



Third-Quarter 2022 Earnings Conference Call Prepared Remarks November 1, 2022

[Slide 5: Opening Remarks – Albert Bourla]

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

Today, I will briefly touch on some recent highlights. I will then spend the bulk of my time speaking to our expectations for what we feel will be a promising and prosperous future for Pfizer and the patients we serve.

[Slide 6: Recent Highlights (1 of 2)]

In addition to generating stellar financial performance, since our last earnings call:

- We reported positive pivotal data for several exciting pipeline programs – including our RSV vaccine candidate for older adults, Prevnar 20 for children, the potential combination treatment of Talzenna and Xtandi in men with metastatic castration-resistant prostate cancer, and our pentavalent meningococcal vaccine candidate for adolescents and young adults, as well as exciting progress for our GLP1 program in type 2 diabetes and obesity. And, just this morning we announced positive top-line data from the Phase 3 clinical trial investigating our bivalent RSV vaccine candidate when administered to pregnant participants to help protect their infants from RSV disease after birth.
- We established a new commercial structure within our Global Biopharmaceuticals Business that is focused on three broad therapeutic areas (primary care, specialty care and oncology). We believe this new structure will enable us to maximize the commercial success of the multiple exciting product launches — including several potential blockbusters — that are poised to emerge from our scientific pipeline over the next few years.
- We have continued to advance potentially game-changing vaccines in the fight against respiratory disease by entering into a phase 3 study for our mRNA flu vaccine candidate and initiating a phase 1 study for a vaccine candidate that combines our mRNA flu and COVID-19 vaccines in one shot.

[Slide 7: Recent Highlights (2 of 2)]

- We completed the acquisitions of Biohaven Pharmaceuticals and Global Blood Therapeutics, giving us market-leading franchises in both migraine and sickle cell disease, respectively.
- Less than six months after launching An Accord for a Healthier World, a breakthrough initiative designed to close the health equity gap for 1.2 billion people living in 45 lower-income countries, I'm proud to say that the first shipments of our products have arrived, and we are working with governments on health system improvements that can help make sure these products reach those in need.
- And, of course, we continue to lead the fight against COVID-19. Most notably, our Omicron-adapted bivalent COVID-19 vaccine has been authorized by the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA) and several other regulatory bodies. And as part of Pfizer's commitment to providing equitable access to COVID-19 oral treatments, we agreed to supply, at a not-for-profit price, up to six million Paxlovid treatment courses to the Global Fund for low- and lower-middle-income countries.

[Slide 8: What's Next?]

An exciting quarter, for sure, but in our company and our industry, it's all about what's next. The next breakthrough medicine or vaccine. The next game-changing technology. The next solution to an unmet patient need.

This continued pursuit of "what's next" is embedded in Pfizer's DNA and a foundational driver of our purpose: Breakthroughs that change patients' lives.

It's also why we have confidence that Pfizer's story is a story of growth.

[Slide 9: Fortifying Our Long-Term Growth Plans]

We recognize that some are questioning Pfizer's longer-term growth prospects – particularly in the 2025-2030 timeframe. That's understandable given that we currently expect a negative impact of approximately \$17 billion in revenues from losses of exclusivity (LOE) during that period.

We believe we not only can overcome these expected declines, but also can potentially generate strong growth through the end of the decade.

Let's take a closer look at how we expect to accomplish that.

Our strong capital position has given us the ability to pursue business development opportunities with the potential, if successful, to add at least \$25 billion of risk-adjusted revenues to our 2030 topline expectations. We believe the deals we have already done for Arena, Biohaven, Global Blood Therapeutics

and ReViral have the potential to get us more than one third of the way there and that we have more than enough capital to invest in the additional opportunities needed to meet or exceed this target.

Perhaps even more exciting is the wave of potential growth drivers emerging from our R&D pipeline in the near term. Over the next 18 months, we expect to have up to 19 new products or indications in the market - including the five for which we have already begun co-promotion or commercialization earlier this year. You can find a list of these launches in the appendix of the presentation we posted today for this earnings call. If successful, these 19 launches -- of which more than two thirds have the potential to be blockbusters -- would be the most ever in Pfizer's history. The 15 in-house-developed projects alone could potentially represent approximately \$20 billion in 2030 sales, which would more than offset the expected LOE impact. Many of these programs are already largely de-risked from a clinical perspective, the majority of them were discovered in-house, and nearly all of them would be for indications outside of COVID-19. If approved, we expect each of these to be key contributors to our growth aspirations through 2025 and beyond.

And, of course, we have many more potential vaccines and medicines in our pipeline, with numerous launches expected in the 2024-2030 timeframe. These include gene therapy candidates for hemophilia A, hemophilia B and Duchenne muscular dystrophy (DMD), our oral GLP-1 for diabetes and obesity, a potential combo vaccine that would cover flu and COVID-19 in one shot, and many more.

With regard to our COVID-19 products, while their sales may fall from our expected 2022 levels, we believe our COVID-19 franchises will remain multi-billion-dollar revenue generators for the foreseeable future, which should serve as a buffer for any unforeseen challenges with other products in our portfolio.

[Slide 10: We Have the Resources and Capabilities to Execute this Plan]

Our confidence to execute this plan stems from:

- The depth of our financial resources and the firepower it gives us to pursue business development opportunities.
- The powerful brand equity we have built up over the past 170 years and further enhanced in the past two years. According to a recent survey, our brand awareness now stands at an impressive 82%, and our favorability stands at 61% (compared with 42% for the industry as a whole).
- And, of course, the strength of the three foundational pillars of our company: our world-class scientific, commercial and manufacturing engines.

Let me now briefly highlight three potential blockbusters that we expect to contribute to our long-term growth.

[Slide 11: RSV Vaccine: Preparing for Potential Older-Adult Launch Ahead of Fall 2023 Season and Potential Maternal Launch]

RSV is an area of significant unmet need -- particularly in older adults and infants.

Each year, it's estimated that more than 177,000 older adults are hospitalized and 14,000 of them die in the U.S. alone due to RSV that is confirmed by a diagnostic test. We believe we have the potential to be a leader in this space and have a real impact on public health.

On March 24 of this year, the FDA granted Breakthrough Designation for our RSV vaccine candidate for the prevention of lower respiratory tract disease caused by RSV in individuals 60 years of age or older. We were excited to report positive top-line data from the Phase 3 RENOIR trial in late August, with a recent presentation of detailed results at ID Week 2022.

A pre-planned, interim analysis showed vaccine efficacy of 67% against RSV-associated lower respiratory tract illness defined by two or more symptoms. And vaccine efficacy of 85.7% was observed in participants with more severe disease presenting three or more RSV-associated symptoms of lower respiratory tract illness (LRTI-RSV).

We are also excited about the potential for our maternal RSV vaccine candidate. Globally each year, RSV sickens more than six and a half million infants under 6 months old and kills approximately 45,000. As announced this morning, our maternal RSV study met the success criterion for one of two primary endpoints. Vaccine efficacy of 81.8% was observed against severe medically attended lower respiratory tract illness due to RSV in infants from birth through the first 90 days of life. And high efficacy of 69.4% was demonstrated through the first six months of life.

So, there is the potential that, subject to regulatory approval, by late 2023/early 2024 we could have the only RSV maternal vaccine on the market, along with an RSV vaccine for older adults that has high efficacy and is well-tolerated with no safety concerns. Combined, the two indications represent a potential multi-billion-dollar peak revenue opportunity, if approved, especially with our highly respected Primary Care sales force executing the launches.

Including the RSV antiviral investigational candidates we acquired with ReViral, we aim to have end-to-end solutions – with both preventative vaccines and therapeutics to treat those infected with RSV.

[Slide 12: Etrasimod: Preparing for a Potential Launch in 2H 2023]

Ulcerative colitis, or UC, is a chronic and often debilitating inflammatory bowel disease that affects an estimated 1 million people in the U.S. alone. Many patients living with this disease never achieve or maintain remission, and physicians are seeking effective, proven, oral therapies with a favorable

benefit/risk profile that can be an attractive first-line advanced therapy option. As a result, we expect the market opportunity to grow by about 50% over the next five years.

The positive phase 3 data from the ELEVATE-UC-12 and -52 trials reinforce our belief that etrasimod has a differentiated clinical profile and can be an important treatment option, if approved. We believe that etrasimod can be a multi-billion-dollar blockbuster product.

We expect to launch the product in the U.S. as soon as the second half of 2023, pending regulatory approval, through our Specialty Care salesforce, which already has strong relationships in the UC market thanks to its work with Xeljanz, biosimilars, etc.

[Slide 13: CGRPs for Migraines: Nurtec ODT / Vydura and Zavegepant]

Lastly, let's look at migraine. Following our acquisition of Biohaven in early October, we are now aiming to build the world's leading global migraine franchise with the potential to impact 1 billion patients around the world.

Migraine is a debilitating disease and has 11.6% prevalence worldwide. In the U.S. alone there are 40 million patients with migraine, and one out of five women are migraine sufferers. The economic burden is significant at \$36 billion per year.

We believe our portfolio – including Nurtec ODT / Vydura and zavegepant – could meet a range of needs in the market, allowing physicians and patients to decide how to appropriately manage migraine treatment and prevention. As a result, we see the potential to reach more than \$6 billion in peak revenues.

In the U.S., Nurtec is growing very well. Including the impact of Pfizer's co-promoting, which began in August (pre-close), Nurtec has further strengthened its No. 1 market share position in the oral CGRP market. And we expect even stronger growth as we deliver on our promise to further enhance our commercial efforts behind this product. Outside the U.S., it has been approved in the EU, the UK, Israel, Kuwait, and UAE, and we have filed for registration in an additional 10 markets.

While this is not a new product launch, we believe this is a great example of how we can take this portfolio to new heights by leveraging the full strength of Pfizer's global commercial engine.

Moving over to zavegepant, we currently expect to launch zavegepant intranasal in the U.S. next year, pending FDA approval, and we plan to globally commercialize. Lastly, the oral zavegepant prevention phase 3 trial is ongoing with a data readout expected in the third quarter of 2023.

With that, I will turn it over to Dave to update you on our results and outlook. After Dave, Mikael will speak about the progression of our pipeline.

[Slide 14: Financial Review – David Denton]

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

[Slide 15: Efficient Capital Deployment Focused on Three Pillars: Q1 to Q3 2022]

Thank you, Albert and good morning, everyone.

I'll begin this morning with a few comments regarding how the company continues to deploy capital in a disciplined manner in support of long-term growth and enhanced shareholder returns. As you know, Pfizer's cash generation capabilities have expanded significantly over the past few years, and the efficient deployment of this capital is more critical than ever.

During the first nine months of 2022, the Company has deployed and committed capital in three main areas:

First -- we have invested \$7.8 billion in internal R&D as we continue to support our growing pipeline of innovative medicines. These investments are squarely focused on driving revenue growth through 2030.

Secondly, in the first three quarters of 2022, we have invested approximately \$8 billion in completed business development transactions. Additionally, early in the fourth quarter, the company completed investments of more than \$18 billion in transactions including Biohaven & GBT, which brings us to approximately \$26 billion in capital deployed for business development transactions thus far in 2022. These transactions illustrate our progress toward the goal of adding \$25 billion in risk-adjusted 2030 revenues through business development.

And finally, we have returned nearly \$9 billion of capital to shareholders through a combination of dividends and value-enhancing share repurchases.

Clearly, maximizing shareholder value through prudent capital allocation will continue to be a major focus for Pfizer.

[Slide 16: Quarterly Income Statement Highlights]

Now, let me briefly review our financial results for the quarter. I will limit my remarks largely to adjusted and operational growth figures.

Third quarter revenues demonstrated strength across many areas of our business, but much of that strength was somewhat obscured by our incredibly strong performance in third-quarter 2021. Given the strength in the prior year, revenues this quarter decreased 2% operationally. However, looking at it on a two-year basis, revenues this quarter were up by more than 120% compared to third-quarter 2020.

The slight decrease compared to last year was in line with our expectations, given the phasing of scheduled deliveries of Comirnaty (Co-MIRN-uh-tee) which we discussed in our earnings call last quarter. Also underlying our results this quarter was the strong performance of Paxlovid as well as continued strength from a number of our other key products.

Excluding direct sales and alliance revenues related to our COVID-19 products, Pfizer's revenues grew 2% operationally in the quarter.

Gross margin expanded by 1450 basis points vs. the third quarter of last year. This improvement is largely due to increased sales of higher-margin Paxlovid and decreased sales of lower-gross margin Comirnaty compared to last year. These improvements were partially offset by the impact of a \$400 million charge related to excess raw materials for Paxlovid. Given the unpredictable nature of the virus, we intentionally chose to order additional stock to ensure we could meet any global health demand if an extreme need were to arise.

Adjusted SI&A expenses in the third quarter grew 23% operationally. The increase was primarily driven by spending for Paxlovid and Comirnaty (Co-MIRN-uh-Tee), and higher healthcare reform fees.

The 2% operational increase in Adjusted R&D expense in Q3 was primarily driven by increased costs to develop recently acquired assets, as well as investments for certain oncology and non-COVID-19 vaccines programs, partially offset by lower spending on programs to prevent and treat COVID-19 and various late-stage clinical programs.

The effective tax rate on adjusted income in the quarter was 4.4%, significantly lower than typical, driven by tax benefits related to global income tax resolutions in multiple tax jurisdictions spanning multiple tax years. Excluding these tax resolutions, the underlying tax rate was consistent with historical trends.

As a result, reported diluted EPS of \$1.51 grew by 6%, while Adjusted diluted EPS of \$1.78 grew 44% on an operational basis in the quarter.

Foreign exchange movements continue to dampen our results; negatively impacting revenues by approximately \$950 million and Adjusted diluted EPS by \$0.05 this quarter.

[Slide 17: 2022 Financial Guidance: Revenues and Adjusted Diluted EPS]

Let's move to our updated 2022 guidance.

Given our strong third quarter performance and our improving outlook for the year, we are increasing our operational expectations for revenues by ~\$1.7 billion and Adjusted diluted EPS by ~\$0.19. This operational increase on the bottom line would have been even higher if not for an incremental \$0.06 negative impact due to higher acquired IPR&D expenses.

Partially offsetting these operational increases is the impact of additional strengthening of the U.S. dollar since we last updated guidance in late July. Incremental foreign exchange changes negatively impacted our expectations for 2022 revenues and Adjusted diluted EPS by \$700 million and \$0.09, respectively.

The net impact of these cross currents resulted in increases to the midpoints of our revenue and Adjusted diluted EPS guidance ranges. These revised ranges reflect operational growth rates of 31% for revenues and 70% for Adjusted diluted EPS at the midpoints compared to 2021, up from our previous operational growth expectations for revenue and Adjusted diluted EPS of 29% and 65%, respectively.

Regarding our COVID-19-related revenues, we now expect the vaccine revenue for the year to be approximately \$34 billion, up by \$2 billion compared to our prior guidance. For Paxlovid, we expect sales of approximately \$22 billion, keeping the guidance unchanged despite the negative incremental impact of changes in foreign exchange.

[Slide 18: 2022 Financial Guidance – Other Components]

You can see on this slide our updated cost and expense guidance, which incorporates our performance to date, our recent acquisitions and our updated expectations for the remainder of the year. More information on each of these updates can be found in this morning's press release.

2022 guidance once again assumes no incremental share repurchases, beyond the \$2 billion of share repurchases we completed in March 2022.

In closing, it's an exciting time in the history of Pfizer. We believe that our strong financial performance in the quarter and our improving operational outlook for the year sets the stage for long-term shareholder value creation.

With that, let me turn it over to Mikael.

[Slide 19: Scientific Updates – Mikael Dolsten]

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

Thank you, Dave.

Today, I will focus attention on high-value programs that will potentially deliver breakthroughs in areas of high unmet need and expected to be key contributors to our growth aspirations through 2025 and beyond.

[Slide 20: Select Scientific Franchises Aimed At Sustainable Growth]

With anchor products such as COMIRNATY, PAXLOVID, IBRANCE, and XTANDI, we are building out comprehensive franchises in several areas, including respiratory, metabolic disorders, genetic hematology and certain cancers.

We have deep expertise in these areas and there is exciting science emerging.

I will share updates from three of these today—respiratory, metabolic and prostate cancer.

[Slide 21: Establishing Respiratory Leadership]

Building on our success with COMIRNATY and PAXLOVID, we see enormous potential to help address major causes of respiratory disease through vaccines and therapeutics.

Work on the next-generation vaccine candidates are well underway and last week we started a Phase 1 clinical trial of our second-generation oral therapeutic candidate.

Our quadrivalent modRNA flu program has progressed into Phase 3, and we will start shortly a Phase 1 study of an mRNA-based vaccine candidate that combines our quadrivalent modRNA flu vaccine candidate with the Omicron-adapted bivalent COVID-19 vaccine based on BA.4/5.

In RSV, we believe a dual focus on developing a vaccine and anti-virals could make a significant impact globally. I will share new data with you shortly.

[Slide 22: Leading the COVID-19 Treatment Landscape]

PAXLOVID continues to be an important tool in helping to combat the impact of COVID-19, and secondary endpoints from the EPIC-High Risk study as well as data from real world evidence support the product's efficacy profile.

In the EPIC-HR study, PAXLOVID reduced COVID-19-related all-cause deaths and ICU admissions by 100 percent and COVID-19-related hospitalizations by 86 percent in unvaccinated high-risk patients, compared to placebo. It also reduced the duration of COVID-19 symptoms by two to three days, compared to placebo.

We are pleased to see PAXLOVID leading the COVID-19 treatment landscape and remain confident in its safety and efficacy in treating patients at high-risk for severe outcomes.

[Slide 23: RSVpreF Highly Efficacious Against RSV-LTRI in Older Adults]

We recently reported a positive interim analysis from a Phase 3 study in older adults of our novel RSV vaccine candidate, which targets the pre-fusion F protein of both RSV A and B without need for an adjuvant.

We saw remarkable vaccine efficacy across the first RSV season.

[Slide 24: RSVpreF: Potential Best-in-Class Safety Profile in Older Adults]

The vaccine was extremely well-tolerated, with favorable systemic tolerability—a key consideration for vaccines.

[Slide 25: RSVpreF Highly Efficacious Against Severe MA-LTRI in Infants in Phase 3 IA]

We also are developing the RSVpreF vaccine candidate for use in pregnant women, so that protection may be conferred to newborns, and this morning we announced exciting results from a pre-planned interim analysis of our Phase 3 trial.

We observed vaccine efficacy of nearly 82% against severe medically attended lower respiratory tract illness or MA-LRTI due to RSV in infants from birth through the first 90 days of life and efficacy of more than 69% through the first six months of life.

Success criterion was not met for the second primary endpoint, however clinically meaningful efficacy was observed for MA-LRTI of 57% in infants from birth through the first 90 days of life. Efficacy for MA-LRTI of 51% was observed over the six-month follow up period.

The Data Monitoring Committee indicated the vaccine was well-tolerated with no safety concerns for either vaccinated women or their newborns.

Given these impressive results, we look forward to filing Biologics License Applications for both older adults and pregnant women with the U.S. Food & Drug Administration by year-end, with potential launches in 2023.

If approved, our maternal RSV vaccine candidate potentially would be the first available to help prevent this common and potentially life-threatening respiratory illness in young infants.

[Slide 26: Building Upon Standard of Care in Prostate Cancer]

Turning now to prostate cancer, we are building upon the standard of care set by XTANDI in castration-sensitive and castration-resistant populations.

The Phase 3 EMBARK study of Xtandi in non-metastatic castration sensitive prostate cancer is expected to read out in the first half of 2023, and the Phase 3 TALAPRO-3 study of TALZENNA and XTANDI is expected in 2024. These trials may indicate benefit in up to 20 percent more patients than are currently treated and potentially prolong duration of use, subject to clinical success and regulatory approval.

[Slide 27: TALAPRO-2: First Clinical Benefit with PARPi + XTANDI in mCRPC]

In TALAPRO-2, we observed the first clinical benefit of a PARP inhibitor plus XTANDI in men with metastatic castration resistant prostate cancer, with or without homologous recombination repair or HRR gene mutations.

Irrespective of HRR gene mutation status, the study achieved its primary endpoint. The combination delivered a significant and clinically meaningful improvement in radiographic progression free survival and appears to have resulted in the longest observed such survival in a randomized trial in this setting.

We are encouraged by these results and believe that TALZENNA in prostate cancer may have blockbuster potential, subject to regulatory approval.

[Slide 28: Oral GLP-1 RAs: Potential Full Agonist Differentiation]

Turning to metabolic disorders, I have previously shared that we are developing two oral GLP-1 receptor agonists—danuglipron and ‘1532.

Recently presented Phase 1b data for ‘1532 showed dose-dependent reductions from baseline at four to six weeks in mean daily glucose, fasting plasma glucose, HbA1c and body weight.

Both candidates are potentially best-in-class and differentiated by offering full agonism which may be required to achieve the same level of response as injectable GLP-1 receptor agonists while offering a convenient once-daily dose. Glucose effects plateau at lower doses while body weight effects continue to increase at higher doses.

[Slide 29: GLP-1 RA Clinical Development Plan]

The planned Phase 2b study will evaluate ‘1532 versus both oral semaglutide and placebo in Type 2 diabetes, and separately versus placebo in obesity. Using semaglutide as a comparator in the Type 2 diabetes arm should allow us to observe potential early signs of differentiation in efficacy, tolerability and safety.

We will evaluate doses up to 260 milligrams in this study, higher than that studied in the Phase 1b. We plan to begin dosing soon and anticipate a readout in the first quarter of 2024.

The ongoing Phase 2b study of danuglipron in obesity with once monthly titration is expected to complete in the second half of 2023.

Data from these studies will be available in relatively quick succession and, assuming clinical success, allow us to select one based on efficacy, tolerability and dosing to advance to Phase 3 in both Type 2 diabetes and obesity.

[Slide 30: Select Scientific Franchises Aimed at Sustainable Growth]

In closing, we are excited about the developing science within these franchises and share here recent and anticipated milestones in the next 18 months. We look forward to continuing their development both for potential patient benefit and sustainable growth.

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 November 1, 2022. 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 contain 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, 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, and our ability to successfully capitalize on these opportunities; manufacturing and product supply; our efforts to respond to COVID-19, including the Pfizer-BioNTech COVID-19 Vaccine (Comirnaty), the Pfizer-BioNTech COVID-19 Omicron BA.4/BA.5 Vaccine, Bivalent (the Pfizer-BioNTech COVID-19 bivalent vaccine), other vaccines that may result from the BNT162 program, including new variant-based or next-generation vaccines, 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 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;*

- *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 the COVID-19 pandemic), including the impact of vaccine mandates where applicable, 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 a vaccine to help prevent COVID-19 and an oral COVID-19 treatment, as well as challenges related to their manufacturing, supply and distribution, including, among others, uncertainties inherent in research and development, 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, the Pfizer-BioNTech COVID-19 bivalent vaccine, any monovalent, bivalent or variant-adapted vaccine candidates or any other vaccine candidate in the BNT162 program or Paxlovid or any other 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, the Pfizer-BioNTech COVID-19 bivalent vaccine, any monovalent, bivalent or variant-adapted vaccine candidates or other vaccines that may result from the BNT162 program, Paxlovid or any other 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, the Pfizer-BioNTech COVID-19 bivalent vaccine, any monovalent, bivalent or variant-adapted vaccine candidates or any future vaccine to prevent, or Paxlovid or any other future COVID-19 treatment to be effective against, COVID-19 caused by emerging virus variants; the risk that more widespread use of the vaccine 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 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 these and any future pre-clinical and clinical studies; whether and when submissions to request emergency use or conditional marketing authorizations for Comirnaty, the Pfizer-BioNTech COVID-19 bivalent vaccine, or any potential future vaccines in additional populations, for a potential booster dose for Comirnaty, the Pfizer-BioNTech COVID-19 bivalent vaccine, any monovalent or bivalent vaccine candidates or any potential future vaccines (including potential future annual boosters or re-vaccinations), and/or biologics license and/or EUA applications or amendments to any such applications may be filed in particular jurisdictions for Comirnaty, the Pfizer-BioNTech COVID-19 bivalent vaccine, any monovalent or bivalent vaccine candidates or any other potential vaccines that may arise from the BNT162 program, including a potential variant-based, higher dose, or bivalent vaccine, and if obtained, whether or when such EUA or licenses will expire or terminate; whether and when submissions to request emergency use or conditional marketing authorizations for Paxlovid or any other future COVID-19 treatment and/or any drug applications for any indication for Paxlovid or any other future COVID-19 treatment may be filed in particular jurisdictions, and if obtained, whether or when such EUA or licenses will expire or terminate; whether and when any application that may be pending or filed for Comirnaty, the Pfizer-BioNTech COVID-19 bivalent vaccine, any monovalent, bivalent or variant-adapted vaccine candidates or other vaccines that may result from the BNT162 program, Paxlovid or any other 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 development of products or therapies 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; the risk that demand for any products may be reduced or no longer exist which may lead to reduced revenues or excess inventory; the possibility that COVID-19 will diminish in severity or prevalence, or disappear entirely; 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; 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; 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 or scale up manufacturing capacity on a timely basis or maintain access to logistics or supply channels commensurate with global demand for our vaccine or any treatment for COVID-19, which would negatively impact our ability to supply the estimated numbers of doses of our vaccine or treatment courses of Paxlovid within the projected time periods; risks related to our ability to achieve our revenue forecasts for Comirnaty and Paxlovid or any potential future COVID-19 vaccines or treatments; whether and when additional supply or purchase agreements will be reached; 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 or awareness of our COVID-19 vaccine or Paxlovid, including challenges driven by misinformation, access, concerns about clinical data integrity and prescriber and pharmacy education; trade restrictions; potential third-party royalties or other claims related to our COVID-19 vaccine 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 in countries experiencing high inflation rates;*
- any significant issues involving our largest wholesale distributors or government customers, which account for a substantial portion of our revenues;*
- the impact of the increased presence of counterfeit medicines or vaccines in the pharmaceutical supply chain;*
- any significant issues related to the outsourcing of certain operational and staff functions to third parties; and any significant issues related to our joint ventures and other third-party business arrangements;*
- uncertainties related to general economic, political, business, industry, regulatory and market conditions including, without limitation, uncertainties related to the impact on us, our customers, suppliers and lenders and counterparties to our foreign-exchange and interest-rate agreements of challenging global economic conditions, such as inflation, and recent and possible future changes in global financial markets;*

- *any changes in business, political and economic conditions due to actual or threatened terrorist activity, geopolitical instability, civil unrest or military action;*
- *the impact of product recalls, withdrawals and other unusual items, including uncertainties related to regulator-directed risk evaluations and assessments, including our ongoing evaluation of our product portfolio for the potential presence or formation of nitrosamines;*
- *trade buying patterns;*
- *the risk of an impairment charge related to our intangible assets, goodwill or equity-method investments;*
- *the impact of, and risks and uncertainties related to, restructurings and internal reorganizations, as well as any other corporate strategic initiatives, and 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;*

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., including China, affecting pharmaceutical product pricing, intellectual property, reimbursement or access, including, in particular, continued government-mandated reductions in prices and access restrictions for certain biopharmaceutical products to control costs in those markets;*
- *the exposure of our operations globally to possible capital and exchange controls, economic conditions, expropriation and other restrictive government actions, changes in intellectual property legal protections and remedies, as well as the impact of political unrest or civil unrest or military action, including the ongoing conflict between Russia and Ukraine and the continued economic consequences, unstable governments and legal systems and inter-governmental disputes;*
- *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 adequacy of reserves related to legal proceedings;*

- *the risk and impact of tax related litigation;*
- *governmental laws and regulations affecting our operations, including, without limitation, the recently enacted Inflation Reduction Act of 2022, changes in laws and regulations or their interpretation, including, among others, changes in tax laws and regulations internationally and in the U.S., the potential adoption of global minimum taxation requirements 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, extortion or integrity compromise resulting from a cyber-attack or other malfeasance by third parties, including, 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*
- *our ability to protect our patents and other intellectual property, such as against claims of invalidity that could result in loss of exclusivity; claims of patent infringement, including asserted and/or unasserted intellectual property claims; challenges faced by our collaboration or licensing partners to the validity of their patent rights; and in response to any pressure, or legal or regulatory action by, various stakeholders or governments that could potentially result in us not seeking intellectual property protection for or agreeing not to enforce or being restricted from enforcing intellectual property related to our products, including our vaccine to help prevent COVID-19 and our oral COVID-19 treatment.*

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 November 1, 2022.

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

Paxlovid and emergency uses of the Pfizer-BioNTech COVID-19 Vaccine or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5), have not been approved or licensed by the FDA. Paxlovid has not been approved, but has been authorized for emergency use by the FDA under an Emergency Use Authorization (EUA), for the treatment of mild-to-moderate Coronavirus Disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg [88 lbs]) with positive results of direct SARS-CoV-2 viral testing, and who are at high-risk for progression to severe COVID-19, including hospitalization or death. Emergency uses of the vaccines have been authorized by the FDA under an EUA to prevent COVID-19 in individuals aged 6 months and older for the Pfizer-BioNTech COVID-19 Vaccine and 5 years and older for the Pfizer-BioNTech COVID-19 Vaccine, Bivalent. 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 FD&C Act unless the declaration is terminated or authorization revoked sooner. Please see the EUA Fact Sheets at www.cvdvaccine-us.com and www.covid19oralrx.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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