



## **Second-Quarter 2023 Earnings Conference Call Prepared Remarks August 1, 2023**

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

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

**[Slide 5: Q2 2023: Solid Quarter for Financial Performance and Patient Impact]**

Our second-quarter financial results were solid and in line with our expectations. Non-COVID-19 revenues grew 5% operationally compared with the year-ago quarter. Total revenues declined 53% operationally primarily due to the anticipated revenue declines in both Paxlovid and Comirnaty. Even with these declines, our COVID-19 portfolio remained a significant contributor to the business with more than \$1.6 billion in combined revenues during the quarter.

Of course, our patient impact data are equally important because patients are the reason we exist. Through the first six months of the year, more than 356 million patients around the world were treated with our medicines and vaccines.

**[Slide 6: New and Expected Launches: Revenue Contributions Largely Begin in H2 2023]**

We continue to make progress toward our goal of executing an unprecedented number of launches of new products or indications. In fact, Pfizer is more than halfway to its goal of launching 19 new products or indications in an 18-month span.

In addition to the six approvals and five launches that occurred prior to 2023, we had six approvals and four launches in the first six months of 2023. For the second half of 2023, we expect six additional approvals and six additional launches – including the two launches that occurred in July.

Then in 2024, we expect one approval and four launches, which, if approved and recommended, would raise the total to 19 new launches in approximately 18 months.

As you can see in this chart, for this year's launches, we expect the revenue contribution to occur largely in the second half of 2023 because the first-half launches occurred late in the second quarter. And then in

2024, with the additional impact of next year's expected launches, we anticipate an even greater total contribution from the 19 launches.

It's important to note that 18 of the 19 potential launches have been largely de-risked from a technical perspective at this point, with the only one remaining being our RNA flu candidate.

**[Slide 7: Progress with Longer-term Pipeline Candidates]**

Equally encouraging is that our pipeline is expected to continue generating breakthrough treatments and vaccines long after the 19 we have been discussing.

We recently reported milestones from several exciting pipeline candidates with the potential to be significant future value-drivers. These include:

- Phase 3 data from marstacimab, a novel antibody being studied for the treatment of hemophilia A or B;
- regulatory filing acceptance for our hemophilia B gene therapy candidate, fidanacogene elaparovect;
- the publication in the New England Journal of Medicine of Phase 2 results for our vaccine candidate for maternal immunization against Group B Streptococcus (GBS); and
- first-in-human data from our pipeline of potential next-generation breast cancer treatments, including our novel CDK4, CDK2, and KAT6 inhibitors.

**[Slides 8 and 9: Reinvesting the Profits from our COVID-19 Products]**

Now, I would like to provide some commentary on our COVID-19 portfolio.

During the pandemic, Pfizer demonstrated impressively the power of our research and manufacturing capabilities by bringing to the world the first and most widely used vaccine and oral treatment for COVID-19. These scientific breakthroughs have played a significant role in bringing the global health crisis under control, and we are very proud of our contributions.

The profits these products have generated to date have enabled us to invest in acquiring Arena, ReViral, Biohaven and Global Blood Therapeutics, which together we expect to contribute approximately \$10 billion of revenues in 2030. In fact, the acquisitions of Biohaven and Global Blood Therapeutics are already contributing to our operational growth, while the acquisition of Arena is expected to start generating revenues toward the end of this year. We also remain very excited about our planned acquisition of Seagen, which, if approved, is expected to contribute more than \$10 billion in 2030 revenues.

## **[Slide 10: Navigating the Major COVID-19 Uncertainties]**

As a result of the positive momentum of our non-COVID-19 revenues and, more importantly, the success of our COVID-19 portfolio, Pfizer's overall revenues have increased exponentially compared with our 2019 revenues, pro forma for the divestitures of Upjohn and our consumer business. This allowed us to increase investments in R&D and SI&A to support this new revenue base and our expected new product launches.

The increased investments we are making in R&D and SI&A this year were sized based on certain revenue assumptions we made in January for both our COVID-19 and non-COVID-19 products. These assumptions also were incorporated in our 2023 financial guidance.

Clearly, there is a higher level of uncertainty regarding the demand projections for our COVID-19 products than for the rest of the business.

For example, in January, we shared our expectation that approximately 100 million doses of COVID-19 vaccines would be administered in the U.S. this year – of which we estimated Pfizer to capture 60% market share. In the first six months of 2023, 12.4 million doses were administered in the U.S. While the 12.4 million doses are behind our earlier projections, our market share for COVID-19 vaccines is ahead of our previous expectations at 65%. However, the vast majority of respiratory vaccinations happen during the fall and winter respiratory disease season, which starts in September, and we expect COVID-19 vaccinations to follow this pattern going forward.

The uncertainty of the exact timing of Comirnaty commercialization was largely removed with the decision by the FDA and CDC to request a change in the composition of the vaccine to address the Omicron XBB 1.5 strain. We believe this will allow us to commercialize the vaccine in September – assuming the updated vaccines are approved and available by the end of August.

In the European Union, the uncertainty regarding the vaccine's revenue contributions for 2023 and beyond was removed when we renegotiated our long-term agreement. This agreement spreads the agreed volumes over four years, and while it puts pressure on this year's volumes, we believe it also provides longer-term revenue certainty in this important market.

Similar to what we are experiencing with the vaccine, the second half of the year will play a bigger role in informing our expectations for the long-term demand for Paxlovid, the utilization of which follows very closely the COVID-19 infection rates. We expect a new COVID-19 wave to start in the U.S. this fall, and this expectation is supported by the increase in infection rates we are already seeing. Obviously, the severity of disease and people's desire for treatment also will be factors – as will the ongoing dialogue with the U.S. government regarding when we will transition to a commercial model for Paxlovid.

We are acutely aware that all these uncertainties are making it difficult to project the future revenues of Pfizer – and also affecting our stock price.

The good news is we will have much more clarity and certainty regarding how our COVID-19 products will perform in a commercial market, by the time we report our third-quarter financial results, and we expect the uncertainties to be largely eliminated by the end of the year. That's because we expect the vaccination and treatment rates from the upcoming respiratory disease season to be a reliable predictor of trends in subsequent years – with some potential upside if a combination flu and COVID-19 vaccine is brought to market in the future. Additionally, by that point the timing of transitioning to full commercialization of both Comirnaty and Paxlovid should become clear.

Despite this uncertainty, we will continue to invest in our COVID-19 portfolio this year in advance of the upcoming respiratory disease season.

Given this uncertainty, we are preparing to have the ability to adjust our 2024 total cost base to align with various future COVID-19 revenue scenarios.

In fact, we have already identified specific areas where we can make adjustments – primarily within our COVID-19 cost base – if demand comes in lower than expected. Dave will provide more details during his remarks.

#### **[Slide 11: Seagen Planning Progressing Well]**

Next, I wanted to share a few quick updates on our planned acquisition of Seagen – which we believe will be a major driver of our future success.

Seagen's shareholders recently overwhelmingly approved the planned acquisition, and we have already raised most of the external financing needed to fund the transaction. We also continue to work closely with regulators, including the Federal Trade Commission (FTC) and the European Commission.

In the meantime, our integration planning continues, which will allow us to hit the ground running following an anticipated close later in 2023 or early in 2024, subject to the satisfaction of customary closing conditions.

Last week, we announced that Chris Boshoff has joined Pfizer's Executive Leadership Team as Chief Oncology Research and Development Officer and Executive Vice President, reporting to me. In this role, Chris will lead a new, end-to-end Oncology R&D organization and be the single point of accountability for the entire oncology pipeline – from discovery to early- and late-phase clinical development. This is similar to the structure we currently have in place for our Vaccines R&D organization, which has proven to be productive.

Pfizer and Seagen share a common vision to deliver life-saving treatments for people living with cancer, which is why I am so pleased that, after closing, Chris's Oncology leadership team will include talented, purpose-driven and highly productive leaders from both companies. We believe this new structure will help further accelerate the delivery of cancer therapies, which is critical because in the battle against cancer, time is life.

**[Slide 12: Continuing to Build Trust with External Stakeholders]**

At Pfizer, one of our core business principles is the belief that "Trust is Everything." I'm proud to share that in recent months, we have received some wonderful accolades that speak to the trust we are building with external stakeholders.

- We were named one of the 2023-2024 "Best Companies to Work For" by U.S. News & World Report.
- We were listed in Newsweek's list of "America's Greatest Workplaces 2023."
- For the third year in a row, Pfizer has earned a top 100 score in the 2023 "Disability Equality Index."
- And our own Rady Johnson received the Disability:IN 2023 Executive Sponsor of the Year Award at the National Conference in July.
- Lastly, our PGS site in Ascoli, Italy is being recognized by the United Nations for the "Welcome Award – Working for Refugee Integration."

These recognitions are very important because they strengthen the unprecedented brand equity that Pfizer built during the COVID-19 pandemic.

Before I hand it over to Dave, I want to quickly comment on the situation at our facility in Rocky Mount, North Carolina.

First, all of us at Pfizer were relieved that no colleagues were seriously injured when the tornado struck. That said, our facility sustained substantial damage – as did the neighborhoods where many of our colleagues live.

The local leadership team has done an incredible job responding to this devastating event, and we are proceeding with both urgency and caution to determine the best way to get the site back online as quickly as possible, so as to minimize any impact on patients. Of course, we are also taking steps to ensure the continued safety of our colleagues and contractors, which remains our top priority.

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

### **[Slide 13: Financial Review – David Denton]**

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

Thank you, Albert, and good morning.

Over the past 24 months, Pfizer has made important investments to position it squarely on track to achieving profitable and sustainable growth in the back half of the decade. We have strategically invested to expand our commercial portfolio and late-stage pipeline, strengthen our market launch capabilities, and enhanced innovation through internal R&D and business development actions. These deliberate efforts continue to solidify Pfizer's ability to overcome upcoming LOEs and drive sustainable revenue growth while enhancing long-term shareholder value.

### **[Slide 14: Efficient Cash Deployment Strategy Focused on Three Pillars]**

To further support our long-term growth objectives, we are executing a capital allocation strategy designed to effectively deploy our cash. This strategy is focused on three main pillars: reinvesting in the business; growing our dividends over time; and making value-enhancing share repurchases.

In the first half of 2023, we:

- Invested \$5.2 billion in internal R&D;
- Returned \$4.6 billion to shareholders via our quarterly dividend;
- And, allocated approximately \$43 billion towards the proposed acquisition of Seagen.

During Q2, Pfizer successfully completed a \$31 billion unsecured debt offering across 8 tranches. The net proceeds of this debt offering will be used to substantially fund the Seagen acquisition. The new debt carries a weighted average yield of 4.93% and a weighted average maturity of 16.3 years, consistent with our expectations. On a full year run rate basis, the annual financing cost associated with the acquisition is expected to be nearly \$2 billion. With the completion of this debt offering, the company is now positioned to close the Seagen acquisition immediately upon post regulatory approvals.

While we plan to continue investing in our business, we also expect to de-lever our capital structure following the anticipated closing of the Seagen transaction. As we de-lever it is our expectation to return to a more balanced capital allocation strategy inclusive of share repurchases.

### **[Slide 15: Quarterly Income Statement Highlights]**

Now, let me briefly cover a few highlights of our quarterly financial performance. Our Q2 results were solid and in line with our expectations from both a top and bottom-line perspective, albeit slightly better than EPS consensus.

As expected in our guidance, overall Q2 revenues declined 53% operationally. The contraction in revenues was driven by the anticipated decline in Paxlovid and Comirnaty sales. We expect these products to transition to a commercial market expected in the second half of this year. Our operational revenue growth excluding our COVID products was in line with expectations at 5% vs Q2 of last year, with strong contributions from the inclusion of Nurtec and Oxbryta, as well as the continued growth from the Vyndaqel family.

During Q2, adjusted SI&A expenses were \$3.4 billion and grew by 20% operationally vs last year. We continue to invest in support of our upcoming launches and grow our recently acquired products. While it's clear that these near-term investments are dampening current profitability levels, we are laser-focused on maximizing the longer-term performance of these products.

Moving to the bottom line, reported diluted EPS this quarter declined by 77% to \$0.41, while Adjusted diluted EPS of \$0.67 declined 65% on an operational basis in the quarter. Earnings compressed at a greater rate than revenue primarily due to the steep, anticipated contraction in Paxlovid sales during the quarter.

Once again, foreign exchange movements unfavorably impacted our results, reducing second-quarter revenues by \$283 million, or 1%, and Adjusted diluted EPS by \$0.05, or 2%, compared to last year.

#### **[Slide 16: Narrows 2023 Revenue Range and Maintains Adjusted Diluted EPS]**

Now that we are at the halfway point of our 2023 financial plan, I would like to reflect on how we are executing across our business while navigating within an incredibly unique and dynamic environment. As a management team, we remain committed to transparency and sharing our assessment of the evolving marketplace given the magnitude of launches; the ongoing shifting nature of the COVID landscape; and the continued integration of acquired assets.

Let me begin by elaborating on our full-year 2023 financial guidance. We are narrowing our expectations for revenues to between \$67 to \$70 billion and maintaining guidance for Adjusted Diluted EPS of \$3.25 to \$3.45 for the full year.

For our more durable, predictable non-COVID revenues; we are updating our guidance range to 6-8% operational revenues growth. From a launch timing standpoint, I'll point out that the majority of our 2023 launches are anticipated to occur in the second half of 2023 and our commercialization schedule remains materially unchanged. As a company, we always strive to achieve the highest revenue levels possible while maintaining a realistic view of key inputs that inform our outlook. Regarding RSV for older adults, the shared decision-making recommendation by ACIP is likely to slow its uptake in the U.S. In addition, the recent approval of Talzenna in the U.S. results in a more narrow patient population than originally planned. These factors coupled with the impact of the damaged Rocky Mount manufacturing facility present near-

term revenue challenges. However, we expect positive momentum as we exit 2023 and head into 2024. Importantly, the long-term outlook for our non-COVID business remains intact relative to our 2030 ambitions.

Turning now to our less predictable and more variable COVID portfolio. Year-to-date we have booked slightly over 40% of the \$21.5 billion full-year revenue forecast for Comirnaty and Paxlovid with the important fall vaccination and respiratory infection season ahead of us. We are acutely aware that COVID demand depends on many evolving market variables making the range of potential revenue outcomes increasingly large and difficult to predict with certainty. These variables include overall levels of vaccination and infection rates; the speed of draw-down of government inventory levels; and the mutating nature of the virus itself – just to name a few. In the interest of public health and with the important fall season ahead of us; we are maintaining our COVID revenue outlook for the year while continuing to invest, largely on a variable expense basis, to support our COVID products this year. These variable investments are important to support our efforts to reach as many patients as possible; helping to ensure the most at-risk individuals are both vaccinated and treated while maintaining our leading market share.

We are proud of what we have achieved through the COVID portfolio as this has allowed the company to invest in support of its growth agenda for the back half of this decade. Our visibility into future COVID revenues and demand should improve through the remainder of 2023, as we gain clarity on a more typical annual revenue run-rate.

We are well aware, our 2023 profit outlook is currently being dampened by incremental costs in support of our launches, as well as higher R&D investments aligned with the company's current revenue base. We remain committed to defending and growing our overall level of profitability. As Albert mentioned, we expect this fall's performance of our COVID-19 products to help us more effectively forecast future sales performance. To that end, if our COVID-19 revenues are less than what we assumed, we are prepared to launch an enterprise-wide cost improvement program aligned with the longer-term revenue projections for our business. This program would be designed to support our objective of growing our operating profit margin and we would expect it to begin to yield results in 2024. We look forward to sharing specific details of this program in our upcoming earnings calls.

In closing, this is an extraordinary time for Pfizer. Our confidence and commitment to our strategy and to achieving our 2030 goals is unwavering. We will continue to focus our efforts to drive growth while enhancing long-term shareholder value.

With that, let me turn it over to Mikael.



## **[Slide 17: Scientific Updates – Mikael Dolsten]**

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

Thank you, Dave. Today, I will provide updates from a few different therapeutic focus areas, starting with breast cancer.

## **[Slide 18: Goal: Deliver Next Generation of ER+ Breast Cancer Therapies]**

We are working to deliver the next wave of innovative therapies for estrogen receptor-positive breast cancer. The pillars of this strategy are three-fold: establishing our investigational CDK4 inhibitor as a next-generation cell cycle therapy backbone, establishing vepdegestrant as a next-generation endocrine therapy backbone and establishing novel mechanisms like our investigational CDK2 inhibitor and KAT6 inhibitor candidates as next-generation combination partners to enhance efficacy.

Our clinical strategy entails first developing assets for the metastatic setting—in which Ibrance is currently the leader and unmet need is high—followed by an opportunity to expand to earlier-stage breast cancer including the CDK4/6-naïve population and adjuvant/neoadjuvant settings.

## **[Slide 19: Encouraging Data on Next-Generation ER+ Breast Cancer Portfolio]**

Data presented at ASCO from three key investigational medicines from our next-generation portfolio demonstrated anti-tumor activity in heavily pre-treated populations of patients with breast cancer.

As a reminder, the majority of hormone receptor positive breast cancers express low CDK6, while CDK4 is likely to be a major cell cycle driver. We have seen that CDK4/6 inhibition can lead to neutropenia which requires more frequent blood test monitoring—mostly driven by CDK6 inhibition. Across the CDK4/6 inhibitor class, approximately 30-60% of patients experience severe neutropenia.

On the left: In a Phase 1 dose escalation study in patients with hormone receptor-positive, HER 2-negative breast cancer, all of whom had previously received a CDK4/6 inhibitor, treatment with our CDK4 inhibitor in combination with endocrine therapy resulted in a confirmed objective response rate of 29%, clinical benefit response rate of 52% and a median progression-free survival of nearly 25 weeks. The combination was well-tolerated, which may enable maximal CDK4 inhibition. We are actively planning the Phase 3 randomized study.

In addition, I'd like to highlight encouraging data from the Phase 1 dose escalation study of our novel CDK2 inhibitor which showed monotherapy activity, including confirmed partial responses, in breast cancer patients who had previously received a CDK4/6 inhibitor. Also, durable confirmed clinical responses were

observed in a Phase 1 trial of our novel KAT6 inhibitor as a monotherapy and in combination with endocrine therapy in heavily pre-treated patients with breast cancer.

**[Slide 20: Established Strategy to Grow Leadership in Blood Cancers]**

Turning now to blood cancers, Elrexio (also known as elranatamab), subject to regulatory approval, is expected to be the anchor of an anticipated multi-billion-dollar franchise. An FDA decision for the potential first indication—in the triple-class relapsed or refractory multiple myeloma population—is expected this year, and we continue to advance the MagnetisMM clinical programs to expand into earlier lines of treatment.

In addition, the development of maplirpcept (also known as TTI-622) is underway—including in combination with Elrexio—to support potential indications in multiple myeloma and acute myeloid leukemia.

**[Slide 21: ELREXFIO: Potential New Foundational Treatment for MM]**

Here, we show Elrexio data presented at EHA from the MagnetisMM-3 trial in patients with triple-class refractory multiple myeloma who had no prior exposure to BCMA-directed therapy. On the left, we observed highly meaningful survival with Elrexio monotherapy, with a 15-month overall survival of 57%. In patients who achieved a complete response, 15-month survival was remarkably 93%, underscoring the potential for deep and durable responses.

We can see evidence of broad activity in multiple myeloma on the right, with the graph showing a single agent complete response rate of 35%, which rises to 46% in the subset of patients with two to three prior lines of therapy. Our ongoing randomized trials are in less pre-treated to newly diagnosed populations.

Subject to approval, Elrexio may have key differentiators such as a 50% lower hospitalization time during the step-up dosing period per protocol and an extended dosing interval that moves from once weekly to once every other week dosing beyond week 24.

**[Slide 22: Marstacimab: Pivotal Hemophilia Trial Met Primary Endpoints]**

Turning now to hemophilia A and B, the pivotal trial of marstacimab met its primary endpoints, with statistically significant and clinically meaningful effect on annualized bleeding rate (or ABR). There was a 35% reduction in ABR compared to prophylactic factor replacement and 92% reduction in ABR versus on-demand factor replacement. Marstacimab offers a differentiated mechanism of action and dosing regimen compared to standard-of-care therapy. If approved, it has the potential to be the first once-weekly subcutaneous hemophilia B treatment for patients without inhibitors, and the first hemophilia A or B treatment administered in a patient-friendly pre-filled pen as a flat dose. Regulatory submission is expected in the second half of 2023.

### **[Slide 23: LITFULO: FDA Approval for Severe Alopecia Areata]**

Next, Litfulo (also known as ritlecitinib) is the first medicine to receive FDA approval to treat severe alopecia areata in both adults and adolescents 12 years and older. It also recently received a positive opinion from the European Medicines Agency's CHMP recommending body but is not yet approved. It has the potential to redefine the standard of care for alopecia areata. Litfulo is a first-of-its-kind kinase inhibitor with a unique mechanism that inhibits both the TEC kinase family and transiently JAK3—pathways that have been implicated in the alopecia areata pathophysiology.

In addition, we are exploring how its unique mechanism of action could potentially be applied across immune disorders including vitiligo—in which a Phase 3 study is ongoing—and other potential indications.

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

Finally, we are making excellent progress on the milestones we had set out through the first half of 2024.

As Albert noted, we recently received FDA approval for Prevnar 20 in the pediatric population. We have robust strategies in place to potentially improve upon the protection provided by current pneumococcal vaccines. I look forward to sharing more about this in the coming quarters.

In addition, we recently published Phase 2 data in the New England Journal of Medicine showing our Group B Streptococcus maternal vaccine candidate was generally well-tolerated and generated robust antibody levels. The journal also published a natural history study which was used to determine protective antibody levels at birth. These two studies indicated that the vaccine candidate may offer meaningful protection to infants born to immunized mothers. We were highly encouraged that Dr. Carol Baker, an infectious disease expert from the University of Texas Health Science Center, wrote an independent NEJM editorial highlighting the important future prospects of our GBS vaccine candidate.

The progress of the GBS vaccine candidate dovetails nicely with the positive results and anticipated upcoming regulatory decisions for our RSV vaccine Abrysvo for administration to pregnant women. Abrysvo recently received a positive opinion from the European Medicines Agency's CHMP for both older adults and maternal immunization to help protect infants. Abrysvo is approved for older adults in the US and under regulatory review for the maternal indication.

In addition, we remain excited to see Phase 2 data from danuglipron by the end of 2023, which we expect will enable us to finalize our Phase 3 plans.

Finally, I'll call out the Phase 3 trial start of our anti-interferon Beta candidate for the treatment of inflammatory muscle myopathies, and which has received a Fast Track Designation from FDA.

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 August 1, 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 Comirnaty (as defined in our second quarter of 2023 earnings release issued on August 1, 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) 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 demand for any of our COVID-19 products may be reduced, no longer exist or not meet expectations, which may lead to excess inventory on-hand and/or in the channel, inventory write-offs or reduced revenues; challenges related to and uncertainties regarding the timing of a transition to the commercial market for any of our 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 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;*
- 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, 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, 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, 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;*
- 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, 2022 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 August 1, 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, Bivalent (Original and Omicron BA.4/BA.5) and certain uses of Paxlovid have not been approved or licensed by the FDA. 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. 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 FDCA 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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