



## **Third-Quarter 2023 Earnings Conference Call Prepared Remarks October 31, 2023**

**[Slide 4: Opening Remarks – Albert Bourla]**

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

**[Slide 5: YTD Q3 2023: Patient Impact]**

Pfizer continues to have a far-reaching and positive impact on human health.

Through the first nine months of the year, more than 457 million patients around the world were treated with our medicines and vaccines. Compared with the first nine months of 2022, we have reached more patients in several key therapeutic areas, including oncology, cardiovascular disease and anti-infectives.

Patients will always be our North Star, and these figures serve as a testament to our leadership in innovation and our commitment to understanding and serving patients' needs.

**[Slide 6: Q3 2023: Continued Strength in Pfizer's Non-COVID Portfolio]**

During the third quarter, we were encouraged by the continued strong performance of Pfizer's non-COVID products, with revenue from these products growing 10% operationally compared with the year-ago quarter. We saw significant contributions from new launches and robust year-over-year growth for several key in-line brands.

Our recently launched respiratory syncytial virus (RSV) vaccine, Abrysvo, contributed \$375 million in U.S. revenues. With the recent approval of the maternal indication, Pfizer is the only company with an RSV vaccine approved for preventing RSV in older adults and in infants via maternal immunization. We believe Abrysvo will be a significant and growing contributor to revenue as many customers have indicated to us that protecting both populations with one vaccine is desirable and a competitive advantage for Abrysvo. In the U.S. alone, there are approximately 80 million adults over age 60 who are eligible for RSV vaccination, and an estimated 1.5 million pregnant women are eligible for maternal immunization with our RSV vaccine between September 2023 and January 2024.

Nurtec ODT/Vydura and Oxbryta, which were acquired in the fourth quarter of 2022, contributed \$233 million and \$85 million in global revenues, respectively.

- For Nurtec, in the U.S., oral CGRPs represent about 17% of the migraine market, and the unmet need is high. We believe oral CGRPs can ultimately be the first-line therapy for migraine and could eventually account for as much as 40% of the overall migraine market. Primary Care is a clear source of potential growth in the migraine marketplace. Year to date, Primary Care healthcare providers wrote more than 6.1 million prescriptions for Triptans compared with approximately 1 million for oral CGRPs, which highlights a significant potential opportunity for growth.
- Regarding Oxbryta, there is significant burden of illness and unmet need for patients suffering from sickle cell disease (SCD). An estimated 12 million people around the world have SCD, with the highest prevalence in countries with the lowest resources. While in the U.S. 95% of children survive to adulthood, 99% of children in other regions will die before they reach their 5th birthday – many without ever being diagnosed[i].

Our Vyndaqel family of products – including Vyndaqel, Vyndamax and Vynmac – recorded 47% operational growth globally compared with the third quarter of 2022. This growth was driven largely by continued strong uptake of the transthyretin amyloid cardiomyopathy (ATTR-CM) indication, primarily in the U.S. and developed Europe. We estimate there are between 120,000-150,000 people suffering from transthyretin cardiac amyloidosis, with the majority still not yet diagnosed. The largest unmet need continues to be the lack of general understanding and ability to diagnose this deadly disease, which is why we are focused on educational activities to expedite diagnosis and get appropriate patients on to treatment with Vyndaqel/Vyndamax as the proven standard of care. Such efforts significantly contributed to this quarter's revenue increase in the U.S.

And our Prevnar family of products (Prevnar 13 & 20) saw global revenue rise 15% operationally compared with the year-ago quarter. This increase was driven primarily by strong patient demand for Prevnar 20 Adult in the U.S., the U.S. approval of Prevnar 20 Pediatric and associated stocking, and growth of Prevnar 13 Pediatric in certain emerging markets. These were partially offset by anticipated lower market share in the U.S. for Prevnar Pediatric due to competitive entry. Of note, Prevnar 20 Adult remains the category-leading pneumococcal vaccine for adults in the U.S. with a 95% market share in the third quarter.

Year-to-date, revenues for our non-COVID products have grown 7% operationally, and we remain on track to deliver 6-8% operational revenue growth for these products for the full year.

#### **[Slide 7: Excellent Progress Toward Expected Commercial Launches]**

We continue to progress toward our goal of executing an unprecedented number of launches of new products or indications.

Recent milestones include:

- U.S. and EC approvals and launch of Abrysvo in pregnant individuals;
- U.S. approval and launch of Elrexfio in relapsed refractory multiple myeloma;
- U.S. approval of our Braftovi+Mektovi combination in BRAF-mutated metastatic non-small cell lung cancer;
- U.S. approval of Velsipity for moderate to severe ulcerative colitis;
- EC approval of Litfulo for severe alopecia areata; and
- U.S. approval of Penbraya, the first and only pentavalent vaccine that provides coverage against the five most common serogroups causing meningococcal disease in adolescents and young adults 10 through 25 years of age.

To date, we have now executed 13 of the 19 originally identified potential launches, with four other products approved and preparations being made for their launch. In fact, five of the six remaining potential launches have been largely de-risked from a technical perspective. The only one remaining would be our mRNA flu candidate. Given our recent positive results from our next-generation mRNA flu/COVID combination candidate and pending results for our 65-and-older first-generation Phase 3 standalone mRNA flu study, timing for our standalone mRNA flu is now expected after 2024. If successful, our next-generation mRNA flu/COVID combination candidate is expected to market in 2025. Mikael will share more about these programs shortly.

#### **[Slides 8: Seagen Planning Continuing to Progress Well]**

We remain excited about our proposed acquisition of Seagen and the dramatic impact we think this combination can have on human health. One in three people will be diagnosed with cancer in their lifetime. So, conquering cancer would have an almost unimaginable impact on humanity.

We recently gained unconditional antitrust clearance from the EC, and we continue to expect the transaction to close in late 2023 or early 2024, subject to customary closing conditions, including clearance by the U.S. FTC. We have raised \$31 billion in acquisition financing so far and continue to expect incremental 2030 risk-adjusted revenues in excess of \$10 billion and expected cost efficiencies of \$1 billion to be realized by the end of year three post-closing – without impacting R&D programs.

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

## **[Slide 9: Financial Review – David Denton]**

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

Thank you, Albert, and good morning.

Before I review this quarter's results, I will address a couple of topics that have been top of mind with investors since our announcement on October 13th. These topics relate to our future U.S. government Paxlovid revenue forecasts, and our multi-year cost realignment program.

With respect to revenue recognition associated with the amended agreement, the U.S. government is expected to return an estimated 7.9 million EUA-labeled treatment courses and, in return, will receive a volume-based credit at an approximate value of \$4.2 billion at the end of 2023 for future treatment courses. Pfizer will also provide an additional 1 million treatment courses into the U.S. strategic national stockpile. As a result, Pfizer has an obligation to deliver an estimated 8.9 million treatment courses for which we will record approximately \$4.2 billion of revenue starting in 2024 as we deliver treatment courses. It is important to note that there is no cash compensation for the estimated 8.9 million treatment courses.

Regarding our cost realignment program, I want to reiterate that we expect to achieve at least \$3.5 billion of net cost savings by the end of 2024 vs the mid-point of our August 1, 2023, SI&A and R&D guidance. We expect \$1.0 billion of targeted savings in 2023 and expect an additional savings of at least \$2.5 billion in 2024. When I review the components of our revised full-year 2023 guidance in a moment, you will see that we have lowered the midpoints of both our SI&A and R&D guidance ranges by \$500 million, respectively.

## **[Slide 10: Quarterly Statement of Operations Highlights]**

Turning to the quarter. Our Q3 results, both top and bottom-line, were significantly, and negatively, impacted by our COVID products. Revenues declined 41% operationally, the result of the decrease in both Paxlovid and Comirnaty sales, while Adjusted diluted Loss Per Share was also significantly impacted by \$5.6 billion of non-cash inventory write-offs of COVID related inventories.

However, I want to emphasize, as Albert stated previously, that the operational revenue growth of our products in Q3, excluding Paxlovid and Comirnaty, was strong at 10%. Contributing to this strong performance were our newly approved RSV vaccine, Abrysvo, and the family of products associated with Prevnar and Vyndaqel. Additionally, our recently acquired products, Nurtec and Oxbryta, also contributed to this strong growth.

Our Reported diluted loss per share of \$0.42 and Adjusted diluted loss per share of \$0.17 in the quarter are primarily the result of the decline in Paxlovid and Comirnaty sales and the non-cash charge related to write-

offs of COVID related inventories. The inventory write-off of \$4.7 billion for Paxlovid and \$900 million for Comirnaty negatively affected Adjusted loss per share by 84 cents.

Foreign exchange movements had a de minimis unfavorable impact on third quarter revenues, and increased Adjusted diluted loss per share by 4 cents, or 2%, compared to last year.

**[Slide 11: Reaffirms 2023 Revenue and Adjusted Diluted EPS Guidance]**

Given we updated our full-year revenue and EPS guidance on October 13th, I am just going to hit a few highlights.

Total Company full-year 2023 revenues are expected to be in the range of \$58.0 billion to \$61.0 billion versus previous range of \$67.0 billion to \$70.0 billion. Importantly, we continue to expect 6% to 8% full-year operational revenue growth for non-COVID products year over year. As anticipated, the majority of this growth is occurring in the second half of the year, given the timing of our new product and indication launches. I want to remind you that beginning in Q4 we will overlap the acquisitions of Biohaven and Global Blood Therapeutics last year, which we completed on October 3rd and 5th, 2022, respectively.

**[Slide 12: 2023 Financial Guidance: Other Components]**

Adjusted cost of sales as a percentage of revenue is expected to be in the range of 41% to 43% primarily the result of the \$5.6 billion non-cash charge related to inventory write-offs for our COVID products.

Adjusted SI&A expenses are expected to be in a range of \$13.3 billion to \$14.3 billion, and Adjusted R&D expenses to be within a range of \$11.9 billion to \$12.9 billion. The mid-points of both ranges are now \$500 million lower than our original guidance.

As a result of all these items, the company now expects full year Adjusted diluted EPS to be in the range of \$1.45 to \$1.65 versus its original guidance range of \$3.25 to \$3.45.

All additional components of our guidance are included in our press release issued earlier today.

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

As discussed in prior quarters, our capital strategy is based on three core pillars: reinvesting in the business, growing our dividends over time; and making value-enhancing share repurchases.

In the first 9 months of 2023, we:

- Invested \$7.9 billion in internal R&D
- Returned \$6.9 billion to shareholders via our quarterly dividend
- And, allocated approximately \$43 billion towards the proposed Seagen acquisition.

Lastly, in addition to our completed \$31 billion unsecured debt offering in Q2 of this year, we are ready to execute the remaining short-term financing to complete the proposed Seagen acquisition upon fulfillment of the required closing conditions. We expect to de-lever our capital structure following the completion of this transaction, and as we de-lever, we anticipate returning to a more balanced capital allocation strategy, inclusive of share repurchases.

In closing, I want to reiterate that our product portfolio remains strong. We continue to be encouraged by the momentum of our non-COVID products in Q3 and are committed to the successful execution of our new product and indication launches that are taking place now through the end of 2023. We expect that the cost realignment program will improve our operating margins, enhancing long-term shareholder value.

With that, let me turn it over to Mikael.

**[Slide 14: Scientific Updates – Mikael Dolsten]**

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

Thank you, Dave. Today, I will share important updates from our robust respiratory vaccine portfolio.

**[Slide 15: Expanding Leadership Across Respiratory Vaccines]**

Our respiratory vaccines are built upon three cutting-edge platforms that enable us to bring the right science to the right pathogen. These include our mRNA platform in partnership with BioNTech targeting highly variant viruses, our subunit platform targeting viruses that remain relatively consistent season to season, and our conjugate vaccine platform designed to help prevent bacterial infections.

We have achieved FDA approvals of vaccines derived from each platform within the last year and aim to further expand our leadership with additional vaccine candidates in development. Today, I will provide information on our standalone flu vaccine candidate, flu-COVID combination vaccine candidates and next generation pneumococcal vaccine candidate.

**[Slide 16: First Ever Demonstration of Efficacy for an mRNA Flu Vaccine Candidate]**

We are pleased to announce that we achieved both primary endpoints in the 18–64-year-old cohort of our ongoing Phase 3 flu trial. In the trial, our first-generation mRNA flu vaccine candidate demonstrated non-inferiority and superiority to a licensed flu vaccine at the time of the primary analysis. This represents the first and only demonstration of efficacy and superiority for an mRNA-based flu vaccine candidate.

In this age cohort, efficacy was maintained through the trial's end of season analysis, with our candidate remaining non-inferior to the licensed comparator.

Safety was similar to standard flu vaccine.

The primary and end of season efficacy analyses considered both influenza A and B cases collectively. The vast majority of cases recorded in our trial, and during the 2022/23 flu season overall, were influenza A cases. Immunogenicity data showed robust antibody responses against influenza A compared to licensed flu vaccine. Humoral responses against influenza B were lower than those achieved with the comparator.

Recall that our standalone flu vaccine Phase 3 study also includes a 65 and older cohort, and that we previously shared encouraging T cell data for all four strains from the Phase 2 study in this cohort. Our belief is that the ability of the vaccine candidate to induce T cell responses may contribute to improved efficacy over current seasonal flu vaccines, particularly in those 65 and older. We expect a readout from this age group later this year.

To address the lower B responses seen with our first-generation standalone flu candidate, Pfizer created next-generation reformulations. These were incorporated into our mRNA flu candidates in combination with the Pfizer-BioNTech COVID-19 vaccine, which I will review now.

#### **[Slide 17: Positive Phase 1/2 Influenza + COVID-19 Combination Vaccine Data]**

In positive Phase 1/2 topline data announced last week, we observed that reformulation of the lead flu candidates resulted in improved immunogenicity against influenza B, allowing us to meet all criteria for advancement to Phase 3.

In the trial, our lead candidate formulations induced robust immune responses, with point estimates for Geometric Mean Titer ratios that were consistent with criteria applied to approved vaccines for all matched flu and SARS-CoV-2 strains. Notably, point estimates for Geometric Mean Titer ratios with selected candidate formulations were greater than one relative to the licensed comparator for all matched flu vaccine strains.

The safety profiles of evaluated candidates were consistent with Pfizer and BioNTech's COVID-19 vaccine.

Following these positive immunogenicity data, we plan to initiate a Phase 3 study in the coming months.

#### **[Slide 18: Flu Program: Potential Anchor for Seasonal Vaccine Franchise]**

Successfully developing a broad seasonal vaccine franchise anchored around a modFlu mRNA vaccine is a key priority, as it may allow us to tap into the nearly 50% annual flu vaccination rate in U.S. adults.

We are taking a differentiated approach in pursuit of this goal, leveraging both mRNA and protein subunit technologies. Our development program includes double and triple combination vaccines to potentially help protect against flu, COVID-19, and RSV.

**[Slide 19: PREVNAR: Only PCV with FDA Adult Pneumonia Indication]**

Turning to PREVNAR, I'll start by reminding you that this is the only PCV business with an FDA indication for pneumonia in adults. Providing protection specifically against pneumococcal pneumonia is critical. It's the most common form of pneumococcal disease in adults, leading to 150,000 U.S. hospitalizations each year. The prevalence of nonbacteremic pneumococcal pneumonia is more than 15-fold greater than that of invasive pneumococcal disease in U.S. adults 50 and older.

PREVNAR's pneumonia indication is supported by the CAPiTA trial, which was enabled by a pneumococcal vaccine-naïve population and proprietary assay. These innovative characteristics make it challenging for others to conduct a similar study, given the high level of pneumococcal vaccine coverage that exists today.

CAPiTA's innovative design and landmark results helped establish our leading and differentiated position in the PCV space. To solidify this position, we are committed to pursuing continued innovation. Our goal is to potentially maximize valency and improve immunogenicity while maintaining coverage of the serotypes clinically demonstrated to protect against pneumonia.

**[Slide 20: 4<sup>th</sup> Generation PCV Program: Potential to Solidify Leading Position]**

In line with this commitment, we have been developing a fourth-generation PCV candidate that builds on the PREVNAR business' twenty-plus years of innovation. Our next-generation technology leverages cutting-edge conjugation chemistry, carriers, and reformulations.

Using these new proprietary vaccine technologies, we observed a several fold improvement in select serotype immunogenicity in a monovalent Phase 1 study.

Based on these data, we are confident that when we move this technology into our multivalent 4<sup>th</sup> generation candidate, we have the potential to achieve increased valency with improved serotype immunogenicity.

We are now advancing our fourth-generation candidate into a first-in-human trial, which is expected to begin in the fourth quarter of 2023.

**[Slide 21: Strong Launch Execution and Next Wave Pipeline Candidates]**

Finally, I will leave you with our list of milestones and call out the recent approvals of VELSIPITY for ulcerative colitis and PENBRAYA, the first pentavalent meningococcal vaccine. Pfizer has delivered more



than a dozen regulatory approvals this year alone. I'll also note the recent launches of ABRYSVO for maternal immunization and ELREXFIO in multiple myeloma.

Thank you. Let me turn it over to Francesca 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 October 31, 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, including financial guidance and projections; 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, size and utilization rates, 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; an enterprise-wide cost realignment program which we launched in October 2023 (including anticipated costs, savings and potential benefits); manufacturing and product supply; our ongoing efforts to respond to COVID-19, including Comirnaty (as defined in our third quarter of 2023 earnings release issued on October 31, 2023) and our oral COVID-19 treatment (Paxlovid); and our expectations regarding the impact of COVID-19 on our business, operations and financial results. Given their forward-looking nature, these statements involve substantial risks, uncertainties and potentially inaccurate assumptions and we cannot assure that any outcome expressed in these forward-looking statements will be realized in whole or in part. 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; uncertainties regarding the ability to obtain, and the scope of, recommendations by technical or advisory committees; and the timing of, and ability to obtain, pricing approvals and product launches, all of which could impact the availability or commercial potential of our products and product candidates;*
- 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 further 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) in the anticipated timeframe or at all, including the possibility that the proposed acquisition does not close; 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, the risk that as the market for COVID-19 products becomes more endemic and seasonal, demand for any of our COVID-19 products has and may continue to be reduced or not meet expectations, or may no longer exist, which has and may continue to lead to reduced revenues, excess inventory on-hand and/or in the channel which, for Paxlovid and Comirnaty, has resulted in significant inventory write-offs in the third quarter of 2023 and could continue to result in inventory write-offs or other unanticipated charges; challenges related to the transition to the commercial market for our COVID-19 products; uncertainties related to the public's adherence to vaccines, boosters and treatments; risks related to our ability to achieve our revenue forecasts for Comirnaty*

*and Paxlovid or any potential future COVID-19 vaccines or treatments; 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 or any 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 vaccine candidate 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 vaccine candidate 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 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 vaccine candidate 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 vaccine candidates or any other potential vaccines that may arise from the BNT162 program, 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 vaccine candidate 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; 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, including contract negotiations or renegotiations with government customers;*
- *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;*
- *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, unstable governments and legal systems and inter-governmental disputes;*
- *the impact of disruptions related to climate change and natural disasters, including uncertainties related to the impact of the recent tornado at our manufacturing facility in Rocky Mount, North Carolina;*
- *any changes in business, political and economic conditions due to actual or threatened terrorist activity, geopolitical instability, political or civil unrest or military action, including the ongoing conflicts between Russia and Ukraine and in the Middle East and their economic consequences;*
- *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, organizational disruption or other unintended consequences;*
- *the ability to successfully achieve our climate goals and progress our environmental sustainability and other ESG 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, medicine safety, 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;*
- *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 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 October 31, 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.*

*The Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) and certain uses of Paxlovid have not been approved or licensed by the FDA. The Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) has been authorized by the FDA under an EUA to prevent COVID-19 in individuals aged 6 months through 11 years of age. Paxlovid has been authorized for emergency use by the FDA under an EUA for the treatment of mild-to-moderate COVID-19 in pediatric patients (12 years of age and older weighing at least 40 kg) who are at high risk for progression to severe COVID-19, including hospitalization or death. 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 U.S. Federal Food, Drug and Cosmetic Act unless the declaration is terminated or authorization revoked sooner. Please see the EUA Fact Sheets at [www.covid19oralrx.com](http://www.covid19oralrx.com) and [www.cvdvaccine-us.com](http://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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