the commercial success of Pfizer's and Seagen's commercialized and pipeline products; the uncertainties inherent in R&D; whether and when drug applications may be filed in any jurisdictions for Pfizer's or Seagen's pipeline products; whether and when any such applications may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether any such products will be commercially successful; and competitive developments;*
- competition, including from new product entrants, in-line branded products, generic products, private label products, biosimilars and product candidates that treat or prevent diseases and conditions similar to those treated or intended to be prevented by our in-line products and product candidates;*
- the ability to successfully market both new and existing products, including biosimilars;*

- *difficulties or delays in manufacturing, sales or marketing; supply disruptions, shortages or stock-outs at our facilities or third-party facilities that we rely on; and legal or regulatory actions;*
- *the impact of public health outbreaks, epidemics or pandemics (such as COVID-19) on our business, operations and financial condition and results, including impacts on our employees, manufacturing, supply chain, sales and marketing, research and development and clinical trials;*
- *risks and uncertainties related to our efforts to develop and commercialize our COVID-19 products, as well as challenges related to their manufacturing, supply and distribution, including, among others, uncertainties inherent in R&D, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with pre-clinical and clinical data (including Phase 1/2/3 or Phase 4 data for Comirnaty, any monovalent, bivalent or variant-adapted vaccine candidates or any other vaccine candidate in the BNT162 program or Paxlovid or any future COVID-19 treatment) in any of our studies in pediatrics, adolescents or adults or real world evidence, including the possibility of unfavorable new pre-clinical, clinical or safety data and further analyses of existing pre-clinical, clinical or safety data or further information regarding the quality of pre-clinical, clinical or safety data, including by audit or inspection; the ability to produce comparable clinical or other results for Comirnaty, any monovalent, bivalent or variant-adapted vaccine candidates or other vaccines that may result from the BNT162 program, Paxlovid or any future COVID-19 treatment or any other COVID-19 program, including the rate of effectiveness and/or efficacy, safety and tolerability profile observed to date, in additional analyses of the Phase 3 trial for any such products and additional studies, in real-world data studies or in larger, more diverse populations following commercialization; the ability of Comirnaty, any monovalent, bivalent or variant-adapted vaccine candidates or any future vaccine to prevent, or Paxlovid or any future COVID-19 treatment to be effective against, COVID-19 caused by emerging virus variants; the risk that demand for any products may be reduced, no longer exist or not meet expectations, which may lead to excess inventory on-hand and/or in the channel or reduced revenues; challenges related to a transition to the commercial market for any of our products; uncertainties related to the public's adherence to vaccines, boosters and treatments; the risk that use of Comirnaty or Paxlovid will lead to new information about efficacy, safety or other developments, including the risk of additional adverse reactions, some of which may be serious; the risk that pre-clinical and clinical trial data are subject to differing interpretations and assessments, including during the peer review/publication process, in the scientific community generally, and by regulatory authorities; whether and when additional data from the BNT162 mRNA vaccine program, Paxlovid or other COVID-19 programs will be published in scientific journal publications and, if so, when and with what modifications and interpretations; whether regulatory authorities will be satisfied with the design of and results from existing or future pre-clinical and clinical studies; whether and when submissions to request*

emergency use or conditional marketing authorizations for Comirnaty or any future vaccines in additional populations, for a potential booster dose for Comirnaty, any monovalent or bivalent vaccine candidates or any potential future vaccines (including potential future annual boosters or re-vaccinations), and/or biologics license and/or EUA applications or amendments to any such applications may be filed in particular jurisdictions for Comirnaty, any monovalent or bivalent vaccine candidates or any other potential vaccines that may arise from the BNT162 program, including a potential variant-based, higher dose, or bivalent vaccine or any other potential vaccines, and if obtained, whether or when such EUA or licenses, or existing EUAs, will expire or terminate; whether and when submissions to request emergency use or conditional marketing authorizations for Paxlovid or any future COVID-19 treatment and/or any drug applications and/or EUA applications or amendments to any such applications for any indication for Paxlovid or any future COVID-19 treatment may be filed in particular jurisdictions, and if obtained, whether or when such EUA or licenses, or existing EUAs, will expire or terminate; whether and when any application that may be pending or filed for Comirnaty, any monovalent, bivalent or variant-adapted vaccine candidates or other vaccines that may result from the BNT162 program, Paxlovid or any future COVID-19 treatment or any other COVID-19 program may be approved by particular regulatory authorities, which will depend on myriad factors, including making a determination as to whether the vaccine's or drug's benefits outweigh its known risks and determination of the vaccine's or drug's efficacy and, if approved, whether it will be commercially successful; decisions by regulatory authorities impacting labeling or marketing, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of a vaccine or drug, including the authorization or approval of products or therapies developed by other companies; disruptions in the relationships between us and our collaboration partners, clinical trial sites or third-party suppliers, including our relationship with BioNTech; the risk that other companies may produce superior or competitive products; risks related to the availability of raw materials to manufacture or test any such products; challenges related to our vaccine's formulation, dosing schedule and attendant storage, distribution and administration requirements, including risks related to storage and handling after delivery by Pfizer; challenges and risks related to medication errors such as prescribing or dispensing the wrong strength, improper dosing and self-administration errors; the risk that we may not be able to successfully develop other vaccine formulations, booster doses or potential future annual boosters or re-vaccinations or new variant-based or next generation vaccines, potential combination respiratory vaccines or next generation COVID-19 treatments; the risk that we may not be able to recoup costs associated with our R&D and manufacturing efforts; risks associated with any changes in the way we approach or provide research funding for the BNT162 program, Paxlovid or any other COVID-19 program; challenges and risks associated with the pace of our development programs; the risk that we may not be able to maintain manufacturing

capacity or access to logistics or supply channels commensurate with global demand for our COVID-19 products, which would negatively impact our ability to supply our COVID-19 products within the projected time periods; risks related to our ability to achieve our revenue forecasts for Comirnaty and Paxlovid or any potential future COVID-19 vaccines or treatments; whether and when additional supply or purchase agreements will be reached or existing agreements will be completed or renegotiated; uncertainties regarding the ability to obtain recommendations from vaccine or treatment advisory or technical committees and other public health authorities and uncertainties regarding the commercial impact of any such recommendations; pricing and access challenges for such products; challenges related to public confidence in, or awareness of Comirnaty or Paxlovid, including challenges driven by misinformation or disinformation, access, concerns about clinical data integrity, or prescriber and pharmacy education; uncertainties around future changes to applicable healthcare policies and guidelines issued by the U.S. federal government in connection with the declared termination of the federal government's COVID-19 public health emergency as of May 11, 2023; trade restrictions; potential third-party royalties or other claims related to Comirnaty or Paxlovid; and competitive developments;

- trends toward managed care and healthcare cost containment, and our ability to obtain or maintain timely or adequate pricing or favorable formulary placement for our products;*
- interest rate and foreign currency exchange rate fluctuations, including the impact of possible currency devaluations and monetary policy actions in countries experiencing high inflation rates;*
- any significant issues involving our largest wholesale distributors or government customers, which account for a substantial portion of our revenues;*
- the impact of the increased presence of counterfeit medicines or vaccines in the pharmaceutical supply chain;*
- any significant issues related to the outsourcing of certain operational and staff functions to third parties; and any significant issues related to our joint ventures and other third-party business arrangements;*
- uncertainties related to general economic, political, business, industry, regulatory and market conditions including, without limitation, uncertainties related to the impact on us, our customers, suppliers and lenders and counterparties to our foreign-exchange and interest-rate agreements of challenging global economic conditions, such as inflation, and recent and possible future changes in global financial markets;*
- any changes in business, political and economic conditions due to actual or threatened terrorist activity, geopolitical instability, civil unrest or military action;*
- the impact of product recalls, withdrawals and other unusual items, including uncertainties related to regulator-directed risk evaluations and assessments, including our ongoing evaluation of our product portfolio for the potential presence or formation of nitrosamines;*

- *trade buying patterns;*
- *the risk of an impairment charge related to our intangible assets, goodwill or equity-method investments;*
- *the impact of, and risks and uncertainties related to, restructurings and internal reorganizations, as well as any other corporate strategic initiatives and growth strategies, and cost-reduction and productivity initiatives, each of which requires upfront costs but may fail to yield anticipated benefits and may result in unexpected costs or organizational disruption;*
- *the ability to successfully achieve our climate goals and progress our environmental sustainability priorities;*

Risks Related to Government Regulation and Legal Proceedings:

- *the impact of any U.S. healthcare reform or legislation or any significant spending reductions or cost controls affecting Medicare, Medicaid or other publicly funded or subsidized health programs, including the Inflation Reduction Act of 2022, or changes in the tax treatment of employer-sponsored health insurance that may be implemented;*
- *U.S. federal or state legislation or regulatory action and/or policy efforts affecting, among other things, pharmaceutical product pricing, intellectual property, reimbursement or access or restrictions on U.S. direct-to-consumer advertising; limitations on interactions with healthcare professionals and other industry stakeholders; as well as pricing pressures for our products as a result of highly competitive insurance markets;*
- *legislation or regulatory action in markets outside of the U.S., such as China or Europe, including, without limitation, laws related to pharmaceutical product pricing, intellectual property, regulatory data protection, environmental impact of medicines, reimbursement or access, including, in particular, continued government-mandated reductions in prices and access restrictions for certain biopharmaceutical products to control costs in those markets;*
- *the exposure of our operations globally to possible capital and exchange controls, economic conditions, expropriation and other restrictive government actions, changes in intellectual property legal protections and remedies, the impact of political or civil unrest or military action, including the ongoing conflict between Russia and Ukraine and its economic consequences, unstable governments and legal systems, inter-governmental disputes and natural disasters or disruptions related to climate change;*
- *legal defense costs, insurance expenses, settlement costs and contingencies, including those related to actual or alleged environmental contamination;*
- *the risk and impact of an adverse decision or settlement and the risk related to adequacy of reserves related to legal proceedings;*
- *the risk and impact of tax related litigation and investigations;*

- *governmental laws and regulations affecting our operations, including, without limitation, the recently enacted Inflation Reduction Act of 2022, changes in laws and regulations or their interpretation, including, among others, changes in tax laws and regulations internationally and in the U.S., the adoption of global minimum taxation requirements outside the U.S. and potential changes to existing tax law by the current U.S. Presidential administration and Congress;*

Risks Related to Intellectual Property, Technology and Security:

- *any significant breakdown or interruption of our information technology systems and infrastructure (including cloud services);*
- *any business disruption, theft of confidential or proprietary information, security threats on facilities or infrastructure, extortion or integrity compromise resulting from a cyber-attack or other malfeasance by, but not limited to, nation states, employees, business partners or others;*
- *the risk that our currently pending or future patent applications may not be granted on a timely basis or at all, or any patent-term extensions that we seek may not be granted on a timely basis, if at all; and*
- *risks to our products, patents and other intellectual property, such as: (i) claims of invalidity that could result in loss of exclusivity; (ii) claims of patent infringement, including asserted and/or unasserted intellectual property claims; (iii) claims we may assert against intellectual property rights held by third parties; (iv) challenges faced by our collaboration or licensing partners to the validity of their patent rights; or (v) any pressure, or legal or regulatory action by, various stakeholders or governments that could potentially result in us not seeking intellectual property protection or agreeing not to enforce or being restricted from enforcing intellectual property rights related to our products, including Comirnaty and Paxlovid.*

We cannot guarantee that any forward-looking statement will be realized. Should known or unknown risks or uncertainties materialize or should underlying assumptions prove inaccurate, actual results could vary materially from past results and those anticipated, estimated or projected. Investors are cautioned not to put undue reliance on forward-looking statements. A further list and description of risks, uncertainties and other matters can be found in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 and in our subsequent reports on Form 10-Q, in each case including in the sections thereof captioned “Forward-Looking Information and Factors That May Affect Future Results” and “Item 1A. Risk Factors,” and in our subsequent reports on Form 8-K.

These prepared remarks include discussion of certain financial measures that were not prepared in accordance with generally accepted accounting principles (GAAP). Reconciliations of those non-GAAP financial measures to the most directly comparable GAAP financial measures can be found in the Company’s Current Report on Form 8-K dated May 2, 2023.

These prepared remarks may include discussion of certain clinical studies relating to various in-line products and/or product candidates. These studies typically are part of a larger body of clinical data relating to such products or product candidates, and the discussion herein should be considered in the context of the larger body of data. In addition, clinical trial data are subject to differing interpretations, and, even when we view data as sufficient to support the safety and/or effectiveness of a product candidate or a new indication for an in-line product, regulatory authorities may not share our views and may require additional data or may deny approval altogether.

Paxlovid and the Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) have not been approved or licensed by the FDA. Paxlovid has been authorized for emergency use by the FDA under an EUA, for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with a current diagnosis of mild-to-moderate COVID-19 and who are at high risk for progression to severe COVID-19, including hospitalization or death. The Pfizer-BioNTech COVID-19 Vaccine, Bivalent has been authorized by the FDA under an EUA to prevent COVID-19 in individuals aged 6 months and older. The emergency uses are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product during the COVID-19 pandemic under Section 564(b)(1) of the FFDCA unless the declaration is terminated or authorization revoked sooner. Please see the EUA Fact Sheets at www.covid19oralrx.com and www.cvdvaccine-us.com.

The information contained on our website or any third-party website is not incorporated by reference into this earnings release.

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